


<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			 Accurate results for patient care
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

# Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures

## 1. Purpose

This procedure describes the process of reviewing nominated Certified Reference Materials (CRMs) and Reference Measurement Methods/Procedures (RMM/Ps) to assure they meet the quality requirements of the JCTLM for inclusion in its database of available higher-order materials and methods/procedures.

## 2. Contents

1.	<b>PURPOSE</b> .....	1
2.	<b>CONTENTS</b> .....	1
3.	<b>SCOPE</b> .....	1
4.	<b>ACRONYMS AND DEFINITIONS</b> .....	1
5.	<b>RESPONSIBILITIES AND AUTHORIZATIONS</b> .....	1
6.	<b>PROCEDURE</b> .....	2
7.	<b>RELATED DOCUMENTS</b> .....	6
8.	<b>REVISION HISTORY</b> .....	7
9.	<b>FLOW CHART</b> .....	8

## 3. Scope


This procedure will be applied to all complete nominations received by the DB WG Chair and Vice-Chairs for inclusion in the JCTLM database of CRMs and RMM/Ps of higher metrological order.

## 4. 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.

## 5. Responsibilities and Authorizations


- 5.1. The DB WG Chair and Vice-Chairs are responsible for appointing the leaders of the Review Teams (RTs) and for assuring their compliance with this procedure.
- 5.2. The DB WG Vice-Chairs are responsible for transferring recommendations based on the reviews of the nominated materials and methods/procedures from the RTs to the JCTLM Secretariat for submission to the JCTLM Executive Committee (EC) for approval.

<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			 Accurate results for patient care
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

- 5.3. DB WG RTs are responsible for reviewing CRMs and RMM/Ps for a given class of measurands for which they have expertise.
- 5.4. DB WG RT members have the responsibility to become familiar with the appropriate standards against which the nominations are reviewed. (See DB WG P-06)
- 5.5. DB WG RT Leaders are responsible for ensuring completion, review and submission of the review documents, DBWG-P-02A-F-01, DBWG-P-02A-F-02, DBWG-P-03A-F-03.

## 6. Procedure

- 6.1. Completed nomination forms submitted according to DBWG-P-02A are forwarded from the JCTLM Secretariat to the DB WG RT Leaders.
  - 6.1.1. The deadline for distributing the nominations to the appropriate RT Leader is 15 July.
- 6.2. The RT Leader distributes the completed forms and supporting documentation to the RT members.
  - 6.2.1. JCTLM DB WG-P-02A-F-01 Reference Material Nomination Form
  - 6.2.2. JCTLM DB WG-P-02A-F-02 Reference Methods Nomination Form
  - 6.2.3. Validation data for CRMs or RMM/Ps must be available in documents or open access references provided by CRM producers or RMM/P developers/owners to support their nominations.
    - 6.2.3.1. Validation data provided by CRM or RMM/P nominators must support the claims for the CRM or RMM/P as provided on nomination form, DBWG-P-02A-F01 or DBWG-P-02A-F02, respectively.
    - 6.2.3.2. Validation data for RMM/Ps MUST include measurement values obtained from listed CRMs whenever applicable.
    - 6.2.3.3. CRM and RMM/P nominations must include extent-of-equivalence data with at least one other RMM/P already listed in the JCTLM database that is fit for the same purpose and the same measurand. See the demonstration of extent-of-equivalence procedures DBWG P-04A for CRMs, and DBWG P-04B for RMM/Ps.
- 6.3. The RT reviews the completed forms for the purpose of identifying inadequate information required for review against the relevant ISO standards.
  - 6.3.1. Any RT member being also representative of the nominating organization will be excluded by the RT Leader from the evaluation of the nomination until the process ends. See JCTLM DB WG-P-06 for dealing with potential or perceived conflicts of interest.
    - 6.3.1.1. If RT Leader has potential conflict of interest for reviewing nomination(s), he/she will ask if there are members who are prepared to lead the review and a member should be identified as temporary RT Leader for this specific task. The JCTLM Secretariat and the concerned DBWG Vice-Chair shall be copied

<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

to email exchanges related to the task, starting from the task assignment to another lead person.

6.4. RT Leaders may at their discretion via the Secretariat inform the nominator of missing information required for review against the relevant ISO standards and extent-of-equivalence data with listed CRMs and/or RMM/Ps.

6.4.1. Requested information received by the RT Leader by the receipt date indicated by the RT Leader will result in the review occurring during the current review cycle.

6.4.2. Requested information NOT received by the RT Leader by the receipt date indicated by the RT Leader will result in the review being deferred until the next review cycle.

6.5. The RT reviews the completed nominations.

6.5.1. Review criteria based on ISO 15194:2009 and ISO 15193:2009 normative standards are identified on the Compliance Demonstration Spreadsheet of the CRMs and RMM/Ps nomination forms and are used by the RTs to facilitate uniform review by all teams.

6.5.1.1. ISO 15194:2009 is the appropriate standard for CRMs.

6.5.1.2. ISO 15193:2009 is the appropriate standard for RMM/Ps.

6.5.1.3. Prior to the review of nominations according to the standards, the mandatory elements specified in the ISO standards are reviewed with regard to compliance requirements using the Compliance Demonstration Spreadsheet.

6.5.1.4. An attribute may be waived if it is not applicable.


6.5.1.5. If an attribute is waived by a RT, technical justification for recommending waiver must be recorded on the reviewed Compliance Demonstration Spreadsheet.

6.5.1.6. Justification for a waiver must be included on the CRM or RMM/P Review Report DB WG-P-03A-F-03 submitted to the DBWG Vice-Chairs who will determine if the justification is appropriate or unacceptable. The Vice-Chairs may use the entire membership of DB WG to assist with this determination. See DBWG-P-05.

6.5.2. Non-compliance is categorized according to the following criteria:

6.5.2.1. **Major non-compliance:** Indicates that an element of the ISO standard is missing or has been incompletely or inadequately addressed making the nomination inadequately demonstrated to be fit for purpose. A major non-compliance prevents listing in the JCTLM database. The CRM or RMM/P may be listed in the JCTLM database if the corrective action is completed and accepted within a time set by the RT for re-review. The nomination with corrective action may also be resubmitted for the next review cycle.

6.5.2.2. **Minor non-compliance:** Indicates lack of adequate implementation for an element of the ISO standard but does not prevent being fit for purpose.

<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

A minor non-compliance will not prevent listing in the JCTLM database. A minor non-compliance is expected to be corrected within a time set by the RT or the entry will be delisted. Multiple minor non-compliances may be classified as a major non-compliance with corrective actions required before listing.

6.5.2.3. **Observation:** A finding, either positive or negative, which is noted by the RT but does not imply a non-compliance to the elements of a standard and does not prevent listing in the JCTLM database. Observations may be addressed by the nominator to improve the quality of the listing.

6.5.3. Non compliances and their classifications are noted on the Review Report Form to communicate the review team’s findings to the individuals making a given nomination.

6.5.4. Individual RT members, working either individually or in a group, review the individual nominations for compliance with the appropriate ISO standards.

6.5.4.1. Additional information may be required from the nominator for clarification, even though an entry on the nomination template is present. When necessary, the additional information that is required will be noted on the reviewed Compliance demonstration spreadsheet, as appropriate to the particular nomination.

Non compliances and their classifications are noted by individual RT members in the Compliance Demonstration Spreadsheet.

6.5.5. Upon completion of the review, the RT Leader will circulate the recommendations and supporting forms and reviewed Compliance demonstration spreadsheet to all members of the team for review.

6.5.6. Consensus among the RT members will be obtained by the RT Leader for each recommendation.

6.5.7. If a dissenting view exists that could preclude consensus, a brief description of the basis for the dissent may be attached to the review report, DB WG-P-03A-F-03 for consideration by the entire DB WG at its annual meeting.


6.6. Documentation of the basis for the decision to list or not list for each CRM and RMM/P will be recorded by the RT Leader in the Reference Material or Method/Procedure Review Report DB WG-P-03A-F-03.

6.7. The RT Leader forwards the recommendation, forms and reviewed Compliance demonstration spreadsheet to the Secretariat and DB WG Chair and Vice-Chairs.


6.7.1. The deadline for submitting the review documentation is 31<sup>st</sup> October.

6.8. The secretariat compiles all review forms and recommendations and forwards these to the DB WG Vice-Chairs for verification.

6.9. The DB WG Vice-Chairs will review the recommendation and documentation for compliance with this procedure and clarity of the information, particularly with regard to criteria employed if a requirement is to be waived.


<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

- 6.9.1. If clarification is needed, the DB WG Vice-Chairs will request it from the RT Leaders. Answers to queries and the review teams' recommendations and review forms are returned to the JCTLM Secretariat.
- 6.10. The DB WG reviews at its annual meeting the recommendations from the RTs prior to formal approval by the JCTLM EC. (See DB WG P-05)
- 6.10.1. The review forms are forwarded to the nominator at the end of the review cycle following approval of the recommendation by the JCTLM EC. (See EXE-P-05)
- The annual schedule for JCTLM review process is available at <https://www.bipm.org/en/committees/jc/jctlm/jctlm-nominations-and-review>
- 6.11. For all CRMs or RMM/Ps evaluated, the RT evaluates whether other currently listed CRMs or RMM/Ps are intended for the same purpose. When multiple CRMs or RMM/Ps intended for the same use exist, the RT assesses the status and the report for extent-of-equivalence study initiated by the nominator of newly evaluated CRMs or RMM/Ps for comparing with listed CRMs or RMM/Ps for the same measurand. See procedure DB WG P-04A or B.
- 6.12. RT Leaders will note on the Reference Material or Method Review Report that CRMs or RMM/Ps are already listed in the JCTLM database.
- 6.12.1. Lack of extent-of-equivalence data, or non-equivalence, will be noted as a major non-compliance for listing the CRM or RMM/P in the JCTLM database.
- 6.13. Values for measurands approved to be listed for CRMs that are provided by CRM producers on nomination form DBWG-P-02A-F01, will be presented for public access and evaluation as described in DBWG-P-04A. Data for all listed CRMs will be displayed.
- 6.14. Any action required because of unsuitable extent-of-equivalence will be communicated by the JCTLM Secretariat.
- 6.15. Completed Reference Material or Method/Procedure Review Report forms DBWG-P-03A-F-03 will be maintained by the JCTLM Secretariat.

<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

## 7. Related Documents

- EN 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
- EN 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.
- JCTLM EXE-P-05 Review of recommendations from Database Working Group
- JCTLM DBWG-P-02A Requesting and accepting nominations for Certified Reference Materials and Reference Measurement Methods/Procedures
- JCTLM DBWG-P-02A-F-01 Certified Reference Material Nomination Form  
Microsoft Excel Spreadsheet available at:  
<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>
- JCTLM DBWG-P-02A-F-02 Reference Measurement Method/Procedure Nomination Form  
Microsoft Excel Spreadsheet available at:  
<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>
- JCTLM DBWG-P-02A-I-01 Instructions for completing Excel spreadsheets for the nomination of Reference Materials and Reference Measurement Methods/Procedures for the JCTLM database, available at:  
<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>
- JCTLM DBWG-P-03A-F-03 Materials and Methods Review report Form, available at:  
<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>
- JCTLM DBWG-P-04A Process for comparing certified values of the same measurand in multiple reference materials
- JCTLM DBWG-P-04B Demonstrating the extent-of-equivalence of Reference Measurement Methods/Procedures for the same nominal measurand
- JCTLM DBWG-P-05 Communicating DBWG recommendations
- JCTLM DBWG-P-06 Application, nomination and approval for membership on JCTLM review teams
- JCTLM-EC-07 Annex II, Criteria to Assess the Quality of Nominated Nucleic Acid Reference Materials with Stated Nominal Properties (2008)
- JCTLM EXE-G01 Glossary of terms and definitions; Available at:  
<https://www.bipm.org/en/committees/jc/jctlm/jctlm-procedures>

<b>Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures</b>			 Accurate results for patient care
Date : 01 February 2023 Version : 6.0	Authorized : JCTLM Executive	JCTLM DB WG P-03A	

## 8. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	02/23/2004	Initial issue of WG1 Quality System Procedures
2.0	10/15/2005	Clarification of mandatory attribute requirements, form revisions and general text clarity improvement. Replaced term “comparability” with “extent of equivalence” and introduced a request for evidence of extent of equivalence of CRMs or RMM/Ps from validation studies performed by nominating organizations. Added the opportunity for a brief statement to be prepared if a dissenting opinion cannot be resolved within the RT regarding a nomination.
2.1	24/01/2006	Correction of minor textual errors
2.2	09/11/2009	Clarifications of wording to ensure conformity to ISO standards
3.0	27/01/2011	Corrections made in version 2.2 accepted
4.0	03/02/2014	Modifications made following the 11 <sup>th</sup> Executive Committee meeting decision that nominating organizations must demonstrate compliance with ISO 15194: 2009( E) and ISO 15193 :2009(E)
5.0	27/01/2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups
5.1	13/05/2020	Modification made following the 21 <sup>st</sup> Executive Committee meeting: Amendment of paragraph 6.3 related to exclusion from the evaluation process of members representative of nomination organization; and in paragraph 6.4 for clarification of the process for requesting information to nominating organization
5.2	01/02/2022	Editorial changes
6.0	01/02/2023	Modifications discussed at the December 2022 Executive Meeting

**9. Flow chart**

**Process for review and approval of nominated Certified Reference Materials (CRMs) and Reference Measurement Methods/Procedures (RMM/Ps)  
DB WG-P-03A**

