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L@b Brief Standards Newsletter – November/December 2025

Experts are being sought for two committees, one working on ISO 15195:2018, Laboratory medicine—Requirements for the competence of calibration laboratories using reference measurement procedures and the other on ISO 35001:2019 Biorisk management. If you would like to participate, Jacqueline can nominate you, please email, jacqueline.balian@gambica.org.uk

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NEW WORK ITEMS PROPOSED

CEN_TS pre-exam infectious pathogens this proposal has been put up for public comment. Any comments received will be submitted to the national committee for consideration when deciding the UK response to the associated Standards Development Organisation. Those who wish to comment need to register here if they have not used this system before.

Revision of ISO387 ： 1977 Hydrometers—Principles of construction and adjustment**.**

ISO/PWI 13319-3 Determination of particle size distribution — Electrical sensing zone method — Part 3: Resistive pulse sensing method.

ISO/PWI TS 20776-3 Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 3: Quality performance of disc-diffusion agar method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases.

ISO/NP 26314 - Sterile polymer vials ready for filling, has been made available for public comment. Feel free to share this information with your wider organisations or colleagues who may have an interest. Any comments received will be submitted to the national committee for consideration when deciding the UK response to the associated Standards Development Organisation. If those who would like to comment have not used this system before, they will need to register here.

NEW WORK ITEMS ACCEPTED

PWI on In vitro diagnostic medical devices – Performance evaluation – Requirements and guidance.

ISO/NP 2599 Single-use receptacles for human arterial blood specimen collection (arterial blood gas collection needles).

ISO/PWI TS 20776-3 Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 3: Quality performance of disc-diffusion agar method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases.

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DRAFT STANDARDS

ISO/DTS 7446 Implementation guidance for biorisk management for laboratories and other related organizations, ballot closes on 2 December.

ISO/CD TS 8219 Sequencing and clinical application to infectious diseases, has been circulated as a committee draft.

ISO/DIS 8536-5 (Ed 3) Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed, ballot closes 13 December.

ISO/DIS 11607-3 Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly, the ballot on this draft has now closed.

ISO 13408-2:2018/DAmd 1 (Ed 2) Aseptic processing of health care products — Part 2: Sterilizing filtration — Amendment 1, this ballot is open until 21 December.

ISO/CD 14488 Particulate materials — Sampling and sample splitting for the determination of particulate properties, has also been circulated as a committee draft.

prEN 15154-3 Emergency safety showers - Part 3: Non plumbed-in body showers, is out for voting at enquiry stage until 12 February 2026.

prEN 15154-4 Emergency safety showers - Part 4: Non plumbed-in eyewash units , is out for voting at enquiry stage until 12 February 2026.

ISO/CD TS 20327 Packaging for terminally sterilized devices — Receiving, handling, transporting, distributing and storing of packaged sterile medical devices under the control of health care facilities, has been circulated as a committee draft for comment.

ISO/CD 21474-4: In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 4: Detection of pathogens, ballot closes 13 December

ISO/DIS 24884 Electronic Instructions for Use for In Vitro Diagnostic Medical Devices — Minimum required information and means of delivery, ballot closes on 10 December.

ISO/CD 25379-1 In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Human DNA examination, ballot closes 15 December.

ISO/CD 25379-2 In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 2: Human RNA examination, ballot closes 15 December.

ISO/NP 26314 Sterile polymer vials ready for filling, ballot closes on 31 December.

IEC 63590-1 ED1: Cold storage equipment for medical use - Part 1: Terminology, is out for voting until 18 December.

FINAL DRAFTS CIRCULATED

ISO/FDIS 15883-6 (Ed 2) Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors

employing thermal disinfection for non-critical medical devices and health care equipment, this ballot is open until 7 December.

ISO/FDIS 18704:2025 Molecular in vitro diagnostic examinations - Requirements and recommendations for pre-examination processes for urine and other body fluids - Isolated cell-free DNA, voting on this FDIS closes on 12 January 2026.

ISO/FDIS 22544 Laboratory design – vocabulary, was circulated for final vote which closed on 25 November.

STANDARDS OUT FOR REVIEW

None

STANDARDS RECONFIRMED

ISO 21474-1:2020 In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 1: Terminology and general requirements for nucleic acid quality evaluation

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STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN 12469-1:2025 - Biological safety cabinets - Part 1: Classes and basic requirement

BS EN 12469-2:2025 - Biological safety cabinets - Part 2: BSC class II

BS EN 14056-1:2025 - Laboratory furniture — Recommendations for design and installation - Part 1: General

BS EN 17242:2025 - Recirculatory Filtration Fume Cabinets

STANDARDS WITHDRAWN

None