

Guide for on-site visits by peers in the frame work of CIPM MRA

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0 Introduction

This guide is developed with the purpose of having an agreed method to conduct formal on-site visits by peers, clearly laying down the objectives, requirements for development and documentation of the findings and for reporting the review outcomes.

In writing this guide, the documents included in the bibliography were taken into consideration (mainly from CIPM, EURAMET and ISO).

1 Objectives

To propose general guidelines for the performance of on-site visits by peers ensuring that:

- the staff assigned to the measurement and/or calibration activities is technically competent;
- the laboratory is capable of obtaining valid technical results according to the declared measurement and calibration capabilities; and
- the quality management system (QMS) complies with the requirement of the CIPM MRA.

2 Definition of terms

2.1 Institute: for the purpose of this document it is either a National Metrology Institute (NMI) - a signatory to CIPM MRA or a Designated Institute (DI) registered by EURAMET or an international organization to be a signatory of the CIPM MRA.

2.2 Peer review group: a group of institutes to make mutual peer review visits to cover their scope of CMCs as required. This activity is to be registered as an official TC-Q project. These groups are to be formed by institutes themselves on the basis of geographical, technical, language or other natural affinities.

2.3 Peer-reviewer: a person participating in/conducting a peer review assessment of an institute's technical competence who is recognized by EURAMET by fulfilling the following conditions:

- 1) All the members of the peer-review team shall comply with the criteria of reviewers in document CIPM 2007-25 [6], Section 3;
- 2) The peer-reviewer to assess the management part of the QMS should have a qualification of at least a Quality Manager and should have successfully completed a training course on the ISO/IEC 17025 requirements;
- 3) Peer reviewers may not necessarily have assessor qualifications but shall have sound knowledge of ISO/IEC 17025.

For the purpose of this document the following additional categories of assessors fall under the specification of a peer reviewer as well:

- an assessor employed at the BIPM;
- a highly competent foreign assessor who recently left an institute;
- world-leading experts in specific calibration fields, either retired or employed.

In the latter 2 cases the decision on meeting those criteria is to be made by TC-Q.

2.4 On-site visit by peers: a review of specified requirements made on-site in an institute by peer reviewer(s) external to the institute being peer reviewed. For the purpose of this document the following arrangements are considered to be compliant with this definition:

- a) a team of reviewers covering the management system and the subject fields under consideration makes an audit at a single period of time;
- b) audits are made separately by various peer reviewers (per partes);
- c) an internal audit with an external expert – peer reviewer;
- d) a NMI having a suitably qualified peer reviewer makes an audit in its DI or vice versa.

3 The application of the guide

The Guide shall be used, among others, especially for the following purposes:

- periodical on-site peer review visits as approved by EURAMET in pursuance of its responsibility to review quality management systems of its members (see par. 4.3 of the QMS review procedure [8]);
- extraordinary on-site peer review visits in case of evidence-based serious doubts in the performance of a quality management system, whether accredited or self-declared, as stipulated by par. 4.6 of the QMS review procedure [8].

All the on-site peer review visits shall be formally registered as TC-Q projects.

4 Formalization of on-site visit by peers

On-site peer reviews are made either within peer review groups to compensate the associated costs by a high level of mutual exchange of peer reviewers or the institute interested in an on-site visit by peers (also on request from EURAMET) shall simply agree on the peer reviewers taking into account their professional experience and their recognition by the international metrological community (par. 2.3 is applicable here). This is with the purpose of having a team with adequate technical depth to review both the quality system, the laboratory's activities and the way it realizes and maintains its technical competence and one which will enjoy international credibility. Each peer review group should ideally present a 5-year plan of on-site peer reviews, in the least however a 2-year plan.

5 The scope of an on-site visit by peers

Ideally, the aim is to cover all the declared CMCs of the concerned institute which will be reviewed by each peer reviewer in accordance with their area of expertise. The requirements are basically given by ISO/IEC 17025 and ISO Guide 34 if applicable.

If the laboratory decides to use a reference document for the review it shall indicate it in advance to the peer reviewer(s). The specialists shall consider their technical competence and knowledge of the reference documents proposed for the review to accept or reject the request.

6 On-site visit

This section contains guidance on planning and conducting peer-review activities. The extent to which provisions of this section are applicable depends on the scope and complexity of the peer-review and the intended use of the peer-review conclusions. In all cases of the on-site visits by peers the peer-reviewer shall meet at least the criteria outlined in CIPM 2007-25, Section 3 [6]. The following should be considered as a recognized practice. It is recommended that the on-site peer review includes at least the following activities:

6.1 Visit preparation

Prior to the visit, it is recommended that the following points are agreed upon between the peer reviewers and the peer-reviewed institute:

- Objective and scope of the review;
- Place and date of the visit;
- Language for oral and written communication
- The financial arrangements (see 8).

6.2 Document review

It is recommended that, previous to the visit, the peer reviewers have the following information:

- The list of services included in the Appendix C of the MRA - CMCs to be reviewed by reference to the KCDB (see <http://kcdb.bipm.org/>);
- The list of participation in key, supplementary or any other comparisons since the last review visit (see Annex II or in any other form providing the same amount of information);
- Measurement and/or calibration procedures used;
- Reference written standards (if applicable);
- Quality manual (its relevant part).

The peer reviewer reviews the documentation and verifies if it is sufficient and adequate to support the activities needed for the CMCs and/or the quality management system.

6.3 On-site visit activities

6.3.1 Visit opening meeting

The first activity is a visit opening meeting among the peer reviewer(s) and the staff of the reviewed laboratory, with the purpose of verifying the objectives and scope of the visit by peers. At least the Quality Manager of the reviewed institute should be present at the opening meeting. The work program during the visit as well as the laboratory staff to participate in the activities is also to be agreed upon here.

In this meeting, the laboratory will assign the responsible person to attend each peer reviewer during the exercise.

6.3.2 Collecting and verifying information

The most important aspects of the review are (as applicable):

- a) The staff technical competence to perform the measurement and/or calibration activities to be reviewed, including their education, experience and abilities;
- b) If the equipment, staff, methods and ambient conditions are adequate to obtain results technically valid in accordance to the measurement and calibration capabilities declared in MRA Appendix C;
- c) The compliance of the quality management system with the requirements of the MRA and its full implementation.

It is expected that each CMC of the Appendix C of the MRA declared in the scope of the on-site visit by peers will ideally be covered – as this is unrealistic in some cases, preferences should be established in planning the audit based on the following:

1. newly submitted CMCs;
2. a risk assessment of CMCs to be covered:
 - complaints
 - identified non-conformities
 - unsatisfactory performance in KCs or SCs
 - sampling of CMCs to review their validity
 - peer reviewer's own experience with technically demanding areas.

6.3.3 Documentation of findings

The findings identified should be documented stating the subject and the level of concern for each one. The level of concern may range from Critical, a finding that seriously compromises the laboratory's ability to support a CMC, to a Recommendation, which is simply a suggestion that may help the laboratory in a given task (an opportunity for improvement).

6.3.4 Peer review conclusions

All the findings (including observations, improvement opportunities and additional information requests) and agreed actions with deadlines shall be given in a Peer Review Record. An example – see Annex I.

6.3.5 Visit closure meeting

A visit closure meeting takes place among the peer reviewer(s) and the involved institute staff. The draft Peer Review Record (or at least, orally the findings) is presented and any problems or misunderstandings are clarified on-the spot.

7 On-site visit by peers - final record

After the peer reviewer(s) receive any additional requested information from the laboratory and analyzes it, the final Peer Review Record is written. These records are to be issued separately for each reviewed field inclusive the management system (part) - example see G-OPS-TMP-002 - Template of the final Peer Review Record (in the English language). In case of extraordinary peer review visits (see par. 3) the use of the template in Annex I is mandatory. The peer review records are to be written and forwarded to the Quality Manager of the laboratory within a short and agreed upon time after the closure meeting – ideally on-the spot. The records should be addressed to the contact person of the given country in TC-Q as well (if a different person) who will send any records immediately to the TC-Q Secretariat to be placed in a TC-Q database.

8 Financial arrangements

To cover the costs incurred during on-site peer reviews the following principles are recommendable and most convenient for peer review groups:

- no invoices are sent
- hotel accommodation is arranged and paid for by the hosting institute
- working hours, flights, daily allowances etc. are paid by the sending institute.

Peer review groups can agree on different financial rules at their discretion. Whereas this financial model will be used especially by peer review groups with a high level of mutual exchange of peer reviewers the other extreme case is when the receiving institute outside such an arrangement will seek peer reviewers on an individual basis – in the latter case all direct costs associated with the visit + working hours will have to be covered if not agreed otherwise.

REFERENCES (see also <http://www.euramet.org/technical-committees/tc-q/>)

1. CIPM MRA. Mutual Recognition of National Measurement Standards and of Calibration and Measurement Certificates Issued by National Metrology Institutes. CIPM, BIPM. October 1999. Technical Supplement revised in October 2003 (pages 38-41)
2. CIPM Report. Evolving Needs for Metrology in Trade, Industry and Society and the Role of the BIPM. April 2003.
3. ISO 19011 Guidelines for quality and/or environmental management systems auditing.
4. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
5. ISO/IEC 17040 General requirements for peer assessment of conformity assessment bodies.
6. CIPM 2007-25: Recommendations for on-site visits by peers and selection criteria for on-site visit peer reviewers.
7. CIPM 2009-24: Traceability in the CIPM-MRA
8. EURAMET Quality management system review procedure