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L@b Brief Standards Newsletter – June 2023

A new IEC project committee - IEC/PC 130 Cold storage equipment for medical use - was established in March 2023. BSI needs to ensure that a national committee is responsible for mirroring this work and providing UK input, and has chosen CH/212 to do so. This will be done through PC130. Please let me know if you are interested in participating in PC 130 or know of anyone else who might be.

BSI circulated some information on 17 June about a proposal from the Chinese National Committee for a new Project Committee (PC) on Performance of cold storage equipment for medical use. All national bodies were invited to vote on the proposal. Unfortunately the closing date appears to have preceded the date upon which the information was circulated.

NEW WORK ITEMS PROPOSED

Spaulding classification of reprocessable dental devices. This proposal may have some overlaps with CH/198's remit. It is open for comments until 5 August.

ISO/NP 11607-3, Packaging for terminally sterilized medical devices -- Part 3: Requirements for process development for forming, sealing and assembly.

Revision of **EN 12469:2000 Biological safety cabinets – Part 1: Classes and Basic Requirements.**

Revision of **EN 12469:2000 Biological safety cabinets – Part 5: Installation, commissioning and maintenance.**

NEW WORK ITEMS ACCEPTED

EN 12469-2 Biological safety cabinets – Part 2: BSC class II.

N 1269 Guideline for sample preparation and calibration to evaluate particle concentration of suspended particles in liquid.

BS EN 1422:2014 Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.

Amendment of ISO 21881:2019 Sterile packaged ready for filling glass cartridges.

I. BS EN 1422:2014

STANDARDS TO BE REVISED OR OUT FOR REVIEW

BS 3985:2003 Haemiglobincyanide (cyanmethaemoglobin) preparation as a standard for spectrometric haemoglobinometry.

BS 2975-2:2008 Sampling and analysis of glass-making sands - Methods for chemical analysis.

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DRAFT STANDARDS

LAB GENERAL

ISO/CD TS 5973.2:2023 Good practice for laser diffraction measurements.

ISO/DIS 13100 Methods for zeta potential determination — Streaming potential and streaming current methods for porous materials has been approved to progress to FDIS.

ISO/DIS 19430 Determination of particle size distribution and number concentration by particle tracking analysis has been approved at enquiry stage.

prEN ISO 23783-1 Automated liquid handling systems - Part 1: Vocabulary and general requirements is out for voting until 29 July.

prEN ISO 23783-2 Automated liquid handling systems - Part 2: Measurement procedures for the determination of volumetric performance is out for voting until 29 July.

prEN ISO 23783-3 Automated liquid handling systems - Part 3: Determination, specification and reporting of volumetric performance is out for voting until 29 July.

STERILISING

BS_2646-2 Autoclaves for sterilization in laboratories – Part 2: Planning and installation – Code of Practice.

BS_2646-3 Autoclaves for sterilization in laboratories – Part 3: Safe use and operation – Code of Practice has been circulated for final approval.

ISO/DIS 11135 (Ed 3) Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices has been circulated for voting.

ISO/DIS 11137-1 (Ed 2) Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

ISO 11139/DAmd1, Sterilization of health care products —Vocabulary of terms used in sterilization and related equipment and process standards - AMENDMENT 1: Amended and additional terms and definition has been approved at enquiry stage.

ISO 11607-1:2019/FDAmd 1 (Ed 2) Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1: Application of risk management

EN ISO 11607-2/FprA1, Packaging for terminally sterilized medical devices — Part 1: Validation requirements for forming, sealing and assembly processes — Amendment 1 has been circulated for parallel formal vote by 11 August.

ISO/NP 11607-3 : Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly.

EN 14180 Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers. Requirements and testing has been circulated for national comment.

prEN 13060 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing has been circulated at enquiry stage.

ISO/DIS 15883-2 (Ed 2) Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices is out for voting until 17 July.

ISO/DIS 15883-3 (Ed 2) Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers is currently out for voting.

IVDs etc

ISO/AWI 8536-13 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact has been recommended to skip the CD ballot and go directly to DIS ballot.

ISO 11040 Prefilled syringes Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling and **Part 7: Packaging systems for sterilized subassembled syringes ready for filling** have been circulated for voting.

FINAL DRAFTS

FprEN ISO 10991Microfluidics - Vocabulary is out for formal vote until 4 July.

FprCEN ISO/TS 11137-4 Sterilization of health care products - Radiation - Part 4: Guidance on process control has been approved at formal vote.

ISO 11139:2018/DAmd1, Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Amendment 1: Amended and additional terms and definitions has been approved for publication.

prEN ISO 13004 Substantiation of selected sterilization dose: Method VDmaxSD has been approved for publication.

ISO/FDIS 13408-1, Aseptic processing of health care products — Part 1: General requirements has been approved for publication.

prEN 14180 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing is out for approval to publish.

amd EN ISO 14937 requirements for characterization of sterilizing agent & development, validation & routine control of sterilization process has been approved for publication.

FprEN ISO 20916 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019) is out for formal vote until 6 July.

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STANDARDS RECONFIRMED

ISO 8536-5:2004 infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed

ISO 9276-4:2001 Representation of results of particle size analysis — Part 4: Characterization of a classification process

ISO 18747-1:2018 Determination of particle density by sedimentation methods — Part 1: Isopycnic interpolation approach

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STANDARDS APPROVED

None

STANDARDS PUBLISHED

None

STANDARDS WITHDRAWN

None