EURAMET Procedures and Review Criteria for CMCs

EURAMET

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EURAMET e.V. Bundesallee 100 D-38116 Braunschweig Germany

E-Mail: secretariat@euramet.org
Phone: +49 531 592 1960

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Changes to the previous version: The Guide passed substantial revision to describe adoption of practices on using KCDB 2.0 in CMC review process as well as to reflect implementation of the recent JCRB resolutions.

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Further information

For further information about this Guide, please contact the EURAMET Secretariat (secretariat@euramet.org).

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EURAMET Procedures and Review Criteria for CMCs

This EURAMET Guidance Document specifies requirements and the procedures for reviewing calibration and measurement capabilities (CMCs) declared by National Metrology Institutes (NMIs) or Designated Institutes (DIs)¹ being Members or Associates of EURAMET under CIPM's Mutual Recognition Arrangement of national measurement standards and of calibration and measurement certificates issued by national metrology institutes (CIPM MRA)².

The measurement capabilities of each NMI are published after final approval in the Key Comparison Database (KCDB)³, maintained by the BIPM and publicly available on the web. In order for CMCs to be approved for publication in the BIPM KCDB, they must first be reviewed and approved by the appropriate Technical Committee of EURAMET. Once this approval is obtained, CMCs undergo a JCRB (interregional) review, where TCs/WGs⁴ from other Regional Metrology Organisations (RMOs) verify that the JCRB criteria for acceptance of data⁵ have been met, thus providing the technical confidence required for publication.

TCs/WGs play a key role in this process as they conduct the intra-regional and JCRB technical reviews and eventual approval of each CMC submission. This document specifies the requirements and explains the steps that EURAMET TC Chairs and people involved in CMCs submission and review need to follow in order to carry out this process.

¹ In this document the acronym NMI is used both in reference to National Metrology Institutes and/or further Designated Institutes (see document CIPM-MRA-P-13 Participation in the CIPM MRA National Metrology Institutes, Designated Institutes, International organizations for more details).

² https://www.bipm.org/en/cipm-mra

³ https://www.bipm.org/kcdb/

⁴ Groups of technical experts in each area are called "Technical Committees" in APMP, COOMET and EURAMET, and "Working Groups" in AFRIMETS and SIM.

⁵ Please see CIPM-MRA-G-13, chapter 3 and 4, and CIPM MRA-P-11 for metrological traceability details.

1. General policy

For calibration and measurement capabilities to be recognised under the CIPM MRA they must outline the measurement capabilities ordinarily available to the customer through the NMI's services. In addition, each one of these CMCs must be supported, in range and uncertainty of measurement, by a fully implemented Quality Management System (QMS) satisfying the CIPM MRA requirements in accordance with CIPM MRA-G-12 and be approved and regularly reviewed by EURAMET TC-Quality as described in the document "Quality Management System review procedure" (G-TCQ-PRC-001)⁶.

The CMCs are reviewed by the appropriate EURAMET Technical Committee under the responsibility of the TC Chair, based on this guide and according to the procedure described in chapter 3. Depending on the subject field, additional field specific requirements may apply, e.g. rules defined by the respective CIPM Consultative Committee (CC) or Working Group (WG).

2. Managing CMCs

CMCs should be submitted by country, by metrology area, and where necessary by category (e.g. TC-MC) via the publicly available BIPM Key Comparison Database (KCDB). The KCDB provides users with reliable quantitative information on the comparability of national metrology services, gathering not only the results of scientific comparisons that underpin the CMCs of participating institutes, but also detailed information of these internationally recognised CMCs.

Modifications of CMCs are performed via the same web platform. Only registered users are approved to interact at different levels in the management of CMCs. The set of roles and related responsibilities are detailed below:

- Writer: person entering CMC data, acting on behalf of their institute for a specific field with an account approved by the TC Chair (after checking with NMI / DI TC contact person)
- **TC Chair**: coordinator in the technical field in EURAMET, acting on behalf of the EURAMET with an account approved by the KCDB office
- TC-Q Chair: coordinator for the confirmation of quality management system in EURAMET
- **CMC reviewer**: technical expert invited to review CMCs, with an account approved by EURAMET TC Chair
- CC WG Chair: coordinator of the CMC review process at the CC level, with an account approved by the KCDB office
- **Member Service Manager**: person representing EURAMET with full access to the review process in 'read only' mode

TC Chairs have the right to set the roles "writer" and "reviewer".

For further help and advice on the use of the KCDB platform and management of CMCs under this platform, please refer to guidance documents and videos available on the BIPM webpage: https://www.bipm.org/en/cipm-mra/kcdb-help

Additional advice can be given by the coordinator of the KCDB or JCRB Executive Secretary.

⁶ https://www.euramet.org/technical-committees/tc-q/qms-review-process/

3. CMC review criteria

According to the CIPM MRA rules (CIPM MRA-G-13), the range and uncertainty of the CMCs submitted shall be consistent with information from some or all of the following sources⁷:

- 1. Results of key and supplementary comparisons;
- 2. Documented results of past CC, RMO or other comparisons (including bilateral) and pilot studies;
- 3. Active participation in RMO projects;
- 4. Publicly available information on technical activities, including publications;
- 5. On-site peer-assessment reports, including those from accreditation assessment with appropriate technical peers;
- 6. Other available knowledge and experience, as agreed by the appropriate CC.

Additional to these, specific documents from EURAMET TC or CC WG (e.g. EURAMET Declaration of Coverage of CMCs by QMS⁸) may be applicable.

Technical support for CMCs is achieved mainly through the results of comparisons. Key comparisons are designed to provide evidence on the competence and proficiency of NMIs in the principal techniques in each field. Supplementary comparisons are undertaken by RMOs when CMCs require additional support not provided by key comparisons. While it is important that each CMC submission is supported by some comparison evidence and EURAMET NMIs are encouraged to participate in comparisons whenever they have the possibility to do so, it is not the intention of the CIPM MRA to have a one-to-one correspondence between CMCs and comparisons.

While the results of comparisons are the ideal supporting evidence, all other sources listed above may be considered to underpin CMCs. CCs are responsible for providing clear guidance on the required technical evidence. As well, the NMIs that submit the CMCs are primarily responsible for providing the information that they believe is necessary to support their claims. And to confirm these, the experts involved in the intra-regional and JCRB review may request additional information, if needed.

4. CMC review process

In order for CMCs from EURAMET NMIs to be approved for publication on the KCDB, they must first be reviewed and approved by the appropriate Technical Committee within EURAMET (intra-regional review). Once this approval is obtained, CMCs undergo a JCRB review, where the TC/WGs from other RMOs verify that the review criteria have been followed, thus providing the technical confidence required for publication and international recognition.

The flowcharts in Appendix 1 and Appendix 2 illustrate these (successive) review processes.

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⁷ https://www.bipm.org/en/cipm-mra/kcdb →CIPM MRA-G-13, Chapters 3 and 4.

^{8 &}lt;a href="https://www.euramet.org/technical-committees/tc-projects">https://www.euramet.org/technical-committees/tc-projects: "Declaration of Coverage of CMCs by QMS (G-OPS-FRM-013)

4.1 Intra-regional reviews

CMCs are created and submitted for intra-regional review through the KCDB. These CMCs shall be approved by the NMI's management, accompanied by appropriate (technical) evidence that support their CMC claims, and be fully covered by its quality management system.

The intra-regional review of CMCs is the responsibility of EURAMET TC Chair who will engage experts in the specific technical sub-fields as reviewers in the CMC review process. Every time an intervention occurs on the KCDB web platform, automatic notifications will be sent to the individuals involved.

Submitted CMCs shall be accompanied by documentary evidence. The documentary evidence of the QMS coverage of CMCs submitted for the review is the form "Declaration of Coverage of CMCs by QMS" (G-OPS-FRM-013). In case of new CMCs, the documentary evidence should include:

- List of relevant documents (description, uncertainty evaluation and calibration instructions) from quality documentation
- Uncertainty budget for the claimed CMC(s)

Part I of the form is filled out by the participating institute contact person who then sends it to the TC-Q Chair. Preferably Part II of the form is already prepared with support of the TC-Q contact person of the participating institute. The TC-Q Chair checks the form for completeness and checks the status of the QMS of the submitting NMI/DI and whether the QMS covers the submitted CMC claims based on information available from the TC-Q database and other relevant sources (minutes of the TC-Q meetings, project reports, etc.). If satisfactory evidence exists of coverage of the CMCs by a fully operational QMS meeting the requirements of the CIPM MRA, the TC-Q Chair makes sure that Part II of the form is properly filled in and confirms the coverage of the submitted CMCs by the QMS of the submitting institute by signature and provides it to the contact person (the writer) for upload to the KCDB. The TC Chair has to check that the information provided in the Declaration for Coverage of CMCs corresponds with the submitted or modified CMCs.

The TC Chair should verify that the Declaration of Coverage of CMCs by QMS is signed before start of review process. In case of missing signature, CMCs will be returned for revision.

Though CMCs can be submitted on an ongoing basis, some TCs have set up a Working Group for CMC Review and set a fixed date for submission (e. g., the annual TC meeting) and a fixed period for intra-regional review in order to control and simplify the process. In this case, the TC Chair, the CMC writer / reviewers of the TC that are directly involved in this process, will review the CMCs at the agreed time. The CMC review is performed by direct contact between the reviewers and the persons responsible from the submitting NMIs or via TC/WG Chair until a consensus can be reached. In case that not all concerns can be resolved, the TC Chair contacts the reviewers and the submitting NMIs for resolution, the final decision being with the EURAMET TC Chair.

The results of the review together with potential comments of the reviewers and the submitting NMIs are recorded in the KCDB. The intra-regional review is only complete when the relevant TC has accepted the CMC.

The intra-regional review process is presented as a flowchart in Appendix 1.

4.2 JCRB review

Once, the intra-regional review has been completed, the JCRB review will start9.

The reviewing RMO TC/WG Chairs are responsible for organising the review in their region and should involve local reviewers if considered necessary. The JCRB review procedure is explained in detail in the CIPM MRA-G-13 document (5.2).

As for intra-regional review, JCRB review is performed via the KCDB web platform.

Once all reviewing RMOs have accepted a CMC, a notification is automatically transmitted to the KCDB office for publication in the KCDB. In the event of non-approval, the CMC can be revised and undergo another web submission process requiring unanimous approval by reviewing RMOs. Failure to conduct reviews according to the CIPM MRA may require discussion with the RMOs. Any outstanding disagreements will be resolved by the JCRB, which may request arbitration by the CIPM.

4.3 Modifying CMCs already published in the KCDB

Modifications of a published CMC usually arise for reasons falling into one of four categories:

- a) material or editorial errors and improvements to the explanatory text for a quantity, instrument, method, etc;
- b) voluntary updating of a CMC by increasing its measurement uncertainty or reducing its range, allowing the issuing institute to adjust its engagement in specific measurement activity;
- c) significant unresolved deviation of a comparison result with respect to a CMC, in which case an increase of the measurement uncertainty or a reduced range may be required;
- d) change of the method of measurement or traceability, reduction of the measurement uncertainty or increase in range/scope.

For modifications of categories a) and b), the intra- and JCRB reviews are unnecessary.

For modifications of category c) the EURAMET TC Chair and NMI TC Contact Person shall verify that the reduced range or increased measurement uncertainty is sufficient to assure equivalence of the measurement.

In case of modifications under category d) NMIs should follow the full procedure of intra-regional and JCRB reviews, as if they were new CMCs.

If an NMI decides to delete CMCs from the BIPM database, this decision is communicated by the NMI (TC Contact Person) to the relevant TC Chair and RMO Secretariat, and implemented via KCDB platform. Confirmation that CMCs have been deleted will be sent to the contacts listed after:

- institute to which the CMCs belong, copied to
- EURAMET representative to the JCRB;
- Chair of the relevant EURAMET TC;
- Chair of the EURAMET TC-Q.

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⁹ The JCRB review process is detailed in the flowchart form in Appendix 2.

5. Comparison results and CMCs' consistency

It must be ensured that CMC claims made by an NMI are consistent with the results obtained in key and supplementary comparisons. In general, a measurement in a key comparison is considered to be discrepant when the degree of equivalence represented by the difference $d_i = x_i - x_{KCRV}$ and the expanded measurement uncertainty $U(d_i) = k \cdot u(d_i)$ do not fulfil the condition $|d_i| < U(d_i)^{10}$. However, practices may change from one TC to another, calling for verification with TC / CC rules before assessing consistency. The NMI making the CMC claim has primary and principal responsibility, i.e., it must check the comparison results against its CMC claims and state whether or not these claims are supported by the comparison results. If not, it must take appropriate actions to remove this inconsistency. The TC Chair of the respective field should follow this situation until it is resolved.

Through its TCs, EURAMET must monitor the impact of key and supplementary comparison results on CMC claims for its member NMIs. This can best be done by means of a comparison executive report in which the participants of a comparison declare in writing, that they have checked their CMC claims in the light of the comparison results. This comparison executive report is confidential to the comparison participants, the TC Chair and is not part of the publicly available comparison report. Reasons for withdrawals or changes in results, according to CIPM MRA rules, shall also be given in this report.

If the CMCs published in the KCDB are found to be inconsistent with comparison results, the institute has the choice between:

- increasing the corresponding measurement uncertainties, as described in 4.3
- within six months, demonstrating that appropriate actions have been taken to eliminate the root source of the inconsistency (see also Section 11 of CIPM MRA-G-11)
- temporarily withdrawing (greying-out) its CMCs
- deleting CMCs from the KCDB

6. Greying out CMCs

A greyed-out CMC is a calibration and measurement capability published in the KCDB that has been temporarily withdrawn, with the intention of being reinstated at a later date. The greyed-out CMCs are not visible on the public KCDB website but are retained in the database for possible reinstatement for a maximum period of five years.

Greying out of CMCs published in the BIPM KCDB is considered because of temporarily non-compliance with the criteria for acceptance of CMCs described in Chapter 3 (and 5), and usually occurs in the following cases:

- a) An NMI decides to temporarily suspend a service linked to a published CMC;
- b) The TC-Q obtains knowledge of the non-validity of published CMC(s) through the QMS Annual Report submitted by an NMI or other sources;
- c) A TC determines that, based on the results of a comparison, a published CMC is not anymore consistent.

If an NMI decides to temporarily suspend a service linked to a published CMC (for strategic reasons, due to lack of ad-hoc equipment or qualified staff), the NMI contact

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¹⁰ M.G. Cox, "The evaluation of key comparison data", Metrologia, vol. **39** (2002), pp. 589-595

person can do it directly via KCDB. The contact person should inform the EURAMET Secretariat and Chairs of the concerned TC (including TC-Q).

In case of a permanent discontinuation of activities linked to a published CMC, the CMC shall be deleted by the holding institute, informing the JCRB Executive Secretary, the EURAMET Secretariat, Chairs of the concerned TCs and TC-Q.

In cases where there are doubts about the validity of published CMCs, an evaluation of the situation shall be performed by the TC-Q in cooperation with related TC. Doubts may be based on the information reported by the NMI to the TC-Q in the QMS Annual Report, reports of peers or other relevant documentation¹¹. Wherever possible, consensus between the participating institute, TC-Q and the related TC shall be achieved. The TC-Q Steering Committee, in consultation with the concerned TC, shall analyse the situation and prepare a position of the TC-Q plenary on the actions to be implemented (e.g. on-site peer review) and proposed to the EURAMET Board of Directors (BoD). In case of clear and obvious evidence of the non-validity of the CMC(s) and in case that the participating institute is refusing to grey out or withdraw the invalid CMCs, the TC-Q Chair shall send a request to the JCRB Executive Secretary to grey out the concerned CMC(s), after approval by the BoD. If a decision on the greying out CMC(s) cannot be reached based solely on the documentary evidence, the TC-Q, in cooperation with the concerned TC, shall arrange a peer review to check the validity of the CMC(s) under question. The peer review shall be carried out on-site or remotely. following the principles mentioned in that respect in CIPM MRA-G-13 document (please see chapter 5.), and consult the EURAMET Guide for on-site visits by peers in the framework of CIPM MRA which is clarifying the requirements of CIPM MRA-G-12 document for clearer specifications on on-site visits by peers, and TC-Q for on-site peer reviews. The peer review could result either in a confirmation of the non-validity of the CMC(s) or in the identification of non-conformities that must be addressed by the NMI.

As a result of this process, the NMI must either take the necessary measures to remove the non-conformities within 6 months or agree to the greying-out or permanent deletion of CMCs. In the latter case, the NMI shall grey-out or delete CMCs via KCDB. If the TC-Q and the NMI are unable to reach an agreement, the case shall be brought to the BoD for a decision through the Vice Chairperson (GA). The BoD shall then issue a final decision to be implemented by the involved parties.

Greyed-out CMCs must be re-instated within 5 years or they will be permanently deleted. A re-instatement plan should be available after 4 years at the latest.

When a CMC has been greyed-out for four years, the JCRB Executive Secretary shall send a notice to the following contact list stating the maximum five-year period will be reached within the going year:

- institute holding the greyed-out CMC, copied to
- EURAMET representative to the JCRB
- Chair of the relevant EURAMET TC
- Chair of the EURAMET TC-Q

The notice shall state that a detailed reinstatement plan is to be submitted within six weeks to prevent deletion of the CMC and advise that the proposed period to execute the plan cannot exceed one year. If a response to the first notice is not received within three weeks, a second (and final) notice will be sent. If no satisfactory response is

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¹¹ Results of ILCs reported by TCs or information received about the lack of *ad-hoc* equipment or qualified staff, on-site peer reviews or some complaint.

received within a further three weeks, the greyed-out CMCs will be permanently deleted from the KCDB.

There are two possible courses of action following a notice being issued:

- Re-instatement: The RMO, after consulting with the member institute, responds
 with a reinstatement plan to be prepared by the participating institute including
 a timetable with a deadline for completion not exceeding one year. Following
 successful implementation of the agreed actions, the CMCs in question will be
 reinstated.
- Deletion of the CMCs: This course of action occurs when:
 - o no reply has been received to the second notice;
 - the response received by the JCRB from EURAMET or the institute indicates approval for deletion;
 - o an agreed reinstatement plan has not been successfully executed.

In any of these circumstances the JCRB Executive Secretary will send a request to the KCDB Office to permanently delete the relevant CMCs from the KCDB. Confirmation that CMCs have been deleted will be sent by the JCRB Executive Secretary to the contacts listed above.

It should be noted that no further extension to the time allowed for greyed-out status of the CMCs will be permitted.

For further information about greyed-out CMCs, please refer to the related section in CIPM-MRA G-13 document.

Appendix 1: Intra-regional review of CMCs organised through the KCDB platform

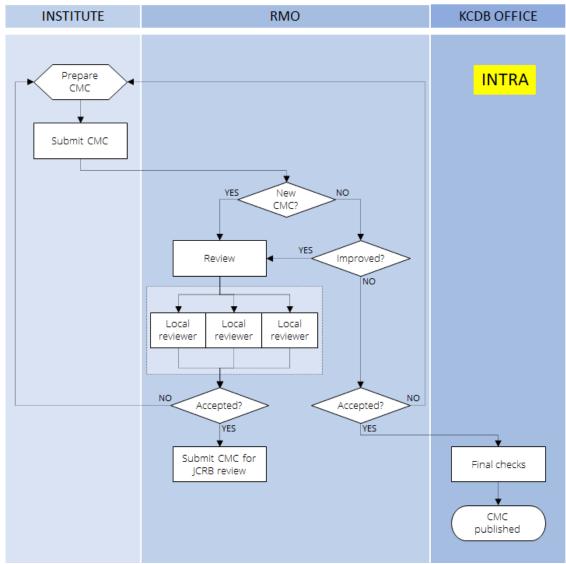


Figure 1: Intra-regional review of CMCs organised through the KCDB platform (Source: CIPM-MRA-P-13, Calibration and measurement capabilities in the context of the CIPM MRA: Guidelines for their review, acceptance and maintenance, BIPM, Version 1.2 (2022)

Submit CMCs means: uploading all required documentary evidence including "<u>Declaration of Coverage of CMCs by QMS' (G-OPS-FRM-013)</u>. Otherwise, the CMCs will be sent back for re-submission.

Appendix 2: JCRB review of CMCs organised through the KCDB platform

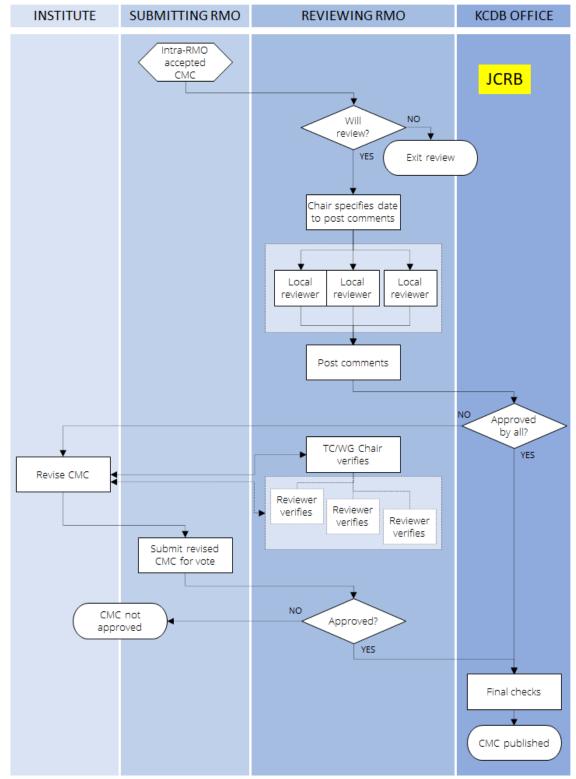


Figure 2: JCRB review of CMCs organised through the KCDB platform (Source: CIPM-MRA-P-13, Calibration and measurement capabilities in the context of the CIPM MRA: Guidelines for their review, acceptance and maintenance, BIPM, Version 1.2 (2022)

Figures 1 and 2 courtesy of BIPM.

EURAMET e.V. Bundesallee 100 38116 Braunschweig Germany Phone: +49 531 592 1960 Fax: +49 531 592 1969

E-mail: secretariat@euramet.org