

Removal of listed entries from the JCTLM Database			
Author: R I Wielgosz	Date: 12 Nov. 2008 Version : 1.1	Authorized : JCTLM Executive	JCTLM Sec P-04

***PROCESS FOR THE REMOVAL FROM
THE JCTLM DATABASE OF LISTED
REFERENCE MATERIALS,
REFERENCE MEASUREMENT
METHODS/PROCEDURES AND
REFERENCE MEASUREMENT
SERVICES***

PROCEDURE

JCTLM SECRETARIAT P-04

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PROCESS FOR THE REMOVAL FROM THE JCTLM DATABASE OF LISTED REFERENCE MATERIALS, REFERENCE MEASUREMENT METHODS/PROCEDURES AND REFERENCE MEASUREMENT SERVICES

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2. Purpose

This procedure describes the process to be followed by the JCTLM Secretariat for the removal of listed CRMs, RMM/Ps and RMSs from the JCTLM Database, and the publication of these removed CRM and RMM/P entries on the Withdrawn Entries List (WEL) (.PDF file).

3. Scope

The procedure applies to all requests received for the removal of listed entries from the JCTLM Database.

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, except for the following.

WEL Withdrawn Entries List

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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.

Withdrawn Entries ListPreviously available CRM and RMM/P that is no longer found on the JCTLM Database.

6. Responsibilities and Authorizations

- 6.1. The JCTLM Secretariat has the authority to remove entries from the JCTLM Database following a confirmed request from the producer of a CRM, the developer/owner of a RMM/P or a provider of a RMS.
- 6.2. The JCTLM Secretariat has the authority to remove CRMs from the JCTLM Database where the request for removal does not originate from the producer when the request has been investigated and upheld by WG1 according to the criteria specified in WG1-P-03 or WG1-P-04A, and approved by the Executive.
- 6.3. The JCTLM Secretariat has the authority to remove RMM/Ps from the JCTLM Database where the request for removal does not originate from the developer/owner of the RMM/P when the request has been investigated and upheld by WG1 according to the criteria specified in WG1-P-03 or WG1-P-04B, and approved by the Executive.
- 6.4. The JCTLM Secretariat has the authority to remove RMSs from the JCTLM Database where the request for removal does not originate from the provider of the RMS when the request has been investigated and upheld by WG2 according to the Procedure WG2-P-05 and approved by the Executive.
- 6.5. It is the responsibility of the WG1 joint Chairs to inform the JCTLM Secretariat of CRM and RMM/P entries to be removed from the JCTLM Database.
- 6.6. It is the responsibility of the WG2 joint Chairs to inform the JCTLM Secretariat of RMS entries to be removed from the JCTLM Database.
- 6.7. It is the responsibility of the JCTLM Secretariat to implement authorized changes to the JCTLM Database of higher order CRMs, RMPs and RMSs and make transfer of a previously listed item from List I or List II to the WEL (.PDF).

7. Procedures

Receiving requests for removal of listed CRMs, RMM/Ps and RMSs from the JCTLM Database

- 7.1. The JCTLM Secretariat will receive requests for removal of listed CRMs, RMM/Ps or RMSs from the JCTLM Database.
 - 7.1.1. Individual or organization will send by email to jctlm@bipm.org request to the JCTLM Secretariat.

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7.1.1.1. When the JCTLM Secretariat receives an automatic email from the back office JCTLM Database web system for a listed CRM which is due to expire in one month's time, the producer will have to confirm if this entry has to be removed from the JCTLM Database or if the certificate of the material has been modified to a new expiry date.

- 7.2. The JCTLM Secretariat will acknowledge receipt of the request to the party submitting the request.
- 7.3. The JCTLM Secretariat will forward the request to the joint Chairs of the appropriate JCTLM WG for confirmation of the identity of the person and/or organization making the request.
- 7.4. The WG1 or WG2 joint Chairs will confirm the identity and inform the Secretariat of any additional pertinent information related to the request or that might impact other entries in the JCTLM Database.

Processing of Requests

- 7.5. The JCTLM Secretariat will remove entries from the JCTLM Database when the request has been made by the producer of the CRM, the developer/owner of the RMP or by the provider of the RMS and the request has been verified as noted in 7.4. Such requests will be automatically granted.
- 7.5.1. The JCTLM Secretariat will transfer the removed entry of CRM and RMM/P to the JCTLM WEL (.PDF File) with the explanatory comment provided by the producer of the CRM and the developer/owner of the RMM/P.
- 7.6. Where the request for removal of the entry **DOES NOT** originate from the producer of the CRM, developer/owner of the RMP or the provider of the RMS, the Secretariat will forward the request to the relevant producer, developer or provider and request consent for the removal of the listed CRM, RMM/P or RMS from the JCTLM Database and the transfer of the CRMs or RMM/Ps to the JCTLM WEL.
- 7.6.1. The rationale and evidence that form the basis for the request for removal originating from a party other than the producer, developer or provider will be made available to the WG1 or WG2 joint Chairs if it is deemed prudent to do so by the Secretariat
- 7.6.2. In the case that consent **IS** given, the Secretariat will inform the requestor that the transfer from the JCTLM Database to the WEL has been made.
- 7.6.3. The identity of the third party requesting removal of an entry from a JCTLM Database will be considered confidential by the JCTLM Executive, Secretariat and the WG1 or WG2 joint Chairs, unless the third party waives confidentiality in writing to the JCTLM Secretariat.
- 7.6.4. In the case that consent **IS NOT** given, the WG1 or WG2 joint Chairs will ask their WG via its appropriate RT to review the request and the basis for the request.
- 7.6.5. The RT will make a recommendation to either maintain or remove the entry to the WG joint Chairs.

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7.6.5.1. Criteria described in WG1-P-03, WG1-P-04A or B or WG2-P-03A, B or C will be employed in the re-review and data from WG2 inter-laboratory comparison studies be used to make the decision by the WG RT.

7.6.5.2. The WG1 or WG2 joint Chairs will inform the JCTLM Secretariat of the recommendation and provide copies of any correspondence relevant to the decision-making process. Removal of entries from the JCTLM Database is a permanent agenda point for meetings of the JCTLM Executive. Following approval of the Executive, the JCTLM Secretariat is authorized to take the action recommended by the JCTLM WG joint Chairs.

7.6.6. The Secretariat will inform the organization or person who requested removal of the entry from the JCTLM Database and the CRM producer, RMM/P developer or RMS provider as applicable of the action taken. A copy of the Review Report, WG1-P-03-F03 or WG1-P-03-F-02, and the comparison data used in the decision-making process will be included in the communication to the CRM producer or RMM/P developer or RMS provider from the Secretariat.

Update of the JCTLM Database.

7.7. The JCTLM Secretariat will implement authorized changes to the JCTLM Database.

7.7.1. Entries will be removed from the JCTLM Database

7.7.2. Removed entries for CRM or RMM/P will be transfer to the WEL with a comment field in which the responsible person or organization can state the reasons for the removal of the CRM or RMM/P.

7.7.2.1. The JCTLM Secretariat receives statements sent by the producer, or developer/owner for entry into the comment field.

7.7.2.2. The entry in the comment field for a de-listed item that has been transferred subsequent to a re-evaluation by WG1 RTs may supplement the comments provided by a producer or developer

7.7.3. Re-evaluation reports from a WG RT will be the same as an original review report and recommendation and will be available as described in WG1-P-03-F03 or WG2-P-03-F-02

8. Related Documents

JCTLM WG1-P-00	Quality Policy and Definitions
JCTLM WG1-P-03	Process for Review and Approval of Nominated Certified Reference Materials and Reference Measurement Methods/Procedures
JCTLM WG1-P-03-F-03	Reference Material or Method/Procedure Review Report
JCTLM WG1-P-04A	Process for Comparing Certified Values of the Same Measurand in Multiple Certified Reference Materials (CRMs)

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- JCTLM WG1-P-04B Process for the Demonstrating the Extent-of-Equivalence of Multiple Reference Measurement Methods/Procedures (RMM/Ps) for the Same Nominal Measurand
- JCTLM WG2-P-00 Outline of the Calibration and Measurement Hierarchy in Laboratory Medicine - Quality Policy and Definitions
- JCTLM WG2-P-03-A Process for Verification and Publication of Calibration and Measurement Capability (CMC) Claims in the JCTLM Database (National Metrology Institutes)
- JCTLM WG2-P-03-B Process for Review of Reference Measurement Services from Laboratories that are Accredited as Calibration Laboratories (ISO/IEC 17025 and ISO 15195)
- JCTLM WG2-P03-C Process for Review of Reference Measurement Services from Laboratories Preparing for Accreditation
- JCTLM WG2-P-05 Process for Delisting Reference Measurement Services
- JCTLM WG2-P-03-F-02 Reference Measurement Laboratory Service Review Report

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9. Revision History

Version number	Date of Issue/Review	Summary of change
0.1	10 Aug. 2007	Initial issue of Secretariat Quality System Procedures
1.0	04 Dec. 2007	Initial issue of procedure
1.1	12 Nov. 2008	Secretariat review

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10. Flowchart

Revised on 12 November 2008

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