


Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures			 Accurate results for patient care
Author : Robert Wielgosz	Date : 01 February 2022 Version : 5.2	Authorized : JCTLM Executive	

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.

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3. Scope


This procedure will be applied to all complete nominations received by the DB WG Chair and vice-chair(s) for inclusion in the JCTLM lists 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-chair(s) are responsible for appointing the leaders of the 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 for approval.
- 5.3. DB WG RTs are responsible for reviewing materials and methods/procedures for a given class of measurand for which they have expertise.

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- 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 RTLs 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 RTs.
- 6.1.1. The deadline for distributing the nominations to the appropriate RTL is 15 July.
- 6.2. The RTL 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. Method validation data for RMM/Ps must be available in documents or references provided by reference measurement method/procedure developers to support their nominations
- 6.2.3.1. Validation data provided by reference measurement method/procedure developers must support the claims for the RMM/P as provided on nomination form, DBWG-P-02A-F02.
- 6.2.3.2. Validation data MUST include measurement values obtained from listed certified reference materials whenever applicable.
- 6.2.3.3. Validation data must include information on comparison of measurement results achieved with other RMM/Ps that are fit for the same purpose whenever applicable. See the procedure DBWG P-04B for demonstration of extent-of-equivalence for nomination for RMM/Ps for the same measurand.
- 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 team member being also representative of the nominating organization will be excluded 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.
- 6.4. RT leaders may at their discretion via the Secretariat inform the nominator of missing information required for review against the relevant ISO standards.
- 6.4.1. Requested information received by the RTL by the receipt date indicated by the RTL will result in the review occurring during the current review cycle.
- 6.4.2. Requested information NOT received by the RTL by the receipt date indicated by the RTL will result in the review being deferred until the next periodic review cycle.

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6.5. The RT reviews the completed nominations.

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

6.5.1.1. ISO 15194 is the appropriate standard for CRMs.

6.5.1.2. ISO 15193 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 Reference Material or Method/Procedure Review Report DB WG-P-03A-F-03 submitted to the DBWG vice-chair(s) who will determine if the justification is appropriate or unacceptable. The Chair(s) 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. **Critical non-compliance:** indicates that a mandatory element of the standard is not present or its implementation highly ineffective, preventing listing in the JCTLM lists.

6.5.2.2. **Major non-compliance:** Indicates that a mandatory element of the standard has been incompletely implemented. A major non-compliance indicates corrective action is required but the non-compliance by itself will not prevent listing in the JCTLM lists. Multiple major non-compliances can result in the decision not to list in the JCTLM lists.


6.5.2.3. **Minor non-compliance:** Does not meet the criteria of a critical or major non-compliance, but represents a lack of full implementation for an element of the standard. A minor non-compliance will not prevent listing in the JCTLM lists, but corrective action is generally expected to enhance the overall product.

6.5.2.4. **Observation:** A finding, either positive or negative, which is noted by the reviewer but does not, without further classification, imply a non-compliance to the elements of a standard.

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.

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- 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 RTL 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 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 RTL in the Reference Material or Method/Procedure Review Report DB WG-P-03A-F-03.
- 6.7. The RTL forwards the recommendation, forms and reviewed Compliance demonstration spreadsheet to the Secretariat and DB WG Chair and vice-chair(s).
- 6.7.1. The deadline for submitting the review documentation is 31st October.
- 6.8. The secretariat compiles all review forms and recommendations and forwards these to the DB WG vice-Chair(s) for verification.
- 6.9. The DB WG vice-chair(s) 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.
- 6.9.1. If clarification is needed, the DB WG vice-chair(s) will request it from the RTLs. 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 formal approval by the JCTLM Executive. (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 Executive Committee. (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 newly evaluated or 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 nominator of newly evaluated CRMs


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or RMM/Ps for comparing with previous listed CRMs or RMM/Ps for the same measurand. See to procedure DB WG P-04A or B.

- 6.12. RTLs will note on the Reference Material or Method Review Report that CRMs or RMM/Ps are already present on the JCTLM lists.
- 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. Where existing or subsequently obtained data indicate that suitable evidence of comparability might NOT exist, this will be communicated to the DB WG by the organization or laboratory that has made the nomination.
- 6.15. Any action required because of unsuitable extent of equivalence will be communicated by the JCTLM Secretariat.
- 6.16. Completed Reference Material or Method/Procedure Review Report forms DBWG-P-03A-F-03 will be maintained by the JCTLM Secretariat.

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
JCTLM DBWG-P-02A-F-02	Reference Measurement Method/Procedure Nomination Form
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
JCTLM DBWG-P-03A-F-03	Materials and Methods Review report Form
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

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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>

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 th 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 st 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

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JCTLM DB WG P-03A



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**

