

Requesting processing nominations for JCTLM listing of reference measurement laboratory services

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1. Purpose

This document describes the process employed by the Joint Committee for Traceability in Laboratory Medicine (JCTLM) for soliciting, receiving and reviewing for completeness the nominations of reference measurement services provided by calibration (reference) laboratories for evaluation by the JCTLM Database working group...

2. Scope

This procedure will be applied to the documents submitted from all Reference Measurement Laboratories (RMLs) and National Metrology Institutes (NMIs) who nominate services for listing in the JCTLM database.

3. Acronyms and definitions

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

4. Responsibilities and Authorizations

4.1.

Oversight responsibility and authority for the operations of the DB WG reside with its Chair and vice-chair(s). Communicating recommendations to the JCTLM Secretariat for listing reference measurement services provided by National Metrology Institutes (NMIs) is the responsibility of the DB WG vice-chair(s).

Communicating recommendations to the JCTLM Secretariat for listing reference measurement services of laboratories accredited (according to ISO/IEC 17025 and ISO 15195) is the responsibility of the DB WG vice-chair(s).

Communicating recommendations of nominated reference measurement services of laboratories accredited (according to ISO/IEC 17025 and ISO 15195) to the JCTLM Secretariat is the responsibility of the expertise-based team leaders of Review Teams.

Communicating recommendations of nominated reference measurement services provided by NMIs to the JCTLM Secretariat is the responsibility of the expertise-based team leaders of Review Teams

Communicating recommendations of reviewed reference measurement services of laboratories accredited (according to ISO/IEC 17025 and ISO 15195) to the DB WG Chair and vice-chair(s) is the responsibility of the JCTLM Secretariat.

Communicating recommendations of reviewed services provided by NMIs to the DB WG Chair and vice-chair(s) is the responsibility of the JCTLM Secretariat.

4.2.

Oversight responsibility for the DB WG Chair and vice-chair(s) resides with the JCTLM Executive.

4.3.

Authority for deciding recommended reference measurement services to be placed in the JCTLM Database resides with the JCTLM Executive.

4.4.

Responsibility for the maintenance of procedures employed by DB WG resides with the Quality System Development Team

4.5.

Authority to approve procedures of the JCTLM DB WG resides with the Executive.

5. Procedure

5.1.

The process for nominating and reviewing reference measurement services for recommendation by the JCTLM for listing will occur annually (see flow chart in the Attachment).

5.2.

Solicitation of nominations from calibration (reference) laboratories wishing their services to be listed on the JCTLM Database:

5.2.1.

The JCTLM Secretariat announces an open solicitation for nominations of reference measurement services for inclusion in the JCTLM database. The solicitation is made each year from February to the end of May. The solicitation announcement is found on the website of the BIPM at: <https://www.bipm.org/en/committees/jc/jctlm/jctlm-nominations-and-review.html>

5.2.2.

A fixed date for receiving completed nominations will be specified in the announcement. Nominations received after the date specified in the annual announcement will be held for consideration in the subsequent annual cycle.

5.3.

Obtaining nomination forms:

5.3.1.

Reference measurement laboratory management can obtain the nomination form from download from the BIPM website:

Reference Measurement Services Nomination Form available at: <https://www.bipm.org/utis/common/pdf/JCTLM/DBWG-P-02B-F-01.xls>

5.4.

Submitting nomination forms for consideration by the DB WG:

5.4.1.

Nominating forms must be submitted by email to the JCTLM Secretariat at jctlm@bipm.org.

5.4.2.

Only nominations submitted from reference measurement laboratory management will be accepted by the JCTLM Secretariat.

5.4.3.

Reference measurement laboratory management personnel acknowledge that a submitted nomination constitutes consent to be included in the JCTLM database of Reference Measurement Laboratory Services

5.4.4.

Candidate Reference Laboratories are requested to submit nomination forms containing **complete documentation on**

5.4.4.1.

the legal identity and address,

5.4.4.2.

the measurand (analyte and system/body fluid),

5.4.4.3.

statement on SI-traceability of results

5.4.4.4.

the analytical principle of the method applied,

5.4.4.5.

a short outline of the standard operating procedure,

5.4.4.6.

the service provided by the RML which must use a reference method listed in the JCTLM database.

5.4.4.6.1.

If the procedure implemented in the laboratory to deliver the reference measurement service differs from the Reference Method listed in the JCTLM database, but uses the same basic principle of measurement, and has been fully validated, the laboratory must provide the validation report of the modified method for its assessment by the experts of the review teams and its publication in the database if approved by JCTLM

5.4.4.7.

documents on the reference materials used for calibration,

5.4.4.8.

documents on the reference materials used for trueness control,

5.4.4.9.

literature references,

5.4.4.10.

range of concentration (activity),

5.4.4.11.

statement on the typical uncertainty of the measurement procedure that must be consistent with the expanded uncertainty statement in the certificate of accreditation (Section 5.4.4.12, see p. 12),

5.4.4.12.

the relevant CMC listed in Appendix C of the BIPM-KCDB (National Metrology Institutes),
or copies of the accreditation certificate for laboratories accredited according to ISO 15195
and ISO/IEC 17025 as calibration laboratory

5.4.4.13.

participation in regular (annual) inter-laboratory comparisons conducted by an accepted proficiency testing scheme dedicated to reference measurement services. Criteria for the acceptance of proficiency testing schemes are listed in Chapter 6.

5.5.

Submitting nomination forms for consideration by the DB WG:

5.5.1.

The JCTLM Secretariat preliminary reviews submitted nominations for completeness within six weeks of their receipt in consultation with the DB WG Chair and vice-chair(s).

5.5.2.

The preliminary review is only concerned with completeness and is NOT a review of the qualification of the nominated RML service.

5.5.3.

Incomplete forms will be returned to the individual making the nomination.

5.5.4.

Returned nomination forms that are incomplete **can** be amended and resubmitted.

5.5.5.

Acceptance of resubmission after the initial review for completeness is at the discretion of the JCTLM Secretariat and the DB WG Chair and vice-chair(s).

5.5.6.

Resubmissions must be received by the date specified on the solicitation (Section 5.2, see p. 10).

5.5.7.

Nominations or resubmissions which are received after the date specified may be held until the next review cycle.

5.6.

Distributing Nominations from National Metrology Institutes.

The JCTLM Secretariat, after consulting the DB WG Chair and vice-chair(s), distributes nominations from National Metrology Institutes, which should include information on published CMC claims in the BIPM Key comparison database, to the team leaders of the Review Teams with the appropriate expertise to perform the review according to procedure P-03-B1.

5.7.

Distributing Nominations from Accredited Laboratories to Review Teams.

The JCTLM Secretariat, after consulting the DB WG Chair and vice-chair(s), distributes nominations to the team leaders of the Review Teams with the appropriate expertise to perform the review according to different procedures according to the status of accreditation.

For laboratories that are accredited according to ISO 15195 and ISO/IEC 17025 as calibration laboratories nomination is submitted to the review team for application of procedure P-03-B2.

5.8.

Any Review Team member affiliated to a nominating organization will not participate in the evaluation of reference measurement laboratory services **from that organization**. See JCTLM DB WG-P-06 **for dealing with a potential or perceived conflicts of interest**.

5.9.

The distributed nominations from Reference Measurement Service providers are reviewed by the Review Teams according to:

- JCTLM DB WG P-03-B1 “Process for Verification and Publication of Calibration and Measurement Capability (CMC) Claims in the JCTLM Database (National Metrology Institutes)”, or
- JCTLM WG P-03-B2 “Process for Review of Reference Measurement Services from Laboratories who are accredited as Calibration Laboratories (ISO/IEC 17025/ 15195)”.

5.10.

The results of the review are recorded in JCTLM DB WG P-03B-F-02 by the RT leader and returned to the JCTLM Secretariat by 31st October.

5.11.

The secretariat compiles all review forms and recommendations and forwards these to the DB WG vice-Chair(s) for verification. Queries raised by the vice-Chair(s) are returned to the Review Team Leader and the JCTLM Secretariat. Answers to queries and the review teams' recommendations and review forms are returned to the JCTLM Secretariat.

5.11.1.

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)

5.11.2.

The review forms are forwarded to the nominator at the end of the review cycle following approval of the recommendation by the JCTLM Executive Committee. (EXE-P-05)

5.12.

Reference measurement services listed on the JCTLM website will be re-reviewed every three years, and this process was first implemented in December 2013.

The laboratory having a reference measurement service listed in the database must provide evidence that its status for accreditation for compliance with ISO/IEC 17025 and ISO 15195 is up-to-date, and that its participation in appropriate EQAS Scheme for Reference Laboratory fulfill the two following JCTLM requirements;

1. The laboratory must participate every year for at least one measurand in a group of analyte for which a service is listed, and,
2. The laboratory must participate for each listed measurand at least once in a time period of three years.

The RELA advisor will review the participation of the laboratories having reference measurement services listed in the JCTLM Database with respect to the above cited criteria and report on the status of the laboratories' RELA participation to the JCTLM Executive.

5.13.

Any appeal against recommendations of the JCTLM DB WG will be submitted to the Secretariat and finally decided by the JCTLM Executive after consulting the DB WG Chair, vice-chair(s). The appealing process is described in the procedure document DBWG-P-09.

6. Requirements for acceptable proficiency testing scheme providers

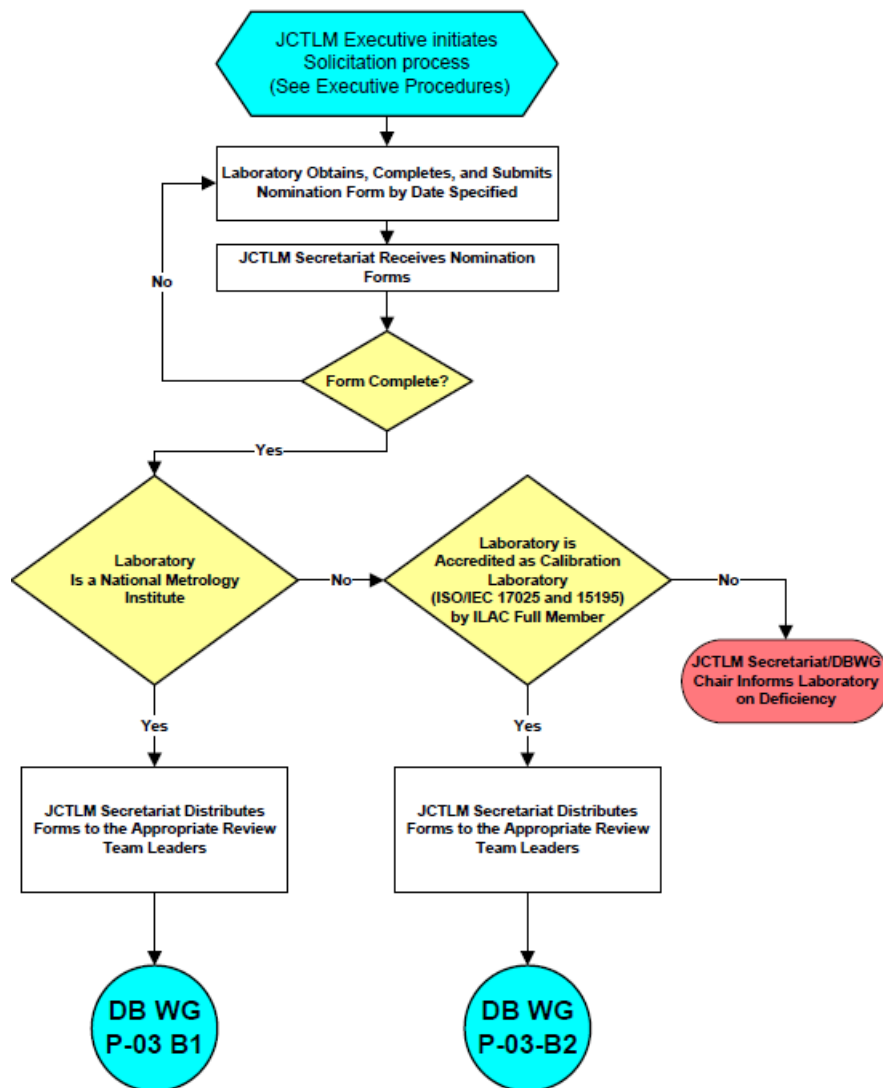
1. The proficiency testing provider should organize intercomparisons dedicated to reference measurement laboratory services.
2. The proficiency testing provider should be accredited according to ISO Guide 43-1 (1997), ILAC Guide G-13 (2000) ISO/IEC 17043:2010 and IFCC/EMD/C-AQ: Guidelines for the Requirements for the Competence of EQAP organizers in medical laboratories (2002/3, EN ISO/IEC 17043:2010-05: Conformity Assessment—General Requirements for Proficiency Testing or EN 14136: Use of External Quality Assessment Schemes in the Assessment of the Performance of In Vitro Diagnostic Examination Procedures by an ILAC full member (signatory).
3. The proficiency testing provider should have an international scientific advisory board.
4. The proficiency testing provider should conduct intercomparisons regularly (at least annually).
5. The proficiency testing provider should ensure availability of scientific advice to discuss inter-laboratory discrepancies.
6. The proficiency testing provider should make publicly available the identity of the participating laboratories with their results and uncertainties.

7. 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	Dec. 01, 2006	Modifications in 7.7 and 7.11
1.3	Nov. 27, 2007	Modifications following 5 th Executive Committee meeting decisions
1.4	Dec., 14, 2007	Modifications following 6 th Executive Committee meeting decisions
1.5	May 04, 2009	Modifications following the approval of new accreditation deadlines
1.6	Mar 11, 2010	Modifications following the 8 th Executive Committee meeting decisions
2.0	Jan 27, 2011	Modifications following the removal of WG2-P-03-C
3.0	Jan 19, 2012	Corrections made in version 2.0 accepted
3.1	Mar 16, 2012	Modifications following the 10 th Executive Committee meeting decision that requires full consistency for the statement of the expanded uncertainty range declared by a Reference Laboratory and that stated in the accreditation certificate for its measurement service
3.2	Apr 30, 2013	Corrections made in version 3.1 accepted
3.3	Jan 26, 2015	Modifications 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

Version number	Date of Issue/Review	Summary of change
4.0	Jan 29, 2016	available to and approved by the review team, and published in the database Corrections made in version 3.3 accepted
5.0	Jan 27, 2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups
5.1	Feb. 01, 2019	Update of hyperlinks
5.2	Jun. 11, 2020	Modification made following the 21 st Executive Committee meeting: Revision of paragraph 6.8 to include a clause on conflict of interest and confidentiality which would applied during the review process; and Update of the version of Standards in 7.2 and Related documents section

Appendix 1. Flowchart



Process for requesting and processing nominations for JCTLM Listing of Reference Measurement Laboratory Services (DB WG P-02B)

Related documents

- [1] 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, Geneva, Switzerland (2009).
- [2] ISO 15194:2009 In vitro diagnostic medical devices—Measurement of quantities in samples of biological origin—Requirements for certified reference materials and content of supporting documentation. ISO, Geneva, Switzerland (2009).
- [3] ISO 15195:2003 In vitro diagnostic systems—Requirements for reference measurement laboratories
- [4] ISO/IEC 17025:2017 ... General requirements for the competence of testing and calibration laboratories
- [5] JCTLM DBWG-P-02B-F-01 JCTLM DBWG-P-02B-F-01 Reference Measurement Services Nomination Form, Microsoft Excel Spreadsheet available at: <https://www.bipm.org/utis/common/pdf/JCTLM/DBWG-P-02B-F-01.xls>
- [6] JCTLM DB WG-P03 B1 JCTLM DB WG-P03 B1 Process for verification and publication of calibration and measurement capability (CMC) claims in the JCTLM Database (National Metrology Institutes).
- [7] JCTLM DB WG-P03 B2 JCTLM DB WG-P03 B2 Process for the review of reference measurement services from laboratories accredited as calibration laboratories (ISO 17025+15195)
- [8] JCTLM DB WG-P-03B-F-02 JCTLM DB WG-P-03B-F-02 Review Report form for a nominated Reference Measurement Service
- [9] JCTLM DB WG-P-09 JCTLM DB WG-P-09 Process for appealing decisions of the JCTLM Executive



