

Requesting and accepting nominations for Certified Reference Materials and Reference Measurement Methods/Procedures

1. Purpose

This document describes the process employed by the Joint Committee for Traceability in Laboratory Medicine (JCTLM) for soliciting, receiving and verifying the completeness of the nominations of certified reference materials (CRMs) and reference measurement methods/procedures (RMM/Ps) to be listed as being of a higher metrological order.

2. Contents

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

3. Scope

This procedure applies to all nominations of CRMs and RMM/Ps for classification as being of a higher metrological order i.e., at position m.3 or higher in ISO 17511:2020, by the JCTLM DB WG review teams according to the criteria given in the normative ISO standards.

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. Oversight responsibility and authority for the operations of the DB WG resides with the DB WG Chair, and Vice-Chairs.

5.1.1. Communicating recommendations to the JCTLM Secretariat for listing CRMs and RMM/Ps of a higher metrological order is the responsibility of the DB WG Vice-Chairs

- 5.1.2. Communicating recommendations of nominated CRMs and RMM/Ps to the DB WG Vice-Chairs based on their fulfillment of the criteria specified by ISO 15194:2009 and ISO 15193:2009 is the responsibility of the team leaders of the review teams (RTs).
- 5.2. Oversight responsibility for the DB WG Chair and Vice-Chair(s) resides with the JCTLM Executive Committee (EC).
- 5.3. Authority for deciding that recommended CRMs and RMM/Ps be listed resides with the JCTLM EC.
- 5.4. Responsibility for the maintenance of procedures employed by DB WG resides with the Quality System Development Team
- 5.5. Authority to approve procedures of the JCTLM DB WG resides with the EC.

6. Procedure

6.1. The process for nominating and reviewing CRMs and RMM/Ps of a higher metrological order for recommendation by the JCTLM for listing in the database will occur annually.

6.1.1. In the case where the recommendation for listing is pending corrective actions from the nominating organization, responses to the RTs' comments shall be submitted within the time agreed with the RT. Responses must be reported in the report form where appropriate for further consideration by the concerned RT.

Responses received after the specified date may be deferred to the next review cycle.

6.2. Nominations are solicited exclusively from producers of CRMs and developers/owners of RMM/Ps

The Secretariat announces an open solicitation for nominations of CRMs and RMM/Ps for inclusion in the JCTLM database of available materials and methods/procedures of a higher metrological order. The solicitation is made each year from February to the end of May. The solicitation announcement is found on the website of the BIPM at:
<https://www.bipm.org/en/committees/jc/jctlm/jctlm-nominations-and-review>

6.2.1. Higher order CRMs correspond to positions m.1, m.2 and m.3, and higher order RMM/Ps correspond to position p.3, described in ISO 17511:2020.

6.2.2. A fixed date for receiving completed nominations will be specified in the announcement. Nominations received after the date specified in the solicitation announcement may be deferred for review in a subsequent review cycle.

6.2.2.1. The deadline for submitting nominations is normally 31st May. ~~In the case of RMM/P nominations, the submission deadline remains the same, but it is possible to submit the final version (non-changeable format) of its supporting documentation for publication by the 30th September.~~

6.3. Obtaining Nomination Forms:

Providers of CRMs and developer/owners of RMM/Ps can obtain nomination forms from download on the BIPM website at:

<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>

Requesting and accepting nominations for Certified Reference Materials and Reference Measurement Methods/ProceduresDate : 01 February 2026
Version : 8.0Authorized :
JCTLM Executive

JCTLM DBWG-P-02A

**Reference Material Nomination Form (DBWG-P-02A-F-01)****Reference Method/Procedure Nomination Form (DBWG-P-02A-F-02)****6.4. Submitting Nomination Forms for consideration by the DB WG:**

- 6.4.1. Nominating forms must be submitted by email to the JCTLM Secretariat at jctlm@bipm.org. Instructions for completing the forms can be found in the document DBWG-P-02A-I-01.
- 6.4.2. Only nominations submitted from producers of CRMs or developer/owners of RMM/Ps will be accepted for review.
- 6.4.3. Producers of CRMs and developer/owners of RMM/Ps acknowledge that a submitted nomination constitutes consent to include the CRM or RMM/P in the JCTLM database.

6.5. Certified Reference Materials

- 6.5.1. Only CRMs for which the requisite information required by ISO 15194:2009 for evaluation is publicly available can be candidates for listing.
- 6.5.2. CRMs can be listed only if the producer conducts extent-of-equivalence studies with the same measurand(s) in other CRMs already listed in the JCTLM database.
 - 6.5.2.1. When submitting a nomination of a CRM, the producer must identify if currently listed CRMs are intended for the same purpose, and submit an extent-of-equivalence study with at least one other CRM already listed for the same measurand when appropriate. See document DBWG P-04A which describes methods to ascertain extent-of-equivalence of performance of CRMs.
 - 6.5.2.2. If comparison results indicate unacceptable equivalence amongst CRMs, the nominated CRM under review will not be accepted for listing in the database until the discrepancies are resolved. The nominator and provider of existing CRM(s) are expected to collaborate with the RT to investigate the issue.

- 6.5.3. By submitting a nomination of a CRM, the producer acknowledges that, if the nomination is accepted, the results of comparison studies with other listed CRMs for the same measurand(s) will be publicly available for consultation on the JCTLM website and consents to this requirement.

6.6. Reference Measurement Methods/Procedures

- 6.6.1. Only RMM/Ps for which the requisite information required by ISO 15193:2009 for evaluation for performing the RMM/P is publicly available can be considered for listing.
- 6.6.2. RMM/P can be listed only if the developer conducts comparison studies to establish the extent-of-equivalence with at least one other RMM/P already listed in the JCTLM database that is fit for the same purpose. See procedure DBWG-P-04B.
 - 6.6.2.1. When submitting a nomination of a RMM/P, the developer must identify if currently listed RMM/Ps are intended for the same purpose, and submit

an extent-of-equivalence study with at least one other RMM/P already listed for the same measurand when appropriate.

6.6.2.2. The extent-of equivalence shall include an assessment of the influence of the RMM/P when used within calibration hierarchies already in use for available end-user laboratory measurement results, when such end-user measuring systems exist.

6.6.2.3. If comparison results indicate non-equivalence or uncertainty too large to be fit for purpose amongst RMM/Ps, the nominated RMM/P under review will not be accepted for listing in the database until the discrepancies are resolved. The nominator and developers/owners of existing RMM/Ps are expected to collaborate with the RT to investigate the issue.

6.6.2.4. By submitting a nomination for a RMM/P, the developer acknowledges that the results of comparison studies with other listed RMM/Ps that are fit for the same purpose will be publicly available for consultation on the JCTLM website and consents to this requirement.

6.7. Nomination Process

6.7.1. Nominations for CRMs or RMM/Ps are to be made by completing in full the following forms.

6.7.1.1. Materials nomination spreadsheet (Microsoft Excel) form (DBWG-P-02A-F-01 Reference Material Nomination Form) is referenced to ISO 15194:2009.

6.7.1.1.1. A Compliance demonstration spreadsheet included in the reference material nomination form being submitted, must be completed by the nominating organization to describe how compliance is met for all requirements listed in ISO 15194:2009.
The submission of a separate supporting document summarizing how compliance is met with references in the nomination spreadsheet is acceptable.

6.7.1.1.2. When submitting a revised nomination for a CRM, the producer must provide a point-to-point response to RT's observations from a preceding review cycle, with a written explanation added in the compliance demonstration spreadsheet describing modifications and corrective actions completed for addressing observed non-compliances against ISO 15194:2009 requirements. If a revised version of the certificate of analysis and/or the certification report is also being submitted, all modifications should be highlighted using a different color (e.g., in red if the original text is in black) in the new version of these supporting documents.

6.7.1.2. RMM/P nomination spreadsheet (Microsoft Excel) form (DBWG-P-02A-F-02 Reference Measurement Method/Procedure Nomination Form) is referenced to ISO 15193:2009.

6.7.1.2.1. A Compliance demonstration spreadsheet included in the RMM/P nomination form being submitted, must be completed by the

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JCTLM DBWG-P-02A



nominating organization to describe how compliance is met for all requirements listed in ISO 15193:2009.

The submission of a separate supporting document summarizing how compliance is met with references in the nomination spreadsheet is acceptable.

6.7.1.2.2. When submitting a revised nomination for an RMM/P, the developer must provide a point-to-point response to RT's observations from a preceding review cycle, with a written explanation added in the compliance demonstration spreadsheet describing modifications and corrective actions completed for addressing observed non-compliances against ISO 15193:2009 requirements. If a revised version of the RMM/P supporting documentation is also being submitted, all modifications should be highlighted using a different color (e.g., in red if the original text is in black) in the new version of the documentation.

6.8. The Secretariat reviews nominations for completeness within one month of their receipt.

6.8.1. The preliminary review is only concerned with completeness and is NOT a review of the qualification of the nominated material or method/procedure.

6.8.2. Incomplete forms will be returned to the individual making the nomination.

6.8.3. Returned nomination forms that are incomplete may be amended and resubmitted once during a review cycle.

6.8.4. Resubmissions must be received by the date specified on the solicitation.

6.8.5. Nominations or resubmissions which are incomplete will not be reviewed in the current cycle.

6.8.6. Nominations or resubmissions which are received after the date specified may be held until the next review cycle.

6.9. Distributing Nominations to the DB WG review teams

6.9.1. The Secretariat distributes in consultation with the DB WG Vice-Chairs the nominations to the RT leaders of the appropriate RTs to perform the review.

6.9.2. Any DB WG review team member affiliated with a nominating organization will not participate in the evaluation of a material or method/procedure from that organization. See JCTLM DB WG-P-06 for dealing with potential or perceived conflicts of interest.

6.9.2.1. Should a lack of experts make this restriction unenforceable, an exception can be made only with prior consent of the JCTLM EC.

6.10. The distributed nominations are reviewed by the DB WG RTs according to JCTLM DBWG-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
EN ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
JCTLM Preamble	Available at - https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications
JCTLM DBWG-P-00	Quality Policy of the JCTLM Database working group
JCTLM DBWG-P-01A	Outline of JCTLM DB WG process for evaluating and listing higher order materials and methods
JCTLM DBWG-P-03A	Review and approval of nominated Certified Reference Materials and Reference Measurement Methods/Procedures
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 measurand
JCTLM DBWG-P-02A-F-01	Reference Material Nomination Form, Microsoft Excel 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 Method/Procedures for the JCTLM Database, available at: https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications
JCTLM DBWG-P-06	Application, nomination and approval for membership on JCTLM review teams
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	01/08/2004	Initial issue of WG1 Quality System Procedures
2.0	10/15/2005	Transfer of Section 6.3 to a FAQ file to be available on JCTLM website, introduction of website links into document for nomination forms and contacts for JCTLM. Clarification of ambiguous wording. Formalization of Secretariat as official for receipt of nomination and communication with nominators of CRMs and RMM/Ps.
2.1	24/01/2006	Correction of minor textual errors
3.0	09/11/2009	Revised to comply with ISO 15194:2009(E) and ISO 15193:2009(E)
4.0	27/01/2011	Corrections made in version 3.0 accepted
4.1	30/04/2013	Modifications made following the 10 th Executive Committee meeting decisions with addition of paragraphs 7.2.2.1 and 7.2.2.2
5.0	03/02/2014	Modifications made following the 11 th Executive Committee meeting decision that nominating organizations must declare compliance with ISO 15194:2009(E) and ISO 15193:2009(E)
6.0	27/01/2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups
6.1	01/02/2019	Update of hyperlinks
6.2	11/06/2020	Modification made following the 21 st Executive Committee meeting: Revision of paragraph 6.6.2 to include a clause on conflict of interest and confidentiality which apply during the review process
6.3	10/02/2021	Modifications of paragraph 6.4.11 made following the 22nd Executive Committee meeting decision that the submission of a separate supporting document summarizing how compliance is met with reference in the nomination spreadsheet is acceptable
6.4	01/02/2022	Editorial changes; Modifications of paragraph 6.4.11 made following the 23 rd Executive Committee meeting decision that nominating organizations must submit written explanation of their response to review teams' observations and recommendation for corrective action for addressing non-compliance against ISO 15194:2009(E) and ISO 15193:2009(E) requirements.
7.0	01/02/2023	Modifications discussed at the December 2022 Executive Meeting
8.0	01/02/2026	Modifications of section 6.2.2.1 discussed at the December 2025 Executive Meeting with the removal of the 30 th September deadline for provision of supporting documents.

9. Flow chart

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures

DB WG-P-02A

