


<b>Requesting and accepting nominations for Certified Reference Materials and Reference Measurement Methods/Procedures</b>			 Accurate results for patient care
Author : Robert Wielgosz	Date : 01 February 2022 Version : 6.4	Authorized : JCTLM Executive	

# 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.

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## 3. Scope


This procedure applies to all nominations of certified reference materials and reference measurement methods/procedures for classification as being of a higher metrological order 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(s).
  - 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-chair(s)

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- 5.1.2. Communicating recommendations of nominated materials and methods/procedures to the DB WG vice-chair(s) based on their fulfillment of the criteria specified by ISO 15194:2009(E) and ISO 15193:2009(E) is the responsibility of the team leaders of the review teams.
- 5.2. Oversight responsibility for the DB WG Chair and vice-chair(s) resides with the JCTLM Executive.
- 5.3. Authority for deciding that recommended CRMs and RMM/Ps be listed resides with the JCTLM Executive.
- 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 Executive.

## 6. Procedure

- 6.1. The process for nominating and reviewing materials and methods/procedures of a higher metrological order for recommendation by the JCTLM for listing in the database will occur annually.
- 6.2. Nominations are solicited exclusively from producers of CRMs and developer/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. 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.
  - 6.2.1.1. The deadline for submitting nominations is 31<sup>st</sup> May. In the case of reference method nominations, the submission deadline remains 31<sup>st</sup> May, but it is possible to submit the final version (non-changeable format) of its supporting documentation or publication by the 30<sup>th</sup> 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>

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](mailto:jctlm@bipm.org). Instructions for completing the forms can be found in the document DBWG-P-02A-I-01.

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- 6.4.2. Only nominations submitted from producers of CRMs or developer/owners of RMM/Ps will be accepted for review by the review teams.
- 6.4.3. Producers of reference materials and developer/owners of RMM/Ps acknowledge that a submitted nomination constitutes consent to include the material or method/procedure on the JCTLM List I of CRMs and RMM/Ps, or JCTLM List II of CRMs, or JCTLM List III of CRMs.
- 6.4.3.1. Distinctions between List I, List II, and List III materials are given in the Preamble to the JCTLM DB WG Quality Manual.
- 6.4.3.2. JCTLM DB WG will recommend on which list nominated CRMs are to be included.
- 6.4.4. Only materials for which the requisite information required by ISO 15194 for evaluation is publicly available can be candidates for listing.
- 6.4.5. Materials can be listed only if the producer consents to comparison studies with the same measurand(s) in other materials already listed or that are nominated.
- 6.4.5.1. When submitting a nomination of a CRM, the producer must identify if currently listed CRMs are intended for the same purpose, and subsequently carry out a comparison study for comparing certified values of the same measurand in multiple Reference Materials when appropriate. See document DBWG P-04A which describes methods to ascertain comparability of CRM values.
- 6.4.6. By submitting a nomination of a CRM, the producer acknowledges that 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.
- 6.4.7. Only methods for which the requisite information for performing the RMM/P is publicly available can be considered for listing.
- 6.4.8. Methods can be listed only if the developer consents to comparison studies with other methods already listed or nominated for inclusion in JCTLM lists that are fit for the same purpose. See procedure DBWG-P-04B.
- 6.4.8.1. When submitting a nomination of a RMM/P, the developer must identify if currently listed RMM/Ps are intended for the same purpose, and subsequently carry out a comparison study of methods for the same measurand when appropriate.
- 6.4.8.2. If subsequently obtained comparison results indicate that variability greater than expected from the combined uncertainties of compared methods exists, the developers of the concerned methods shall be informed and are required to investigate and resolve the differences. The need for corrective actions shall be reported and may result in temporary delisting until the discrepancies are resolved, and the developer consents to this requirement.
- 6.4.9. 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

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purpose will be publicly available for consultation on the JCTLM website and consents to this requirement.

6.4.10. When submitting a nomination for a RMM/P for a measurand not yet covered by JCTLM the developer shall state the expected impact of the method within a calibration hierarchy on available routine laboratory measurement results.

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

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

6.4.11.1.1. 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(E).

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


6.4.11.1.2. When submitting a revised nomination for a CRM, the producer must provide a point-to-point response to review team'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(E) 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.

6.4.11.2. Reference method/procedure nomination spreadsheet (Microsoft Excel) form (DBWG-P-02A-F-02 Reference Measurement Method/Procedure Nomination Form) is referenced to ISO 15193.

6.4.11.2.1. A Compliance demonstration spreadsheet included in the reference method/procedure nomination form being submitted, must be completed by the nominating organization to describe how compliance is met for all requirements listed in ISO 15193:2009(E).

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

6.4.11.2.2. When submitting a revised nomination for a RMM/P, the developer must provide a point-to-point response to review team's observations from a preceding review cycle, with a written explanation added in the compliance demonstration spreadsheet describing modifications and corrective actions completed for


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addressing observed non-compliances against ISO 15193:2009(E) requirements. If a revised version of the method 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.

- 6.5. The Secretariat reviews nominations for completeness within one month of their receipt.
- 6.5.1. The preliminary review is only concerned with completeness and is NOT a review of the qualification of the nominated material or method/procedure.
- 6.5.2. Incomplete forms will be returned to the individual making the nomination.
- 6.5.3. Returned nomination forms that are incomplete may be amended and resubmitted once during a review cycle.
- 6.5.4. Resubmissions must be received by the date specified on the solicitation.
- 6.5.5. Nominations or resubmissions which are incomplete will not be reviewed in the current cycle.
- 6.5.6. Nominations or resubmissions which are received after the date specified may be held until the next review cycle.
- 6.6. Distributing Nominations to the DB WG review teams
- 6.6.1. The Secretariat distributes in consultation with the DB WG vice-chair(s) the nominations to the team leaders of the appropriate review teams to perform the review.
- 6.6.2. 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.
- 6.6.2.1. Should a lack of experts make this restriction unenforceable, an exception can be made only with prior consent of the JCTLM Executive.
- 6.7. The distributed nominations are reviewed by the DB WG review teams according to JCTLM DBWG-P-03A.

## 7. Related documents

- EN ISO 15193:2009(E) 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(E) 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 18153:2003 *In vitro* diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

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JCTLM Preamble	Available at - <a href="https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications">https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications</a>
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 Spreadsheet available at: <a href="https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications">https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications</a>
JCTLM DBWG-P-02A-F-02	Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet available at: <a href="https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications">https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications</a>
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: <a href="https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications">https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications</a>
JCTLM DBWG-P-06	Application, nomination and approval for membership on JCTLM review teams
JCTLM EXE-G01	Glossary of terms and definitions; Available at: <a href="https://www.bipm.org/en/committees/jc/jctlm/jctlm-procedures">https://www.bipm.org/en/committees/jc/jctlm/jctlm-procedures</a>

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P-02A**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 <sup>th</sup> 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 <sup>th</sup> 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 <sup>st</sup> 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 22 <sup>nd</sup> 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 <sup>rd</sup> 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.

## 9. Flow chart

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

#### DB WG-P-02A

