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L@b Brief Standards Newsletter – September 2024

Wayne Spencer

All those involved in the revision of the autoclave standards will be saddened to hear of the sudden death of Wayne Spencer who chaired the work of the committee. Wayne was an excellent chair, managing to keep progress steady while taking into account all views and engaging all participants. He will be very much missed.

Volunteers wanted
Many important committees are struggling to find sufficient participants to carry out their programmes of work. A recent example of this relates to a provisional work item which has been approved but there are currently insufficient expert committee members to take forward the work.
The technical committee responsible for: *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use* has therefore circulated a request for individuals with knowledge of Medical devices — Infusate compatibility — Requirements and assessment methods.
Do let me know if you would be willing to participate.

NEW WORK ITEMS PROPOSED

Revision EN 868-5 Packaging for terminally sterilized medical devices Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods

Revision EN 868-8 Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Revision EN 868-9 Packaging for terminally sterilized medical devices - Uncoated nonwoven materials of polyolefines. Requirements and test methods

Revision of EN 868-10 Packaging for terminally sterilized medical devices Uncoated nonwoven materials of polyolefines. Requirements and test methods

Revision of EN ISO 11607-3 Packaging for terminally sterilized medical devices Part 3: Requirements for process development for forming, sealing and assembly

ISO/PWI TS 21385 Guidance for emerging technologies intended for medical laboratory use

PWI 21474-4, In vitro diagnostic medical devices – Multiplex molecular testing for nucleic acids – Part 4: Detection of pathogens

ISO/NP 25379-1 - In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Part 1: Human DNA examination

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ISO/NP 25391-2 - In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 2: Part 2: Human RNA examination

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NEW WORK ITEMS ACCEPTED

ISO/AWI TS 18701, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for human specimens — Isolated microbiome DNA has been reverted to PWI status.

ISO/AWI TS 18702, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood — DNA, RNA and proteins has been reverted to PWI status.

ISO/AWI 18703, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Isolated circulating cell free RNA from plasma has been reverted to PWI status.

IEC TR 60601-4-1 Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy is to be revised in the light of its systematic review results.

DRAFT STANDARDS

ISO/DIS 877-2:2024 Plastics - Methods of exposure to solar radiation - Part 2: Direct weathering and exposure behind window glass has been circulated for comment.

ISO/DTR 8417 Risk management of particulate contamination for devices with intravascular access has been approved.

ISO/DIS 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers has been circulated for comment.

ISO 8655-7:2022/DAmd 1 (Ed 2) Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume — Amendment 1 has been approved at enquiry stage.

ISO 9276-1 Representation of results of particle size analysis — Part 1: Graphical representation, the technical contents of this draft have been approved.

ISO/CD 11607-3, Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly has been circulated for voting at committee stage.

prEN 12469-1 Biological safety cabinets - Part 1: Classes and basic requirements has been circulated for comment.

prEN 12469-2 Biological safety cabinets - Part 2: BSC class II

prEN 12469-5 Biological safety cabinets - Part 5: Installation, commissioning and routine testing

ISO/DIS 15883-7 (Ed 2) Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment has been approved at enquiry stage.

ISO/DTS 16766 Manufacturers' considerations for in vitro diagnostic medical devices in a public health emergency this draft technical standard has been circulated for comment.

PrEN 17180 Sterilizers and associated equipment for processing of medical devices is to have a second enquiry stage due to negative responses to its first and negative HAS assessment.

ISO/CD 18704, Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for urine and other body fluids — Isolated cell free DNA is to be referred for DIS ballot

ISO/CD 22367 Medical laboratories — Application of risk management to medical laboratories comments have been sought on this committee draft.

ISO/DIS 22412 (Ed 3) Particle size analysis — Dynamic light scattering (DLS) has been approved at enquiry stage.

ISO/CD 24884 Electronic Instructions for Use for In Vitro Diagnostic Medical Devices (Minimum required information and means of delivery) is out for voting which closes on 3 October.

IEC 61010-2-011 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment has been circulated for comment.

IEC 61010-2-012 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-012: Particular requirements for climatic and environmental testing and other temperature conditioning equipment has been circulated for comment.

IEC 61010-2-020 ED4: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges has been circulated to national committees as a draft standard.

FINAL DRAFTS

ISO/FDIS 5649 Medical laboratories — Concepts and specifications for the design, development, implementation and use of laboratory-developed tests has been circulated for final approval.

ISO/FDIS & FprEN ISO 8536-13Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact has been approved for publication.

ISO/FDIS 8536-13 (Ed 2) Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact has been approved as a final draft for publication as changes have been made to the text.

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ISO/FDIS 15883-2:2024 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices has been circulated for formal ballot.
FprEN ISO 15883-3 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers has been circulated for parallel formal vote

prEN 17242 Recirculatory Filtration Fume Cabinets has been circulated for approval as a European Standard.

ISO/FDIS 19996 Charge conditioning of aerosol particles for particle characterization and the generation of calibration and test aerosols has been approved as a final draft for publication as changes have been made to the text.

ISO/FDIS 21474-3In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 3: Interpretation and reports has been circulated for final approval of the technical contents.

STANDARDS OUT FOR REVIEW

ISO 15197:2013, In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus It has been agreed that this standard should be revised.

STANDARDS RECONFIRMED

ISO 12154:2014 Determination of density by volumetric displacement — Skeleton density by gas pycnometry

ISO/TC 76 N 1685 Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process

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STANDARDS APPROVED

None

STANDARDS PUBLISHED

PD ISO/TS 5973:2024 - Laser diffraction measurements. Good practice

BS EN 14175-1:2003 - Fume cupboards. Vocabulary

BS EN 14175-2:2003 - Fume cupboards. Safety and performance requirements

BS EN 14175-4:2004 - Fume cupboards. On-site test methods

DD CEN/TS 14175-5:2006 - Fume cupboards. Recommendations for installation and maintenance

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

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BS EN 14175-3:2019 - Fume cupboards. Type test methods

BS ISO 19430:2024 - Determination of particle size distribution and number concentration by particle tracking analysis (PTA). Particle tracking analysis (PTA) method

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STANDARDS WITHDRAWN

prEN ISO 11135 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices, a proposal has been circulated to abandon this publication.

ISO 15198:2004, Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer, a proposal to withdraw this standard has been circulated.