

	<b>Annex 3 to the COOMET Recommendation</b> <b>COOMET R/AQ/13:2019 "Rules and Procedure for the evaluation of the quality management systems of National metrology institutes/Designated institutes"</b>	
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## RECOMMENDATIONS FOR ON-SITE VISITS BY PEERS AND SELECTION CRITERIA FOR ON-SITE VISIT PEER REVIEWERS

### 1 Introduction

A Mutual Recognition Arrangement ([CIPM MRA](#)) was drawn up by the International Committee of Weights and Measures ([CIPM](#)), under the authority given to it in the [Metre Convention](#), for signature by directors of the National metrology institutes (NMIs) of [Member States of the Convention and Associates of the CGPM](#). Its objectives are:

- to establish the degree of equivalence of national measurement standards maintained by participating metrology institutes;
- to provide for the mutual recognition of calibration and measurement certificates issued by participating metrology institutes;
- thereby to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs.

These objectives are to be accomplished by the execution/implementation of:

- international comparisons of measurements (*i.e.*, key comparisons);
- supplementary international comparisons of measurements;
- quality systems and demonstrations of competence by the participating metrology institutes.

The CIPM MRA requires that participating metrology institutes operate quality systems (QS) that comply with [JCRB guidelines](#)<sup>1</sup> and have been reviewed and accepted by the local regional metrology organization (RMO). Similarly, their calibration and measurement capabilities (CMCs) have to be submitted for review to the local RMO (intra-RMO review), which afterwards forwards them to the JCRB for [inter-RMO review](#)<sup>2</sup>. It is worth noting that in all cases, the intra-RMO review of the CMCs and the review of the QS supporting them need to be conducted within the same RMO.

The review process for the QS and CMCs may require on-site reviews by peers selected by the local RMO. While the recommendations for such reviews are listed in the above-referenced JCRB documents, the recommendations for on-site visits by peers and the selection criteria of visiting reviewers can be found hereafter. Recommendations are also provided for those inter-RMO CMC review processes that require on-site visits by peers.

<sup>1</sup> See *JCRB Guidelines for the monitoring and reporting of the operation of Quality Systems by RMOs*, [JCRB-10/8\(1c\)](#).

<sup>2</sup> See *Criteria for acceptance of data for Appendix C*, [JCRB-14/06\(2a\)](#).

## 2 Recommendations for on-site visits by peers

### 2.1 Quality management system review

The rules of the CIPM MRA obligated each RMO to review the QS of its member metrology institutes. For compliance with this requirement all RMOs have established committees which have developed equivalent approval procedures.

Some RMOs make use of the option<sup>3</sup> outlined in section 2.1 of the document *Revised JCRB Guidelines for the monitoring and reporting of the operation of Quality Systems by RMOs*:

“If considered necessary, the RMO may request that review visits by ‘peers’ be undertaken, in order that the metrology institute may demonstrate confidence and capability in their claimed CMCs. The metrology institute itself may request the review visits by peers. Where such visits take place, the RMO must ensure that the ‘peers’ have the necessary experience and are suitably qualified and independent.”

Other RMOs use on-site visits by peers only in those cases where the regular procedures instituted by their committees cannot establish sufficient confidence to confirm the QS under review. Under this option, the metrology institute itself may also ask for a visit by other peers from another metrology institute in order to establish the required confidence in their QS.

In all cases, it is recommended that the visiting peers meet the criteria outlined in Section 3 below.

### 2.2 CMC review

#### 2.2.1 Intra-RMO CMC review

Within the scope of the CIPM MRA, the RMO technical committees (TCs) are responsible for CMC review on the basis of the criteria outlined in document *Criteria for acceptance of data for Appendix C*<sup>3</sup>.

If the information is considered insufficient to judge the competence and capability of the submitting metrology institute, the TC may request an on-site visit by peers before deciding on acceptance of the respective claims. In addition, a TC may request an on-site visit by peers if sufficient doubt is cast on CMCs already published in the KCDB. Further, a metrology institute may ask for an on-site visit by peers in order to establish the required confidence in their CMCs.

In all cases, the TC shall rely upon a visiting peer or team of visiting peers to obtain the information required. If the TC finds it necessary to name more than one peer reviewer, it should name a team leader who will be responsible for the administration of the visit.

Peers selected by a TC for an on-site visit should meet the criteria given in Section 3 below.

#### 2.2.2 Inter-RMO CMC review

On-site visits by peers are also foreseen by the CIPM MRA as a tool for aiding during the inter-RMO review process.

During the inter-RMO CMC review, it is expected that the RMOs reach consensus on an evaluation that is satisfactory to all reviewers. In the extraordinary case that agreement cannot be reached among the experts from the various RMOs, the involvement of the CIPM Consultative Committee (CC) with jurisdiction in that area of metrology is recommended using the following procedure:

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<sup>3</sup> On-site visits can be used for example, where an RMO requires third-party accreditation to ISO/IEC 17025 using other metrology institute peers as technical assessors.

In the case that an inter-RMO CMC review process cannot yield consensus, the Chair of the [CC WG on CMCs](#)<sup>4</sup> should report the impasse to the JCRB and bring the subject to the

attention of the relevant CC of the CIPM and ask for evaluation and decision. The CC shall discuss the matter in the appropriate working groups, where the members with the highest technical competence in the field under review can be found.

If the dispute cannot be assessed by evidence provided via correspondence, it is the right of the CC to name a peer or a team of peers and request an on-site visit aimed at obtaining findings that might shed light on the dispute. It is advisable that the peer(s) selected fulfill the criteria outlined in Section 3 below.

### **2.3 Notification procedures and settlement of disputes**

It is expected that the Committee requesting a visit by peers and the metrology institute submitting its QS or CMCs for review will cooperate in the most effective way to minimize the efforts of both the participating peers and the participating parties. In the case of differing opinions about the scope and time of the visit, the following recommendations are provided:

The Chairperson of the involved committee informs the Director of the metrology institute and the Chairperson of the RMO of the decision that an on-site visit by peer(s) of the committee is required, for further processing of the submitted QS or CMC claims. The names of the selected peer(s) and the list of the open questions should be included in the communication.

The metrology institute will inform the Committee Chairperson and the RMO Chairperson if the metrology institute is willing to accept the visit. If the metrology institute refuses the visit it has to provide the reasons for the refusal to the Committee Chairperson and the RMO Chairperson. In this case the RMO Chairperson will try to arbitrate an on-site visit agreement. Until this agreement is achieved, the review is on hold. If the visit is requested for the confirmation of CMC already in the KCDB the CMC have to be withdrawn when no agreement on an on-site visit has been achieved within one year.

If the metrology institute accepts the visit but rejects the suggested peer or peers, the Chairperson of the Committee and the Director of the metrology institute will try to negotiate. The review will remain on hold until agreement can be reached.

It is the responsibility of the visited metrology institute to cover the travel and subsistence costs of the peer(s), unless otherwise agreed by the participants.

No later than 90 days after the visit, the peer(s) will provide a written report on their findings including the responses to the list of open questions. The report shall be submitted to the Committee Chairperson with copies to the RMO Chairperson and the Director of the visited metrology institute.

The committee will then decide – with the help of the report – on the validity of the QS or CMC claims of the metrology institute.

## **3 Criteria for the selection of visiting reviewers**

### **3.1 General characteristics**

The selection of peer reviewers should be guided by the principles provided in [ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing](#). In addition the following should be considered.

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<sup>4</sup> See *Consultative Committee Working Groups on CMCs*, [JCRB-11/6\(2\)](#).

### 3.2 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 in the selected reviewers:

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

### 3.3 Work experience

A peer reviewer should have:

- (a) generally five year experience in developing, providing or being responsible for a calibration or a measurement service in a technical field relevant to the CMCs being investigated;
- (b) two year experience of quality management, quality assurance or QS auditing related to laboratory activities at the metrology institute level;
- (c) in the absence of QS experience the peer reviewer should, during the assessment, work with a QS 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.

### 3.4 Training

At least one member of the peer review team should have successfully completed a training course on the [ISO/IEC 17025:2005](#) requirements, conducted by a competent organization (*e.g.*, 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 additionally sufficient knowledge and experience with the requirements of [ISO Guide 34:2000](#).

## 4 Scope of on-site visits

The review process for the QS and CMCs may require on-site reviews by peers. In addition a metrology institute can ask by itself for on-site visits to support the peer review process. The CIPM MRA peer review process is also 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 aspects recommended to be taken into account for such on-site visits are listed in the following.

### 4.1 Quality management system review

#### 4.1.1 Aspects to be assessed

It is the role of the RMOs to review the QS operated by their members metrology institutes and to report on their acceptance or otherwise to the JCRB. For recommendations see:

JCRB Guidelines for the monitoring and reporting of the operation of quality systems by RMOs, [JCRB-10/8\(1c\)](#).

In addition all listings in the appendix C of certified reference materials in the field of the CCQM must meet the requirements of the ISO Guide 34:2000 which pertain to the production of CRMs and to the assignment of certified values. For requirements see:

Guidelines for the Acceptance of Certified Reference Materials in Appendix C of the CIPM MRA, [CIPM 2005-08](#).

## **4.2. CMC review**

### **4.2.1 Aspects to be assessed**

It is recommended that the following be included, as a minimum:

- (a) Qualifications and technical capabilities of staff ordinarily performing the services, and their supervisors.
- (b) Control and monitoring of environmental conditions.
- (c) Calibration and measurement methods, uncertainty estimations and method validation.
- (d) Suitability of equipment and equipment maintenance programs.
- (e) Measurement traceability.
- (f) Methods used for assuring the quality of measurements and calibrations.
- (g) Content and format of calibration / measurement reports.
- (h) Technical records that demonstrate that the claimed uncertainties have been ordinarily achieved by the metrology institute.

## **5 Reporting of the Review Outcomes**

The review report should 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 that the reviewers recognise the NMI as having the competence to deliver ordinarily)
- (e) identification of the reference documents used
- (f) review findings against all the aspects specified in the scope (4.2)
- (g) comments on the metrology institute's non-conformities and, where applicable, actions taken to correct non-conformities
- (h) the adequacy of metrology institute's quality system and its implementation to demonstrate the conformity with the requirements of CIPM-MRA
- (i) an explanation of any significant differences of opinion between the reviewer and metrology institute.