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L@b Brief Standards Newsletter – August 2020

Smart manufacturing map approved

The development of a Smart Manufacturing Standards Map Framework has been approved. The new map will be registered as a technical report ISO/IEC TR 63306-1 Ed 1, this month.

International and regional standards developing organizations identified the need for clarifying the standards landscape of thousands of publications related to manufacturing in general and more specifically to Smart Manufacturing. The *Smart Manufacturing Standards Map* (SM2) project was initiated by ISO and IEC in order to provide a credible, central, and neutral repository of information about standards related to Smart Manufacturing.

Deletions from the official journal of the EU

CEN/TC 102 which is responsible for sterilizers and associated equipment for processing of medical devices, has agreed a proposal to delete the following work items from the Official Journal EU under the Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC.

- – EN ISO 11138-2:2009, Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138- 2:2006)
- – EN ISO 11138-3:2009, Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)
- – EN ISO 11140-1:2009, Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)

  – EN ISO 11140-3:2009, 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 11140-3:2007, including Cor) (listed only under MDD)

STANDARDS UP FOR REVIEW/RECONFIRMATION

None

NEW WORK ITEMS PROPOSED

ISO/NP TS 5441 Competence of Biorisk Management Advisors was out for voting until 20th August.

NEW WORK ITEMS ACCEPTED

PNW 65-734: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-203: Particular requirements for industrial communication circuits and communication port interconnection

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STANDARDS TO BE REVISED OR OUT FOR REVIEW

ISO 3826-4_2015 - Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features is out for Systematic Review - Implemented by BSI as BS EN ISO 3826-4:2015

ISO 8362-2_2015 - Injection containers and accessories - Part 2: Closures for injection vials ISO 8362-2:2015 is out for Systematic Review

ISO 11137-2:2013, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose – the proposal to amend was out for voting until the end of July.

BS 6256:2020 Packaging for terminally-sterilized medical devices – Method for determination of methylene blue particulate penetration out for public consultation till 30 Sept

17664:2017 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices a minor revision is proposed.

ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices is proposed for revision.

ISO 11137-2:2013 Sterilization of healthcare products — Radiation — Part 2: Establishing the sterilization dose is being balloted for revision.

DRAFT STANDARDS

ISO/DIS 23118 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma – out for voting until 14th September.

ISO/DIS 20166-4 Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: In situ detection techniques also out for voting till the 14th September.

EN 285:2015/FprA1 Sterilization - Steam sterilizers - Large sterilizers (WI 00102155); this was previously rejected and is out for a second FDIS ballot now that the issues have been addressed.

ISO/CD 8536-15 Infusion equipment for medical use — Part 15: Light-resistant infusion sets for single use – is out for approval to circulate as a DIS until 27th August.

FINAL DRAFTS

IEC 61326-1 ED3 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements has been circulated for approval by 25th September.

ISO/DIS 22413 (Ed 3) Transfer sets for pharmaceutical preparations — Requirements and test methods this final draft was recommended for changes, so a revised text is to be submitted to ISO.

ISO/FDIS 17822-2 In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Part 2: Laboratory quality practice guide is out for approval until 15th September.

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STANDARDS RECONFIRMED

None

STANDARDS APPROVED

ISO/CD TS 16775, Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2. As this work item is developed under Vienna Agreement, a parallel DTS ballot will follow.

IEC 60601-1/AMD1/ISH1 ED3: Common aspects of electrical equipment used in medical practice

ISO/DIS 22413 (Ed 3) Transfer sets for pharmaceutical preparations — Requirements and test methods

ISO/DIS 20184-3 Molecular *in vitro* diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Isolated DNA

STANDARDS PUBLISHED

PD ISO/TR 22814:2020 Good practice for dynamic light scattering (DLS) measurements

BS 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 WITHDRAWN

New project **ISO/CD 24075: Determination for di(2-ethylhexyl)-phthalate (DEHP) released from PVC medical devices** has been cancelled due to lack of expertise to drive the project forward within ISO/TC 76.

The revision of **ISO 8872 Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods** has also been cancelled.

ENDS