

## **APMP-G1 ver.4**

**(ver. 4 March 2006 ver. 3 October 2003 ver.2 March 2003 ver.1 December 2000)**

### **APMP Procedure for CMC entry in Appendix C**

The JCRB Procedure (latest version to be referred) specifies the steps-required for a NMI's CMCs to be entered into Appendix C.

This document describes general procedure for intra-APMP reviews conducted by APMP TCs, in accordance with the JCRB Procedure.

#### **Review process of the APMP CMCs**

##### **(a-0) Quality System establishment**

Member NMIs are requested to establish Quality System (QS) in advance to the CMCs submission. The QS must be in compliance with the guideline (APMP-QS2 APMP GUIDELINES FOR ACCEPTING A QUALITY SYSTEM) and shall cover all CMCs in range and uncertainty to be declared.

##### **(a-1) Submission of CMCs**

An APMP member NMI may send its draft CMCs list and the QS information to the chairs of relevant APMP Technical Committees. At the same time, the member NMI should send a copy of the CMC list and the QS information to the APMP Secretariat. Each TC chair may set the deadline for the acceptance of CMCs lists with a suitable period. If the CMC list is submitted after the deadline, it should be left until the next deadline.

When a CMC in the relevant technical area is the first submission, APMP Secretary is to send its QS information to TCQS and request for the review whether that QS fulfills the requirements of APMP-QS2. See (a-3).

##### **(a-1-2) Essential materials for QS information and additional information at submission of CMCs**

QS information must include materials described in "3 Evidence" of APMP-QS2.

An NMI submitting its CMC list is encouraged to provide materials useful to convince reviewers of its technical competence and CMC claims. These materials may include:

- Information of international comparisons supporting the CMC claims,
- Information of traceability to external NMIs supporting the CMC claims,
- Peer Review report,
- Any other technical paper or documents supporting the CMC claims.

These materials may be voluntarily sent to TC chairs at the submission of CMC list for intra-APMP review, and may be forwarded to the reviewers via the TC chair. If the NMI is not sending these materials at the time of submission of CMC list, the NMI is recommended to prepare these materials so that it can provide those materials to the reviewers quickly when relevant questions are raised during review processes.

(Although the Excel book of CMC list is the final material to be forwarded to KCDB for entry, the reviewers generally would like to have access to much information useful to judge the technical competence of the subject NMI and validity of its CMC claims. On the other hand, sending too many materials will not be useful but may become an obstacle to conduct a

smooth review. Selecting appropriate material, and processing them to suit the review, and providing them timely, may be considered as an important part of the technical competence of the NMI. )

(a-2) Review by TC

The TC chair will send the CMC list to the reviewers appointed by each TC chair when the CMC is submitted according to the guideline (a-1). Each reviewer will review the CMC, in accordance with the criteria recommended by relevant CC working group.

QS information (accredited scope) is most reliable anchorage to fall back on in reviewing CMC. But, it is to be noted that the CMC review process is independent from QS review done by the on-site peer reviewers. In CMC review, accredited scope can be declined, and at the same time, a smaller uncertainty or wider scope which exceeds that of QS accredited is improbably accepted. This will also happen in the inter-RMO review process.

APMP Guidelines for acceptance of data for Appendix C (APMP-G3) will apply to the Review criteria.

Sample review will not be accepted barring exceptions during the intra-APMP review. If the review was done using any sampling data, the relevant sampling data and evidences must be clearly demonstrated. (Sample review may be accepted for inter-RMO review to reduce burden.)

Each reviewer is encouraged to ask questions about the CMC under the review to the member NMI that submitted the CMC. The results of review, which include the information indicating the approved CMCs and comment, will be sent to the TC chair by the date requested by the TC chair.

When disagreement arises, it should be discussed among the reviewers to obtain consensus. But the TC chair will make the final decision on the CMC approval.

The TC chair sends the approved CMC with a brief report, which should include the names and affiliations of the reviewers, actions in the review process and review results referring to the "Criteria for acceptance of data for Appendix C", (latest version), to the NMI who submitted the CMC and to the APMP secretariat. If the NMI does not agree with the review results, the NMI may appeal to the APMP Secretariat. The APMP Chairperson should resolve it, with consultation by APMP Executive Committee (EC) members.

Duration of the review by the TC should be no more than two months, but this duration may be extended with the consent of the TC chair and the reviewers. When the duration is extended, the TC chair notifies the member NMI who submitted the CMC list and the APMP Secretariat who informs the EC members

(a-3) Confirmation of QS and approval by Chairman

The TCQS chair should review the QS by referring to the QS documents within two months and reporting the results to the APMP Secretariat and the TC chair of the relevant quantities. The TC Chair confirms the TC chair's report, approved CMC list and the TCQS report. The APMP Chairperson should make decision to approve the CMCs or not by consultation with EC members if the TC Chair reported any problem in the CMCs.

(b) The TC Chair posts the approved CMC with the TC chair's report to the JCRB website.

(c) Following procedures will take place in accordance with the JCRB CMC-REVIEW PROCEDURES (version and document number to be referred).

(d) Inter-regional review takes place which includes direct contact between technical working group chairmen<sup>2</sup> of RMOs; interim and final reports are sent to Chairman of their own RMO by each review team (see below for detailed rules on inter-regional review).

(e-1) The NMI should revise their CMC list or make comments if necessary and re-submit it to the APMP TC chair.

(e-2) The TC Chair reviews the re-submitted CMC list in collaboration with the reviewers appointed by the TC, and the result will be sent to the JCRB throughout the JCRB website.

(f) Provided all RMOs indicate their approval on the website, the CMCs are entered into Appendix C. This action is noted on the website with the date of entry.

#### **Procedures for inter-regional review of other RMO's CMCs**

(A) CMC list from other RMOs are posted throughout the JCRB website and the notification of the post is delivered to the relevant TC Chair by e-mail.

(B) TC Chairs are encouraged to indicate their interest in participating in the review of the posted CMCs by acknowledging receipt in the website and indicating the date by which they plan to send their first comments.

TC Chairs are responsible to coordinate the review with the reviewers of each TC and post the review report within the date throughout the JCRB website. Procedures are indicated in JCRB CMC-REVIEW PROCEDURES (version and document number to be referred)

It is recommended that;

- This report should include the names of the members of the review team.
- The review include the detailed examination of a small number of the proposed CMCs chosen to evaluate the more critical CMCs.

The JCRB accepts that not every RMO will wish to review the CMCs of all NMIs in every other RMO. However, to ensure a reasonable coverage of review the JCRB recommends that the technical working groups of each RMO make contact and come to an agreement on sharing the task.

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During the review process the JCRB recommends that communication is established directly between the appropriate working group chairmen to deal with questions and resolve, as far as possible, inconsistencies. Unresolved problems or disagreements that cannot be resolved by the technical experts must come to the RMOs and, if necessary, to the JCRB as foreseen in the MRA.