

Making changes in DB WG Quality Manual Procedures				 JCTLM Accurate results for patient care
Author: Robert Wielgosz	Date : 02 February 2022 Version : 3.1	Authorized : JCTLM Executive	JCTLM DB WG-P-07	

Making changes in Database WG Quality Manual Procedures

1. Purpose

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

It is the policy of JCTLM Database WG 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 Manual document are those by which the changes in Database WG procedures are made and placed in operation.

2. Contents

1.	PURPOSE	1
2.	CONTENTS	1
3.	SCOPE	1
4.	ACRONYMS AND DEFINITIONS	1
5.	RESPONSIBILITIES AND AUTHORIZATIONS	1
6.	PROCEDURE	2
7.	RELATED DOCUMENTS	5
8.	REVISION HISTORY	5
9.	FLOWCHART	6

3. Scope

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

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. Proposal for changes in Database WG documents can be made by:
 - 5.1.1. The JCTLM Executive
 - 5.1.2. Members of any JCTLM Working Group or Review Team

Making changes in DB WG Quality Manual Procedures				 Accurate results for patient care
Author: Robert Wielgosz	Date : 02 February 2022 Version : 3.1	Authorized : JCTLM Executive	JCTLM DB WG-P-07	

- 5.1.3. JCTLM members
- 5.1.4. Nominators of certified reference materials (CRMs), reference measurement methods/procedures (RMM/Ps), and services of reference measurement laboratories (RML) for review by Database WG
- 5.1.5. Users of the lists of higher-order CRMs, RMM/Ps, and RMLs.

6. Procedure

Procedure for Proposing Changes to Database WG Documents

- 6.1. Changes in procedures and procedure documents can be proposed by any of the groups or individuals identified in Section 5, above.
- 6.2. 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, DBWG-P-07-F-01 and can be found and downloaded from the Database WG webpage:
<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>
- 6.3. Proposals for changes are made by completing the Procedure Change Request Form attached to this procedure.
 - 6.3.1. All sections of the Procedure Change Request Form, DBWG-P-07-F-01, must be completed before it can be forwarded to the JCTLM Quality System Team by the Secretariat.
 - 6.3.1.1. Authorized parties and reviewers are responsible for completing the pertinent sections of the form as indicated on the form.
 - 6.3.1.2. 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.
 - 6.3.1.3. 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.
 - 6.3.2. Completed Procedure Change Request Forms, DBWG-P07-F01 are to be submitted to the JCTLM Secretariat as attachments to email messages directed to: jctlm@bipm.org
 - 6.3.2.1. The Secretariat will assign a document tracking number to the form received at BIPM.
 - 6.3.2.2. Incomplete Procedure Change Request Forms will be returned to the individual or organization submitting the form.
 - 6.3.2.3. 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 Database WG Chair or the JCTLM Secretariat or Executive.
- 6.4. Completed Procedure Change Request Forms are forwarded by the JCTLM Secretariat to the Database WG Chair

Making changes in DB WG Quality Manual Procedures				 JCTLM Accurate results for patient care
Author: Robert Wielgosz	Date : 02 February 2022 Version : 3.1	Authorized : JCTLM Executive	JCTLM DB WG-P-07	

6.5. The Database WG Chair may at his discretion transfer the change forms to the DB WG Quality System Team Leader for initial review and subsequent distribution to the QS Team Members.

Procedure for Reviewing and Recommending Changes to DB WG Documents

6.6. Proposals for changes are reviewed by the JCTLM Quality System Team Leader for review category prioritization as follows:

6.6.1. Are the proposed changes consistent with the JCTLM mission?

6.6.1.1. Changes inconsistent with the objectives of JCTLM cannot be considered.

6.6.2. Are the proposed changes concordant with the ISO standards used by JCTLM in its activities?

6.6.2.1. Changes inconsistent with the ISO standards cannot be considered except under highly unusual circumstances.

6.6.3. Are the proposed changes limited to clarification of wording without substantive change in criteria or process?

6.6.3.1. Changes that simplify or clarify wording within the Database WG procedure documents may at the discretion of the WG Chairpersons be reviewed and a revised procedure document substituted for the document with unclear wording by the Secretariat.

6.6.3.1.1. Changes that simply clarify will be assigned revision numbers to the right of the decimal point of the current revision number.

6.6.4. 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?

6.6.4.1. Proposed changes related to deviations from the ISO standards will be reviewed by the Quality System Team and review teams.

6.6.4.2. The rationale for such deviations and/or making changes to remove such deviations will be recorded on the Procedure Change Request Form.

6.6.5. Does the proposed change result in alteration in a criterion employed in review or for decision making?

6.6.5.1. Proposed changes that will alter a criterion used in the review and recommendation processes of Database WG in a substantive way will be reviewed by the Quality System Team and review teams.

6.6.5.2. 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.

6.6.6. Is the proposed change an alteration in the basic process described in the procedure document?

6.6.6.1. Proposed changes that will fundamentally alter the processes used in the review and recommendation activities of Database WG in a substantive way will be reviewed by the Quality System Team and review teams.

Making changes in DB WG Quality Manual Procedures				
Author: Robert Wielgosz	Date : 02 February 2022 Version : 3.1	Authorized : JCTLM Executive	JCTLM DB WG-P-07	

6.6.6.2. The rationale for making changes that will fundamentally alter the processes used in the review and recommendation activities of Database WG will be recorded on the Procedure Change Request Form.

6.7. 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 Quality System Review Team for comments.

6.7.1. 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.

6.7.2. All substantive changes, i.e., changes in criteria or process, will be discussed in a face-to-face Database WG 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.

6.7.2.1. 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.

6.7.3. 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 Database WG members for full WG consensus.

6.7.3.1. If no response is received within one month of circulation of the proposed changes, agreement will be assumed.

6.7.4. 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.

6.7.4.1. If no response is received within one month of circulation of the proposed changes, agreement will be assumed.

6.7.5. Any changes for which consensus is not obtained by electronic communication will be discussed and consensus obtained at a Database WG meeting prior to the changes put into effect.

Procedure for Evaluating, Adopting and Implementing Changes

6.7.6. Criteria employed in evaluating the proposed changes are as follows:

6.7.6.1. Is the proposed change inconsistent with the mission of the JCTLM as presented in the JCTLM Declaration of Cooperation

6.7.6.2. Would the change be incompatible with any ISO or other standard adopted by JCTLM?

6.7.6.3. Would the change alter the JCTLM review process to make it less transparent?

6.7.6.4. Would the change be likely to alter prior decisions and thus provoke re-examination of earlier decisions to list or not list CRMs, RMM/Ps or RMLs?

Making changes in DB WG Quality Manual Procedures				 Accurate results for patient care
Author: Robert Wielgosz	Date : 02 February 2022 Version : 3.1	Authorized : JCTLM Executive	JCTLM DB WG-P-07	

6.7.6.4.1. If changes would alter prior decisions, the drafting of a “brief report” that will address the consequences of such changes will be initiated.

6.7.7. The Database WG Quality System Team Leader will present proposed substantive changes for discussion by the JCTLM Database WG at a general meeting of WG.

6.7.7.1. 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.

6.7.7.2. Changes recommended by the consensus process will be forwarded by the JCTLM Secretariat to the Executive for approval.

6.7.7.3. All processed Change Request Forms will be kept by the Secretariat for future reference.

6.7.7.4. 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 WG Review Teams.

6.7.7.4.1. Secretariat will post notice of change to the affected procedure and the date of implementation on the JCTLM website.

6.7.8. Database WG Review Teams will be informed by their leaders of the changes and the possible effects of the changes on post-adoption reviewing of nominated CRMs, RMM/Ps and RMLs.

6.7.8.1. The consequences of the changes for any given review team will be discussed by general email communication or by conference call between the leader and members of the review team. This mechanism will be used as training for review team members.

7. Related documents

JCTLM Database WG Quality Manual Procedures; Available at:

<https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications>

JCTLM EXE-G01 Glossary of terms and definitions; Available at:

<https://www.bipm.org/en/committees/jc/jctlm/jctlm-procedures>

8. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	11/15/2005	Initial draft of JCTLM Change Control Procedure
2.1	24/01/2006	Minor text corrections
3.0	27/01/2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups
3.1	01/02/2019	Update of hyperlinks
3.2	01/02/2022	Editorial changes

9. Flowchart

PROCESS FOR MAKING CHANGES IN DB WG QUALITY MANUAL PROCEDURES DB WG-P-07

