

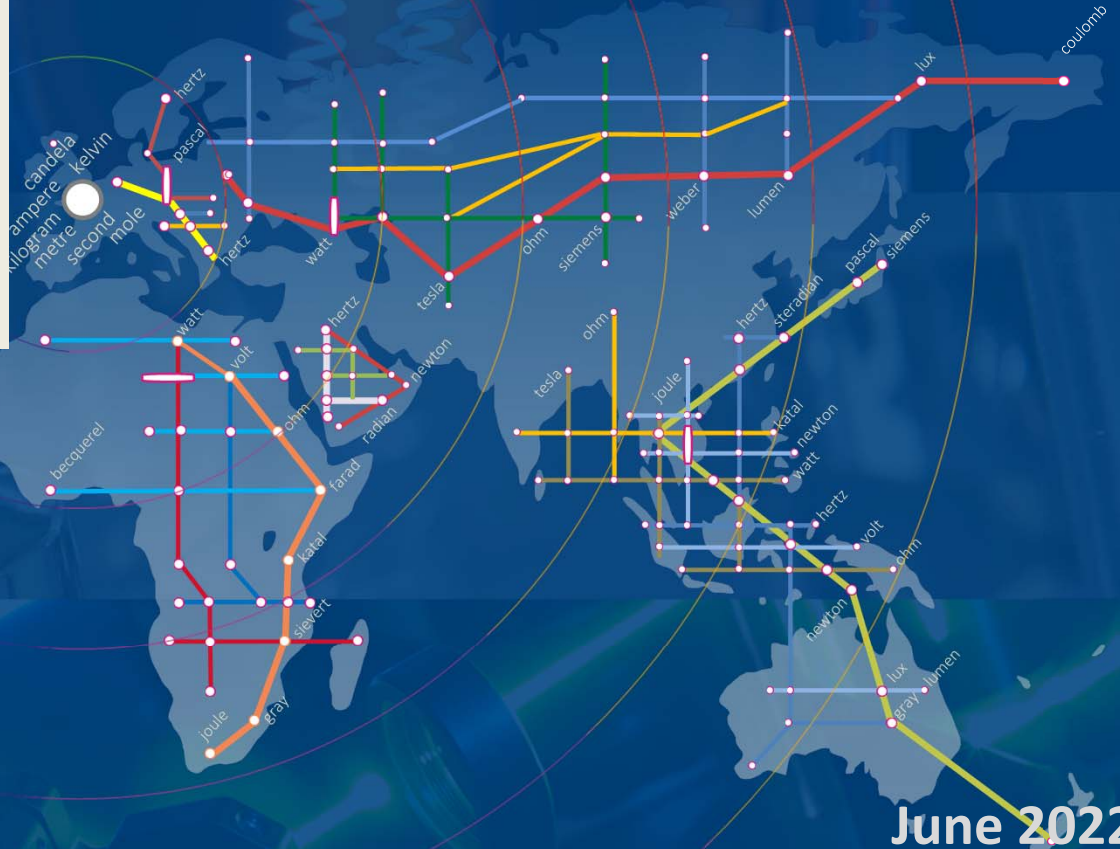
BIPM-GULFMET-2022

CIPM MRA Overview

– Quality Management Systems –

Bureau
International des
Poids et
Mesures

June 2022
Olav WERHAHN
BIPM



Quality infrastructure

“The system ..

comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices

needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.

it relies on

- *metrology*
- *standardization*
- *accreditation*
- *conformity assessment, and*
- *market surveillance” (in regulated areas)”*

“The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets.

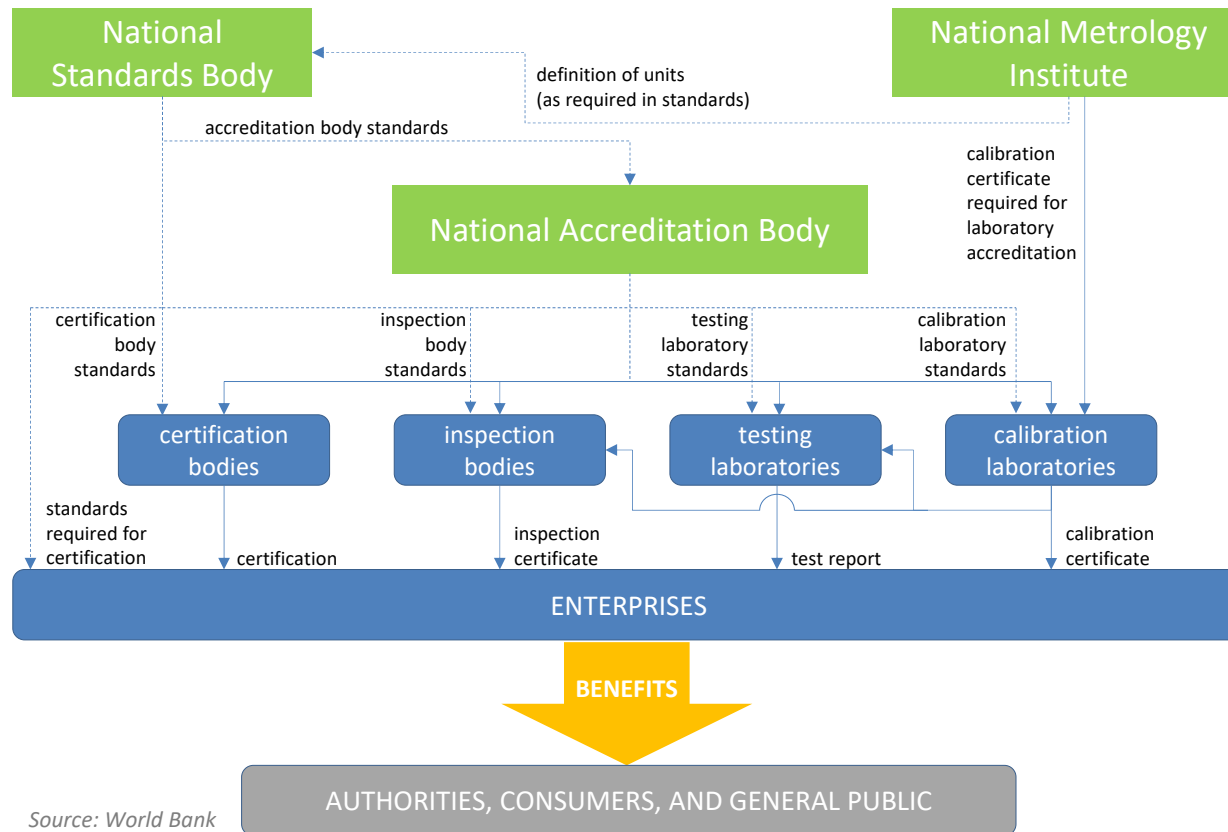
It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.”

adopted in June 2017 by the DCMAS Network.

Now INetQI.

Members: BIPM, IAF, IEC, IIOC, ILAC, IQNET Association, ISO, ITC, ITU, OIML, UNECE, UNIDO, WTO and World Bank.

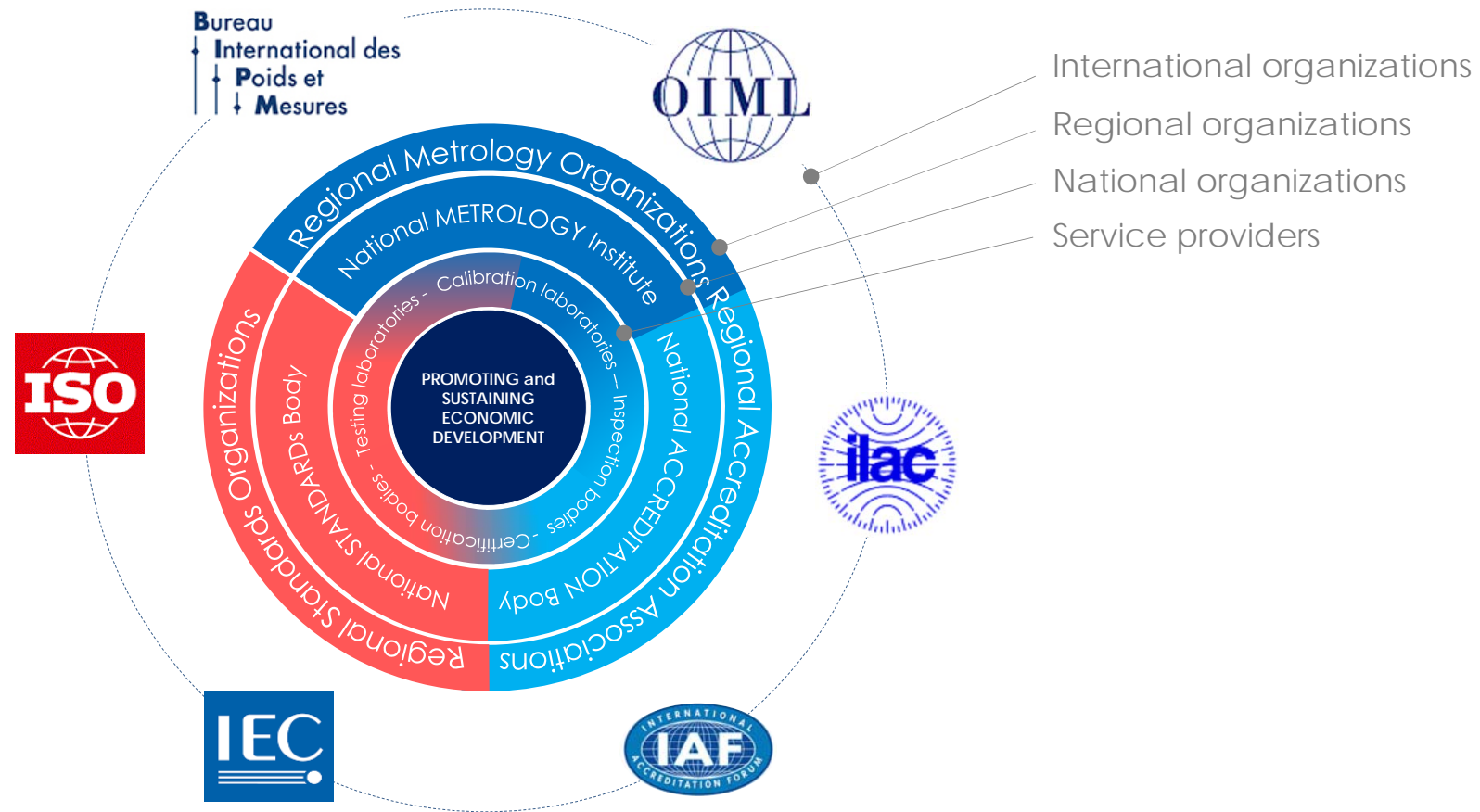
Global QI



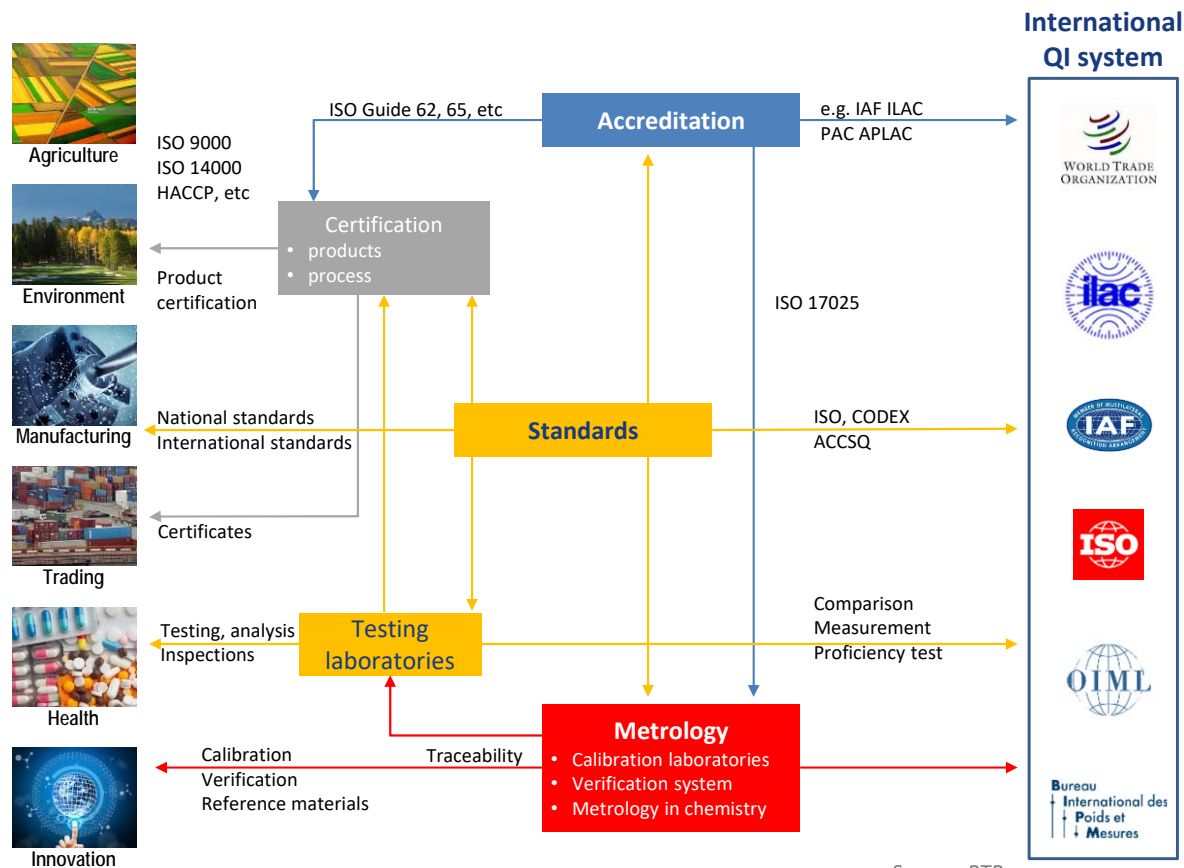
- Enhanced product quality and compatibility
- Enhanced safety and health
- Decreased environmental impact
- Increased trade opportunities
- Facilitating innovations to the market place

Source: World Bank

Key players of QI



Global “Quality Infrastructure”

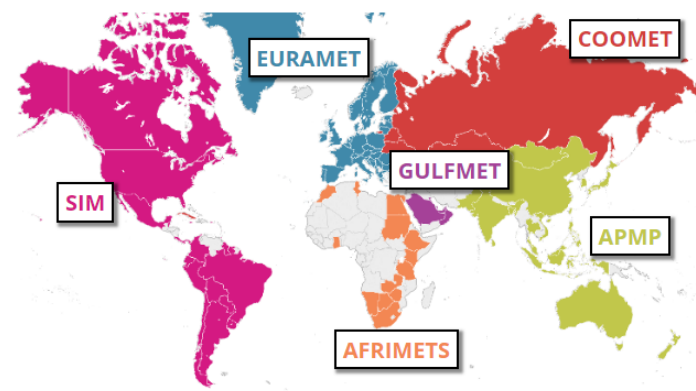


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- ♦ Metrology is a key part of the global “quality infrastructure” that underpins world trade.
- ♦ The work of the NMIs is made visible and transparent through the CIPM-MRA signed in 1999.
- ♦ The CIPM MRA provides the technical basis for the **world-wide acceptance** of national measurement standards and calibration and measurement certificates from NMIs.
- ♦ The work of the CIPM MRA now goes far beyond matters of trade to cover climate change, healthcare, etc.
- ♦ Thus it is not surprising that the NMIs participating in the CIPM MRA are from countries that collectively cover **more than 90 % of world trade**.

Calibration and Measurement Capability

- Internationally recognized outcome of the CIPM MRA
- Measured quantity and associated measurement uncertainty
- Traceable to the SI
- Subject to open two-tier peer review process
- Backed up by technical evidence
- **Supported by Quality assurance**
- Published in the KCDB



Currently in the KCDB there are

250

CIPM MRA participants

1124

key comparisons

25787

CMCs

653

supplementary comparisons

In the context of the CIPM MRA and ILAC Arrangement the common definition is:
A CMC is a calibration and measurement capability available to customers under normal conditions:
–as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
–as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement.

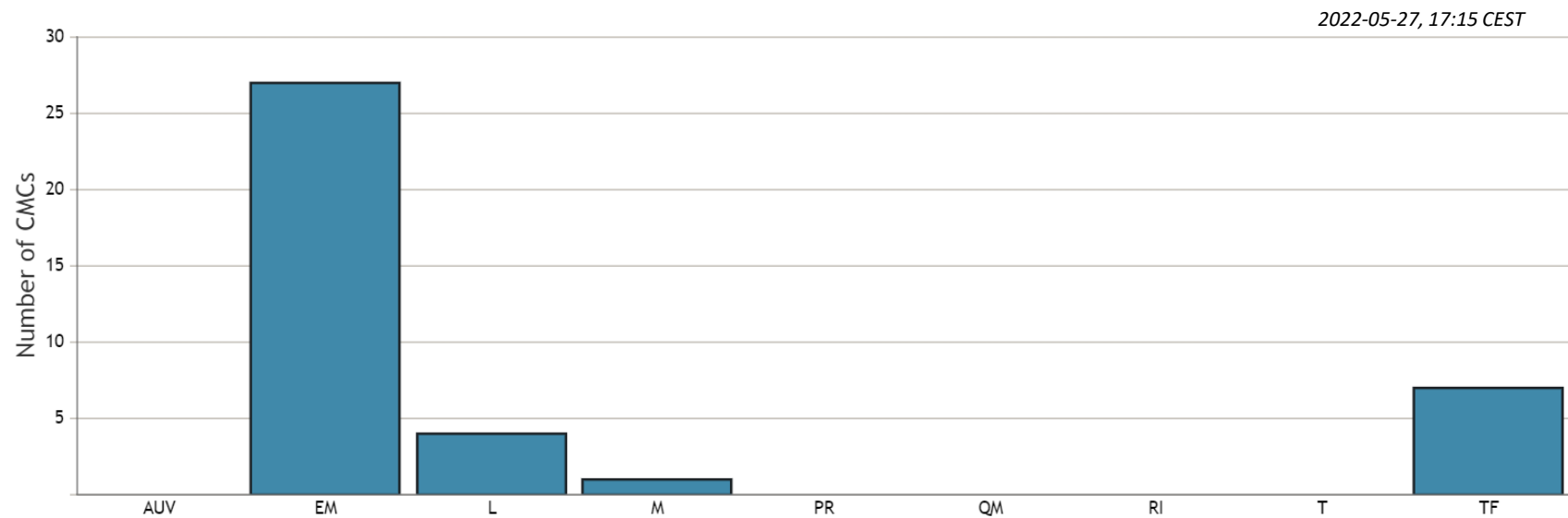
Calibration and Measurement Capability

HELD BY GULFMET PARTICIPANTS

Number of CIPM MRA participants: 6

Number of CMCs published in the KCDB: 39

Calibration and Measurement Capability



CMCs

- Are calibration and measurement capabilities available to customers under normal conditions
 - as published in the BIPM KCDB of the CIPM MRA; or
 - as described in the laboratory's scope of accreditation granted by a signatory of the ILAC Arrangement
- Shall reflect the services available to customers and shall not be artificially subdivided
- Institutes are encouraged to use the percentage of coverage of services as a metric of success rather than the number of CMCs
- CMC declarations shall be self-consistent, and a CMC specification shall not depend on references to other services

CIPM MRA-P-11, Section 8
CIPM MRA-G-13, Section 1

CMC review: intra-RMO review

Each RMO is responsible

- for establishing the intra-RMO review
- assuring that CMCs from the RMO have sufficient technical support, and
- assuring that the CMCs are covered by a QMS in both ranges and uncertainties;

The intra-RMO review

- is technically supported by and performed on the KCDB 2.0 platform;
- does not have any CIPM MRA-required deadlines.

Tier one: intra-RMO review

The intra-regional review is completed when the RMO TC/WG has accepted the CMC and the RMO TC/WG QS Chair has confirmed that the ranges and the measurement uncertainties of the CMCs are fully covered by the quality management system of the institute submitting the claims.

CIPM MRA-G-13
Section 5.1

Quality assurance

Requirements for the quality management system

- ISO/IEC 17025:2017 for calibration and measurement services
- ISO 17034 for certified reference materials production

Requirements for establishing confidence

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

Evidence of approval by RMO to be submitted with the CMC
following the practice adopted by the RMO

CIPM MRA requirements on QMS:

Overview and implementation of the CIPM MRA

CIPM MRA-P-11

Version 1.1
30/03/2021

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CIPM MRA-P-11

30/03/2021

2 / 20

Version 1.1

CIPM MRA requirements on QMS:

Quality management systems in the CIPM MRA

Guidelines for monitoring and reporting

CIPM MRA-G-12

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

CIPM MRA-G-12

CIPM MRA-P-11 / CIPM MRA-G-12:

CIPM MRA-P-11, Section 7 “Quality Management Systems” (QMS)

- the CIPM MRA requires that participating institutes establish and maintain a QMS;
- no explicit specification by the CIPM MRA how QMS are accepted by other participants; but
- participants’ QMS shall meet requirements of ISO/IEC 17025 and where appropriate ISO/IEC 17034; and
- it is the RMO to peer review the QMS of members (with or without support of ISO/IEC 17011 compliant body); and its
- QS working group/technical committee.
- The QMS supporting CMCs of the institutes participating in the CIPM MRA shall undergo a full review with a period not longer than five years.
- The RMOs provide annual summary reports as part of their report to the JCRB.

CIPM MRA-P-11 / CIPM MRA-G-12:

CIPM MRA-G-12

- an approved QMS is a prerequisite for the submission of CMCs;
- each RMO reviews and monitors the QMS and reports the outcomes to the JCRB.
- Each institute's QMS within an RMO shall meet ISO/IEC 17025 and where applicable ISO/IEC 17034 requirements,
- RMOs to make guidance documents on QMS review openly available at the RMO website

For GULFMET available from [here](#)

CIPM MRA-G-12:

Peer review with the support of an accreditation body

- if institutes wish the accreditation of their services 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.
 - Institute wishing 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

CIPM MRA-G-12:

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.

CIPM MRA-G-12:

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.

CIPM MRA-G-12:

Initial *review* should include a presentation of the quality management system featuring:

- a diagram showing the organizational structure of the institute;
- quality system management mechanisms;
- a detailed table of the contents of the quality management system documentation (e.g., of the quality manual when available);
- a list of administrative and technical procedures;
- a table of cross references between ISO/IEC 17025 and/or ISO 17034 and the quality documentation of the institute;
- a list of CMCs covered by the quality management system;

CIPM MRA-G-12:

Initial *review* should include a presentation of the quality management system featuring:

- customer complaints – process employed and statistics;
- nonconforming work – process employed and corrective actions;
- a report on internal audits;
- the status of management reviews;
- the outcomes of peer-reviews where these have taken place;
- a plan and implemented action to address major identified risks and opportunities.

CIPM MRA-G-12:

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 that support their corresponding CMCs.

CIPM MRA-G-12:

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. to:

- ensure that the quality management systems continues to cover the declared CMCs and that the peer-reviews continue to be valid, and 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.

CIPM MRA-G-12:

Monitoring – shall include

- 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.

CIPM MRA-G-12:

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, as
- **requested by the institute** itself or the **local RMO** to establish the required level of confidence in the quality management systems; or
- **when** regular procedures instituted by their TC/WGs are **unable to verify satisfactory performance** of the quality management system under review.
- 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:

CIPM MRA-G-12:

On-site visits by peers –

- The selection of **peer reviewers** should be guided by the principles provided in ISO 19011 Guidelines for auditing management systems.
- 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;

CIPM MRA-G-12:

On-site visits by peers –

- publication record in internationally refereed metrology journals;
- experience in undertaking national or international assessments of calibration or testing in laboratories.
- 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;

CIPM MRA-G-12:

On-site visits by peers –

- 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.
- 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.

CIPM MRA-G-12:

On-site visits by peers – 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. The reporting of the review outcome shall include:

- 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;

CIPM MRA-G-12:

On-site visits by peers – reporting of the review outcome shall include:

- 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.

CIPM MRA-G-13:

The intra-regional review is completed when the RMO TC/WG has accepted the CMC and the RMO TC/WG QS Chair has confirmed that the ranges and the measurement uncertainties of the CMCs are fully covered by the quality management system of the institute submitting the claims.

CIPM MRA-G-13
Section 5.1

Thank you

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