


Review of Reference Measurement Services from laboratories that are accredited as calibration laboratories (ISO/IEC 17025 and ISO 15195)			 Accurate results for patient care
JCTLM DBWG-P-03-B2 Version : 5.0	Date : 27 January 2017	Authorized : JCTLM Executive	

Review of Reference Measurement Services from laboratories that are accredited as calibration laboratories (ISO/IEC 17025 and ISO 15195)

1. Purpose

This procedure describes the processes to be followed by review teams for reviewing nominations of reference measurement services provided by reference laboratories that are accredited according to ISO/IEC 17025 and ISO 15195 as calibration laboratories.

Nominations from National Metrology Institutes with CMCs published in Appendix C of the BIPM KCDB according to CIPM MRA will have these reviewed according to P-03-B1.

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3. Scope


This procedure will be applied by the review teams for assessment of laboratory services according to the criteria listed under ‘6. Procedure’ of this document based on the documentation provided by the laboratories and also regarding publicly available information on the laboratory performance (e.g. results of inter-comparison studies).

4. 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.

5. Responsibilities and Authorizations

Responsibilities and authorizations are given in the document JCTLM DB WG-P-02B.

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6. Procedure

6.1. The process for reviewing RML services by the Review Teams will take place annually. The JCTLM Secretariat sends received nominations to the JCTLM Review Teams after consultation with the DB WG vice-chair(s). The appropriate review team will assess the nomination and other publicly available information according to the following criteria.

6.1.1. The appropriate JCTLM review team ascertains that the RML is accredited according to ISO/IEC 17025 **and** ISO 15195 as calibration laboratory on the basis of successful, and in general on-site, assessments by technical and management experts from accreditation bodies which are ILAC members (signatories). A copy of the laboratory's accreditation certificate shall be submitted to the JCTLM secretariat as part of the Reference Measurement Service nomination procedure.

6.1.2. The appropriate JCTLM review team ascertains whether the Reference Method applied by the candidate laboratory is listed in the JCTLM Database. If the applied method has not yet been included in the JCTLM database the laboratory will be notified to nominate the Reference Method for review and acceptance by JCTLM DB WG.


If the Reference Method is not yet listed but submitted for listing simultaneously the JCTLM Executive will decide on the listing of the Method and the Reference Measurement Service at the same meeting.

It is also acceptable that a reference measurement service provider improves/modifies a formerly listed reference measurement procedure without additional publication and listing provided the basic principle of the measurement procedure (e.g. IDMS) is maintained. A peer-reviewed publication of a modified method is the preferred route for fulfilling JCTLM requirements. An alternative, if the former is not possible, will be through the production of a method validation report, which will need to be reviewed and accepted by the experts of the review team confirming that there is no bias observed between the measurement results obtained from the original and modified method.

Also, such a validation report shall be provided when reference measurement service providers implement JCTLM listed reference measurement procedures on matrices which are different from the one(s) on which validation reports already exist.

Experts of the review teams will assess the validation report for the modified/improved methods for its publication in the JCTLM database for the specific reference measurement service.

6.1.3. The appropriate review team will ascertain regular (at least annual) participation of the candidate laboratory in inter-laboratory comparisons provided by an appropriate proficiency testing/external quality assessment scheme for reference laboratories which fulfills the requirements of DBWG-

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P-02B Sec.7. The results of the inter-comparisons as well as the result of the individual laboratory related to its identity shall be made publicly available.


It is also acceptable that a laboratory participates for another measurand of the same group of quantities (e.g., metabolites & substrates, low-molecular hormones, therapeutic drugs, enzymes) provided the same principle of measurement - e.g., IDMS, kinetic spectrophotometry for enzyme activities - is applied.

However, a laboratory must participate for each listed measurand at least once in a time period of three years.

- 6.1.4. The results of the review are recorded in the submitted nomination Excel form, the review report form JCTLM D WG P-03B-F-02 and returned to the JCTLM Secretariat. The review report form is forwarded to the nominator at the end of the review cycle.
- 6.1.5. The Review Team recommendations and related documentation are forwarded to DB WG vice-chairs by the JCTLM Secretariat.
 - 6.1.5.1. If clarification is needed, the DB WG vice-chair(s) will request it from the RT leader(s). Answers to queries and the review teams' recommendations and review forms are returned to the JCTLM Secretariat.
- 6.1.6. The DB WG reviews at its annual meeting the recommendations from the review teams prior formal approval by the JCTLM Executive. (See DB WG P-05)

7. Related documents

- JCTLM DBWG-P-02B Process for requesting and accepting nominations for JCTLM listing of reference measurement laboratory services
- JCTLM DBWG-P03 B1 Process for verification and publication of calibration and measurement capability (CMC) claims in the JCTLM Database (National Metrology Institutes).
- JCTLM DBWG-P03 B2 Process for the review of reference measurement services from laboratories accredited as calibration laboratories (ISO 17025+15195)
- JCTLM DB WG-P-05 Process for consensus review of recommendations from DB WG Review Teams and communicating the recommendations to the JCTLM Secretariat

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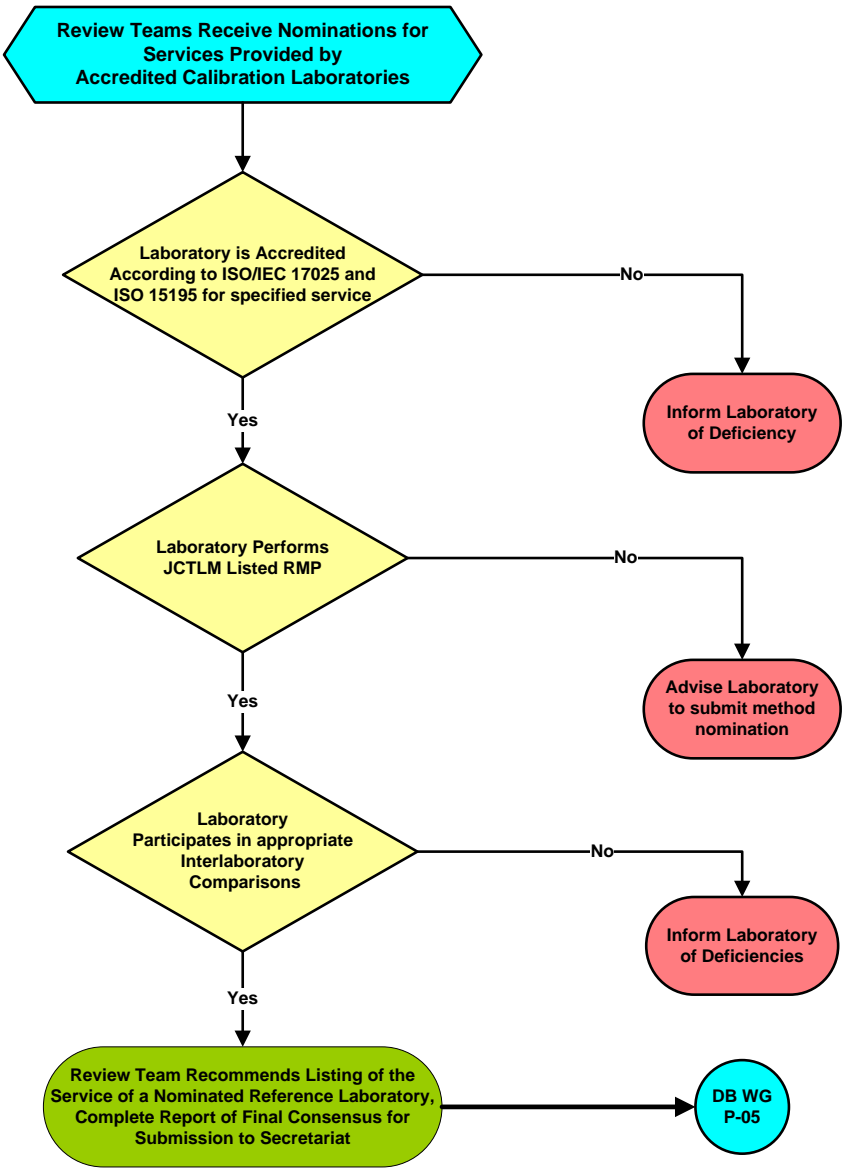
8. Revision History

Version number	Date of Issue/Review	Summary of change
1.1	Dec. 06, 2005	Document approved by Executive Meeting Nov 14, 2005
1.2		Modification in 7.1.2
1.3	27 Nov 2007	Modifications following 5 th Executive meeting decisions
1.4	11 Mar 2010	Modifications following 8 th Executive meeting decisions
2.0	27 Jan 2011	Modifications made in version 1.4 accepted
2.1	26 Jan 2015	Modification in 7.1.2 following the decision taken at 13 th Executive Meeting to include the new acceptance criteria for listing a reference measurement service of a provider using a modified listed reference measurement method, with the provision that the basic principle of measurement was maintained and that the validation report would have been made available to and approved by the review team, and published in the database
3.0	29 Jan 2016	Modifications made in version 2.1 accepted
4.0	27 Jan 2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups

Attachment 1 Flowchart

**PROCESS FOR REVIEW OF REFERENCE MEASUREMENT SERVICES FROM LABORATORIES WHO ARE ACCREDITED AS CALIBRATION LABORATORIES (ISO-17025/ 15195)
DB WG P-03-B2**

Responsibility: JCTLM Review Teams



January 2017