ISO/TC212/Working Group 2 Progress Report to JCTLM

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Sèvres, France

ISO TC212 - Clinical laboratory testing and in vitro diagnostic test systems

SCOPE

- Standardization and guidance in the field of laboratory medicine and *in vitro* diagnostic test systems
- Includes quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance

ISO TC212 - Clinical laboratory testing and in vitro diagnostic test systems

WORKING GROUPS

- WG 01 Quality and competence in the medical laboratory
- WG 02 Reference systems
- WG 03 In vitro diagnostic products
- WG 04 Microbiology and molecular diagnostics
- WG 05 Laboratory biorisk management

TC212 Working Group 2 – Current Projects

- ISO/NP 17511 - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.
- ISO/NP 21151 - Requirements for international harmonization protocols intended to establish metrological traceability of values assigned to product (end user) calibrators and patient samples
- ISO/CD 15195 - Requirements for the competence of calibration laboratories using reference measurement procedures
- ISO/NP TS20914 - Medical laboratories -- Practical guide for the estimation of measurement uncertainty

ISO/NP 17511 – Metrological Traceability

PRECURSOR DOCUMENTS

- ISO 17511:2003. Metrological traceability of values assigned to calibrators and control materials
- ISO 18153:2003. Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

ISO/NP 17511 – Metrological Traceability

SCOPE AND RATIONALE

- Specifies how to assure metrological traceability of assigned values… EU Directive 98/79/EC essential requirement
  - Revised ISO 17511 will be considered as EU harmonised standard supporting new EU IVD regulations
- Planned improvements:
  - Underscores end-user expectations – traceability extends to final patient sample
  - improved descriptions of model calibration hierarchies
  - Adds model calibration hierarchy for harmonization protocols - measurands with no higher order MPs or materials
  - Incorporates ISO 18153 (enzymes) content, eliminating need for two standards

ISO/NP 17511 – Metrological Traceability

Project logistics/ISO timeline

- Project leader: Dr. Neil Greenberg (USA)
- ISO development track: 36 Months
- Project Registration date: 2016-01-19
- Time since project registration: 23 months
- DIS Registration Limit Date: 2018-01-19 **(Warning)**
- IS Publication Date (per 36-month [default] development track): 2019-01-19

ISO/NP 17511 – Metrological Traceability

STATUS & ACTION PLAN:

- Strong interest from all stakeholders to proceed ASAP to DIS registration with new/next draft
- TC212 Secretariat will submit 9-month extension request to ISO/TMB
- With very constructive feedback received on latest draft at 29 Nov. – 01 Dec. meeting of ISO/TC212/WG2 in Brussels, new draft now in preparation, to be distributed to WG2 for comments by Feb. 2018
- Subsequent WG2 meeting to be scheduled April/May 2018 to resolve further comments on next draft; anticipating DIS preparation (by July 2018), with DIS registration by October, 2018; revised IS publication date 10/2019

ISO/NP 21151 - Requirements for international harmonization protocols

SCOPE AND RATIONALE

When higher order certified reference materials and/or reference measurement procedures are not available, standardisation of values among two or more measurement procedures for the same measurand following an internationally defined harmonisation protocol is a preferred alternative to non-equivalent values from multiple IVD medical devices from different manufacturers, provided that certain technical requirements are satisfied.

ISO/NP 21151 - Requirements for international harmonization protocols

SCOPE – cont.

- Specifies requirements for establishment of harmonisation protocols defining metrological traceability of values assigned to product (end user) calibrators and patient samples when there is no higher order reference measurement procedure and no fit for purpose certified reference material or international conventional calibrator
- Harmonisation protocols meeting requirements of this IS define highest available level of metrological traceability for the stated measurands; are intended to be implemented by international scientific bodies

ISO/NP 21151 - Requirements for international harmonization protocols

SCOPE – cont.

- With availability of this IS, manufacturers of IVDs, medical laboratory IVD users, and producers of laboratory developed tests will have clearly-defined requirements for establishment of harmonised calibrations for IVD MD's
- This IS will enable JCTLM to credential and list in its database the international harmonization protocols that conform to this standard

ISO/NP 21151 - Requirements for international harmonization protocols

Project logistics/ISO timeline

- Project leader: Dr. W. Greg Miller (USA)
- ISO development track: 36 Months
- Project Registration date: 2016-01-19
- Time since project registration: 23 months
- DIS Registration Limit Date: 2018-01-19 **(Warning)**
- IS Publication Date (per 36-month [default] development track): 2019-01-19

ISO/NP 21151 - Requirements for international harmonization protocols

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ISO/CD 15195 - Requirements for …calibration laboratories using reference MPs

Precursor Document

- **ISO 15195:2003** Laboratory medicine -- Requirements for reference measurement laboratories

ISO/CD 15195 - Requirements for …calibration laboratories using reference MPs

Scope and Rationale

- Specifies requirements for competence in performing reference measurement procedures in laboratory medicine, using ISO/IEC 17025:2017 as a normative reference; lists additional requirements beyond ISO 17025
- Title revised to avoid ambiguity concerning the types of laboratories covered by this standard
- This IS is used by JCTLM to support review of reference measurement laboratory services for listing in JCTLM database. Full alignment with ISO 17025:2017 as normative reference reduces accreditation complexity for covered laboratories (redundant accreditation to both 17025 and 15195)

ISO/CD 15195 - Requirements for …calibration laboratories using reference MPs

Project Logistics & ISO Timeline

- Deliverable: International Standard
- Project leader: Dr. Robert Wielgosz (BIPM)
- DEVELOPMENT TRACK: 48 Months
- ISO Project Registration date: 2015-09-17
- Time since project registration: 27 months
- DIS Registration Limit Date: 2018-09-17
- IS Publication Date (per 48 month development track): 2019-09-17

ISO/CD 15195 - Requirements for …calibration laboratories using reference MPs

Status and Action Plan

- New draft, fully aligned to ISO/FDIS 17025:2017, was reviewed at the Nov. 29 – Dec. 1 at ISO/TC212/WG2 meeting in Brussels.
- Final draft now in preparation, to be submitted to WG2 for final comments and consensus review by February, 2018.
- Expecting DIS registration by April, 2018 (ahead of 2018-09-17 DIS limit date)

ISO/NP TS20914 – Practical guide for the estimation of measurement uncertainty

Scope and Rationale

- The business plan of ISO/TC 212 has an overarching objective of promoting the application of quality systems (QS) in medical laboratories to improve healthcare worldwide. The QS objective is reflected in ISO 15189, increasingly adopted worldwide as the quality system standard for medical laboratories.
- In support of ISO 15189 requirements to estimate uncertainty of laboratory measurements, labs need a coherent, standardized and practical approach to performing the statistical calculations.
- This Technical Specification defines terms, establishes general principles, specifies statistical approaches, and provides guidelines for estimating the uncertainty of quantitative measurements in the medical laboratory.

ISO/NP TS20914 – Practical guide for the estimation of measurement uncertainty

Project Logistics & ISO Timeline

- Deliverable: Technical Specification
- Project leader: Dr. Graham White (Australia)
- Collaboration with ISO/TC212/WG1
- Development Track: 36 Months
- ISO Project Registration date: 2015-11-11
- Time since project registration: 25 months
- TS Publication Date (per 36-month [default] development track): 2018-11-11

ISO/NP TS20914 – Practical guide for the estimation of measurement uncertainty

Status and Action Plan

- New draft reviewed at Nov. 29 – Dec. 1 Brussels meeting. Based on very constructive comments and minor concerns, further revision now in preparation, expected to be submitted to WG1/WG2 for review & comments by March 2018; with comments to be resolved at WG2 meeting in April/May 2018.
- Subsequent/final version expected to be prepared by July, 2018, followed by circulation for TC212 voting cycle starting August, 2018. If TC212 votes to approve (~8 weeks), expecting submission to ISO/CS for publication by project target date (2018-11-11.)

ISO/TC212/Working Group 2
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Thank you for your attention.

Questions?