


Removal of listed entries from the JCTLM Database				 Accurate results for patient care
Author: Robert Wielgosz	Date : 27 Jan. 2017 Version : 2.0	Authorized : JCTLM Executive	JCTLM Sec P-04	

## Removal of listed entries from the JCTLM Database

### 1. 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listed CRMs, RMM/Ps and RMSs from the JCTLM Database, and the publication of these removed CRM and RMM/P entries on the Withdrawn Entries List (WEL) (.PDF file).

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### 3. Scope

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


### 4. Acronyms and definitions

All acronyms and definitions employed in the procedures of the JCTLM Secretariat Quality Manual are given in the procedure document JCTLM EXE-G01, Glossary of terms and definitions, except for the following.

Withdrawn Entries List (WEL) : Previously available CRM and RMM/P that is no longer found on the JCTLM Database, and placed in a file (.PDF) for no longer listed items available at : <http://www.bipm.org/jctlm/>

### 5. Responsibilities and Authorizations

- 5.1. 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.
- 5.2. 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 the DB WG according to the criteria specified in DBWG-P-03A or DBWG-P-04A,-and approved by the Executive.

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- 5.3. 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 the DB WG according to the criteria specified in DBWG-P-03A or DBWG-P-04B, and approved by the Executive.
- 5.4. 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 the DB WG according to the Procedure DBWG-P-03B1, B2 and approved by the Executive.
- 5.5. It is the responsibility of the DB WG vice-Chairs to inform the JCTLM Secretariat of CRM, RMM/P and RMS entries to be removed from the JCTLM Database.
- 5.6. 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 to the WEL (.PDF).


## 6. Procedures

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

- 6.1. The JCTLM Secretariat will receive requests for removal of listed CRMs, RMM/Ps or RMSs from the JCTLM Database.
  - 6.1.1. Individual or organization will send by email to [jctlm@bipm.org](mailto:jctlm@bipm.org) request to the JCTLM Secretariat.
    - 6.1.1.1. 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.
- 6.2. The JCTLM Secretariat will acknowledge receipt of the request to the party submitting the request.
- 6.3. The JCTLM Secretariat will forward the request to the JCTLM DB WG Chairs for confirmation of the identity of the person and/or organization making the request.
- 6.4. The DB WG 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

- 6.5. 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 6.4. Such requests will be automatically granted.
  - 6.5.1. 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.

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6.6. 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.

6.6.1. 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 DB WG Chairs if it is deemed prudent to do so by the Secretariat

6.6.2. In the case that consent **IS** given, the Secretariat will inform the requestor that JCTLM Database has been updated accordingly to his request.

6.6.3. 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 DB WG Chairs, unless the third party waives confidentiality in writing to the JCTLM Secretariat.

6.6.4. In the case that consent **IS NOT** given, the DB WG vice-Chairs will ask their appropriate RT to review the request and the basis for the request.

6.6.5. The RT will make a recommendation to either maintain or remove the entry to the DB WG vice-Chairs.

6.6.5.1. Criteria described in DB WG-P-03A or P-03B will be used in the re-review to make the decision by the WG RT.

6.6.5.2. The DB WG vice-Chair 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 DB WG vice-Chairs.

6.6.6. 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, DBWG-P-03A-F03 or P-03B-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.


6.6.7. Any appeal against decisions of the Executive will be submitted to the Secretariat, and addressed according to the appealing process described in the procedure document EXE-P-05.

#### **Update of the JCTLM Database.**

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

6.7.1. Entries will be removed from the JCTLM Database

6.7.2. 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.

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- 6.7.2.1. The JCTLM Secretariat receives statements sent by the producer, or developer/owner for entry into the comment field.
- 6.7.2.2. The entry in the comment field for a de-listed item that has been transferred subsequent to a re-evaluation by a RT of the DB WG may supplement the comments provided by a producer or developer
- 6.7.3. Re-evaluation reports from a RT will be the same as an original review report and recommendation and will be available as described in DB WG-P-03A-F03 or P-03B-F-02

## 7. Related Documents

- JCTLM EXE-G-01 Acronyms and Definitions
- JCTLM DBWG-P-00 Quality Policy of the JCTLM Database working group (DB WG)
- JCTLM DBWG-P-03A Process for the review of nominated Certified Reference Materials (CRMs) and Reference Measurement Methods/Procedures (RMM/Ps)
- JCTLM DBWG-P-03A-F-03 Reference Material or Method/Procedure Review Report
- JCTLM DBWG-P-03B1 Process for verification and publication of calibration and measurement capability (CMC) claims in the JCTLM Database (National Metrology Institutes).
- JCTLM DBWG-P-03B2 Process for the review of reference measurement services from laboratories accredited as calibration laboratories (ISO 17025+15195)
- JCTLM DBWG-P-03B-F-02 Reference Measurement Laboratory Service Review Report
- JCTLM EXE-P-05 Appealing decisions of the JCTLM Executive

## 8. Revision History

Version number	Date of Issue/Review	Summary of change
0.1	10 Aug. 2007	Initial draft of Secretariat Quality System Procedures
1.0	04 Dec. 2007	Initial issue of Procedure
1.1	12 Nov. 2008	Secretariat review
2.0	27 Jan. 2017	Document revised after implementation of new organizational structure of JCTLM and its Working Groups

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## 9. Flowchart

January 2017

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#### SEC-P-04

