

Verification and Publication of calibration and measurement capability (CMC) claims in the JCTLM Database (National Metrology Institutes)			 Accurate results for patient care
JCTLM DBWG-P-03-B1 Version : 4.1	Date : 01 February 2022	Authorized : JCTLM Executive	

Verification and Publication of calibration and measurement capability (CMC) claims in the JCTLM Database (National Metrology Institutes)

1. Purpose

This procedure describes the processes to be followed by review teams (RTs) for verification and publication of calibration and measurement capabilities offered by national metrology institutes (NMIs) to be listed in the JCTLM Database.

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3. Scope

This procedure will be applied by the RTs for assessment of services from NMIs according to the criteria listed under ‘6. Procedure’ of this document based on the calibration and measurement capabilities (CMCs) information published in the BIPM KCDB according to the CIPM MRA as well as 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 of nomination and verification of BIPM KCDB listed CMCs for publication in the JCTLM Database will take place annually. The JCTLM Secretariat receives nominations from NMIs wishing their published CMCs to be listed in the JCTLM Database. The JCTLM Secretariat will pass the documents to the JCTLM RTs after consultation with the DB WG vice-chair(s).

6.1.1. The appropriate JCTLM RT will verify that the nominated CMC is listed in the BIPM-KCDB.

6.1.2. The appropriate JCTLM RT ascertains that the Reference Method which is the basis of the CMC of the NMI 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.

It is also acceptable that a reference measurement service provider claims an extended reference measurement range to a lower limit than the published range of a formerly listed RMP applied by the laboratory, with the provision that a validation report for supporting this extension of the reference measurement range would have been made available to the experts of the review team for confirming there are no modifications of the applied method. A limitation of this acceptance criteria will apply for reference measurement services based on an implemented measurand-defined procedure and the experts of review team may at their discretion request the provision of

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adequate information required for confirming there are no modifications of the applied procedure.

- 6.1.3. The appropriate RT will ascertain regular (at least annual) participation of the candidate laboratory in inter-laboratory comparisons, e.g. the CCQM key comparisons and/or a proficiency testing scheme according to the criteria listed in DB WG 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 DWG 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 RT 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 RTLs. Answers to queries and the RTs' 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 RTs prior formal approval by the JCTLM Executive. (See DB WG P-05)

7. Related documents

JCTLM DBWG-P-02B	Requesting and accepting nominations for JCTLM listing of reference measurement laboratory services
JCTLM DBWG -P03B-F-02	Review report form for reference measurement service nomination
JCTLM DBWG-P-05	Communicating Database WG recommendations
JCTLM EXE-G01	Glossary of terms and definitions; Available at: https://www.bipm.org/en/committees/jc/jctlm/jctlm-procedures

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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 January 2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups
4.1	01 February 2022	Editorial changes; Modification following the decision taken at the 23rd Executive Meeting: Revision of paragraph 6.1.2 to include the new acceptance criteria for listing a reference measurement service of a provider claiming an extended reference measurement range to a lower limit than the acceptable range of the listed RMP, with the provision that a validation report for supporting this extension of the reference measurement range would have been made available to the review team.

Attachment 1 Flowchart

PROCESS FOR VERIFICATION AND PUBLICATION OF CALIBRATION AND MEASUREMENT CAPABILITY (CMC) CLAIMS IN THE JCTLM DATABASE (National Metrology Institutes) - WG DB P-03-B1

Responsibility : JCTLM Secretariat /DB WG

