KCWG 2021-01(Ver. 2)

Guidelines for the CCQM KCWG on the Review of CCQM CMCs for Inclusion in the Key Comparison Database

Glossary

CCQM	Consultative Committee for Metrology in Chemistry and Biology
CIPM MRA	Mutual Recognition Arrangement of the International Committee for Weights and Measure
CMC	Calibration and Measurement Capability
DI	Designated institute
NMI	National metrology institute
JCRB	Joint Committee of the BIPM and the RMOs: https://www.bipm.org/en/committees/jc/jcrb
KCDB	Key Comparison Database: https://www.bipm.org/kcdb/
KCWG	Working group on Key Comparisons and CMC Quality
RMO	Regional Metrology Organisation
TC	Technical Committee

1 Introduction

1.1 Terms of reference

The CCQM Key Comparison and CMC Quality Working Group (KCWG) is responsible for overseeing the review of chemical and biological CMCs within the CCQM. The terms of reference of the CCQM KCWG are described in the CIPM document "Calibration and Measurement Capabilities in the context of the MRA" [CIPM MRA-G-13].[1]

The working group is responsible for

- defining specific technical review criteria;
- coordinating the inter-regional CMC review process;
- seeking guidance from a specific CCQM Technical Working Group on the range of CMCs supported by specific comparisons and identifying where comparisons are needed in view of new CMCs being submitted in new measurement areas; and
- coordinating the review of existing CMCs in the context of new information and evidence becoming available.
- overseeing the review of the broad scope CMCs with a view of enhancing their effective presentation in the KCDB.

1.2 CIPM MRA Policy documents

The open access section of the CIPM MRA website (https://www.bipm.org/en/cipm-mra/cipm-mra-documents/) contains most of the relevant guidance documents for CMC submission and review. The "Policy documents" section contains files related to the MRA and the "Guidance on CMCs" section contains specific information for CMCs. The CIPM MRA document *CIPM MRA-P-11*[2] "Overview and implementation of the CIPM MRA" describes the relevant role of CMCs under the MRA. Section 8 of this document describes specific issues related to CMCs. The document *CIPM*

MRA-G-13[1] is a policy document that provides an overarching description of CMC preparation, criteria for CMC review, the intra-regional and inter-regional review processes and the publication and modification of CMCs. All CCQM KCWG members should be familiar with these documents.

1.3 Aim of this document

This CCQM KCWG Guidance document provides specific information for submission and review of chemistry and biology CMCs. Hereinafter, the KCWG refers to the CCQM KCWG.

2 Summary of the CMC Review Process

2.1 The general CIPM MRA process

The overarching document *CIPM MRA-G-13*[1] describes the general process for CMC submission and review across all the CIPM Consultative Committees. The guidance document "*Getting started on the KCDB web platform*"[3] describes how submissions and reviews are technically accomplished.

2.2 The CCQM CMC review process

The process followed by the CCQM is described in *CIPM MRA-G-13*[1] whereby the co-ordination of the review of CMCs is carried out by the CC Working Group on CMCs, i.e., the CCQM KCWG.

The KCWG coordinates the review of CMCs and liaises with each RMO and the technical working groups (as required) to resolve any issues during the annual review cycle. This is now carried out as follows:

- The CMCs that have been accepted after the intra-RMO review should be submitted by the RMO TC Chair for the JCRB review (inter-RMO review).
- The reviewing RMO TC Chairs (will be referred to as TC Chairs) will attribute CMCs to the appropriate members of the KCWG that are members of their RMO as well as other RMO reviewers with expertise in the specific field.
- The KCWG Chair (and Vice Chair) will have access to a dashboard in the KCDB web platform with an overview of the entire set of submitted CMCs for inter-RMO review. The KCWG Chair/Vice Chair have the rights, upon consultation of the RMO TC Chair, to decide which CMCs should be approved and which CMCs should be rejected.

3 Membership of the CCQM KCWG

3.1 Membership

The KCWG includes the following members:

- The Chair and a Vice-chair nominated by the President of the CCQM and approved by the CCQM.
- A representative from each of the CCQM technical working groups, also from new working groups as they are established, such as the bio and isotope ratio working groups (where CMCs are being submitted by NMIs or DIs participating in those working groups or in relating RMO Metrology in Chemistry Technical Committees - TCs). The role of the representatives from the technical working groups is firstly, to provide two-way communication between the KCWG and the technical working group in terms of strategy and process related to CMCs. Secondly, to assist the KCWG in the review of specialised CMC claims as well as broad scope CMC claims where the strategy from the technical WG needs to be interpreted in a specific way. The WG representatives need to create user accounts to be reviewers in the KCDB 2.0. Their user accounts will be approved by the TC Chair of the RMO that the WG representative is a member of.
- The chairs of the RMO Metrology in Chemistry Technical Committees (or their designated representatives), i.e. TC Chairs.
- Representatives nominated from each of the RMOs, preferably also being a member of a CCQM WG, to cover all relevant technical areas of the KCWG's activities
- The CCQM Executive Secretary and a BIPM representative
- A rapporteur who keeps minutes of the KCWG annual meeting

Note that it is most important that the membership of the KCWG covers the technical areas which are being discussed during the review process. It is also essential that all members actively contribute to the review process in order that all areas of expertise are covered.

Remark: A maximum of one chair and 4 members per RMO was agreed to participate in the physical meeting of the KCWG. TC chairs should confirm to the KCWG Chair, who their RMO representatives will be at the face-to-face KCWG meeting, and who will be the head of the delegation (HOD) if the TC Chair is unable to attend. A maximum of one observer per RMO can be allowed at the KCWG meeting if the RMO quota has not been used. Generally, observers will not contribute to the meeting.

3.2 Other KCWG meeting attendees

The KCWG meeting is also attended by the JCRB Executive Secretary. Other attendees from other NMIs/DIs must obtain the approval of the KCWG Chair to attend as observers, when appropriate.

4 Role of the RMOs

4.1 Responsibility of the RMOs

During the CMC review process the TC Chairs are responsible for:

- the coordination of the intra-regional review process including the assignment of reviewers;
- the submission of the CMCs accepted in the intra-regional review to the inter-regional review using the KCDB web platform;
- the management of the exchange of information between the NMIs/DIs and the KCWG during the inter-regional review process;
- the coordination of the inter-regional review process amongst both the KCWG members and other reviewers appointed by their specific RMO, with oversight of the KCWG Chair/Vice Chair through the dashboard.

4.2 Accounts

A user account is needed to access the KCDB web platform.

- The account for the TC Chairs is created by the KCDB Office.
- NMI/DI representatives should register for an account as writer and/or reviewer.
- KCWG members should register for user accounts as reviewers in their respective RMOs.

The TC Chairs approve the accounts of the writers, KCWG members and other reviewers within their RMO. Each TC Chair can only appoint reviewers from his/her own RMO for the intra- and inter-RMO review.

When updating the account that was created by the KCDB Office, the TC Chair should select all the categories of CMCs (including "not attributed") as well as all the areas of expertise to be able to see all the CMCs that will be submitted by their RMO.

More information on user accounts can be found in "Help on the KCDB"[4] and in "Getting started…"[3].

4.3 Communication of CMC issues via the KCDB web platform

The KCWG targets a consensus agreement on all submitted CMCs. During the CMC review, TC Chairs will exchange information and comments until all issues on submitted CMCs have been resolved. CMCs should not be submitted for final approval until all issues are resolved.

5 Submission of CMCs for intra RMO review

Web-based electronic forms are used for the drafting and submission of CMCs. The person(s) responsible for the submission of CMCs from an NMI/DI will register for a user account in the KCDB database (see above). The CMC must also be supported by the quality system (QS)

confirmation upon submission and the QS confirmation is declared in the KCDB 2.0 platform. – this is declared by filling a tick-box in the form. Categories for CMCs in chemistry and biology covered are listed in https://www.bipm.org/utils/common/pdf/KCDB_2.0/CMC_services/QM_categories.pdf

During the intra-RMO review the TC Chair will assign one or several reviewers to each CMC. There are no fixed timelines for the completion of the intra-RMO review, although the TC Chair may decide to indicate timeframes to the reviewers. The TC Chair may also decide not to assign a CMC to reviewers and review the CMC themselves. If the RMO does not have expertise to review the CMC, the TC Chair can consult reviewers or experts from other RMOs. Also see section 15 on the approach that will continue to be used for the review of CMCs in new measurement areas.

During the intra-RMO review process the CMC may be sent back to the writer for revision an unlimited number of times, before a final decision is made either to approve the CMC and submit it for inter-RMO review or to reject the CMC. (See **Appendix III** for the proposed timeline for CMC review according to a fixed schedule)

Technical information on how to use the web platform by writers, reviewers and TC Chairs is given in "Help on the KCDB" and in "Getting started…".[4&3]

6 Submission of CMCs for inter-RMO review

The CMCs that have been approved within the intra-RMO process should be submitted by the TC Chair for inter-RMO review. The time for submission and review is communicated by the KCWG Chair. For revised or updated CMCs, where the modifications do not require inter-regional review, the TC Chair may submit the CMCs directly to the KCDB Office for publication (see Section 13 for more details). When the TC chairs are in doubt about the need for inter-regional review, they should submit the concerned CMCs for a wider consultation via the inter-regional review.

During the inter-RMO review process, TC Chairs will attribute CMCs to the appropriate members, including but not limited to relevant WG representatives, of the KCWG i.e. the TC Chairs must assign CMCs in a special field of expertise to the relevant WG representative who are appointed by the concerned technical CCQM WG to the KCWG These KCWG members should review the CMCs before the KCWG annual meeting adjacent to the CCQM meeting. The recommendation is that at least three (3) RMOs (other than the RMO submitting the CMC) should review a CMC, if enough expertise is available in different RMOs, otherwise at least three (3) KCWG members should review a specific CMC. The TC Chairs may invite additional experts from their respective RMOs to review specific CMCs during the inter-RMO review process. Normally, CMCs that are directly approved by ALL the reviewing RMOs will not be subject to review by the KCWG. The KCWG Chair may intervene and ask for an additional review by the KCWG if doubts are raised and noted by the KCWG Chair/Vice Chair during inter-RMO review. CMCs that have attracted contradictory

and/or controversial comments should be kept for the KCWG face-to-face meeting where further discussions and a decision will be made, i.e., "Revision requested" should NOT be actioned by the TC Chair before the meeting.

During the inter-regional review stage, expert advice from the relevant CCQM Working Groups may be required. The KCWG Chair/Vice Chair, with the support of the respective WG representative, will continue to serve as a contact point of the KCWG for liaison with the CCQM technical WGs when experts' advice is required.

The KCWG Chair and Vice Chair will have oversight over the inter-RMO review and unresolved issues will be handled during the KCWG meetings during each review cycle. The KCWG Chair may review CMCs and decide whether CMCs should be published without revision or should be rejected. CMCs that have attracted comments should be launched as "Revision requested" by the appropriate TC Chairs at the KCWG face-to-face meeting.

The JCRB rules applied for deadline and voting during the inter-RMO review should be noted:

- After a CMC has been submitted for inter-RMO review, the TC Chairs from the other RMOs have 3 weeks to declare whether a CMC will be reviewed.

- Review date limits set by the TC Chairs for the inter-regional review are firm.

- An RMO must have reviewed a CMC to be entitled to vote for the CMC. Only CMC having attracted a request for revision are subject for vote.

During the inter-RMO review process, a CMC may only be sent back to the writer for revision once. If more iterations are required to finalise the CMC, it will have to be done off-line using e-mail, etc. When the CMC has been revised it is submitted for vote.

To adapt the platform for the CCQM needs, the KCWG will communicate and oversee the submissions for inter-RMO review. See **Appendix I** and **II** for more details on the workflows of the CMC review process and **Appendix III** for the proposed timeline for CMC review according to a fixed schedule.

7 Assessment Guidelines for Chemistry and Biology CMCs

7.1 CIPM assessment guidelines

CIPM-MRA-G-12[5] "JCRB guidelines for the monitoring and reporting of the operation of quality systems by RMO" describes the review process. *CIPM-MRA-G-13*[1] contains the "Criteria for acceptance of CMCs" in Section 3 and outlines for all CMCs in the KCDB the general criteria used to assess CMCs. These criteria are:

1) Results of key and supplementary comparisons
2) Documented results of past CC, RMO or other comparisons (including bilateral)

3) Knowledge of technical activities by other NMIs, including publications
4) On-site peer assessment reports
5) Active participation in RMO projects
6) Other available knowledge and experience

7.2 Underpinning by key comparisons

In general KCs are used to demonstrate the capabilities and competencies, expressed in the form of CMCs, claimed by the NMIs and DIs participating in the CIPM MRA. NMIs/DIs claiming CMCs that are underpinned by the results of defined KCs must participate in these KCs. **Where an NMI/DI offers a service in a particular measurement area and wishes to have a specific CMC claim for that service and a CCQM key comparison occurs for this measurement area, then the NMI/DI has to participate in the comparison unless it has participated in a similar key comparison within the last 5 years. If a key comparison occurs and a parallel pilot study is also co-ordinated at the same time an NMI/DI with CMCs in this area, or an NMI/DI wishing to submit CMCs in this area, must participate in the key comparison, not the pilot study. If an NMI/DI submits CMCs for a measurement service for which direct support or broad scope support from a key comparison is available and they did not participate in pertinent key comparison(s), at a frequency as specified by the respective CCQM WG, the CMC claims will not be approved.**

7.3 Underpinning by evidence from pilot studies

In the chemistry and biology area we have a large number of pilot studies, and these may be used as supporting evidence for CMCs, although key and supplementary comparisons will always be considered to provide a higher level of evidence. **Pilot study results can only be used to support CMCs where no appropriate KC/SC has been carried out.** Where pilot studies are used as evidence the results must demonstrate capability in a transparent way, a full report must be available with laboratories clearly identified. Reference values for the samples involved in such pilot studies must be assigned and approved by the WG, otherwise it is difficult for the KCWG to assess performance with respect to the best estimate of the true value for the samples involved. Official regional pilot studies may be used in a similar way if such transparency issues are considered. Regional pilot studies must be approved by the CCQM for use in supporting CMCs. In this case, pilot study reports will be made available for CMC review in the restricted access areas of the relevant technical working group and will be referenced with a link in the list of comparison approved for CMC review.

This section provides guidance on the use of pilot studies as evidence but whether a pilot study can be counted towards the minimum evidence for a broad scope CMC, institutes have to refer to the guidance from the individual WGs (Section 16) and that the concerned pilot study has been approved to underpin CMCs (Section 7.4).

7.4 List of CCQM and RMO comparisons ready to underpin CMCs

In submitting CMCs linked to key comparisons, supplementary comparisons, bilateral comparisons, or pilot studies, the KCWG maintains a list of all comparison reports which are deemed ready for use in supporting CMCs. This list was developed because the timeframe to reach the stage where a final report is published on the KCDB can be very long. To avoid a long delay, key comparison reports may be deemed ready for use by the KCWG in assessing CMCs if they are at the draft B report stage with the KCRV and its uncertainty approved by the working. The Draft B report that is deemed ready and approved for CMC review, shall be made open access on the WG website, so that it is available to all the KCWG members and other reviewers of CMCs. On publishing the Final report of the comparison, the Draft B report will be removed from open access. When the list of comparisons approved for CMC review is updated by the WG Chairs, link(s) to the approved reports are usually added to the spread sheet for easy access for the KCWG members.

Each key comparison contains a statement on the measurement capabilities that can be supported by the comparison, referred to as the 'How far the light shines' (HFTLS) statement.

Additional guidance, developed by individual CCQM WGs, describing how key comparisons can be used to underpin CMCs within the technical scope covered by different working groups can be found at the websites of different working groups.[6-10]

The CCQM technical working group chairs are responsible for updating the KCWG comparison list. The CCQM WG chairs normally submit their updates twice yearly (in June and December) to the KCWG Chair for consolidation. This list is posted on the KCWG website and must also contain a link to where the report is located on the CCQM website if the final report has not been published in the KCDB yet. **RMOs should not submit CMCs for inter-regional review which are underpinned by comparison reports which are not yet approved for use by the concerned CCQM WG.** If such CMCs are submitted, they will be postponed until the following cycle or until the comparison results have been approved for CMC review by the WG, unless significant additional underpinning evidence is available.

7.5 CMCs linked to comparisons which are about to commence

CMCs should not be submitted where a key comparison is about to commence in that measurement area and NMIs/DIs should wait for the results of the comparison. Obviously, the time that NMIs/DIs should have to wait for this should be reasonable and if a key comparison is simply planned at some undefined date in the future, then CMC submission using other supporting evidence may be possible.

7.6 Evidence from peer reviews and assessments

On-site peer reviews can provide useful additional supporting information. The on-site peer review should be performed according to document *CIPM MRA-G-12*[5]. On-site reviews performed as part of the accreditation assessment, can be used as support for CMCs when they fulfil the conditions of *CIPM MRA-G-12*[5]. NMIs/DIs must be prepared to release the names of

the on-site peer reviewers/assessors and the content of the peer-review reports to the KCWG members and to allow the KCWG to contact these peer reviewers/assessors if necessary.

7.7 Evidence from publications

Other evidence such as publications may be used but as the referee process for such things is not transparent and may not be carried out with the vigour commonly required by the CCQM, then it must be accepted that these provide evidence which would be considered lower in the hierarchy of supporting evidence. Publications should cover all the relevant metrological aspects needed to provide evidence to support claims appropriately. Guidance may be obtained from documents such as ISO 15193 which outlines the requirements of reference measurement procedures in the laboratory medicine field.

8 Links to Key Comparison Results

8.1 CMCs directly underpinned by key comparisons

CMCs are assessed with respect to results obtained in key comparisons by reviewing the claimed measurement capability range and uncertainties in comparison with the x_i and $U(x_i)$ of the NMI/DI's result and the x_{ref} and $U(x_{ref})$ of the key comparison. In general, a result from a particular NMI/DI would be consistent with the KCRV if the 95% confidence interval for the degrees of equivalence for the NMI/DI contained zero. All key comparison reports will contain the Degrees of Equivalence (DoE) graphs, expressed at the 95% confidence level, to allow this assessment to be easily made. **If this criterion is met, then where there is a one-to-one correspondence between the measurand of the key comparison and a CMC the minimum acceptable uncertainty for a CMC would be $U(x_i)$. However, the magnitude of the uncertainty, $U(x_i)$ of the NMI/DI's result, compared with the magnitude of $U(x_{ref})$ must also be considered. Where $U(x_i)$ is significantly smaller than $U(x_{ref})$ then the reliability of the uncertainty estimate of the NMI/DI may require further evidence.**

Where the DoE criterion is not met (i.e. its 95% confidence interval does not cross zero) this would indicate that a particular result was not consistent with the KCRV. In such a case $U(x_i)$ may have been underestimated or there may have been an unidentified source of bias. A CMC claim of an NMI/DI may be supported by a key comparison despite the inconsistency. In this case, the claimed expanded uncertainty may not be smaller than the minimum expanded uncertainty that would provide a consistent result for the submitting NMI/DI in the supporting key comparison. Ideally, the key comparison report should indicate the minimum uncertainty to simplify the review. The concerned NMI/DI must nevertheless review its uncertainty budget adequately. If at that stage it wishes to claim a lower uncertainty than is demonstrated in the key comparison, then further evidence, such as a bilateral comparison, would be required.

8.2 CMC concentration ranges

Obviously, CMCs can often cover a range of concentrations, while key comparisons typically cover a limited number of concentration points. Therefore, the appropriateness of the uncertainties over the whole measurement range must be considered, ideally based on the "How far the light shines" declaration of the key comparison. The assessment of the appropriateness of the adjustment of claimed uncertainty over concentration range for a CMC will need to be made by technical experts. Several of the technical working groups have specific guidance for extrapolation of concentration ranges. For instance, a separate report is prepared for all key gas comparisons to include a table detailing the minimum CMCs each participant can claim, based on their performance in the comparison that is aligned with the extrapolation scheme in the document CCQM-GAWG/19-41.[6]

9 Types of Dissemination Services

Where NMIs/DIs disseminate their measurement capabilities via services described as "value assignment of CRMs", "calibration services", "value assignment for proficiency testing scheme samples", etc the NMI/DI will be expected to provide details of the exact nature of this service including a unique service identifier. These services generally relate to some form of reference measurement provision and details should be given in the "exact nature of service delivered" field of the CMC form. The KCWG will expect the NMI/DI to outline the exact nature of the service, for example, is it reference measurement provision for samples from clients or for samples for PT schemes and to provide information such as:

- are samples unknowns which are submitted by clients?
- are samples prepared by an external group, but the NMI/DI knows the expected composition of such samples?
- are the samples prepared in-house or of known origin?

For the "mechanism of service delivery field" ideally, the nature of the service should be clearly identified, however if an NMI/DI has a service offered to clients that they typically describe in a particular way then they may describe it in that way in this field and provide further information in the "exact nature of service delivered"-field. Ideally this field will have an entry such as "reference value provision for samples of known composition submitted by external clients" that clearly indicates the purpose of the service and the level of information that the NMI/DI has about the samples.

10 Metrological traceability

10.1 Metrological traceability requirements for CMCs

NMIs and DIs with calibration and measurement capabilities in the KCDB must meet the traceability requirements of the *CIPM MRA-G-13*[1]. This outlines two options for achieving traceability (via an in-house primary realisation or via services from another NMI/DI with CMCs or from BIPM). Traceability in the CMC form needs to be identified to a particular

NMI/DI. This implies that the traceability of the results from disseminated services will typically be expected to be to the SI (or another relevant international standard) through the NMI/DI listed in this field of the form. This must of course be justified and there may be cases, for instance where limited sample preparation is involved, where traceability will be to the source of the calibration standards which are used.

Traceability can only be obtained from another NMI/DI that is recognized for that capability under the CIPM MRA. See document *CIPM MRA-G-12*[5], Appendix I. In the relevant field of the CMC form it should be stated that traceability is obtained from NMIX. It is implied in *CIPM MRA-G-12*[5] that if NMIX is to be listed they should have an existing CMC for this service. Due to the very large number of analytes covered by the CCQM there may not be a CMC that covers the specific analyte. In this case NMIX would need to have demonstrated its capabilities in the appropriate CCQM key comparisons.

CCQM has accepted that some NMIs maintain purity or calibration solution measurement capabilities to meet their metrological traceability requirements, but do not offer these capabilities for external services and so do not maintain CMCs for these capabilities. An institute could make claims for matrix materials and have the source of traceability to itself, if the purity or calibration solution capabilities can be shown to meet the 'Criteria for acceptance of CMCs' (see section 7.1), normally this would be expected to be by successful participation in purity or calibration solution comparisons, where applicable. This would be considered to meet the CIPM traceability requirements. The requirement to state the traceability to another NMI/DI refers only to the measurement quantity of the respective CMC. It does not refer to auxiliary quantities of another kind that are a part of the measurement.

Traceability considerations for broad scope CMCs might be more complex and must be carefully considered. For example, a claim for the capability to measure all polar organics in a food requires the submitting institute to have the underlying demonstrated capability to have a calibrant for any polar organic. Several working groups have developed criteria to address this and have outlined the need for participation in comparisons to support the capability to value assign calibration materials in addition to the actual matrix material.[6-10]

One traceability exception has been accepted by the CIPM referring to https://www.bipm.org/utils/common/documents/CIPM-MRA/Traceability-Exception-QM1.pdf. NMIs making CMCs for this type of measurand should refer to the traceability exception document.

10.2 Calibration materials

In all cases where a calibration standard is inherent in the process, NMIs/DIs are expected to state in the "details of calibrants used..." field of the CMC form the nature of the calibrant and how its purity or concentration has been confirmed. For a calibrant that is a CRM from an NMI/DI that meets the criteria specified in 10.1, simply the details of the CRM need to be provided. Where calibrants are from another source, for example, for an analysis of pesticides

in food, an NMI/DI would need to say how the purity value of the pure pesticide used as the calibrant was determined. This could simply involve a statement such as “pure calibrant from commercial source and in-house purity assessment by techniques #### was carried out”. This information is requested because of the importance of calibration standards in ensuring the traceability of results. Any NMI/DI carrying out such in-house assessment is expected to have participated in the relevant CCQM key comparisons for purity assessment, where applicable, and would be expected to have the capability reviewed during relevant assessments or peer reviews.

11 The Inclusion of Certified Reference Materials in CMCs

The *CIPM MRA-G-12*[5] document outlines the criteria which CRMs must meet to be included in the KCDB. Where CRMs are listed under the mechanism of measurement service delivery they should ideally be uniquely identified, where possible (this is usually not possible for primary reference gas mixtures, which are prepared individually per customer request and not in batches) and not just listed as “CRM”. The measurement capability which is listed in the CMC should be the main method used in the certification of the material otherwise there is limited linkage between the capability and the CRM.

The measurement uncertainty of the stated certified value of the CRM would be expected to typically be larger than the measurement uncertainty of the measurement capability. In some cases, this uncertainty may be lower than the measurement capability as considerable time may go into the analysis of a single CRM spanning many months of work. If lower uncertainties are claimed then the evidence for this must be provided, for example by making available the report of an on-site peer review confirming that the lower uncertainty claim is justified. It should also be recognised that some CRMs are produced in large batches, and some are produced on an as required basis and this will potentially alter the achievable uncertainty. The CCQM Gas Analysis Working Group has specific criteria for the assessment of CMCs for CRMs which must be adhered to during CMC review.

12 Subcontracting

The CIPM document *CIPM MRA-P-13*[11] “Subcontracting of measurements under the CIPM MRA” covers the criteria which must be fulfilled by NMIs/DIs who may be subcontracting aspects of their work.

13 Modifications to Existing CMCs

Modifications must be carried out strictly in accordance with Section 10 of *CIPM MRA-G-13*[1]. The CMCs may be updated via the KCDB web platform with the modification indicated in the comment facility included in the CMC form. The updated CMC will be subject to

review based on the extent of the change as per the criteria stated in *CIPM MRA-G-12*[5] and will be subject to intra-RMO review and inter-RMO review as required.

14 Reviewing CMCs considering New Evidence

Section 9 "Measurement comparisons in the CIPM MRA" of the document *CIPM MRA-G-11*[12] outlines the general JCRB guidelines for the review of CMCs considering new evidence becoming available. Each NMI is responsible for acting whenever there is new evidence that impacts their CMCs and must review the reasons for this. Some WGs have developed criteria outlining their expectations, particularly in relation to broad scope CMCs.

The KCWG has accepted the job of co-ordinating this review of existing CMCs. Ideally this review will be carried out by measurement category to ensure that all claims in each measurement area can be reviewed for consistency as well as current underpinning evidence. The KCWG will maintain a plan for the review of existing CMCs to ensure that ultimately each CMC is re-reviewed periodically, say every ten years. The RMOs will be responsible for the initial review of existing CMCs, ideally following the plan developed by the KCWG. Following the RMO review they will submit a report to the KCWG and the KCWG will determine what level of scrutiny is required by the KCWG members.

15 CMCs in new measurement areas

There will inevitably be new measurement areas which are not fully covered by the existing CMC categories. In such cases the relevant CCQM Working Group Chair liaises with the KCWG Chair to propose new categories for inclusion. The review of CMCs in new measurement areas may require the registration of additional experts as reviewers by the RMO TC Chairs. For instance, previously claims in the bioanalysis field were reviewed separately by the CCQM Bioanalysis Review Team and this team provided feedback to the KCWG. In the KCDB web platform the members of a specialised review team can now be registered with user accounts and approved by the respective RMO TC Chairs.

It is envisaged that the practice to review CMCs in new measurement areas by experts appointed by the relevant technical working group before they are submitted by the NMIs/DIs for intra-RMO and inter-RMO review will continue as is currently the case for the technical working groups in the biology area. However, to integrate with the general CMC review process, the KCWG encourages new working groups to appoint WG representatives to become members of the KCWG as soon as possible.

16 Broad scope CMCs

Several technical WGs are developing strategies for broad scope CMCs, i.e. where a single CMC claim could potentially cover a range of analytes in a range of matrices over a large concentration range within a specified uncertainty range. The WGs provide technical experts to the KCWG to assist with the review of these broad scope CMCs and also share the strategy

and guidance documents on broad scope CMCs from their respective WGs through open access documents,[6-10] updates and presentations, at least, during the annual face-to-face KCWG meeting.

Technical WGs are encouraged to develop HFTLS-statements for broad scope CMCs as part of the planning stage of CCQM key and supplementary comparisons. The comparison protocol should attempt to define the scope for broad scope CMCs by describing how the analytes measured in the comparison can be expanded to cover a range of analytes and different matrices and should discuss how the concentration ranges and reported uncertainties could be extrapolated.

Technical WGs are also encouraged to include in their specific guidance for broad scope CMCs how CRMs will be included in the broad scope CMC claims and who the uncertainty of measurement should be reported for broad scope CMCs.

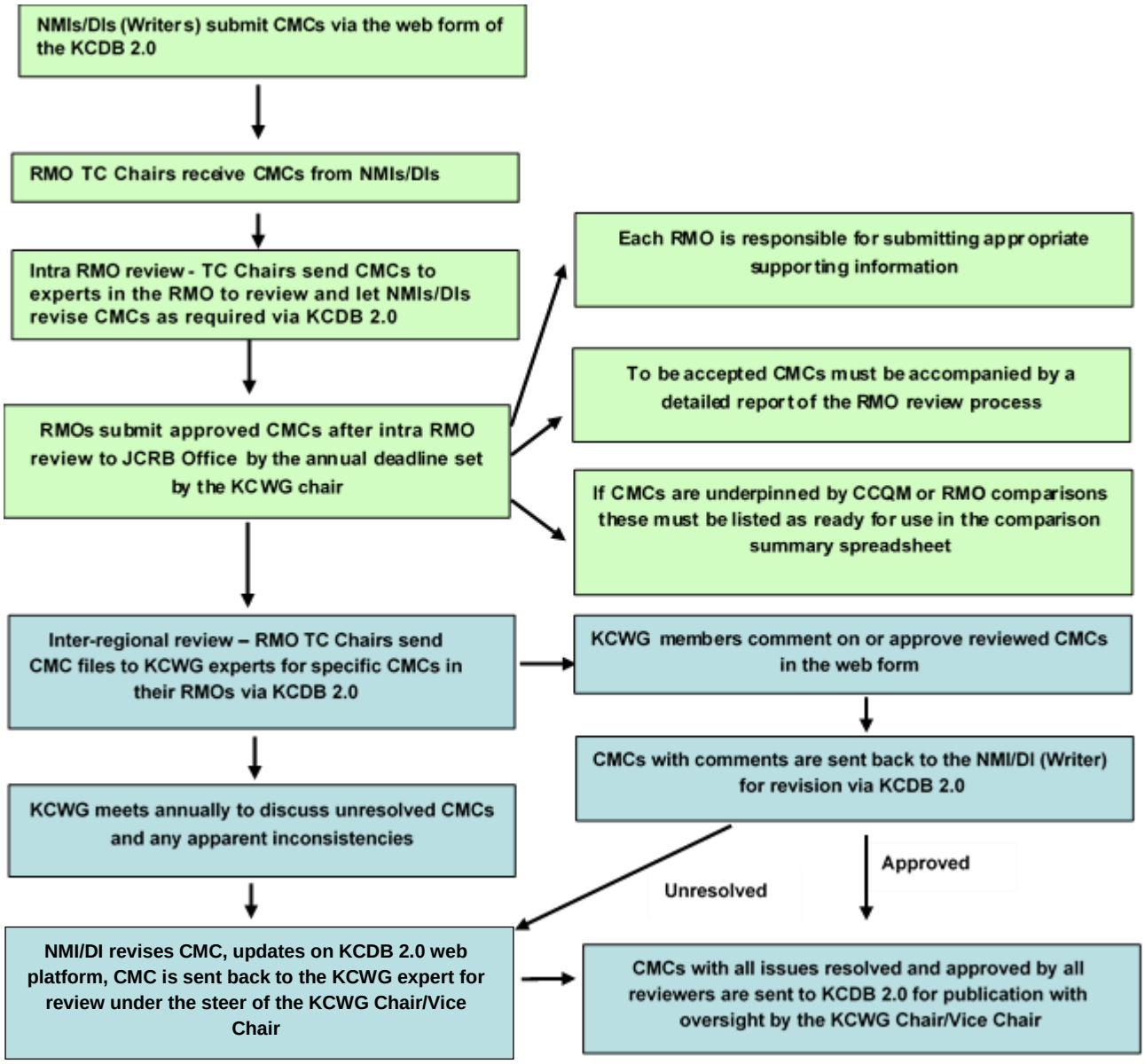
The specific technical WG guidance on the evidence required for the support of broad scope CMCs should be very clear and needs to be harmonised further between the WGs, e.g., the use of pilot studies for support, and other issues.

17. References

When this document was finalized, the revised versions of the policy and guidance documents on the CIPM MRA had not yet been published. We therefore give the references to both the original and revised versions.

1. CIPM MRA-G-13 CMCs in the context of the CIPM MRA: Guidelines for their review, acceptance, and maintenance (covers notably a revised version of CIPM MRA-D-04)
2. CIPM MRA-P-11 Overview and Implementation of the CIPM MRA (covers notably a revised version of CIPM MRA-G-01 and other policy documents)
3. "Getting started on the KCDB web platform"
4 "Help on the KCDB"
5. CIPM MRA-G-12 Quality management systems in the CIPM MRA: Guidelines for monitoring and reporting
6. CCQM-GAWG/19-41 CCQM-GAWG strategy for comparisons and CMC claims
7. GAWG CMC Guidance documents
   CCQM-GAWG/CMC-01 CCQM-K112 CMC Guidance document
   CCQM-GAWG/CMC-02 CCQM-K137 CMC Guidance document
8. CCQM-IAWG/GD-01 The Core Capability approach in support of CMCs for Inorganic Analysis: guidelines for the use of the revised approach
   CCQM-IAWG/GD-02 Core Capability Table
   CCQM-IAWG/GD-03 Record of Participation
9. CCQM-EAWG/GD-01 EAWG guideline for claims of Calibration and Measurement Capabilities
10. CCQM-OAWG/076 Criteria for broad scope claims with the OAWG
11. CIPM MRA-P-13 Participation in the CIPM MRA: NMIs, DIs, IGOs (covers notably a revised version of CIPM/2005-09)
12. CIPM MRA-G-11 Measurement comparisons in the CIPM MRA: Guidelines for organizing, participating and reporting

Appendix I: Overview of CMC review process



Appendix II – **Summary of the CMC Submission and Review Process**

A) Prior to the submission of CMCs, the KCWG Chair posts on the KCWG website an updated comparison list received from each of the WG Chairs so that RMO TC Chairs can ensure that CMCs which are submitted are covered by comparisons which are deemed ready to underpin CMC claims. This will typically happen twice a year after the meetings of the technical WGs in April and October.

B) The intra-RMO review does not have a fixed timeframe. When NMIs/DIs submit their CMCs to the TC Chair, the TC Chair appoints reviewers from the RMO and when the review of the CMCs is completed the TC Chair submits the CMCs for inter-regional review.

C) During the inter-RMO review, the TC Chairs registers to review CMCs from other RMOs and appoints KCWG experts in the respective fields of the CMCs from their RMOs to do the inter-regional review. The KCWG Chair and Vice-Chair oversee the inter-RMO review process.

D) CMCs approved during the inter-RMO review will be made available to the KCDB Office for publication directly.

E) The remaining CMCs and the issues related to these files are discussed with the relevant CCQM Working Groups, with experts in the relevant measurement areas and with the NMI/DI involved (via their RMO) with the aim of revising CMCs to meet the concerns raised during the review process.

F) At the KCWG meeting in April under the steer of the KCWG Chair/Vice Chair attempts are made to finalise and resolve outstanding issues related to submitted CMCs so that they can be completed for publication.

G) As soon as new evidence for the support of CMC claims becomes available (typically an update of the comparison lists is published on the KCWG website) the CMC review process can start again.

Appendix III – Example of annual CMC review timetable

Action	**Deadline**
WG chairs approve comparison reports for use in Cycle XXIII	**1 Dec 2021**
RMOs perform intra-RMO review up to	**11 Feb 2022**
RMO TC Chairs raise hand to review submitted CMCs by	**4 Mar 2022**
KCWG meetings	**April 2022 –**
CMCs published as soon as approved by all RMOs (and checked to have no outstanding review comments)	
CMCs continued to be finalised and approved by all RMOs (and checked to have no outstanding review comments) until	**31 Oct 2022**
WG chairs approve comparison reports for use in the next review cycle	**1 Dec 2022**