

## L@b Brief Standards Newsletter – February 2020

### Input on fume cupboard tracer gas sought

Reply by 2020-04-13

The last meeting of CEN/TC 332/WG 4 proposed replacement of SF6 and agreed to ask members of CEN/TC 332/WG 4 for their input. Unfortunately, only few replies were received and the net for input has been widened. If you have views on the use of tracer gas in relation to fume cupboards, please let me have them before 13<sup>th</sup> April.

Specifically, they would like information on:

1. whether there are any aspects which do not allow a modified containment testing with N<sub>2</sub>O according to EN 14175-3? This includes the question whether there are any arguments or obstacles (e. g. legal requirements) referring to N<sub>2</sub>O as the SF 6 substitute.
2. any safety information (such as handling, national restrictions, concentration) of N<sub>2</sub>O,
3. results from test with SF6 and N<sub>2</sub>O including comparability of the test results between the different gases,
4. published papers,
5. further test results with other replacements for tracer gas.

Any technical questions should be directed to [bernd.schubert@tintschl.de](mailto:bernd.schubert@tintschl.de) with copy to [jenny.blum@din.de](mailto:jenny.blum@din.de).

### Participation in International Sightseeing Organisation suspended (temporarily)

BSI has taken the decision that until 1 June 2020 all committee meetings will only be via virtual means and no face-to-face committee meetings will take place at the BSI Chiswick offices. All committee member training sessions have been cancelled until **1 June**. Information from the international and European standards organisations have been made available on BSI's [eCommittees](#) site and it seems that CEN and ISO are following suit by running meetings as video conferences.

---

### STANDARDS UP FOR REVIEW/RECONFIRMATION

None

---

### NEW WORK ITEMS PROPOSED

It has been proposed that CEN/TS 17441 "**Laboratory installations — Ventilation systems in laboratories**" be published as a 'Technical Specification' (TS). ISO/TC 198 has initiated a ballot on a new work item proposal ISO/TS on water quality for sterilizers, sterilization and washer-disinfectors. A first draft has been provided for comments with N 2233 as **ISO/NP TS 5111**. The closing date will be 26<sup>th</sup> May.

CLC/TC 66X has proposed the following New Work Items under: **Safety of measuring, control, and laboratory equipment** and has circulated them for approval by 18<sup>th</sup> March

- **prEN IEC 61010-2-011:2018/prAA** 'Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment' (PR=71512);
- **FprEN IEC 61010-2-012:2019/prAA** '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' (PR=71289);
- **FprEN IEC 61010-2-032:2019/prAA** 'Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-032: Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement' (PR=71290);

- **FprEN IEC 61010-2-033:2019/prAA** 'Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-033: Particular requirements for hand-held multimeters and other meters, for domestic and professional use, capable of measuring mains voltage' (PR=71291);
- **prEN 61010-2-051:2017/prAA** 'Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring' (PR=71509).

**ISO 25424:2018: Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices**  
An amendment to this standard has been proposed as a new work item – the UK proposes to abstain.

---

## NEW WORK ITEMS ACCEPTED

None

---

## STANDARDS TO BE REVISED OR OUT FOR REVIEW

A proposal that **ENs 61010-2-011, -2-012, -2-032, -2-033, -2-051 and -2-061** be published as mother standards as non-harmonised standards while the amendments with common modifications are being developed has been rejected after a vote.

The UK members of the group reviewing **ISO/CD 22441 Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices** feel that more work is needed before it is circulated.

A resolution to work on an amendment to **ISO 25424:2018 'Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices'** is out for voting until 13<sup>th</sup> April. The UK is likely to abstain.

---

## DRAFT STANDARDS

**ISO/CD 21474-2:2020(E) *In vitro* diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 2: Validation and verification**

A draft has been circulated for comment by CH212

**ISO/CD 11140-6.2 Sterilization of health care products — Chemical indicators — Part 6: Class 2 indicators and process challenge devices for use in performance testing of steam sterilizers**

Is out for comment to decide whether it should be circulated as a DIS.

**ISO/CD 11138-8.2 Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator**

Is out for comment to decide whether it should be circulated as a DIS.

---

## FINAL DRAFTS

**ISO/FDIS 13408-6, Aseptic processing of health care products â Part 6 Isolator systems** has been circulated for vote by 15<sup>th</sup> April, the UK's default vote is to abstain.

**111/573/FDIS, Determination of certain substances in electrotechnical products - Part 3-2: Screening - Fluorine, bromine and chlorine in polymer and electronics by combustion-ion chromatography (C-IC)** has been circulated for vote, the UK's default vote is to approve.

**109/183/FDIS IEC 60664-1 ED3: Insulation coordination for equipment within low-voltage supply systems - Part 1: Principles, requirements and tests** has been circulated for parallel votes by IEC and CENELEC, the UK's default vote is to abstain.

**IEC 62366-1/AMD1 ED1 62A/1386/FDIS, Amendment 1 - Medical devices - Part 1 Application of usability engineering to medical devices** Default vote is approve

**ISO/TC 198 N 1610, Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices**

---

## **STANDARDS RECONFIRMED**

**ISO 13317-4:2014 Determination of particle size distribution by gravitational liquid sedimentation methods — Part 4: Balance method**

---

## **STANDARDS APPROVED**

**IEC/CD 61010-2-040 (Ed.3.0), Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (see N 2190).**

---

## **STANDARDS PUBLISHED**

**BS ISO 15190:2020 Medical laboratories — Requirements for safety**

**BS EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems (Including corrigendum Feb 2020)**

**BS ISO 11040-4:2015+A1:2020 Prefilled syringes Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling**

**BS EN ISO 22367:2020 Medical laboratories – Application of risk management to medical laboratories**

**BS EN ISO 8536-4:2020 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed (Incorporating corrigendum March 2020)**

**BS ISO 28620:2020 Medical devices — Non-electrically driven portable infusion devices**

**BS EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes**

**PD CEN/TS 17390-3:2020 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood Part 3: Preparations for analytical CTC staining**

**PD CEN/TS 17390-2:2020 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood Part 2: Isolated DNA**

**PD CEN/TS 17390-1:2020 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood Part 1: Isolated RNA**

---

## **STANDARDS WITHDRAWN**

None

ENDS