

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES				
Author: C. M. Jackson	Date : 2006/01/24 Version : 2.1	Authorized : JCTLM Executive	JCTLM WG1- P-07	

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WG1 P-07

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SIGNATURE	SIGNATURE

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1. Contents

PARAGRAPH	TITLE	PAGE
<u>1.</u>	<u>CONTENTS</u>	2
<u>2.</u>	<u>PURPOSE</u>	2
<u>3.</u>	<u>SCOPE</u>	2
<u>4.</u>	<u>ACRONYMS</u>	2
<u>5.</u>	<u>DEFINITIONS</u>	3
<u>6.</u>	<u>RESPONSIBILITIES AND AUTHORIZATIONS</u>	3
<u>7.</u>	<u>PROCEDURE</u>	3
<u>8.</u>	<u>RELATED DOCUMENTS</u>	7
<u>9.</u>	<u>ATTACHMENTS</u>	7
<u>10.</u>	<u>REVISION HISTORY</u>	7
<u>11.</u>	<u>FLOWCHART</u>	9
	<u>ATTACHMENT 1 PROCEDURE CHANGE REQUEST FORM</u>	10

2. Purpose

The purpose of the WG1 Change Control Procedure is to describe the process by which changes in WG1 procedures and procedure documents are initiated and tracked, and how users of WG1 procedures are apprised of how adoption and implementation of suggested changes occurs.

It is the policy of JCTLM WG1 to make changes in its procedures and documents by a transparent process using openly distributed procedure documents that can be known to all interested parties.

The procedures provided in this Quality System document are those by which the changes in WG1 procedures are made and placed in operation.

3. Scope

The scope of this document is all procedures that describe the activities of JCTLM WG1.

4. Acronyms

All acronyms employed in JCTLM Procedure Documents are given in the procedure document WG1-P-00, Quality Policy and Definitions. Acronyms particularly relevant to this document are repeated below.

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES			
Author: C. M. Jackson	Date : 2006/01/24 Version : 2.1	Authorized : JCTLM Executive	JCTLM WG1- P-07

- JCTLM Joint Committee for Traceability in Laboratory Medicine
- WG1 Working Group 1 of the JCTLM; is responsible for identifying and recommending for listing reference materials and reference measurement methods/procedures.
- WG1 Chair Leader of WG1, during some time periods the Chair position may be held by more than a single individual to facilitate WG1 activities
- CRM Certified Reference Material
- RMM Reference Measurement Method
- RMP Reference Measurement Procedure, a particular implementation of reference measurement method
- RMM/P The concatenation of RMM and RMP for brevity in the WG1

5. Definitions

All definitions employed in JCTLM Procedure Documents are given in the procedure document WG1-P-00, Quality Policy and Definitions.

6. Responsibilities and Authorizations

- 6.1. Proposal for changes in WG1 documents can be made by:
- 6.1.1. The JCTLM Executive
 - 6.1.2. Members of any JCTLM Working Group or Review Team
 - 6.1.3. JCTLM members
 - 6.1.4. Nominators of CRMs and RMM/Ps for review by WG1
 - 6.1.5. Users of the lists of higher-order reference materials and reference measurement methods/procedures

7. Procedure

Procedure for Proposing Changes to WG1 Documents

- 7.1. Changes in procedures and procedure documents can be proposed by any of the groups or individuals identified in Section 6, above.
- 7.2. Proposals for changes will be accepted, reviewed and if recommended, adopted on a biannual basis. The date for making submissions is specified on the Procedure Change Request Form, WG1-P-07-F-01 and can be found and downloaded from: <http://www.bipm.org/utis/en/doc/WG1-P-07-F-01.doc>.
- 7.3. Proposals for changes are made by completing the Procedure Change Request Form attached to this procedure.
- 7.3.1. All sections of the Procedure Change Request Form, WG1-P-07-F-01, must be completed before it can be forwarded to the JCTLM Procedures Team by the Secretariat.
 - 7.3.1.1. Authorized parties and reviewers are responsible for completing the pertinent sections of the form as indicated on the form.

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES			
Author: C. M. Jackson	Date : 2006/01/24 Version : 2.1	Authorized : JCTLM Executive	JCTLM WG1- P-07

- 7.3.1.2. If any section of the Procedure Change Request Form is not applicable to a proposed change, this must be stated in that section by the responsible party.
- 7.3.1.3. The reasons for a section of the Procedure Change Request Form deemed to not be applicable must be given in writing in the inapplicable section.
- 7.3.2. Completed Procedure Change Request Forms, WG1-P07-F01 are to be submitted to the JCTLM Secretariat as attachments to email messages directed to: jctlm@bipm.org
 - 7.3.2.1. The Secretariat will assign a document tracking number to the form received at BIPM.
 - 7.3.2.2. Incomplete Procedure Change Request Forms will be returned to the individual or organization submitting the form.
 - 7.3.2.3. Unless the amended Procedure Change Request Forms with the omitted sections completed are returned to the JCTLM Secretariat by the final submission date specified on the form, the form will not be considered until the subsequent biannual cycle unless deemed urgent by the WG1 Chair(s) or the JCTLM Secretariat or Executive.
- 7.4. Completed Procedure Change Request Forms are forwarded by the JCTLM Secretariat to the WG1 Chair(s).
- 7.5. The WG1 Chair(s) may at their discretion transfer the change forms to the WG1 Quality System Procedures Team Leader for initial review and subsequent distribution to the Procedures Team of WG1.

Procedure for Reviewing and Recommending Changes to WG1 Documents

- 7.6. Proposals for changes are reviewed by the JCTLM Procedures Team Leader for review category prioritization as follows:
 - 7.6.1. Are the proposed changes consistent with the JCTLM mission?
 - 7.6.1.1. Changes inconsistent with the objectives of JCTLM cannot be considered.
 - 7.6.2. Are the proposed changes concordant with the ISO standards used by JCTLM in its activities?
 - 7.6.2.1. Changes inconsistent with the ISO standards cannot be considered except under highly unusual circumstances.
 - 7.6.3. Are the proposed changes limited to clarification of wording without substantive change in criteria or process?
 - 7.6.3.1. Changes that simplify or clarify wording within the WG1 procedure documents may at the discretion of the WG1 Chair(s) be reviewed and a revised procedure document substituted for the document with unclear wording by the Secretariat.
 - 7.6.3.1.1. Changes that simply clarify will be assigned revision numbers to the right of the decimal point of the current revision number.

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES				
Author: C. M. Jackson	Date : 2006/01/24 Version : 2.1	Authorized : JCTLM Executive	JCTLM WG1- P-07	

- 7.6.4. Is the proposed change related to a discrepancy between a definition given in a procedure(s) and the ISO document on which the definition is based or from which the definition has been taken?
- 7.6.4.1. Proposed changes related to deviations from the ISO standards will be reviewed by the Procedures Team and WG1RTs
- 7.6.4.2. The rationale for such deviations and/or making changes to remove such deviations will be recorded on the Procedure Change Request Form.
- 7.6.5. Does the proposed change result in alteration in a criterion employed in review or for decision making?
- 7.6.5.1. Proposed changes that will alter a criterion used in the review and recommendation processes of WG1 in a substantive way will be reviewed by the Procedures Team and WG1RTS.
- 7.6.5.2. The rationale for making changes to criteria that are used in the review and recommendation process will be recorded on the Procedure Change Request Form.
- 7.6.6. Is the proposed change an alteration in the basic process described in the procedure document?
- 7.6.6.1. Proposed changes that will fundamentally alter the processes used in the review and recommendation activities of WG1 in a substantive way will be reviewed by the Procedures Team and WG1RTs.
- 7.6.6.2. The rationale for making changes that will fundamentally alter the processes used in the review and recommendation activities of WG1 will be recorded on the Procedure Change Request Form.
- 7.7. After categorization of the substance of the submitted suggestion for change, as described above, the procedures team leader will circulate the Procedure Change Request Forms to the members of the Procedures Review Team for comments.
- 7.7.1. The procedures team will query the members of the team for an indication of whether the change discussions can be processed by email or conference call or will require a face-to-face discussion prior to or in conjunction with a general JCTLM meeting.
- 7.7.2. All substantive changes, i.e., changes in criteria or process, will be discussed in a face-to-face WG1 meeting prior to final approval of changes to the current version of the procedure and submitting the revised procedure document(s) to the JCTLM Executive Committee.
- 7.7.2.1. Consensus acceptance will result in transfer of the procedures with the recommended changes to the JCTLM Secretariat for subsequent forwarding to the JCTLM Executive for review and approval.
- 7.7.3. All non-substantive changes will be made without face-to-face discussions using email discussions to achieve consensus of the revised document for subsequent submission to the JCTLM WG1 members for full WG1 consensus.
- 7.7.3.1. If no response is received within one month of circulation of the proposed changes, agreement will be assumed.

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES			
Author: C. M. Jackson	Date : 2006/01/24 Version : 2.1	Authorized : JCTLM Executive	JCTLM WG1- P-07

- 7.7.4. All changes for which unanimous consent is expressed will be made and the changed documents submitted to the members of JCTLM working group for their review and consent.
- 7.7.4.1. If no response is received within one month of circulation of the proposed changes, agreement will be assumed.
- 7.7.5. Any changes for which consensus is not obtained by electronic communication will be discussed and consensus obtained at a WG1 meeting prior to the changes put into effect.

Procedure for Evaluating, Adopting and Implementing Changes

- 7.7.6. Criteria employed in evaluating the proposed changes are as follows:
- 7.7.6.1. Is the proposed change inconsistent with the mission of the JCTLM as presented in the JCTLM Declaration of Cooperation
- 7.7.6.2. Would the change be incompatible with any ISO or other standard adopted by JCTLM?
- 7.7.6.3. Would the change alter the JCTLM review process to make it less transparent?
- 7.7.6.4. Would the change be likely to alter prior decisions and thus provoke re-examination of earlier decisions to list or not list CRMs or RMM/Ps?
- 7.7.6.4.1. If changes would alter prior decisions, the drafting of a “brief report” that will address the consequences of such changes will be initiated.
- 7.7.7. The WG1 Quality System Procedures Team Leader will present proposed substantive changes for discussion by the JCTLM WG1 at a general meeting of WG1.
- 7.7.7.1. Proposed changes will be discussed to obtain consensus regarding the importance, appropriateness and impact of the changes should they be made and a recommendation for the date for implementation.
- 7.7.7.2. Changes recommended by the consensus process will be forwarded by the JCTLM Secretariat to the Executive for approval.
- 7.7.7.3. All processed Change Request Forms will be kept by the Secretariat for future reference.
- 7.7.7.4. Date of implementation of changes will be specified by the JCTLM Executive, but will normally not precede the next cycle for solicitation, nomination and review by WG1RTs.
- 7.7.7.4.1. Secretariat will post notice of change to the affected procedure and the date of implementation on the JCTLM website.
- 7.7.8. WG1RTs will be informed by their RTLs of the changes and the possible effects of the changes on post-adoption reviewing of nominated CRMs and RMM/Ps.

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7.7.8.1. The consequences of the changes for any given RT will be discussed by general email communication or by conference call between the RTL and RT members. This mechanism will be used as training for RT members.

8. Related documents

JCTLM Preamble	Website: http://www.bipm.org/utis/en/pdf/Preamble.pdf
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 (CRMs) and Reference Measurement Methods/Procedures (RMM/Ps)
JCTLM WG1-P-03	Process for Review and Approval of Nominated Certified Reference Materials (CRMs) and Reference Measurement Methods/Procedures (RMM/Ps)
JCTLM WG1-P-04A	Process for Comparing Certified Values of the Same Measurand in Multiple Certified Reference Materials (CRMs)
JCTLM WG1-P-04B	Process for the Demonstration of the Extent of Equivalence of Multiple Reference Measurement Methods/Procedures (RMM/Ps) for the Same Nominal Measurand
JCTLM WG1-P-05	Process for Consensus Review of Recommendations from WG1 Review Teams and Communicating the Recommendations to the JCTLM Secretariat
JCTLM WG1-P-06	Application, Nomination and Approval for Membership on WG1 Review Teams
JCTLM WG1-P-08	Process for Creating, Restructuring and Retiring WG1 Review Teams
JCTLM WG1-P-09	Process for Appealing Decisions of the JCTLM Executive

9. Attachments

JCTLM WG1 Procedure Change Request Form, WG1-P-07-F-01

10. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	11/15/2005	Initial draft of JCTLM Change Control Procedure

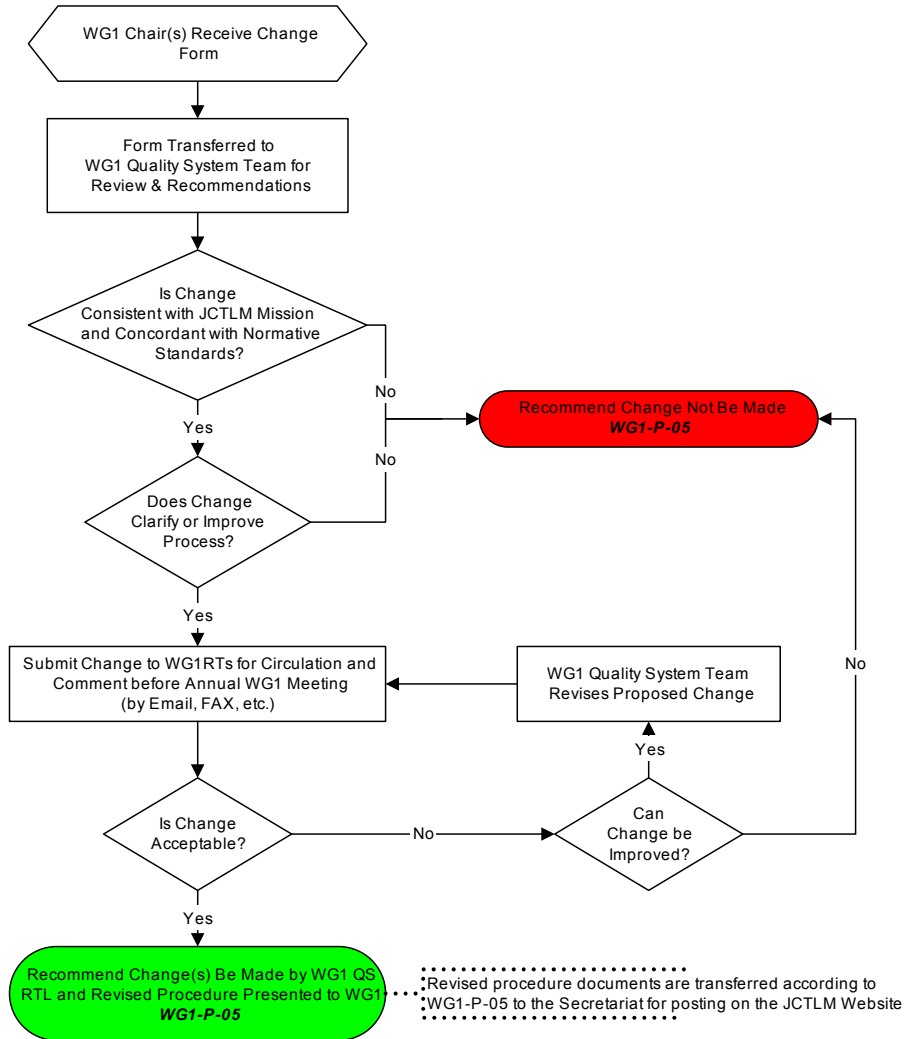
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2.1	24/01/2006	Minor text corrections
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11. Flowchart

PROCESS FOR MAKING CHANGES IN WG1 QUALITY SYSTEM PROCEDURES WG1-P-07



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Attachment 1 JCTLM WG1 Procedure Change Request Form