Quality management systems in the CIPM MRA

Guidelines for monitoring and reporting

CIPM MRA-G-12

Version 1.0
11/01/2021

Contents

Acronyms used in this document are listed in CIPM MRA-P-11.

1. Introduction

The CIPM MRA requires that:

a) participating institutes establish and maintain a quality management system;

b) RMOs review and monitor the quality management systems of their participating institutes;

c) each RMO reports to the JCRB on its processes and the outcomes of its reviews.

An approved quality management system is a prerequisite for the submission of CMCs.

This document (CIPM MRA-G-12) provides the guidance for each of the elements above. It supersedes CIPM MRA-G-02, and together with CIPM MRA-G-13 and CIPM MRA-P-13 supersedes CIPM MRA-G-03. It incorporates the CIPM recommendations for quality management systems set out in CIPM/2007-25 for on-site visits by peers and selection criteria for on-site visit peer reviewers.

2. Requirements

2.1 Requirements for the quality management system

The quality management system established and operated by the institutes shall cover all declared CMCs and meet the requirements of:

- ISO/IEC 17025 for calibration and measurement services, and (if applicable)
- ISO 17034 for certified reference materials production.

2.2 Requirements for establishing confidence

The CIPM MRA does not explicitly specify how participating institutes review, gain confidence and accept each other's quality management systems. Consequently, RMOs have some leeway to optimize their approach to best suit their regional circumstances. However, to confirm the establishment of suitable quality management systems, the RMO shall peer review each quality management system either:

- with the support of an accreditation body; or
- directly, without third-party involvement.

In both cases, the responsibility for the review lies with the individual RMOs under the auspices of their respective technical committees/working groups. Peer reviews using either of these pathways should meet the requirements outlined in Appendix A for example in relation to the qualifications of peer reviewers.

Each RMO should make their guidance documents on quality management system review openly available on their websites.

2.2.1 Peer review with the support of an accreditation body

Those institutes who wish the accreditation of their services to be taken into consideration as part of the CIPM MRA review process should follow the guidelines outlined in the ILAC-CIPM guidance on the accreditation of NMIs, noting that:

- Generally, the scope (range and measurement uncertainty) of an institute's accredited calibration and measurement service should be the same as that published in the KCDB (exceptions outlined in the ILAC-CIPM guidance on the accreditation of NMIs).
- The accreditation body shall operate according to ISO/IEC 17011 and the accreditation body shall be covered by the ILAC MRA or by Regional Arrangements recognized by ILAC.
- If the institute wishes to use the status of accreditation to support their participation in the CIPM MRA, the accreditation body should, wherever practical, use technical assessors/technical experts who can also be accepted as peer reviewers by the RMO. For details, see Section A3 of Appendix A

2.2.2 Peer review without third-party involvement

Each RMO shall establish appropriate processes to ensure that the quality management systems of their member institutes comply with ISO/IEC 17025 for calibration and measurement services, and, where applicable, ISO 17034 for institutes producing reference materials. The requirement is applicable for all fields of metrology where the institute declares or intends to declare CMCs.

3. Review, approval and monitoring guidelines

Each RMO shall develop and maintain an open process for reviewing, approval and monitoring the quality management systems of their member institutes. The process shall satisfy at least the requirements outlined below. The institute shall provide the RMO with necessary information from the quality management system, covering

CMCs and, where applicable, reference materials production. Outcomes of the reviews are reported to the JCRB by the RMO as described in Section 5.

3.1 Review

The RMO shall ensure through its review process that the quality management system operated by each of their member institutes is effective and durable, meeting all requirements in Section 2 of this document, including corrective actions, nonconforming work, risk management and complaints.

The RMO initial review should include a presentation of the quality management system to a panel of experts chosen by the RMO. The presentations shall be delivered by an authorized representative from the relevant institute. Minimum features to be included are:

a) a diagram showing the organizational structure of the institute;

b) quality system management mechanisms;

c) detailed table of the contents of the quality management system documentation (e.g., of the quality manual when available);

d) list of administrative and technical procedures;

e) table of cross references between ISO/IEC 17025 and/or ISO 17034 and the quality documentation of the institute;

f) list of CMCs covered by the quality management system;

g) customer complaints – process employed and statistics;

h) nonconforming work – process employed and corrective actions;

i) report on internal audits;

j) status of management reviews;

k) outcomes of peer-reviews where these have taken place;

l) plan and implement action to address major identified risks and opportunities.

In addition to the requirements of the quality management system, the review process may also take into account:

- participation in RMO projects and activities;
- other available knowledge and experience; updates on facilities, measurement infrastructure and improved metrological capabilities,

participation in scientific and training activities, visits and consultation with technical experts from other RMOs.

3.2 Approval

The RMO shall ensure, through its peer-review process, that the quality management system operated by each member institute has effective systems to comply with the requirements set in Section 2 that support their corresponding CMCs.

3.3 Monitoring

RMOs shall have a process in place for the on-going monitoring of the quality management systems of their member institutes. The individual RMOs are responsible for this review, under the auspices of their respective quality management system TC/WGs. The planned monitoring shall ensure that the quality management systems continues to cover the declared CMCs and that the peer-reviews continue to be valid. It shall include:

a) review of annual reports submitted by the institutes to demonstrate that they are: maintaining quality management systems, regularly reviewing their services and addressing any issues that would affect published CMCs (for example, departure of key staff, loss of facilities and equipment, poor performance in comparisons, etc.). The reports shall be prepared and submitted to the RMO directly by an authorized representative from the relevant institute.

b) a periodic review of the quality management system at the same level as the initial review, undertaken at an interval not exceeding five years. This comprehensive review shall include examination of evidence for the continued validity and vitality of published CMCs. Presentations of the periodic reviews shall be delivered directly by an authorized representative from the relevant institute.

In addition, the RMO shall evaluate changes to member institutes' quality management systems that are brought to its attention at any time, if such changes are likely to affect the validity of CMCs.

3.4 On-site visits by peers during the review of quality management systems

The CIPM MRA also foresees on-site visits by peer reviewers as a possible way to assist the review process of quality management systems. Such visits may be requested by the institute itself or the local RMO to establish the required level of confidence in the quality management systems. Some RMOs only use on-site peer reviews when regular procedures instituted by their TC/WGs are unable to verify satisfactory performance of the quality management system under review.

Where such visits take place, the RMO shall ensure that the peer reviewers involved are independent, have the necessary experience and are suitably qualified to conduct the review. The criteria for peer reviewers apply to both cases where a peer review is undertaken with or without involvement of an accreditation body. Recommendations for on-site visits by peers and selection criteria for on-site visit peer reviewers are described in Appendix A of this document.

4. Options for international organizations

As every international organization's participation in the CIPM MRA is unique, early contact should be made with the JCRB Chair and JCRB Executive Secretary who will facilitate the process with all parties. For international organizations participating in the CIPM MRA, two routes are available for review of quality management systems and CMCs.

Route A: Panel option

A meeting of a panel of quality and technical experts shall be convened, if necessary at the BIPM, to review the quality management systems and the CMC claims of the international organization and/or its DIs who are signatories of the CIPM MRA. The members of this panel shall include staff from all RMOs, who are expected to be well-versed in the operation and review of quality management systems and experts in the relevant metrology areas. Ideally, Chairs of the RMO working groups on quality management systems will be among the panel members, as well as any other RMO representatives deemed appropriate by each RMO.

There shall be no more than three panel members from each RMO. The review panel shall be chaired by the Secretary of the CIPM or the CIPM representative to the JCRB, who will be assisted by the Executive Secretary of the JCRB. The chairperson reserves the right to call upon other individuals to provide expert advice to the panel as needed.

A date for the panel to meet shall be determined in consultation with the international organization, its DIs and members of the review panel. The international organization, and its DIs, shall submit a description of their quality management systems and CMCs to the panel not less than 60 days prior to the panel meeting. The panel will review the material provided using the guidelines outlined in this document and CIPM MRA-G-13, wherein the role of the RMO is assumed by the panel.

The panel shall send a report to the JCRB summarizing its findings no later than 60 days after the meeting. The report to the JCRB shall provide:

a) information on the status of the quality management system including coverage of claimed CMCs;

b) information on the status of CMCs;

c) the standard to which the quality management system is being operated by the international organization and/or its DIs; and

d) whether the quality management system was peer reviewed with the support of an accreditation body or without third-party involvement.

The conclusion of the report shall clearly state whether the CIPM MRA requirements are met for the quality management system and CMCs.

A copy of the report shall be sent to the international organization and/or its DIs as evidence of the panel findings. If the panel does not approve the quality management system, the report shall provide recommendations for improvement.

Route B: Elected option

The international organization may elect to work through one or more RMOs on behalf of all other RMOs for review of the quality management system and first stage intra-regional review of CMCs. This route is available on a case-by-case basis, when a specific proposal is acceptable to the international organization and to all the RMOs. The review and reporting follow the standard practice of the RMO(s) conducting the review and/or guidelines outlined in this document. The second stage shall follow the JCRB review outlined in CIPM MRA-G-13.

Other points to consider

Recognizing that international organizations are part of the wider community and that the provision of traceability is not their primary function, the JCRB may advise on measures that will help build confidence in their quality management system (for

example, training courses/workshops, exchange of information between the international organization and RMOs, and/or interaction with the RMOs).

5. RMO reporting to the JCRB

As part of the regular reports to the JCRB outlined in CIPM MRA-P-12, the RMOs shall provide annual summary reports on the status of the quality management systems of institutes in their region.

The report should include:

a) summary of the RMO's quality management system review process;

b) whether and when each member institute's quality management system was approved by the RMO (necessary details of each institute's quality management system status, for example peer reviewed through support of an accreditation body or without third-party involvement);

c) major changes to the quality management systems of member institutes that affect the validity of CMCs, like changes in key personnel, new installations or equipment, etc.; and

d) other relevant information, which will help build inter-regional confidence (for example training courses/workshops, exchange of information between institutes or interaction with other RMOs regarding quality management systems).

6. Resources related to the CIPM MRA

CIPM-D-01, *Rules of procedure for the Consultative Committees (CCs) created by the CIPM, CC working groups and CC workshops.*

CIPM MRA (https://www.bipm.org/en/cipm-mra/cipm-mra-text/)

CIPM MRA-P-11, *Overview and implementation of the CIPM MRA*

CIPM MRA-P-12, *Coordination within the CIPM MRA: Consultative Committees, Regional Metrology Organizations, JCRB*

CIPM MRA-P-13, *Participation in the CIPM MRA: National Metrology Institutes, Designated Institutes, International organizations*

CIPM MRA-G-11, *Measurement comparisons in the CIPM MRA: Guidelines for organizing, participating and reporting*

CIPM MRA-G-12, *Quality management systems in the CIPM MRA: Guidelines for monitoring and reporting*

CIPM MRA-G-13, *CMCs in the context of the CIPM MRA: Guidelines for their review, acceptance and maintenance*

JCGM 100:2008, *Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM)*

ILAC-CIPM guidance on the accreditation of NMIs, *Joint ILAC–CIPM Communication regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes*

PG0128E1, *Customs Convention on the temporary importation of scientific equipment* (http://www.wcoomd.org/en/about-us/legal-instruments/conventions.aspx)

JCRB directory (https://www.bipm.org/en/committees/jc/jcrb/)

KCDB web portal (https://www.bipm.org/kcdb)

RMO websites (http://www.afrimets.org; http://www.apmpweb.org; https://www.coomet.net; https://www.euramet.org; https://www.gulfmet.org; https://sim-metrologia.org)

7. Revision History

Document and Version number	Date of Issue/ last review	Summary of change
CIPM MRA-G-12 V 1.0	11 January 2021	New document following the CIPM MRA review.

Appendix A - Recommendations for on-site visits by peers

A1 Introduction

The CIPM MRA peer-review process is intended to enhance the confidence of those who use the metrological services of metrology institutes and to demonstrate that all work is being performed in a competent and proper way.

The review process for the quality management systems and CMCs may require on-site peer reviews, or metrology institutes may choose to follow the on-site peer-review process. The review process may require peers that are selected by the RMO or the institute (applied according to local RMO rules). In all cases, it is recommended that the visiting peers meet the criteria outlined in Section A3 of this Appendix.

There shall be clarity regarding the extent of the peer-review activities. The peer review may be requested to cover all or part of the requirements necessary to demonstrate compliance with the CIPM MRA as addressed in CIPM MRA-G-12 and CIPM MRA-G-13.

These recommendations apply to peer reviews undertaken both with and without involvement of a third party such as an accreditation body.

A2 Reporting of the Review Outcomes

The review report shall include at least the following information:

a) name of the metrology institute;

b) date(s), scope and programme of the on-site visit;

c) names and affiliations of the reviewers;

d) scopes of activities (a list of capabilities indicating that the reviewers recognize the institute as having the competence to deliver ordinarily);

e) identification of the reference documents used;

f) review findings against all the aspects specified in CIPM MRA-G-13;

g) comments on the metrology institute's nonconformities and, where applicable, actions taken to correct nonconformities;

h) the adequacy of the metrology institute's quality management system and its implementation to demonstrate the conformity with the requirements of the CIPM MRA

i) an explanation of any significant differences of opinion between the reviewer and the metrology institute.

A3 Criteria for the selection of visiting peer reviewers

A3.1 General characteristics

The selection of peer reviewers should be guided by the principles provided in ISO 19011 Guidelines for auditing management systems. In addition, the following should be considered.

A3.2 Qualifications

The selected reviewers should normally have at least a degree qualification in a scientific/technological discipline. In some cases, extensive experience in the relevant field of expertise may be substituted for formal education. In addition, the following elements are desirable:

- past or present member of an RMO TC/WG;
- participation in key and supplementary comparison programmes;
- publication record in internationally refereed metrology journals;
- experience in undertaking national or international assessments of calibration or testing in laboratories.

A3.3 Work experience

A peer reviewer should have:

- generally no less than five years' experience in developing, providing or being responsible for a calibration or measurement service in a technical field relevant to the CMCs being investigated;
- no less than two years' experience of quality management, quality assurance or quality management system auditing related to laboratory activities at the metrology institute level;
- in the absence of quality management system experience, the peer reviewer should work together with a quality management system expert who has participated in assessments for accreditation by recognized accreditation providers.

Ideally, at least one member of the peer review team should be conversant with the language in which the relevant documentation is provided.

A3.4 Training

At least one member of the peer review team should have successfully completed a training course on the ISO/IEC 17025 requirements, conducted by a competent organization (for example, metrology institute or recognized accreditation body for calibration laboratories). If the review needs to cover the manufacturing of reference materials, then the reviewer should have additional sufficient knowledge and experience with the requirements of ISO 17034.

Bureau International des Poids et Mesures

Bureau International des Poids et Mesures
BIPM – Pavillon de Breteuil, F-92312 Sèvres Cedex