

Report

ISO TC 212 - Clinical laboratory testing and in vitro diagnostic test systems

WG 2 – Reference Systems

December 2, 2019

JCTLM Member and Stakeholder Meeting

Hubert Vesper, PhD

Project Status: in-progress items

ISO 17511 (ed. 2), Requirements for establishing metrological traceability

Project Lead: Dr Neil Greenberg, USA

- DIS vote: closed 06 JUN 2019
- Although sufficient APPROVE votes were received, two negative votes due to technical issues especially with Annex ZA, required preparation of FDIS
- FDIS submitted/registered with ISO/CS: 29 SEP 2019
- FDIS vote: Start 08 NOV 2019 (close: 03 Jan 2020)
- **Expected final publication: ~ APR 2020**

Project Status: in-progress items

ISO 21151 – Requirements for international harmonisation protocols establishing metrological traceability

Project Lead: Dr Greg Miller, USA

- DIS vote closed 05JUN2019; APPROVED (with minor editorial changes requested); FDIS not required
- To ensure parallel publication with ISO 17511 (ed 2), final ISO 21151 text to be submitted to ISO CS for publication in parallel with ISO 17511 following completion of ISO 17511 FDIS voting (~ late Feb 2020)
- **Expected publication: ~ APR 2020**

Project Status: recently completed items

ISO 15195:2018 – Requirements for competence of calibration laboratories using reference measurement procedures

Project Lead: Dr Robert Wielgosz, France

- **International standard published: 19 DEC 2019**
- Aligns with latest version of ISO/IEC 17025:2017 (normative reference)

ISO TS20914:2019 – Practical guidance for estimation of measurement uncertainty

Project Lead: Dr Graham White, Australia

- **Final Technical Specification published: 28 JUL 2019**
- Joint project with ISO/TC212/WG1; supports measurement uncertainty requirements in ISO 15189:2012
- Technical Specification up for systematic review in 2022 (3 year cycle); consider renewal for 2nd 3-year term, or conversion to International Standard at that time
- Dr Isolde Seiden Long (Canada) has assumed role as Project Lead for purposes of future updates and maintenance

Project Status: future work items

ISO 15193:2009 – Requirements for content and presentation of reference measurement procedures

Project Lead: Dr Hubert Vesper, USA

- **Next systematic review to initiate: JAN 2020**
- Vienna agreement document; currently harmonised for EU IVD Directive 98/79/EC

ISO 15194:2009 – Requirements for certified reference materials and the content of supporting documentation

Project Lead: Dr Hubert Vesper, USA

- **Next systematic review to initiate: JAN 2020**
- Vienna agreement document; currently harmonised for EU IVD Directive 98/79/EC

Project Status: future work items

ISO 15193:2009 – Requirements for content and presentation of reference measurement procedures

ISO 15194:2009 – Requirements for certified reference materials and the content of supporting documentation

Both documents

- should be harmonised under new EU REG 2017/746 on IVD-MDs
- may require substantive changes to reflect changes in normative and other underlying references
- **are important for supporting JCTLM's mission**
“...evaluating reference materials, reference measurement procedures and reference measurement services for laboratory medicine with respect to conformity with appropriate international standards..”

Next Steps

1. Systematic reviews of ISO 15193:2009 (Reference Measurement Procedures) and ISO 15194:2009 (Reference Materials)
2. Review/resolve comments from systematic review
3. Decide if documents require substantive revision and initiation of corresponding new work item proposals (NWIPs) for consideration by TC212

WG2 Changes

No formal WG2 meetings in 2019

- Current WG2 Convenor: Dr Neil Greenberg is retiring effective YE2019
- New WG2 Convenor: Dr Hubert Vesper starting 2020

Thank you