Bureau
International des
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Mesures

Quality policy of the Database Working Group

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1. Purpose

The purpose of the Database Working Group (DB WG) of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) is to implement the JCTLM Framework for the international recognition of reference materials and reference measurement methods/procedures of a higher metrological order, and of reference measurement services provided by calibration (reference) laboratories.

2. Scope

The scope of this document is all procedures that describe the activities of JCTLM DB WG.

3. Acronyms and definitions

All acronyms and definitions employed in the procedures of the JCTLM Database Working Group Quality Manual are given in the procedure document JCTLM EXE-G01, Glossary of terms and definitions.

An outline of the calibration and measurement hierarchy in laboratory medicine is provided in Chapter 5.

4. Procedure

The JCTLM Framework facilitates the implementation of traceability to higher-order reference materials and reference measurement methods/procedures as required by the European Commission's *In Vitro* Diagnostic Directive (EC IVDD). Nominated reference materials and reference methods/procedures are reviewed by the JCTLM DB WG for compliance with the normative harmonized standards, ISO 17511:2003(E) and either ISO 15194:2009(E) or ISO 15193:2009(E) and, when appropriate, ISO 18153:2003(E).

The processes employed by the JCTLM DB WG are intended to identify and encourage calibration (reference) measurement laboratories to participate in the processes required to achieve greater comparability of laboratory measurements. This goal will be achieved by assigning traceable values to calibrator and control materials through the use of reference materials and reference measurement procedures qualified as of a higher metrological order and being listed in the JCTLM Database.

It is the policy of the JCTLM DB WG to make the evaluations of materials, measurement procedures and reference measurement services by a transparent process using openly distributed procedure documents that are accessible to all interested parties.
The procedures provided in this Quality Manual describe the processes by which the identification and evaluation are made.

5. Outline of calibra tion and measurement hierarchy in laboratory medicine

The implementation of the concept of traceability results in a hierarchical measurement infrastructure consisting of distinct measurement services (see also the flow chart in the attachment to this document) that rely on the three different categories of laboratory:

- National Metrology Institutes (NMIs) provide calibration and measurement capabilities (CMCs) which have been internationally reviewed and verified via the CIPM MRA process. These measurement services and the uncertainties with which they are offered are listed in the BIPM Key Comparison Database (KCDB), and are often used in the value assignment of certified reference materials, including primary and secondary calibrators (e.g. for NIST SRM or JRC certified reference materials). In addition, National Metrology Institutes may also undertake comparative measurements with Calibration (Reference) Laboratories that are required to demonstrate compliance with ISO 17025 and ISO 15195, or provide reference values for ring trials. This link to the Reference Laboratories is essential for the entire calibration and measurement infrastructure since it enables the demonstration of equivalence of measurements internationally. Reference measurement services of National Metrology Institutes which have been approved via the CIPM MRA, are deemed to fulfil the JCTLM criteria and may also be published in the JCTLM Database.
- The second group of laboratories in the hierarchical infrastructure is that of Calibration (Reference) Laboratories. As outlined in the procedure P-03B of this Quality Manual, in principle, Reference Laboratories applying for inclusion of their Reference Measurement Services in the JCTLM Database have to fulfill the following requirements:
  1. Use of a Reference Method that has been approved and listed by JCTLM.
  2. Accreditation as Calibration Laboratory according to ISO 17025 and ISO 15195.
  3. Regular participation in inter-laboratory comparisons (Ring Trials for Reference Laboratories)

  The JCTLM process provides a mechanism for the review and listing of these laboratories' measurement services.
  Typically, such Reference Measurement Service providers will offer their capabilities to
  - Diagnostic Kit Manufacturers
  - Regulatory Bodies
  - Proficiency Testing Organizations by providing target values for Ring Trials of Testing Laboratories.

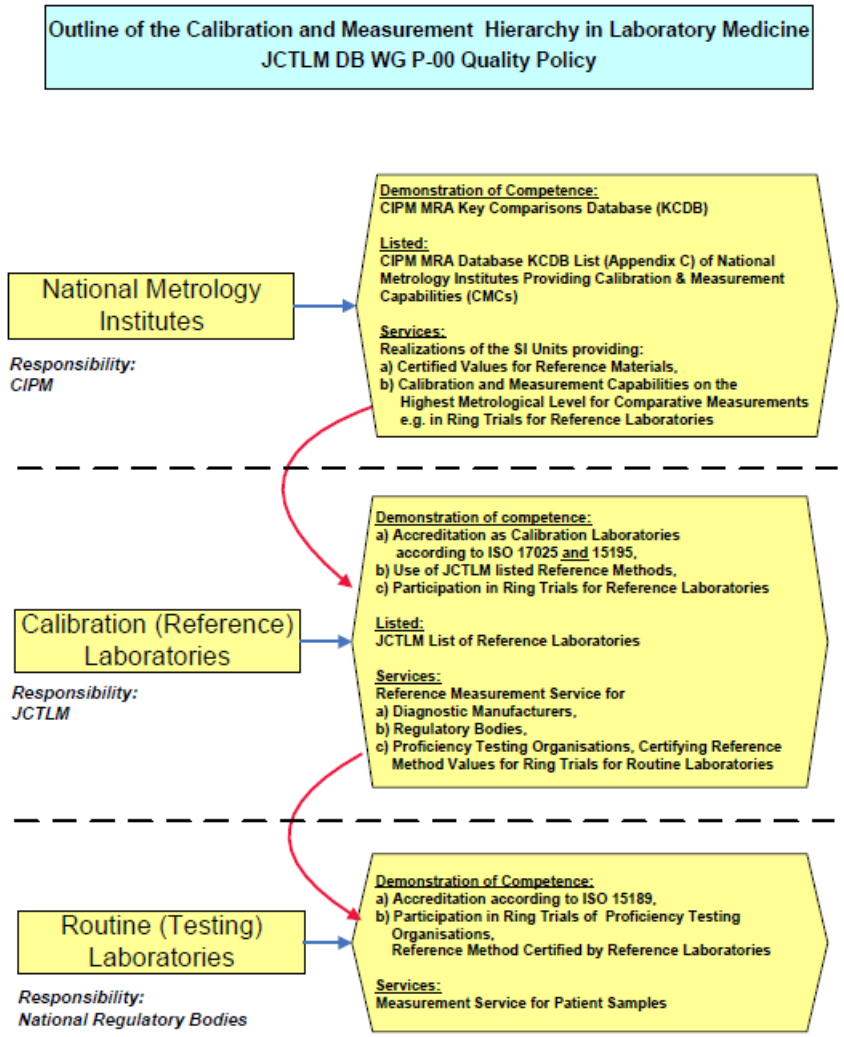
  Thereby, reference laboratories establish the link to the basic routine laboratories which are requested to demonstrate traceability to higher order reference materials and/or procedures.
  National Metrology Institutes which are listed in the BIPM KCDB according to the CIPM MRA may also provide the same service as the Calibration (Reference) Laboratories. In view of their double function they will then be listed in the JCTLM list of reference measurement service providers.
- Routine (Testing) Laboratories form the third group of laboratories in the hierarchical infrastructure. They provide the daily measurement service for medical purposes. Such laboratories usually demonstrate their competence by accreditation according to relevant standards (e.g. ISO 15189) and by participation in proficiency testing ring trials. The

approval of these laboratories (e.g. by national Regulatory Bodies) is outside the scope of JCTLM.

6. Revision History

Version number	Date of Issue/ Review	Summary of change
1.0	27 January 2017	First issue of this document resulting from the merging of previous documents WG1-P-00 (materials and methods) and WG2-P-00 (services).
1.1	01 February 2019	Update of hyperlinks

Annex 1. Flowchart



National Metroloy Institutes having CMCs listed in the BIPM KCDB according to CIPM MRA may also act as Reference Measurement Service providers; They will be listed by JCTLM according to the review process described in the document DBWG P-03B1 (January 2017)

Related documents

[1] JCTLM Framework JCTLM Framework: **Appendix III of the *Declaration of Cooperation*** between the BIPM, IFCC and ILAC, for the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM); Available at: https://www.bipm.org/en/worldwide-metrology/jctlm-cooperation/jctlm-framework.html

[2] JCTLM DB WG JCTLM DB WG Quality Manual available at: https://www.bipm.org/en/committees/cc/wg/jctlm-dbwg.html#manual

[3] ISO 17511:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)

[4] ISO 15193:2009 In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)

[5] ISO 15194:2009 In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)

[6] ISO 18153:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)

[7] ISO/IEC 17025:2005 ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

[8] ISO 15195:2003 ISO 15195:2003 Laboratory medicine — Requirements for reference measurement laboratories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