

TITLE: <i>PROCESS FOR REVIEW OF REFERENCE MEASUREMENT SERVICES FROM LABORATORIES PREPARING FOR ACCREDITATION</i>			
JCTLM WG2-P-03-C Version : 1.56	Date : May <i>Mar 11, 2010 04, 2009</i>	Authorized : JCTLM Executive	

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**PROCEDURE
JCTLM WG2 P-03-C**

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2. 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 not yet accredited but are preparing for accreditation within 3 years after the nomination in the very initial transition period of establishing a JCTLM list of reference laboratories. After 2010 this procedure (P-03-C) will be discarded and reference laboratories have to be accredited when they apply for listing.

3. Scope

This procedure will be applied by the review teams for assessment of laboratory services according to the criteria listed under ‘7. 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

Acronyms used in this procedure are defined in the document JCTLM WG-2 P-00, Outline on 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 WG-2 P-00, Outline on the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions.

6. Responsibilities and Authorizations

Responsibilities and authorizations are given in the document JCTLM WG-2 P-02.

7. Procedure

- 7.1. The process for reviewing services of reference laboratories that are not accredited according to ISO/IEC 17025 and ISO 15195 as calibration laboratories by the Review Teams will take place annually.
- 7.2. The JCTLM Secretariat sends received nominations to the JCTLM Review Teams after consultation with the WG2 chair. The appropriate review team will assess the nomination and other publicly available information according to the following criteria:
 - 7.2.1 Review teams will ascertain that laboratories declare that they are preparing for accreditation according to ISO-17025 **and** ISO-15195. ~~A letter of intent from the laboratory regarding accreditation~~ The official submission letter for accreditation to the Accreditation Body and the response from the Accreditation Body shall be submitted to the JCTLM secretariat as part of the Reference Measurement Service nomination procedure.
 - 7.2.2 Review teams will ascertain 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 Reference Method list the laboratory will be notified to nominate the procedure for review and acceptance by JCTLM WG1.

If the Reference Method is not yet listed but submitted for listing at the same time, the JCTLM Executive will decide on the listing of the Method and the Reference Measurement Service at the same meeting.
 - 7.2.3 Review teams ensure 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 WG-2 P-02-8. The results of the inter-comparisons as well as the result of the individual laboratory related to its identity shall be made publicly available (see also procedure P-02, 8).

It is also acceptable that a laboratory participates for another measurand of the same group of quantities (metabolites & substrates, low-molecular hormones, therapeutic

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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.

- 7.2.4 The results of the review are recorded in the submitted nomination Excel form, the review report form JCTLM WG2 P-03-F-02 and returned to the JCTLM Secretariat. The review report form is forwarded to the nominator at the end of the review cycle.
- 7.2.5 The Review Team recommendations and related documentation are forwarded to WG2 Chairs by the JCTLM Secretariat

8. Related documents

ISO 15195	In vitro diagnostic systems - Requirements for reference measurement laboratories
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
JCTLM WG2-P-00	Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions
JCTLM WG2-P-01	Outline of JCTLM Procedures for Identifying and Listing Reference Measurement Services of Reference Laboratories
JCTLM WG2-P-02	Process for Requesting and Accepting Nominations for JCTLM Listing of Reference Measurement Laboratory Services
JCTLM WG2-P03-A	Process for Review of Reference Measurement Services from National Metrology Institutes which are listed in Appendix C of the CIPM MRA for relevant CMCs.
JCTLM WG2-P-03-B	Process for Review of Reference Measurement Services from Laboratories which are Accredited as Calibration Laboratories (ISO-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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9. Revision History

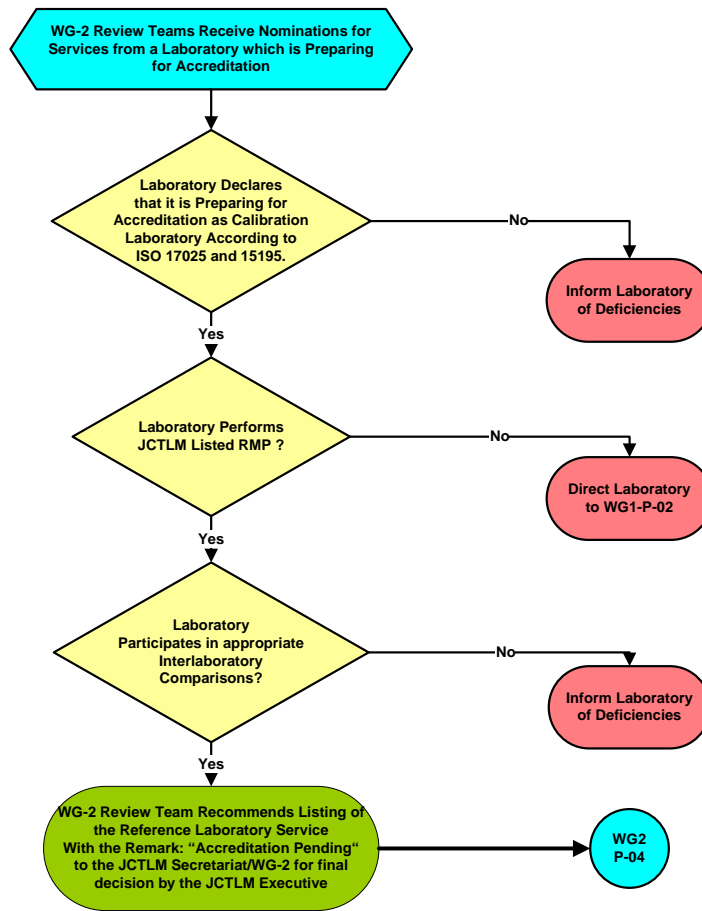
Version number	Date of Issue/Review	Summary of change
1.1	Dec. 06, 2005	Document approved by Executive Meeting Nov 14, 2005
1.2	Dec. 01, 2006	Modification in 7.2.2
1.3	Nov. 27, 2007	Modifications following 5 th Executive meeting decisions
1.4	Dec. 14, 2007	Modifications following 6 th Executive meeting decisions
1.5	May 04, 2009	Modifications following the approval of new accreditation deadlines
<u>1.6</u>	<u>Mar 11, 2010</u>	<u>Modifications following the 8th Executive meeting decisions</u>

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Attachment 1 Flowchart

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WG-2 P-03-C**

Responsibility: JCTLM Review Teams



Rev 05-12-06