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L@b Brief Standards Newsletter – July/August 2023

A chair has been appointed for the controversial new Chinese led, IEC committee on Cold storage equipment for medical use. The Chinese National Committee, proposed Mr Jiang LI and there were no other candidates nominated.

Jiang Li's motivation statement reads:
"I was very glad when I saw this great opportunity to participate in the nomination to the IEC/PC 130 cold storage equipment for medical use. I would like to express my strong motivation and desire to become the part of the team.
With taking leadership position in various TC/SC in the field of HVAC (Heating, Ventilation and Air Conditioning), I have extensive experience to be meeting facilitator and consensus builder in the work of standardization. If I have the honor to be elected as Chair of PC 130, I will strengthen the linkage with related TC/SC/WG from IEC, ISO, and other SDOs, establish a strong partnership and interaction with the stakeholders to contribute the work of PC130.
With the consideration of the characteristics of cross-specialty, cross-field and energy conservation in the global industry of the cold storage equipment for medical use, I will work collaboratively with the Secretariat to build a high-efficient and fair platform for consensus decision-making, to encourage the participation of Affiliate Countries and their experts for common interest of the global industry; I will establish the standardization framework of green and low-carbon, with the aim of ensuring the standardization system and activities of the PC support the transition to a sustainable and globally competitive economy.
Apart from having required skills and expertise for the position, I possess ability to seek challenges and thrive on them. I am ready to cooperate with related standard stakeholders to push the work item of PC130, so as to promote the industry development of the cold storage equipment for medical use and contribute the global biomedical research.

NEW WORK ITEMS PROPOSED

NWIP ISO/TC 336/SG 1 Terminology

ISO/PWI 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers

Revision of ISO 649-2:1981Laboratory glassware — Density hydrometers for general purposes — Part 2: Test methods and use.

The following new work items have been loaded to the BSI Standards Development Portal for comment. To review and comment on the item you need to register here. You are asked to comment before 26 September.

PWI 22544, Laboratory Design -- Terms and Definitions.

ISO/PWI TS 8219, Sequencing and clinical application to infectious diseases.

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ISO/NP 23525 - Revision of ISO 649-2:1981 Laboratory glassware — Density hydrometers for general purposes — Part 2: Test methods and use.

ISO/PWI 19676 - Single particle light interaction methods — Bio-fluorescence airborne particle counter for clean spaces.

NEW WORK ITEMS ACCEPTED

It has been agreed to amend **ISO 8655-7:2022 Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume**

N 1036 Guidance on personnel training and competence

Revision of **EN 12469-2 Biotechnology Performance criteria for microbiological safety cabinets**

Revision of **EN 1422:2014 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods**

Revision of **ISO 22367:2020, Medical laboratories — Application of risk management to medical laboratories**

ISO/TS 22583 Guidance for supervisors and operators of POCT is to receive minor amendments

Digital pathology and artificial intelligence (AI)-based image analysis

General principles for the application of artificial intelligence in medical laboratories

BS EN 1422:2014

DRAFT STANDARDS

LAB GENERAL

ISO/DIS 8536-13 (Ed 2)Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact has been circulated as a committee draft.

ISO/DIS 8655-10 Piston-operated volumetric apparatus — Part 10: User guidance and requirements for competence, training, and POVA suitability has been circulated for approval to move to FDIS stage until 23 Sept.

ISO/DIS 13318-1Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 1: General principles and guidelines has been circulated as a committee draft.

BS ISO 19996 - Charge conditioning of aerosol particles for particle characterization and the generation of calibration and test aerosols a draft for public comment is available, to register to review the document click here.

ISO/DIS 19996 Charge conditioning of aerosol particles for particle characterization and the generation of calibration and test aerosols has been circulated as a committee draft.

ISO/CD 22412 Particle size analysis — Dynamic light scattering (DLS) has been circulated as a committee draft for comments until 30 Sept.

IEC 61010-2-011 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment a committee draft has been circulated to National Committees 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 voting.

STERILISING

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 has been approved by ISO.

prEN ISO 11137-1, Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices has been approved at ISO but rejected by CEN.

ISO 11607-2:2019/FDAmd1, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1: Application of risk management has been approved with comments by CEN and ISO.

prEN ISO 15883-2, Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices has been approved by ISO but disapproved by National Members voting at CEN.

ISO/DIS 15883-3 (Ed 2) Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers has been approved at enquiry stage by ISO but rejected by CEN.

IVDs etc

ISO/DIS 8362-2 (Ed 4) Injection containers and accessories — Part 2: Closures for injection vials has been circulated as a committee draft.

ISO/CD TS 16766 Manufacturers' considerations for in vitro diagnostic medical devices in a public health crisis has been circulated for voting until 24 September.

prEN ISO 17664-2 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices has been circulated as a committee draft.

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FprCEN/TS 17981-1 In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination has been circulated for comment.

ISO/CD 21474-3In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 3: Interpretation and reports has been approved as a committee draft with some comments.

FINAL DRAFTS

ISO/FDIS 10991 (Ed 2) Microfluidics — Vocabulary.

ISO 11607-1:2019/FprEN A1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1: Application of risk management has been approved at final vote.

IEC 61010-2-030 ED3 (66/786/FDIS) (EQV) Subsector: V17 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits has been approved at parallel vote.

STANDARDS OUT FOR REVIEW

ISO 8362-1:2018 (Ed 4) Injection containers and accessories — Part 1: Injection vials made of glass tubing

ISO/TS 11137-4:2020Sterilization of health care products — Radiation — Part 4: Guidance on process control

ISO 11139:2018 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

EN 14175-7:2012 Fume cupboards - Part 7: Fume cupboards for high heat and acidic load

ISO 14488:2007 (vers 4)Particulate materials — Sampling and sample splitting for the determination of particulate properties

ISO 15010:1998 (vers 5)Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods

EN 15154-1:2006Emergency safety showers - Part 1: Plumbed-in body showers for laboratories

ISO 15747:2018 (Ed 3) Plastic containers for intravenous injections

CEN/TS 17441:2020 Laboratory installations - Ventilation systems in laboratories

ISO 18472:2018, Sterilization of health care products — Biological and chemical indicators — Test equipment

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ISO 19001:2013 (Ed 2, vers 2)In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

ISO/TS 21387:2020 Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release

ISO 21501-4:2018 (Ed 2)Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces

ISO 23640:2011 (vers 2)In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents

STANDARDS RECONFIRMED

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN ISO 13004:2023 - Sterilization of health care products. Radiation. Substantiation of selected sterilization dose. Method VDmaxSD

BS EN 14470-1:2023 - Fire safety storage cabinets. Safety storage cabinets for flammable liquids

BS EN ISO 24072:2023 - Aerosol bacterial retention test method for air-inlet on administration devices Biotechnology Performance criteria for microbiological safety cabinets

BS EN IEC 61010-2-061:2021+A11:2021 - Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for laboratory atomic spectrometers with thermal atomization and ionization

STANDARDS WITHDRAWN

None