

TITLE: <i>PROCESS FOR REQUESTING AND PROCESSING NOMINATIONS FOR JCTLM LISTING OF REFERENCE MEASUREMENT LABORATORY SERVICES</i>		
JCTLM WG2-P-02 Version : 3.0	Date : 19 January 2012	Authorized : JCTLM Executive

PROCESS FOR REQUESTING AND PROCESSING NOMINATIONS FOR JCTLM LISTING OF REFERENCE MEASUREMENT LABORATORY SERVICES

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**PROCEDURE
JCTLM WG-2 P-02**

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2. Purpose

This procedure describes the processes to be followed for soliciting, receiving and reviewing nominations of Services provided by Reference Measurement Laboratories for evaluation by the JCTLM WG-2 chair and Review Teams.

3. Scope

This procedure will be applied to the documents submitted from all Reference Measurement Laboratories and National Metrology Institutes who nominate services for listing on the JCTLM list.

4. Acronyms

Acronyms used in this procedure are defined in the document JCTLM WG2-P-00, Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions.

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5. Definitions

Definitions for the terms used in this procedure are given in the document JCTLM WG2-P-00, Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions.

6. Responsibilities and Authorizations

- 6.1. Oversight responsibility and authority for the operations of WG2 reside with the WG2 Chair or the designee of the WG2 Chair.

Communicating recommendations to the JCTLM Secretariat for listing services provided by National Metrology Institutes (NMIs) is the responsibility of the WG2 Chair.

Communicating recommendations to the JCTLM Secretariat for listing RML services of laboratories accredited (according to ISO/IEC 17025 and ISO 15195) is the responsibility of the WG2 Chair.

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

Communicating recommendations of reviewed RML services of laboratories accredited (according to ISO/IEC 17025 and ISO 15195) to the WG2 Chair is the responsibility of the JCTLM Secretariat.

Communicating recommendations of reviewed services provided by NMIs to the WG2 Chair is the responsibility of the JCTLM Secretariat.

- 6.2. Oversight responsibility for the WG2 and WG2 Chairs resides with the JCTLM Executive.
- 6.3. Authority for deciding recommended RML services to be placed on the JCTLM Database resides with the JCTLM Executive.
- 6.4. Responsibility for the maintenance of procedures employed by WG2 and authority to appoint *ad hoc* teams to perform the procedure maintenance reside with WG2 Chair.

7. Procedure

- 7.1. The process for nominating and reviewing RML services for recommendation by the JCTLM for listing will occur annually (see flow chart in the Attachment).
- 7.2. Solicitation of Nominations from RMLs wishing their services to be listed on the JCTLM Database:
- 7.2.1 The JCTLM Secretariat/WG2 chair announce an open solicitation for

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nominations of RML services for inclusion in the JCTLM list. The solicitation announcements will be found on the website of the BIPM.

- 7.2.2 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.

7.3. Obtaining Nomination Forms:

- 7.3.1 Reference measurement laboratory management can obtain nomination forms from the following sources:

Downloading from the BIPM website.

E-mail request from the JCTLM Secretariat.

(Name, address and email address of the JCTLM Secretariat will be listed on the BIPM website)

7.4. Submitting Nomination Forms for Consideration by WG2:

- 7.4.1 Nominating forms must be submitted to the JCTLM secretariat **only**. Contact information is found on the BIPM website.
- 7.4.2 Only nominations submitted from reference measurement laboratory management will be accepted by the JCTLM Secretariat.
- 7.4.3 Reference measurement laboratory management personnel acknowledge that a submitted nomination constitutes consent to be included on the JCTLM List of Reference Measurement Laboratory Services.
- 7.4.4 Candidate Reference Laboratories are requested to submit nomination forms containing **complete documentation on**
- 7.4.4.1 the legal identity and address,
 - 7.4.4.2 the measurand (analyte and system/body fluid),
 - 7.4.4.3 statement on SI-traceability of results,
 - 7.4.4.4 the analytical principle of the method applied,
 - 7.4.4.5 a short outline of the standard operating procedure,
 - 7.4.4.6 the service provided by the RML (e.g. RM listed in the JCTLM WG1 list),
 - 7.4.4.7 documents on the reference materials used for calibration,
 - 7.4.4.8 documents on the reference materials used for trueness control,
 - 7.4.4.9 literature references,
 - 7.4.4.10 range of concentration (activity),
 - 7.4.4.11 statement on the typical uncertainty of the measurement procedure,
 - 7.4.4.12 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,

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- 7.4.4.13 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 8.
- 7.4.5 Submission may be by any of the following means:
- 7.4.5.1 An attachment to an e-mail message to the JCTLM Secretariat.
- 7.4.5.2 Electronic medium, diskette or CD ROM sent to the JCTLM Secretariat.
- 7.5 The JCTLM Secretariat preliminary reviews submitted nominations for completeness within six weeks of their receipt in consultation with the WG2 Chair or the Chair's designee:
- 7.5.1 The preliminary review is only concerned with completeness and is NOT a review of the qualification of the nominated RML service.
- 7.5.2 Incomplete forms will be returned to the individual making the nomination.
- 7.5.3 Returned nomination forms that are incomplete **can** be amended and resubmitted.
- 7.5.4 Acceptance of resubmission after the initial review for completeness is at the discretion of the JCTLM Secretariat and the WG2 Chair.
- 7.5.5 Resubmissions must be received by the date specified on the solicitation (7.2.2).
- 7.5.6 Nominations or resubmissions which are received after the date specified may be held until the next review cycle.
- 7.6 Distributing Nominations from National Metrology Institutes.
- The JCTLM Secretariat, after consulting the WG2 Chair, 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-A.
- 7.7 Distributing Nominations from Accredited Laboratories to Review Teams.
- The JCTLM Secretariat, after consulting the WG2 Chair, 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-B.
- 7.8 Any Review Team member affiliated to a nominating organization will not participate in the evaluation of that reference measurement laboratory service if a potential conflict of interest exists or is perceived to exist.
- 7.9 The distributed nominations from Reference Measurement Service providers are reviewed by the Review Teams according to

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- JCTLM WG2 P-03-A “Process for Verification and Publication of Calibration and Measurement Capability (CMC) Claims in the JCTLM Database (National Metrology Institutes)”, or
 - JCTLM WG2 P-03-B “Process for Review of Reference Measurement Services from Laboratories who are accredited as Calibration Laboratories (ISO/IEC 17025/15195)”.
 -
- 7.10 The results of the review are recorded in JCTLM WG2 P-03-F-02 and returned to the JCTLM Secretariat. The form is forwarded to the nominator at the end of the review cycle.
- 7.11 The secretariat compiles all review forms and recommendations and forwards these to the WG2 Chair for verification. Queries raised by the WG2 Chair are returned to the Review Team Leader and the JCTLM Secretariat. Answers to queries and the review teams’ final recommendations and review forms are returned to the JCTLM Secretariat. 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.
- 7.12 For laboratories where accreditation is pending the status of accreditation is re-examined in 2012 by the JCTLM Secretariat after consulting WG2 chair.
- 7.12.1 If formal accreditation can be demonstrated WG2 chair recommends to remove the remark “pending accreditation” from the list.
- 7.12.2 If formal accreditation cannot be documented WG2 recommends (to the Executive) to remove that laboratory service from the list.
- 7.13 Reference measurement services listed on the JCTLM website will be re-reviewed every three years.
- 7.14 Any appeal against decisions of WG2 chair or review teams will be submitted to the Secretariat and finally decided by the JCTLM Executive after consulting the WG2 chair.

8 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) and IFCC/EMD/C-AQ: Guidelines for the Requirements for the Competence of EQAP organizers in medical laboratories (2002/3) 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.

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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.

9 Related documents

ISO 15193:2009(E)	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). Website: http://www.iso.org
ISO 15194:2009(E)	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). Website: http://www.iso.org
ISO 15195	In vitro diagnostic systems - Requirements for reference measurement laboratories
JCTLM WG2-P-00	Outline of the Calibration and Measurement Hierarchy - Quality Policy and Definitions
JCTLM WG2-P-01	Outline of JCTLM Procedures for Identifying and Listing Reference Measurement Services of Reference Laboratories
JCTLM WG2-P03-A	Process for Verification and Publication of Calibration and Measurement Capability (CMC) Claims in the JCTLM Database (National Metrology Institutes)
JCTLM WG2-P-03-B	Process for Review of Reference Measurement Services from Laboratories who are Accredited as Calibration Laboratories (ISO/IEC 17025 and ISO 15195)
JCTLM WG2-P-03-F-02	Review Report form for a nominated Reference Measurement Service
JCTLM WG2-P-04	Process for Listing Reference Measurement Laboratory Services
JCTLM WG2-P-05	Process for Delisting Reference Measurement Laboratory Services

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10 Revision History

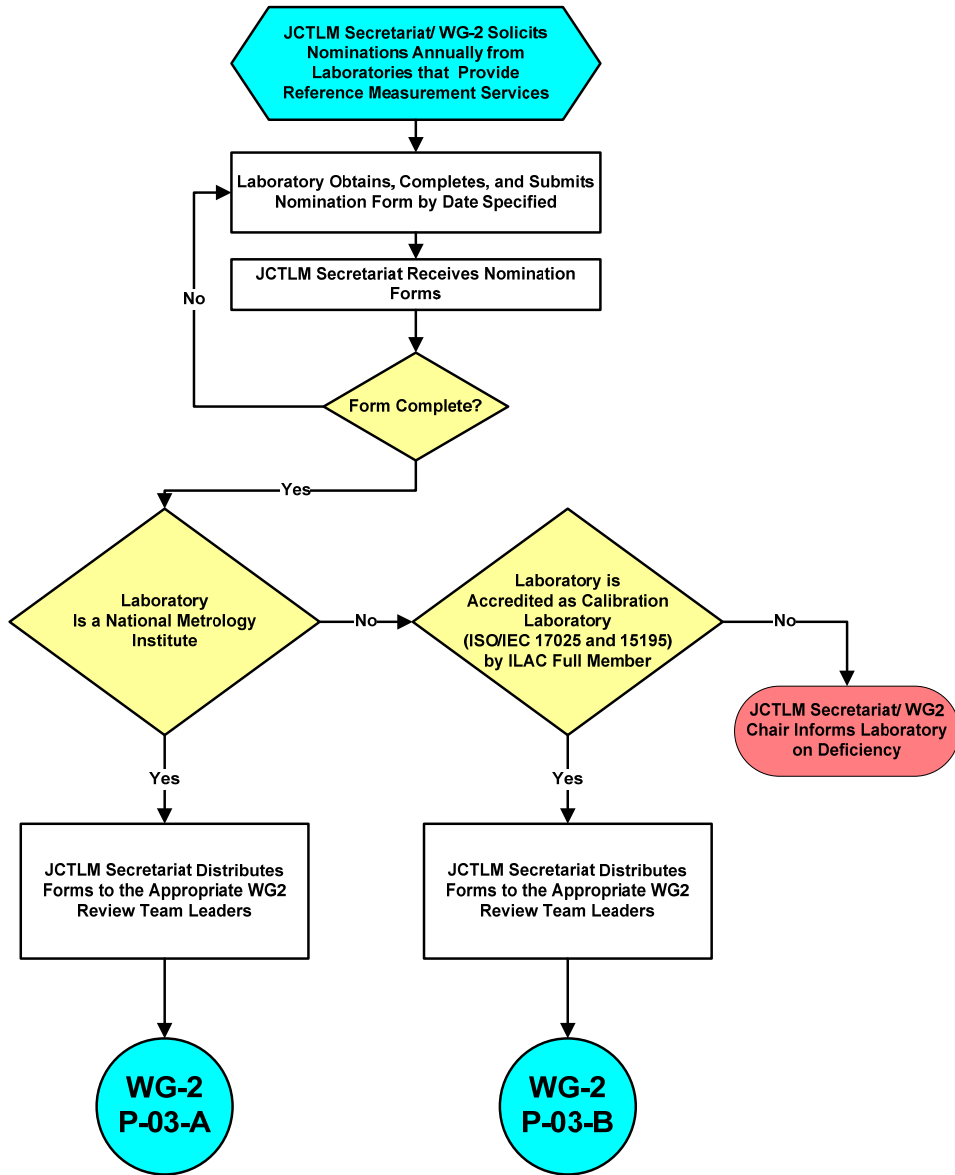
Version number	Date of Issue/Review	Summary of change
1.1	Dec. 06, 2005	Document approved by Executive Meeting Nov. 14, 2005
1.2	Dec. 01, 2006	Modifications in 7.7 and 7.11
1.3	Nov. 27, 2007	Modifications following 5 th Executive Committee meeting decisions
1.4	Dec., 14, 2007	Modifications following 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

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Attachment 1 Flowchart

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Responsibility:
JCTLM Secretariat/ WG-2



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