

Process for Receiving and Processing Proposed Changes in Quality System Documents and Forms			
Author: R I Wielgosz	Date : 12 Nov. 2008 Version : 1.1	Authorized : JCTLM Executive	JCTLM Sec P-05

PROCESS FOR RECEIVING AND PROCESSING PROPOSED CHANGES IN QUALITY SYSTEM DOCUMENTS AND FORMS

PROCEDURE

JCTLM SECRETARIAT P-05

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2. Purpose

This procedure describes the process to be followed by the JCTLM Secretariat for making corrections and changes in the procedure documents of the JCTLM WG1 Quality Manual and WG2 Procedure Manual.

3. Scope

The procedure applies to all requests received for changes in procedure documents of the WG1 Quality Manual and WG2 Procedure Manual of the JCTLM.

4. Acronyms

Acronyms used in this procedure are defined in the document JCTLM WG1-P-00, Quality Policy and Definitions and JCTLM WG2-P-00, Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions.

5. Definitions

Definitions for the terms used in this procedure are given in the document JCTLM WG1-P-00, Quality Policy and Definitions and JCTLM WG2-P-00, Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions.

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6. Responsibilities and Authorizations

- 6.1. The JCTLM Secretariat has the authority to make changes without consultation in JCTLM WG1 Quality Manual and WG2 Procedure Manual documents under the following circumstances.
 - 6.1.1. Change involves a typographical error such as spelling, grammar or punctuation.
 - 6.1.2. Change involves formatting or other similar inconsistencies within a document or between a document and others in the JCTLM WG1 Quality Manual and/or WG2 Procedure Manual.
- 6.2. The JCTLM Secretariat has the authority to incorporate revisions that involve neutral word substitutions within the JCTLM WG1 Quality Manual and WG2 Procedure Manual documents after consultation regarding the proposed changes with the relevant WG and/or its Procedures Team as appropriate.
- 6.3. The JCTLM Secretariat has the authority to request and initiate revision of a JCTLM WG1 Quality Manual and WG2 Procedure Manual document by the appropriate WG Procedures Team whenever an issue of substantive importance arises that might affect the mission, the applications of the international standards used by JCTLM in its review process or approved practices of the JCTLM.
 - 6.3.1. Criteria employed in evaluating a proposed change are as follows:
 - 6.3.1.1. Is the proposed change inconsistent with the mission of the JCTLM as presented in the JCTLM Declaration of Cooperation?
 - 6.3.1.2. Would the change be incompatible with any ISO or other standard adopted by JCTLM?
 - 6.3.1.3. Would the change alter the JCTLM review process to make it less transparent?
 - 6.3.1.4. Would the change be likely to alter prior decisions and thus provoke re-examination of earlier decisions to list or not list CRMs, RMM/Ps or RMSs?
- 6.4. Initiation of a revision of a procedure by the Secretariat that might alter an approved policy or practice will commence by consultation with the relevant WG joint Chairs, the Procedures Team Leader(s), if prudent WG members and the Executive Committee.
 - 6.4.1. Consensus by WG joint Chairs and the Executive Committee shall be sufficient to instruct the Procedures Team Leader(s) to initiate revision of the elements of the procedure at issue.
- 6.5. The JCTLM Secretariat has the responsibility to incorporate approved changes in a timely manner which shall be deemed no later than the next annual solicitation of nominations if an effect on the nomination or review process is anticipated, otherwise the next website update.

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7. Procedures

Changes to Correct Typographical and Formatting Errors

- 7.1. Changes to correct typographical and formatting errors may be suggested to the JCTLM Secretariat by any participant in JCTLM activities who observes the error.
 - 7.1.1. The Secretariat will replace a procedure document corrected for typographical or formatting errors after making the required corrections.
 - 7.1.2. Corrections made will result in a version number change for the procedure by an increment of 0.01 to facilitate adequate document version control.
 - 7.1.3. Documentation of the change made in the revised procedure document will be assured by maintaining an archive of prior versions of all documents.

Substantive Changes in Quality System Procedures

- 7.2. The Secretariat will receive requests for changes in substance within the text of a JCTLM Procedure document. Any written means may be used to communicate suggested changes to a procedure document.
- 7.3. The Secretariat will acknowledge that a suggestion for a change has been received by the Secretariat via an email message to the party suggesting the change.
- 7.4. The Secretariat will communicate with the appropriate WG Procedure Team Leader to produce a draft revision of the relevant procedure to facilitate consideration of the proposed change(s) by the Executive Committee.
- 7.5. The Secretariat will note the request for a change as an item to be included on the agenda of Non Scheduled Actions for the next JCTLM WG or JCTLM Annual meeting as deemed necessary or prudent. Proposed changes will be reviewed and approved by the Executive Committee as described in Exe-P-04.

Implementation of Changes to the JCTLM Quality System Procedures.

- 7.6. The JCTLM Secretariat will implement all authorized changes to the JCTLM WG1 Quality Manual and WG2 Procedure Manual in its next annual update of the JCTLM database and procedure documents.

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8. Related Documents

All JCTLM Procedures for Executive Committee, Secretariat WG1 and WG2.

JCTLM ***Declaration of Cooperation*** between the CIPM, IFCC and ILAC, for the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM) - available at:

http://www.bipm.org/utis/en/pdf/establish_jctlm.pdf

..... Appendix I: JCTLM Members

..... Appendix II: JCTLM Working Groups

..... Appendix III: The JCTLM Framework: A Framework for the international recognition of available higher-order reference materials, available higher-order reference measurement procedures and reference measurement laboratories for laboratory medicine. Available at: http://www.bipm.org/utis/en/pdf/jctlm_framework.pdf

..... Appendix IV: Participation of Organizations in the JCTLM

..... ***Mission Statement*** - available at:

http://www.bipm.org/en/committees/jc/jctlm/declaration_online.html

ISO Standards..... Standards employed by JCTLM in reviewing and judging suitability for listing materials (ISO 15194), methods (ISO 15193) and procedure-defined measurands (ISO 18153) as being of higher metrological order (ISO 17511) as required in the European Community In Vitro Diagnostic Directive (EC IVDD) (98/79/EC, Annex1 (A) (3) 2nd paragraph) and reference measurement service laboratories (ISO 15195).

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9. Revision History

Version number	Date of Issue/Review	Summary of change
0.1	01 Aug. 2004	Initial draft of Secretariat Quality System Procedures
0.2	04 Aug. 2007	Removal of form, simplification of requirements for suggesting revisions
1.0	04 Dec. 2007	Initial issue of procedure
1.1	12 Nov. 2008	Secretariat review

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Attachment 1 Flowchart

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