

Process for Review and Approval of Nominated Certified Reference Materials and Reference Measurement Methods/Procedures			
Author : R. R. Miller/C.M. Jackson	Date : 2011-01-27 Version : 3.0	Authorized : JCTLM Executive	JCTLM WG1 P-03

PROCESS FOR REVIEW AND APPROVAL OF NOMINATED CERTIFIED REFERENCE MATERIALS AND REFERENCE MEASUREMENT METHODS/PROCEDURES

JCTLM WG1-P-03

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1. Purpose

This procedure describes the process of reviewing nominated CRMs and RMM/Ps to assure they meet the quality requirements of the JCTLM for inclusion in its lists of available higher-order materials and methods/procedures.

2. Scope

This procedure will be applied to all complete nominations received by the WG1 Chair(s) for inclusion in the JCTLM lists of CRMs and RMM/Ps of higher metrological order.

3. Acronyms

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

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4. Definitions

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

5. Responsibilities and Authorizations

- 5.1. The WG1 Chair(s) has/have the responsibility to periodically solicit nominations of CRMs and RMM/Ps in response to a request from the JCTLM Executive.
- 5.2. The WG1 Chair(s) receive(s) nominations from the Secretariat according to procedure JCTLM WG1-P-02 “Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures”.
 - 5.2.1. The WG1 Chair(s) is/are responsible for routing received nominations to the appropriate WG1RTs.
 - 5.2.2. The WG1 Chair(s) is/are responsible for appointing the Leaders of the WG1RTs and for assuring their compliance with this procedure.
 - 5.2.3. The WG1 Chair(s) is/are responsible for transferring recommendations based on the reviews of the nominated materials and methods/procedures from the WG1RTs to the JCTLM Secretariat for submission to the JCTLM Executive for approval.
- 5.3. WG1RTs have responsibility for reviewing materials and methods/procedures for a given class of measurand for which they have expertise.
- 5.4. . WG1RTLs have responsibility for ensuring completion, review and submission of the review documents, WG1-P-02-F-01, WG1-P-02-F-02, WG1-P-03-F-03 to the WG1 Chair(s).
- 5.5. It is the responsibility of the JCTLM Secretariat to receive the recommendations of the WG1RTs from the WG1 Chair(s) as described in WG1-P-05, “Process for Consensus Review of Recommendations from WG1 Review Teams and Communicating the Recommendations to the JCTLM Secretariat” and request the Executive to approve the inclusion of new CRM and RMM/Ps nominations in the JCTLM lists of Certified Reference Materials and Reference Measurement Methods/Procedures.

6. Procedure

- 6.1. Completed nomination forms submitted according to WG1-P-02 are forwarded from the JCTLM Secretariat to the WG1 Chair(s).
- 6.2. Completed nomination forms are forwarded from the WG1 Chair(s) and received by WG1RTLs.
 - 6.2.1. JCTLM WG1-P-02-F-01 Reference Material Nomination Form, Microsoft Excel Spreadsheet

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- 6.2.2. JCTLM WG1-P-02-F-02 Reference Measurement Method/Procedure Nomination Form, Microsoft Excel Spreadsheet
- 6.2.3. Each WG1RTL distributes the completed forms and supporting documentation to the WG1RT Members.
- 6.3. The WG1RT reviews the completed forms for the purpose of identifying inadequate information required for review against the relevant ISO standards.
- 6.4. WG1RTLs may at their discretion directly inform the nominator of missing information required for review against the relevant ISO standards.
 - 6.4.1. Requested information received by the WG1RTL 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 WG1RTL will result in the review being deferred until the next periodic review cycle.
- 6.5. The WG1RT reviews the completed nominations.
 - 6.5.1. Prior to reviewing any nominations, the appropriate standards will be reviewed by the WG1RT members.
 - 6.5.2. Review criteria based on ISO 15194 and 15193 normative standards are identified on the JCTLM WG1 Deviation List Spreadsheet and are used by the review teams to facilitate uniform review by all teams.
 - 6.5.3. The Reference Material or Method/Procedure Review Report forms are included with the nominating forms provided to the review team members and are used to facilitate the review and to communicate the review findings to the individuals making a given nomination.
 - 6.5.3.1. ISO 15194 is the appropriate standard for CRMs.
 - 6.5.3.2. ISO 15193 is the appropriate standard for RMM/Ps.
 - 6.5.3.3. Prior to review of nominations according to the standards, the mandatory elements specified in the ISO standards are reviewed with regard to compliance requirements using the WG1 Deviation List Spreadsheet.
 - 6.5.3.4. An attribute may be waived if it is not applicable.
 - 6.5.3.5. If an attribute is waived by a WG1RT, technical justification for recommending waiver must be recorded on the reviewed WG1 Deviation List Spreadsheet.
 - 6.5.3.6. Justification for a waiver must be included on the Reference Material or Method/Procedure Review Report WG1-P-03-F-03 submitted to the WG1 Chair(s) who will determine if the justification is appropriate or unacceptable. The Chair(s) may use the entire membership of WG1 to assist with this determination.
 - 6.5.4. Non-compliance is categorized according to the following criteria:

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- 6.5.4.1. **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.
- 6.5.4.2. **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.
- 6.5.4.3. **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.
- 6.5.4.4. **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.
- 6.5.5. Non compliances and their classifications are noted on the Review Report Form.
- 6.5.6. Individual RT members, working either individually or in a group, review the individual nominations for compliance with the appropriate ISO standards.
- 6.5.6.1. 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 deviation list, as appropriate to the particular nomination.
- 6.5.6.2. Non compliances and their classifications are noted on the Review Report Form
- 6.5.7. Upon completion of the review, the WG1RTL will circulate the recommendations and supporting forms and reviewed deviation list to all members of the team for review.
- 6.5.8. Consensus among the RT members will be obtained by the WG1RT for each recommendation.
- 6.5.9. 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, WG1-P-03-F-03 for consideration by the WG1 Chair(s) and the entire WG1 at a general meeting.
- 6.6. Documentation of the basis for the decision to list or not list for each CRM and RMM/P will be recorded in the Reference Material or Method/Procedure Review Report WG1-P-03-F-03
- 6.7. The WG1RTL forwards the recommendation, forms and reviewed deviation lists to the WG1 Chair.

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- 6.7.1. The WG1 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.
- 6.7.2. If clarification is needed, the WG1 Chair(s) will request it from the WG1RTL.
- 6.7.3. The WG1 Chair(s) may utilize the entire WG1 membership as a resource to assure consistency of the recommendations made by the different review teams.
- 6.8. If the consensus opinion of WG1 is that the CRM or RMM/P **does not** meet the relevant criteria, the JCTLM Secretariat will inform the nominator of the identified deficiencies by providing them with a copy of the Reference Material or Method/Procedure Review Report WG1-P-03-F-03 after the completion of the review process.
- 6.9. If the consensus opinion is that the CRM or RMM/P **does** meet the relevant criteria, the JCTLM Secretariat adds the CRM or RMM/P to the list of CRMs and RMM/Ps that will be provided to the JCTLM Executive for approval for inclusion on the relevant JCTLM lists.
- 6.9.1. The JCTLM Secretariat will inform the nominator of the approval for listing by the JCTLM Executive by providing them with a copy of the Reference Material or Method/Procedure Review Report WG1-P-03-F-03 after the completion of the review process.
- 6.10. For all CRMs or RMM/Ps evaluated, the WG1RT 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, they will be placed by the JCTLM Secretariat on a list of candidates for extent-of-equivalence evaluation according to procedure JCTLM WG1-P-04A “Process for Comparing Certified Values of the Same Measurand in Multiple Certified Reference Materials (CRMs)” or JCTLM WG1-P-04B “Process for the Demonstration of the Extent of Equivalence of Multiple Reference Measurement Methods/Procedures For The Same Nominal Measurand ”
- 6.11. WG1RTLs will note on the Reference Material or Method Review Report that RMs or RMM/Ps are already present on the JCTLM lists.
- 6.12. Method validation data for RMM/Ps must be available in documents or references provided by reference measurement method/procedure developers to support their nominations
- 6.12.1. Validation data provided by reference measurement method/procedure developers must support the claims for the RMM/P as provided on the RMM/P nomination form, WG1-P-02-F02.
- 6.12.2. Validation data **MUST** include measurement values obtained from listed certified reference measurement materials whenever applicable.
- 6.13. Values for measurands approved to be listed for CRMs that are provided by CRM producers for their materials on CRM nomination form, WG1-P-02-F-01 will be

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presented for public access and evaluation as described in WG1-P-04A. Data for all listed CRMs will be displayed.

6.13.1. Where existing or subsequently obtained data indicate that suitable evidence of equivalence might NOT exist, this will be noted and communicated to the organization or laboratory that has made the nomination.

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 WG1-P-03-F-03 and the list of candidate materials for extent-of-equivalence testing will be maintained by the JCTLM Secretariat.

7. Related Documents

- ISO 15193 2nd Ed (2009) In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures
- ISO 15194 2nd Ed (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 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 Process for Requesting and Accepting Nominations for Certified Reference Materials and Reference Measurement Methods/Procedures
- JCTLM WG1-P-02-F-01 Certified Reference Material Nomination Form
- JCTLM WG1-P-02-F-02 Reference Measurement Method/Procedure Nomination Form
- JCTLM WG1-P-02-I-01 Instructions for completing Excel spreadsheets for the nomination of Reference Materials and Reference Measurement Methods/Procedures for the JCTLM database
- JCTLM WG1-P-04A Process for the Demonstration of the Comparability of Certified Values of the Same Measurand in Multiple Certified Reference Materials
- JCTLM WG1-P-04B Process for the Demonstration of the Extent of Equivalence of Multiple Reference Measurement Methods/Procedures for the Same Nominal Measurand
- JCTLM WG1-A02 Criteria to Assess the Quality of Nominated Nucleic Acid Reference Materials with Stated Nominal Properties

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8. Attachments

Attachment 1 Reference Material or Method/Procedure Review Report WG1-P-03-F-03

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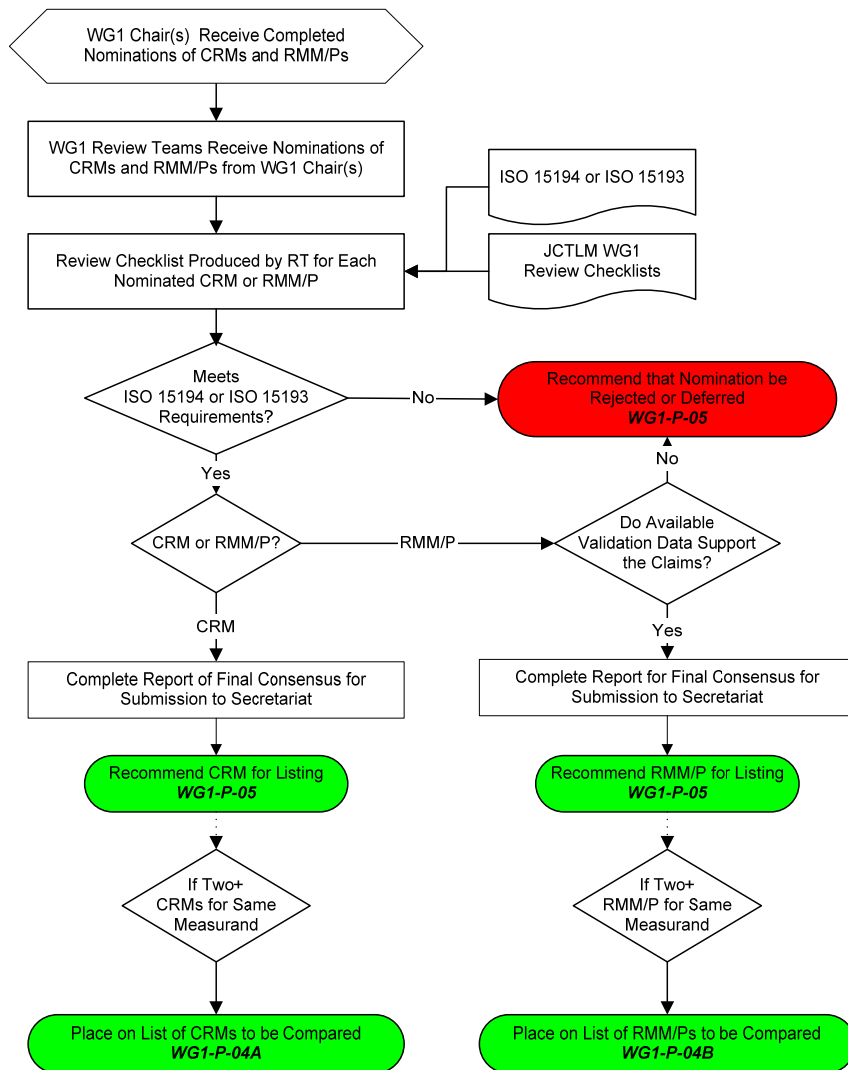
9. Revision History

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

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10. Flow chart

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