CIPM MRA Requirements

(Quality Management Systems)

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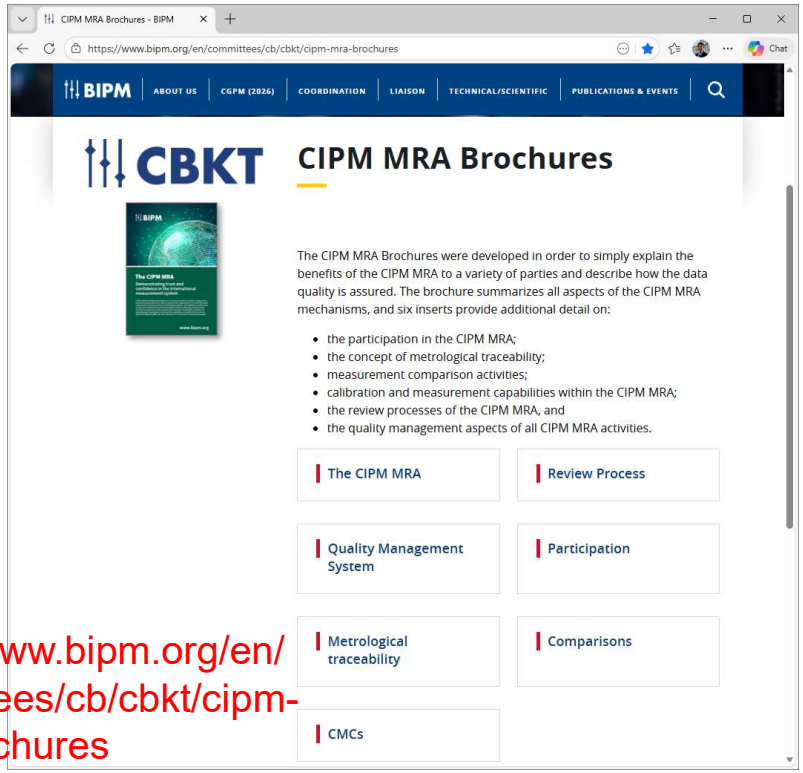
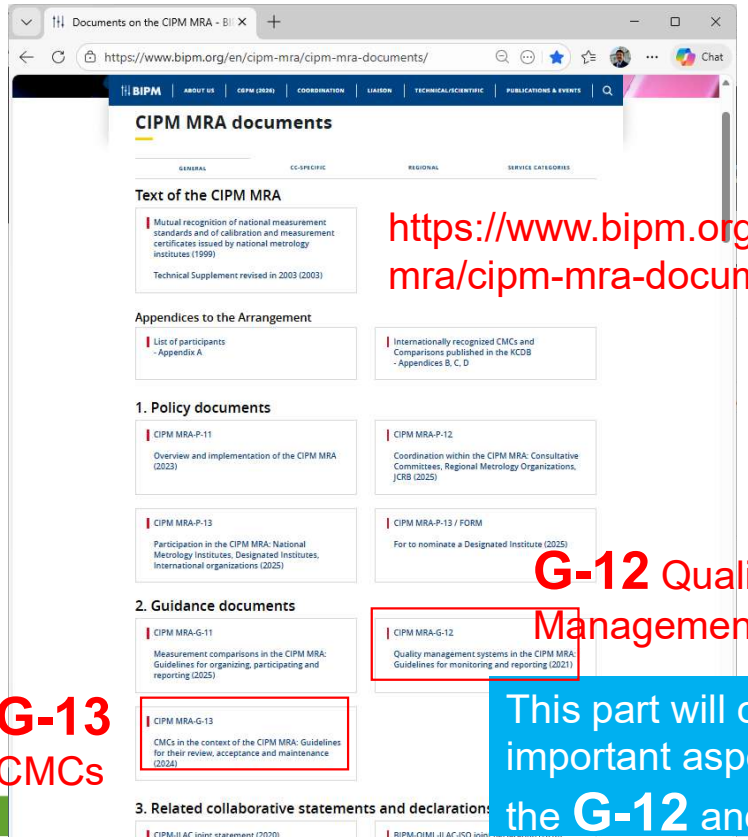
Helpful resources to understand the CIPM MRA (especially the G-12 and G-13)

CIPM MRA Brochures



https://www.bipm.org/en/committees/cb/cbkt/cipm-mra-brochures

Documents on the CIPM MRA



https://www.bipm.org/en/cipm-mra/cipm-mra-documents/

G-12 Quality Management Systems

G-13 CMCs

This part will cover the important aspects of the **G-12** and **G-13**

CIPM MRA G-12 and G-13

Primary responsibilities lies under the RMO's activities
according to **G-12**

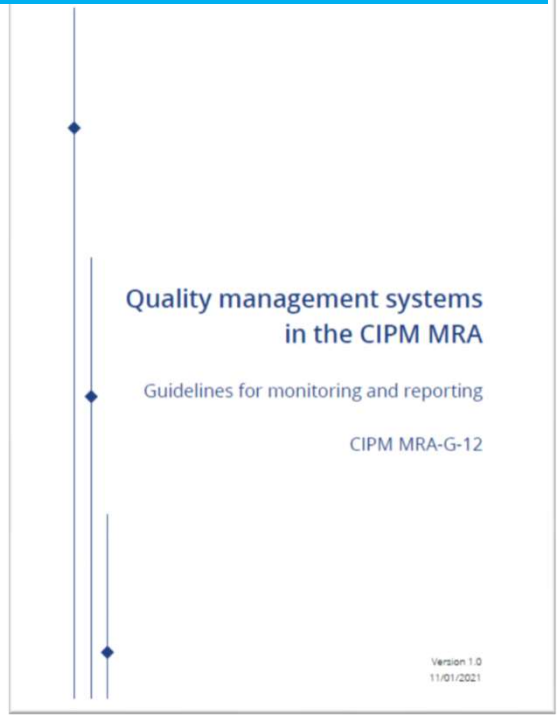
G-12 QMS

Requirements

Guidelines

- Review
- Approval
- Monitoring

and further special rules of international organizations under the CIPM MRA.



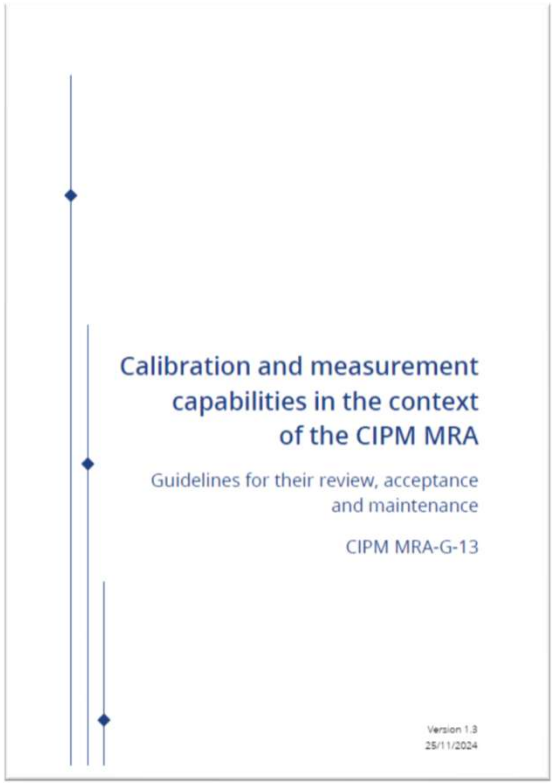
G-13 CMCs

Acceptance criteria

Open peer review & approval process

Maintenance

- Modification
- Responsibilities
- Grey-out



Criteria for acceptance needs to be fulfilled at any time

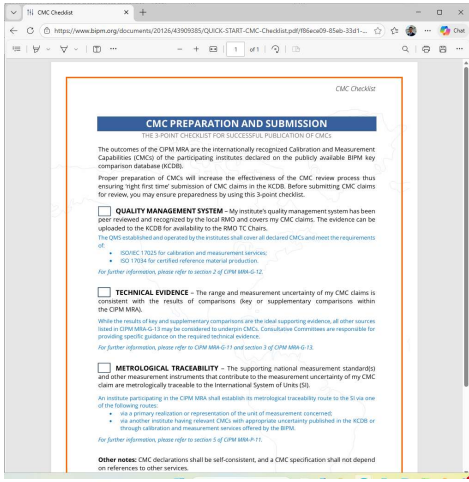
(from its review up to after publication)

G-13 Section 3 and 4 (and G-12)

Technical Evidence

Section 3.3 of G-13

- Results of **key and supplementary comparisons**;
- **Publicly available information** on technical activities including publications;
- **On-site peer-assessment reports**, including those from accreditation assessment with appropriate technical peers;
- **Active participation in RMO projects**;
- **Other evidence of knowledge and experience**, as agreed by the appropriate Consultative Committee.


CMC Checklist

CMC PREPARATION AND SUBMISSION

THE 3-POINT CHECKLIST FOR SUCCESSFUL PUBLICATION OF CMCs

The outcomes of the CIPM MRA are the internationally recognized Calibration and Measurement Capabilities (CMCs) of the participating institutes declared on the publicly available BIPM key comparison database (KCDB).

Proper preparation of CMCs will increase the effectiveness of the CMC review process thus ensuring 'right first time' submission of CMC claims in the KCDB. Before submitting CMC claims for review, you may ensure preparedness by using this 3-point checklist.

☐ **QUALITY MANAGEMENT SYSTEM** – My institute's quality management system has been peer reviewed and recognized by the local RMO and covers my CMC claims. The evidence can be uploaded to the KCDB for availability to the RMO TC Chairs.

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

- ISO/IEC 17025 for calibration and measurement services;
- ISO 17034 for certified reference material production.

For further information, please refer to section 2 of CIPM MRA-G-12.

☐ **TECHNICAL EVIDENCE** – The range and measurement uncertainty of my CMC claims is consistent with the results of comparisons (key or supplementary comparisons within the CIPM MRA).

While the results of key and supplementary comparisons are the ideal supporting evidence, all other sources listed in CIPM MRA-G-13 may be considered to underpin CMCs. Consultative Committees are responsible for providing specific guidance on the required technical evidence.

For further information, please refer to CIPM MRA-G-13 and section 3 of CIPM MRA-G-13.

☐ **METROLOGICAL TRACEABILITY** – The supporting national measurement standard(s) and other measurement instruments that contribute to the measurement uncertainty of my CMC claim are metrologically traceable to the International System of Units (SI).

An institute participating in the CIPM MRA shall establish its metrological traceability route to the SI via one of the following routes:

- via a primary realization or representation of the unit of measurement concerned;
- via another institute having relevant CMCs with appropriate uncertainty published in the KCDB or through calibration and measurement services offered by the BIPM.

For further information, please refer to section 5 of CIPM MRA-P-11.

Other notes: CMC declarations shall be self-consistent, and a CMC specification shall not depend on references to other services.

Checklist is available

Quality Management System

Section 3.4 and Chapter 4 of G-13

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

Metrological Traceability

Section 3.1 (and 3.2) of G-13

- via a **primary realization or representation of the unit of measurement concerned**
- via **another institute having relevant CMCs published in the KCDB or via the BIPM**

For auxiliary influence quantities, an institute is free to use measurement services provided by laboratories accredited by a signatory to the ILAC MRA. (Section 3.2, G-13)

Open peer-review and acceptance process

(in short)

G-13 Section 5

CMC submitted by the Writer

Step 1: Intra RMO review

G-13 Section 5.1

CMC submitted to the JCRB by the RMO TC Chair

Step 2: Inter RMO review (**JCRB Review**)

G-13 Section 5.2 (or 7 for CC Reviews)

CMC Published on the KCDB

Confirmation of QMS coverage
- Range
- Measurement uncertainty

The intra-regional review is complete 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.**

QMS personnel will need to understand this two-stage process.

QS confirmation is done at the point between the two stages!

G-12 Section 3
Review, Approval, Monitoring

Open peer-review and acceptance process

(in detail)

G-13 Section 5

QMS personnel may need to understand this when supporting colleagues (scientists and engineers in lab) **upon assisting them to complete the initial review and further keeping their CMCs vital**

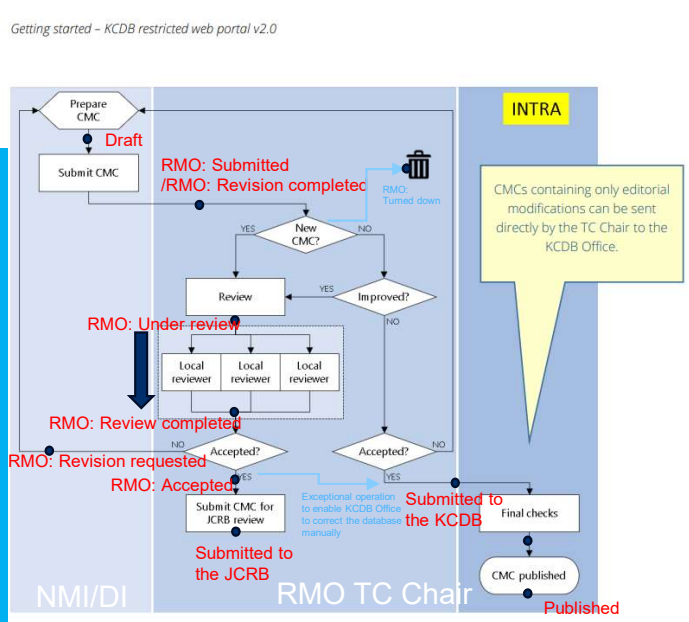


Figure 9 Flow diagram for intra-RMO review (extracted from CIPM MRA G-13).

Section 5.1 of G-13

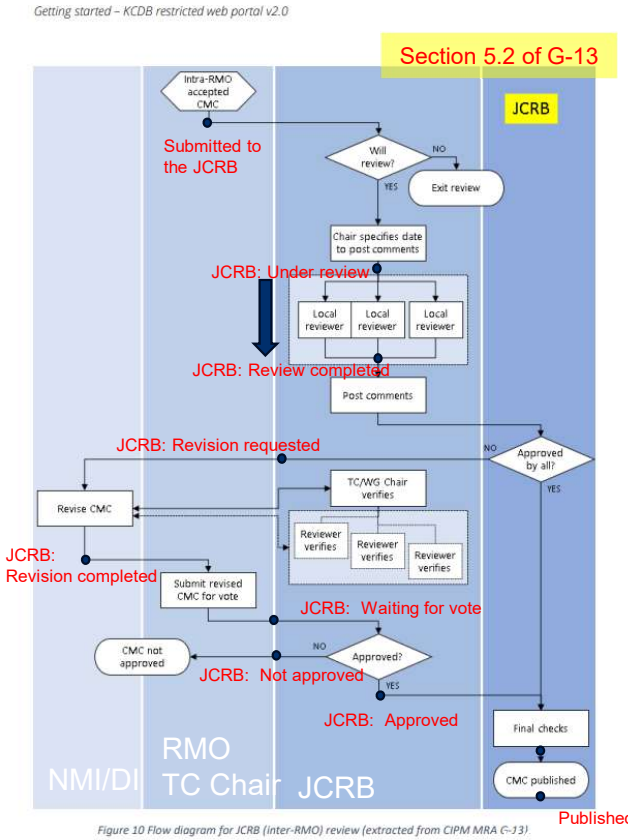


Figure 10 Flow diagram for JCRB (inter-RMO) review (extracted from CIPM MRA G-13)

Diagrams & explanations are also in “KCDB Getting Started” document available from Help on the KCDB - BIPM
Characters indicated in red add the status of the CMC.

Requirements on the G-12

Requirements on standards

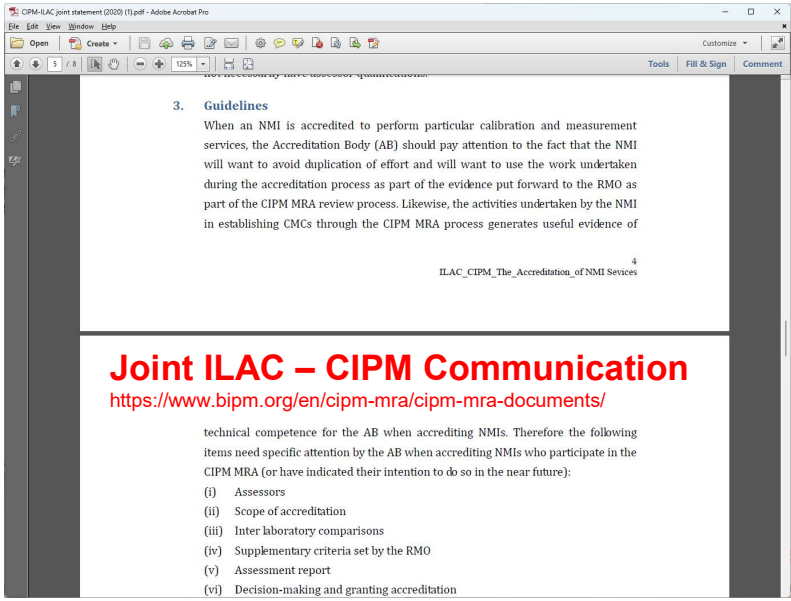
- **ISO/IEC 17025** for calibration and measurement services,
- **ISO 17034** for certified reference materials production.

QMS personnel will need to carefully understand the requirements upon planning peer reviews.

Requirements for establishing confidence

- **With** the support of an accreditation body
  - Operates under **ISO/IEC 17011** and covered by **ILAC MRA**
  - Further details in **Joint ILAC – CIPM Communication**
- **Without** third-party involvement

The **RMOs** have some leeway to optimize their approach to best suit their regional circumstances.



3. **Guidelines**

When an NMI is accredited to perform particular calibration and measurement services, the Accreditation Body (AB) should pay attention to the fact that the NMI will want to avoid duplication of effort and will want to use the work undertaken during the accreditation process as part of the evidence put forward to the RMO as part of the CIPM MRA review process. Likewise, the activities undertaken by the NMI in establishing CMCs through the CIPM MRA process generates useful evidence of

4
ILAC_CIPM_The_Accreditation_of NMI Sevices

Joint ILAC – CIPM Communication
https://www.bipm.org/en/cipm-mra/cipm-mra-documents/

technical competence for the AB when accrediting NMIs. Therefore the following items need specific attention by the AB when accrediting NMIs who participate in the CIPM MRA (or have indicated their intention to do so in the near future):

(i) Assessors
(ii) Scope of accreditation
(iii) Inter laboratory comparisons
(iv) Supplementary criteria set by the RMO
(v) Assessment report
(vi) Decision-making and granting accreditation

Guidelines on Review of QS under RMO's responsibility

Each RMO shall develop and maintain an open process for "Reviewing", "approval" and "monitoring"

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 G-12, 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.

Minimum features to be reviewed from the presentation by the authorized representative of the institute

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.

When onsite visits are used as a method, refer to Section 3.4 of G-12

Review

Guidelines on Acceptance of QS

under RMO's primary responsibility

Each RMO shall develop and maintain an open process for "Reviewing", "Approval" and "Monitoring"

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 of G-12 that support their corresponding CMCs.

Approval

Guidelines on Monitoring of QS under RMO's responsibility

Each RMO shall develop and maintain an open process for "Reviewing", "Approval" and "Monitoring"

QMS personnel will need to carefully understand the requirements set here.

- **Information stated on Annual reports will reach the JCRB through RMO QS reports**
- **QMS Conformation is one of the important reports from the RMO to the JCRB Meetings** (including written reports)

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.

This shall include:

Monitoring

- Review of **annual reports**
- **a periodic review** of the quality management system **at the same level as the initial review**, undertaken **at an interval not exceeding five years**.

Modification of published CMCs

G-13 Section 8

The need to modify a published CMC may arise for the following reasons:

Category of modification (CIPM MRA-G-13)	Intra-RMO review	JCRB review
8.1 material or editorial errors and improvements to the explanatory text for a quantity, instrument, method etc.	-	-
8.2 voluntary updating of a CMC by reducing its range and/or increasing its measurement uncertainty when an institute wants to reduce their engagement in a particular measurement activity	-	-
8.3 significant unresolved deviation from a comparison result with respect to a CMC	-	-
8.4 change of the method of measurement, reduction of the measurement uncertainty or increase in scope	+	+

Note: *Even if formal review is not required, the modifications need to be confirmed by the local RMO Technical committee / Working Group Chair.*

This does not change the essence of the CMC.

The revised CMC is less demanding, and the review is not required.

The revised CMC is less demanding, and the review is not required

The revised CMC is more demanding and requires review.

Sections 8.1 to 8.3 are the cases we don't need a JCRB review.
Section 8.4 are for CMCs that need JCRB review.

Practical cases from the QMS point of view

- Improvements
- Confirmation with a technical peer review
- Completion of a comparison
- Change in equipment/laboratory procedures
- Reinstatement from "Grey-out" etc.

Grey-out (= Temporarily withdrawing CMCs)

A published CMC that has been temporarily suspended is referred to as a **greyed-out CMC.**

Such CMCs are not visible in the KCDB but are retained behind.

- Usually arises because of non-compliance with the criteria for acceptance *(Section 3 of the CIPM MRA –G-13)*

  Unsatisfactory results in comparisons | Expiry of QMS confirmation | Others lacking compliance

- The maximum period for greyed-out status is five years
- An alert is raised at each JCRB meeting when CMCs are within six months of the five-year limit for greyed-out status
- After a maximum of 5 years the greyed-out CMCs must be **reinstated** or **deleted**

Practically, there are many cases when **the lack of QMS recognition by the RMO** leads to this status "**Grey-out**". Quality personnel needs to understand the rules here and support your technical colleagues.

Note: *Reinstatement or deletion can be requested at any time within the 5 years.*

Reinstatement of greyed-out CMCs

CMCs can be reinstated at any time during the 5 years, upon fulfilling the requirements.
Contact your TC Chair (and TC QS Chair) upon initiating the process.
(Operation on the KCDB basically similar with "modification" (Section 8 of G-13))

- Reinstatement of CMCs within the five-year period is made on case-based evaluations of evidence showing that the reasons behind the greying-out have been identified and solved.
- The institute holding the greyed-out CMC, after consulting with the relevant RMO TC/WG Chair (and when appropriate, the RMO TC/WG Chair QS), initiates a reinstatement of the CMC.

When a CMC has been greyed-out for 4 years, the NMI receives an automated alert and has one year to reinstate or permanently delete it.

Deletion of the CMC: The institute holding the greyed-out CMC can delete the CMC through the KCDB or requests the JCRB Executive Secretary to arrange the deletion. When the 5-years-limit has expired the CMC will be deleted.

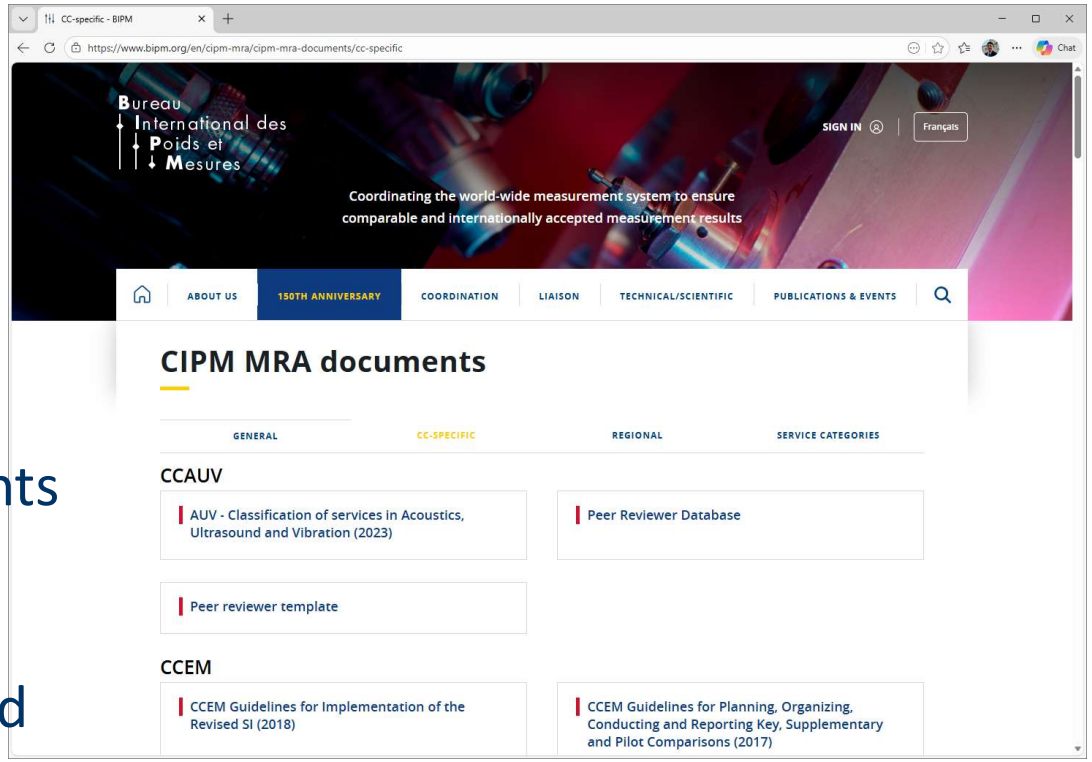
Tips on the technical review of CMCs

Key interest of the Reviewers

- Criteria of acceptance
- Guideline documents set by CCs

Writers can smartly think about…

- Consider what the Reviewer wants to confirm… exactly the items above
- Creating attached documents in line with the requirements would obviously help



QMS personnel may be able to help the Writer (scientist or engineer) to make the submission more effective on the review process.

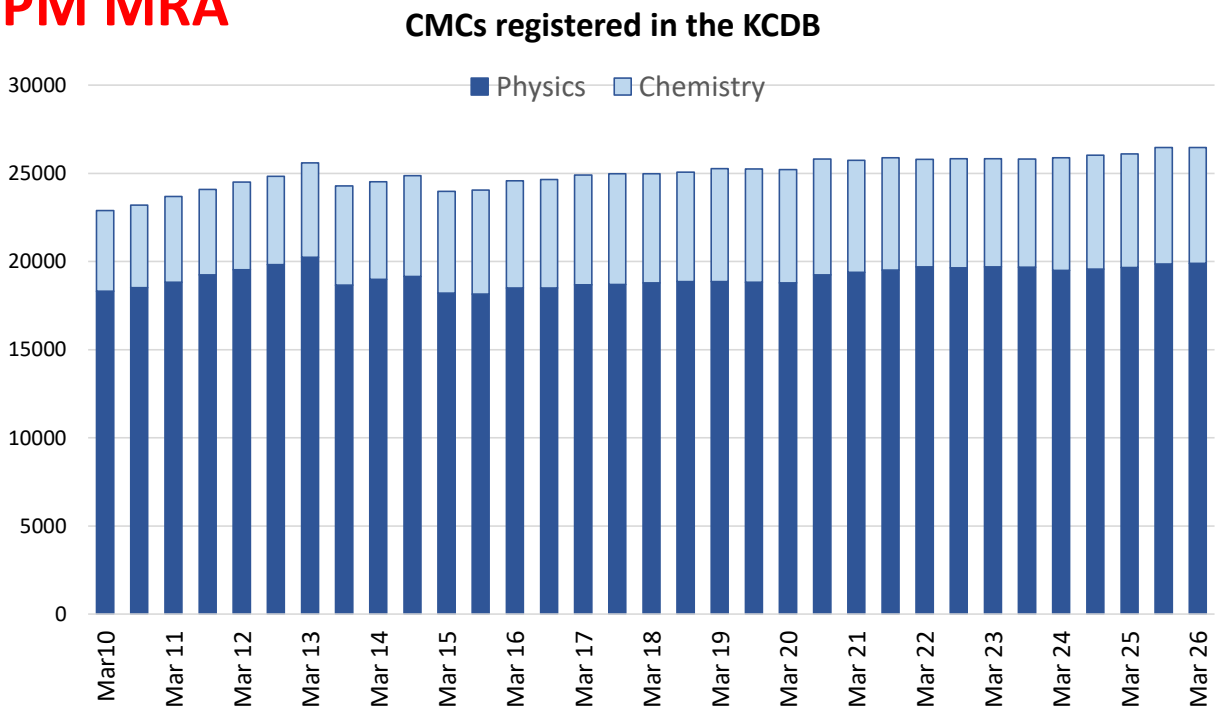
Running CIPM MRA may be costly… but is a strategic tool

Many CMCs to maintain, further external expectations to expand the scope…

Do we really want to have the CIPM MRA simply ending up being as an administrative scheme?

- Increasing CMCs, continuously maintaining them
- Many Comparisons to support the CMCs

How can you as the QMS personnel help?



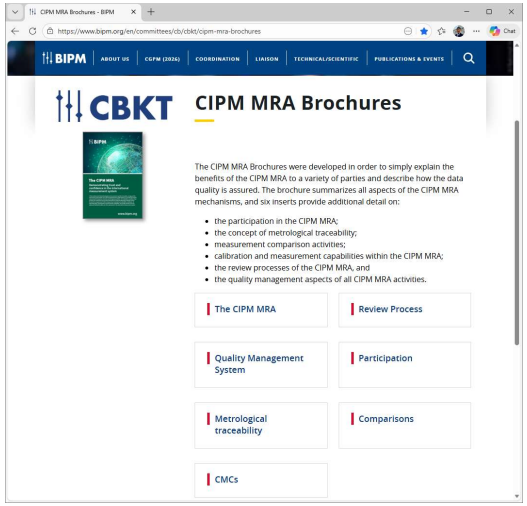
QMS personnel can be the key to strengthen the CIPM MRA on such circumstances

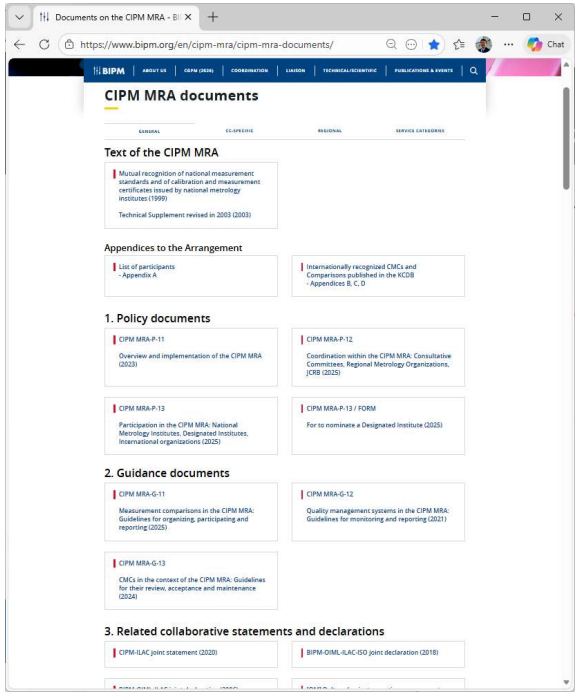
QMS personnel usually oversees various metrology areas/fields

- Opportunity to provide “lessons learnt from others”.
- Further drive initiatives to improve.

Resources available

- Information provided by RMOs
- CIPM MRA Logo
- KCDB “NMI Secretary” profile
- Digitalization (CMC PIDs, KCDB APIs)





Summary: CIPM MRA Requirements for QMS

QMS personnel can help with sufficient knowledge on the CIPM MRA

G-13

- Acceptance criteria
  - Technical evidence, Traceability, **Quality management System**
- Open peer review and approval process
  - **QMS confirmation** under G-12 is checked **in between RMO review and JCRB Review**
- CMC maintenance
  - Modification, Responsibilities, Grey-out

G-12

- **“Review”, “Approval”, “Monitoring” under the RMO’s responsibility**
  - NMI/DIs also need to be aware of the requirements and guidelines
  - Reports and presentations from the NMI/DIs are further reported to the JCRB through RMOs