

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

PROCESS FOR REQUESTING AND ACCEPTING NOMINATIONS FOR CERTIFIED REFERENCE MATERIALS AND REFERENCE MEASUREMENT METHODS/PROCEDURES

JCTLM WG1-P-02

PRIMARY AUTHOR	AUTHORIZED
NAME CRAIG M. JACKSON	NAME JCTLM EXECUTIVE
FUNCTION MEMBER/LEADER, JCTLM WG1 PROCEDURES TEAM	FUNCTION
SIGNATURE	SIGNATURE

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PROCESS FOR REQUESTING AND ACCEPTING NOMINATIONS FOR CERTIFIED REFERENCE MATERIALS (CRMs) AND REFERENCE MEASUREMENT METHODS/PROCEDURES (RMM/Ps)

1. Contents

PARAGRAPH	TITLE	PAGE
1.	CONTENTS.....	2
2.	PURPOSE.....	2
3.	SCOPE.....	2
4.	ACRONYMS.....	3
5.	DEFINITIONS.....	3
6.	RESPONSIBILITIES AND AUTHORIZATIONS.....	3
7.	PROCEDURE.....	3
8.	RELATED DOCUMENTS.....	6
9.	ATTACHMENTS.....	7
10.	REVISION HISTORY.....	7
	ATTACHMENT 1 JCTLM WG1-P-02-F-01 REFERENCE MATERIAL NOMINATION FORM, MICROSOFT EXCEL SPREADSHEET.....	9
	ATTACHMENT 2 JCTLM WG1-P-02-F-02 REFERENCE MEASUREMENT METHOD/PROCEDURE NOMINATION FORM, MICROSOFT EXCEL SPREADSHEET	9
	ATTACHMENT 3 JCTLM WG1-P-02-I-01 INSTRUCTIONS FOR COMPLETING EXCEL FILES FOR THE NOMINATION OF REFERENCE MATERIALS AND REFERENCE MEASUREMENT METHODS/PROCEDURES FOR THE JCTLM DATABASE	9

2. Purpose

This procedure describes the processes employed by JCTLM for soliciting, receiving and verifying the completeness of nominations of certified reference materials and reference measurement methods/procedures to be listed as being of higher metrological order. Completed nomination forms are transferred to JCTLM WG1 for review according to WG1-P-03.

3. Scope

This procedure is applied to all nominations of certified reference materials and reference measurement methods/procedures for classification as being of higher metrological order by

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

JCTLM WG1RTs according to the criteria given in ISO 15194:2009(E) and ISO 15193:2009(E), respectively.

4. Acronyms

Acronyms used in these procedures are defined in the document JCTLM WG1-P-00, Quality Policy and Definitions.

5. Definitions

Definitions for the terms used in these procedures are given in the document JCTLM WG1-P-00, Quality Policy and Definitions.

6. Responsibilities and Authorizations

- 6.1. Oversight responsibility and authority for the operations of WG1 resides with the WG1 Chair(s).
 - 6.1.1. Communicating recommendations to the JCTLM Secretariat for listing CRMs and RMM/Ps of higher metrological order is the responsibility of the WG1 Chair(s).
 - 6.1.2. Communicating recommendations of nominated materials and methods/procedures to the WG1 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 WG1RTs.
- 6.2. Oversight responsibility for the WG1 Chair(s) resides with the JCTLM Executive.
- 6.3. Authority for deciding that recommended CRMs and RMM/Ps be listed resides with the JCTLM Executive.
- 6.4. Responsibility for the maintenance of procedures employed by WG1 and authority to appoint *ad hoc* teams to perform the procedure maintenance resides with WG1 Chair(s).
- 6.5. Authority to approve procedures of the JCTLM WG1 resides with the Executive.

7. Procedure

- 7.1. The process for nominating and reviewing materials and methods/procedures of a higher metrological order for recommendation by the JCTLM for listing will occur no less frequently than biennially.
- 7.2. Nominations are solicited exclusively from producers of CRMs and developer/owners of RMM/Ps.
 - 7.2.1. The WG1 Chair(s) announce an open solicitation for nominations of CRMs and RMM/Ps for inclusion in the JCTLM lists of materials and methods/procedures of higher metrological order. The solicitation is made

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

periodically on the basis of need and availability of resources. The solicitation announcements are found on the websites of the BIPM, the IFCC, and other professional organizations with interests in *in vitro* diagnostic devices. The opening of nominations may also be announced in professional and trade journals by the WG1 Chair(s).

7.2.2. 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.

7.3. Obtaining Nomination Forms:

7.3.1. Providers of CRMs and developer/owners of RMM/Ps can obtain nomination forms by:

7.3.1.1. Downloading from the BIPM or IFCC websites.

<http://www.bipm.org/utills/en/xls/WG1-P-02-F-01.xls>

<http://www.bipm.org/utills/en/xls/WG1-P-02-F-02.xls>

7.3.1.2. Email request to the JCTLM Secretariat at jctlm@bipm.org

7.3.1.3. Letter request to the JCTLM Secretariat at Bureau des Poids et Mesures, Pavillon de Breteuil F, 92312 Sevres Cedex, France.

7.4. Submitting Nomination Forms for Consideration by WG1:

7.4.1. Nominating forms must be submitted to the JCTLM Secretariat at jctlm@bipm.org. Additional information and instructions for completing the forms are found on the BIPM website.

<http://www.bipm.org/utills/en/pdf/WG1-P-02-I-01.pdf>

7.4.2. Only nominations submitted from producers of CRMs or developer/owners of RMM/Ps will be accepted for review by the WG1RTs.

7.4.3. 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 or RMM/Ps or JCTLM List II, or JCTLM List III.

7.4.3.1. Distinctions between List I, List II, and List III materials are given in the Preamble to the JCTLM Quality System Manual and in WG1-P-00.

7.4.3.2. JCTLM WG1 will recommend on which list nominated CRMs are to be included.

7.4.4. Only materials for which the requisite information required by ISO 15194 for evaluation is publicly available can be candidates for listing.

7.4.5. Only materials from producers who are willing to provide the JCTLM-nominated laboratories with sufficient samples of the material free of charge in order to undertake comparability studies can be candidates for listing.

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

- 7.4.6. 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.
- 7.4.7. 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 review on the JCTLM website and consents to this requirement.
- 7.4.8. Only methods for which the requisite information for performing the RMM/P is publicly available can be considered for listing.
- 7.4.9. Nominations for CRMs or RMM/Ps are to be made by completing in full the following forms.
- 7.4.9.1. Materials nomination spreadsheet (Microsoft Excel) form (WG1-P-02-F-01 Reference Material Nomination Form) is referenced to ISO 15194.
- 7.4.9.1.1. All non-compliant items with ISO 15194:2009 requirements will be declare by the nominating organization in the appropriate Deviation List spreadsheet included in the Reference Material nomination form being submitted
- 7.4.9.2. Reference method/procedure nomination spreadsheet (Microsoft Excel) form (WG1-P-02-F-02 Reference Measurement Method/Procedure Nomination Form) is referenced to ISO 15193.
- 7.4.9.2.1. All non-compliant items with ISO 15193:2009 requirements will be declare by the nominating organization in the appropriate Deviation List spreadsheet included in the Reference Method/Procedure nomination form being submitted
- 7.4.10. Submission is to be to the JCTLM Secretariat and may be by any of the following means:
- 7.4.10.1. An attachment to an email message to jctlm@bipm.org
- 7.4.10.2. Electronic medium, diskette or CD ROM sent to the Secretariat at the address given on the website:
<http://www.bipm.org/en/committees/jc/jctlm/>
- 7.5. The Secretariat or designee reviews nominations for completeness within one month of their receipt.
- 7.5.1. The preliminary review is only concerned with completeness and is NOT a review of the qualification of the nominated material or method/procedure.
- 7.5.2. Incomplete forms will be returned to the individual making the nomination.
- 7.5.3. Returned nomination forms that are incomplete may be amended and resubmitted once during a review cycle.
- 7.5.4. Resubmissions must be received by the date specified on the solicitation.

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

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

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

7.6. Distributing Nominations to WG1RTs

7.6.1. The WG1 Chair(s) receive the completed nomination forms from the Secretariat within one month after the deadline date for receipt of nominations.

7.6.2. The WG1 Chair(s) distribute nominations to the team leaders of the appropriate WG1RTs to perform the review.

7.6.3. Any WG1RT member affiliated with a nominating organization will not participate in the evaluation of that material or method/procedure if a potential conflict of interest exists or is perceived to exist. See JCTLM WG1-P-06.

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

7.7. The distributed nominations are reviewed by the WG1RTs according to JCTLM WG1-P-03 "Process for Review and Approval of Nominated Certified Reference Materials and Reference Measurement Methods/Procedures."

8. Related documents

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
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
JCTLM WG1-P-00	Quality Policy and Definitions
JCTLM WG1-P-01	Outline of JCTLM Procedures for Evaluating Certified Reference Materials and Reference Measurement Methods/Procedures to be listed as Being of Higher Metrological Order.
JCTLM WG1-P-02-F-01	Reference Material Nomination Form, Microsoft Excel Spreadsheet
JCTLM WG1-P-02-F-02	Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet
JCTLM WG1-P-03	Process for Review and Approval of Nominated Certified Reference Materials and Reference Measurement Methods/Procedures

Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

JCTLM WG1 –P-02 I-01 Instructions for completing Excel files for the nomination of Reference Materials and Reference Measurement Method/Procedures for the JCTLM Database

JCTLM WG1 –P-06 Application, Nomination and Approval for Membership on WG1 Review Teams

9. Attachments

- Attachment 1 JCTLM WG1-P-02-F-01 Sample Reference Material Nomination Form, Microsoft Excel Spreadsheet – Current version can be downloaded from
<http://www.bipm.org/utis/en/xls/WG1-P-02-F-01.xls>
- Attachment 2 JCTLM WG1-P-02-F-02 Sample Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet – Current version can be downloaded from
<http://www.bipm.org/utis/en/xls/WG1-P-02-F-02.xls>
- Attachment 3 JCTLM WG1-P-02-I-01 Instructions for completing Excel files for the nomination of Reference Materials and Reference Measurement Methods/Procedures for the JCTLM Database. The current version can be obtained from:
<http://www.bipm.org/utis/en/pdf/WG1-P-02-I-01.pdf>

10. Revision History

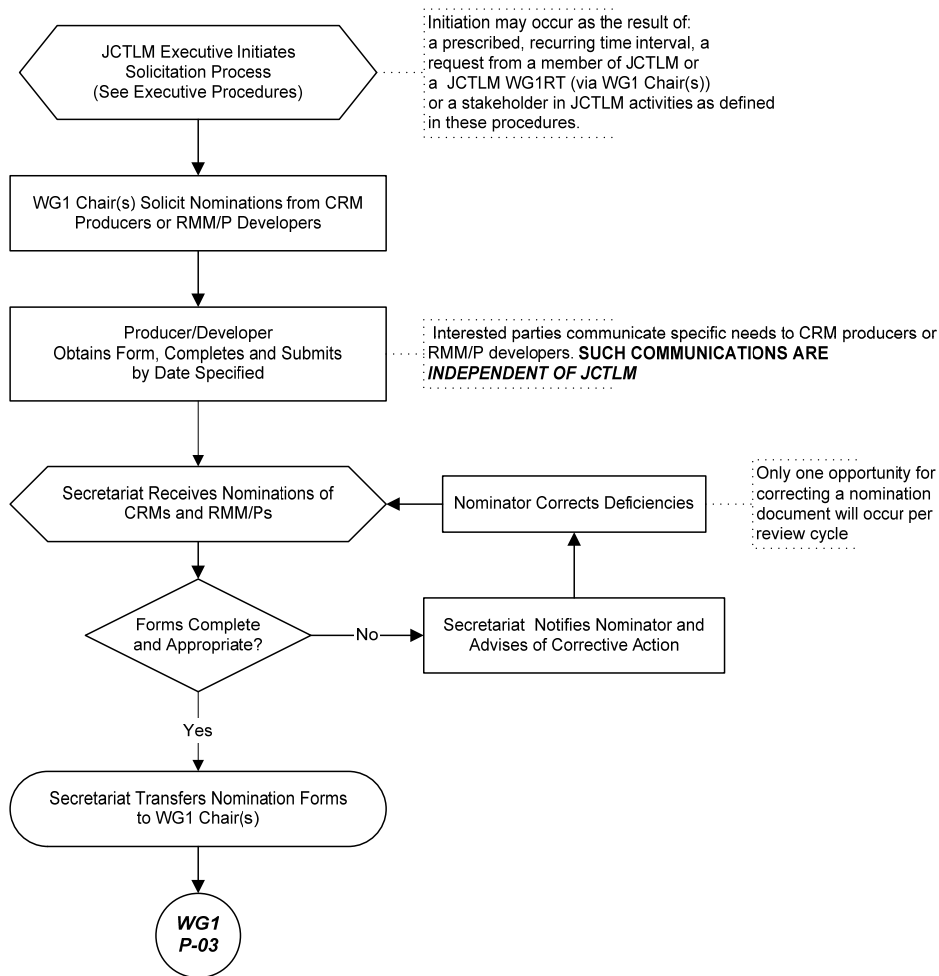
Version number	Date of Issue/Review	Summary of change
1.0	01/08/2004	Initial issue of WG1 Quality System Procedures
2.0	10/15/2005	Transfer of Section 6.3 to a FAQ file to be available on JCTLM website, introduction of website links into document for nomination forms and contacts for JCTLM. Clarification 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

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Flowchart

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Author : C. M. Jackson	Date : 2011/01/27 Version : 4.0	Authorized : JCTLM Executive	JCTLM WG 1 P-02

Attachment 1 JCTLM WG1-P-02-F-01 Reference Material Nomination Form, Microsoft Excel Spreadsheet

JCTLM WG1-P-02-F-01 Reference Material Nomination Form, Microsoft Excel Spreadsheet is a separate item and is included within this procedure document only as an example. The current version can be obtained from <http://www.bipm.org/utis/en/xls/WG1-P-02-F-01.xls>.

Attachment 2 JCTLM WG1-P-02-F-02 Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet

JCTLM WG1-P-02-F-02 Reference Measurement Method Nomination Form, Microsoft Excel Spreadsheet is a separate item and is included within this procedure document only as an example. The current version can be obtained from

<http://www.bipm.org/utis/en/xls/WG1-P-02-F-02.xls>.

Attachment 3 JCTLM WG1-P-02-I-01 Instructions for completing Excel files for the nomination of Reference Materials and Reference Measurement Methods/Procedures for the JCTLM Database

JCTLM WG1-P02-I-01 Instructions for completing Excel files for the nomination of Reference Materials and Reference Measurement Procedures for the JCTLM Database provides explicit descriptions of the contents of each of the fields on the nomination forms and how to complete them. The included version is provided as an example. The current version can be obtained from the link <http://www.bipm.org/utis/en/pdf/WG1-P-02-I-01.pdf>