1. Scope

This document specifies the procedure for reviewing the quality management systems (QMSs) of EURAMET National Metrology Institutes (NMI) and Associates - Designated Institutes (A-DI) within the framework of the review of calibration and measurement capabilities (CMCs) declared by EURAMET Member NMIs and A-DIs for the purpose of recognition under the global CIPM Mutual Recognition Arrangement (MRA). Introduction

This document is based on CIPM MRA, corresponding JCRB resolutions and EURAMET Guide 3. Throughout this guideline the word 'institutes' refers to both NMIs and A-DIs.

All institutes participating in the CIPM MRA must operate a QMS to support their calibration and measurement activities under this arrangement. The mutual recognition concerns the national measurement standards as well as the certificates corresponding to CMCs mutually agreed after a review process and published in the KCDB. This review concerns the evaluation of the results of key and supplementary comparisons as well the review of the implementation of operational QMSs fulfilling the applicable requirements. With regard to the latter, TC-Quality is the EURAMET operational instrument to review the implementation of QMSs based on ISO/IEC 17025 and/or ISO 17034 standards at institutes and share and develop knowledge on ISO/IEC 17025 and ISO 17034.

TC-Q has a mandate to monitor QS life through annual reports and, when necessary, through on-site visits by peers and through seeking information about how an institute's QMS is implemented, and by offering feedback on best practice, TC-Q has become the EURAMET platform to perform QMS review by peers. In this context EURAMET applies the concept of mandatory peer review for self-declared CMCs, what includes both CMCs from self-declared NMIs/DIs and CMCs from accredited NMIs/DIs out of accreditation scope. Peer reviews shall cover both technical and non-technical requirements of ISO/IEC 17025 and ISO 17034 (where applicable) and carry out in accordance with "Guide for on-site visits by peers in the framework of CIPM MRA" (G-TCQ-PRC-006)."

Furthermore, TC-Q submits recommendations and information to EURAMET about:

- on-site visits by peers; and
- organisation of visits by peers.

2. Organisation

The QMS review is mainly organised by TC-Q with support of the EURAMET TC-Q secretariat. Further details are described in the Terms of Reference Technical Committee for Quality (G-PRM-TOR-010).

3. Review criteria

EURAMET has adopted ISO/IEC 17025 as the reference standard to cover calibration and measurement activities under the CIPM MRA. Since 2006, CMCs involving Certified Reference Materials (CRMs) related to the CCQM have to be covered by a quality management system fulfilling the requirements of ISO 17034 standard in combination with ISO/IEC 17025. All declared CMCs shall be covered by the QMS.

3.1. The requirements of the CIPM MRA, regarding the QMS, are detailed in par. 7.3 of the Arrangement. Along the lines of CIPM-MRA EURAMET has adopted two possibilities here:

- a QMS meeting the requirements of ISO/IEC 17025 and ISO 17034 (where applicable) assessed by an accreditation body fulfilling the requirements of ISO/IEC 17011, while accreditation body shall be a signatory to the ILAC MRA or
- a QMS following ISO/IEC 17025 and ISO 17034 (where applicable) without third-party accreditation.

A QMS without third-party assessment is usually referred to as a self-declared QMS.

Under the CIPM MRA, accreditation and self-declaration in conjunction with a review process by TC-Q as specified in this document are considered by EURAMET as equivalent means for institutes to demonstrate confidence in the operation of their QMS.

3.2. Additional guidelines for accredited institutes:

- the claimed CMCs are identical with CMCs assessed by the accreditation body and documented in the assessment report;
- technical assessors shall come from a laboratory which is at least on the level as the assessed laboratory or meets the criteria given in “Guide for on-site visits by peers in the framework of CIPM MRA” (G-TCQ-PRC-006) and meet the requirements of A3 of CIPM-MRA-G12 document, in any case they shall have sound knowledge of ISO/IEC 17025;
- these technical assessors shall be used during the assessments/re-assessments and may also be used for surveillance visits within the re-assessment period in a given subject field;
- the names and qualifications of assessors must be made known to TC-Q;
- the relevant excerpts from assessment reports, especially those concerning findings, must be made available to TC-Q by way of annual reports.

3.3. Additional guidelines for self-declared institutes:

- the QMS shall undergo one or several on-site peer review visits covering both the requirements of ISO/IEC 17025 and/or ISO 17034 (where applicable).
- institutes are to arrange for on-site peer review visits by themselves in compliance with the provisions of “Guide for on-site visits by peers in the framework of CIPM MRA” (G-TCQ-PRC-006) by using external reviewers;
- between the re-evaluations on-site peer review visit(s) at least in each of the metrological areas1 , covered by the QMS of the institute, shall be conducted by external reviewers who meet the requirements described in the Appendix A3 of CIPM-MRA G-12 document;
- results of peer reviews can be recorded by using “Template of the final peer review record” (G-TCQ-TMP-002) issued to peer reviewed institute;
- if the template of the “Template of the final peer review record” (G-TCQ-TMP-002) has not been used in carrying out of an on-site visit by peers the corresponding record actually used has to be identified and reported in the annual report;
- institutes submitting their CMCs for the first time shall undergo an on-site peer review prior to their initial QMS presentation.

[1] the metrological areas as used in the KCDB 2.0 and covered by the Consultative Committees (except CC-U): Acoustics, Ultrasound, Vibrations (AUV), Electricity and Magnetism (EM), Length (L), Mass and related quantities (M), Photometry and Radiometry (PR), Thermometry (T), Time and Frequency (TF), Chemistry and Biology (QM), Ionizing Radiation (IR).

3.4. In addition to the requirements on QMS specified above the review process focused on calibration capabilities may also consider the following:

- CMCs have been established as a result of published scientific work in peer reviewed international journals, etc.
- Piloting CC KCs or EURAMET KCs or SCs.
- Knowledge of the institute's capabilities through active participation in EURAMET projects and activities.
- Participation in scientific and training activities, study visits by peers and consultations with technical experts from other RMOs.

In addition to the periodic actions as specified in par. 5, demonstration of competence and capability may require visits and examination of procedures by an NMI and/or by peers selected by EURAMET (par. 7.3 of CIPM MRA) in case of serious evidence-based doubts about the performance of the QMS of its members, whether accredited or self-declared, at any time – the decision to be taken by TC-Q based on an agreed set of criteria. Those criteria are among others as follows:

- a failure to comply with the requirements of this document;
- identified inconsistencies in the annual report or documentation presented for the initial and re-evaluation presentation of an institute;
- factual evidence about technical mal performance of an institute in areas covered by its CMCs as reported by EURAMET or other RMO technical TCs.
- lack of publications on scientific work in the areas covered by CMCs in impacted international journals, research projects under EU funded programmes etc.

Peer reviews of this kind shall be carried out according to the "Guide for on-site visits by peers in the framework of CIPM MRA" (G-TCQ-PRC-006).

4. Review procedure and timetable

Within the framework of the review of CMCs, institutes first have to present their QMS in TC-Q through the so-called 'Initial QMS presentation'. In the case where the QMS is accepted, institutes have to report about the status of their QMS on an annual basis and are re-evaluated after 5 years.

Thus, the review process and procedure consist of three parts:

- Initial QMS presentation;
- Annual reporting;
- QMS re-evaluation.

4.1. Initial QMS presentation

As explained above, each institute, constituting the national metrological infrastructure of each country, has to present their QMS to the other participants of TC-Q. According to the "Guideline for initial QMS presentation" (G-OPS-PRC-005), each institute has to prepare a written document detailing the required information and give an oral presentation following this specific guideline. The initial presentations of the QMS of A-DIs to TC-Q must be done directly by the responsible person of the DI and not through its NMI. The written documentation is focused on the organisation and the compliance with the requirements of ISO/IEC 17025 and if applicable ISO 17034 and on guidelines given in this document. The oral presentation is more focused on the 'how' and 'what' aspects of the implementation and working of the QMS, on the dynamic attitude of the QMS and on the weak and

strong points of the organisation, thus facilitating reciprocal learning and a better understanding of the operation of the QMS.

The written documentation is first reviewed by the Steering Committee that prepares comments. Following the oral presentation during the plenary meeting of the TC-Q, all the participants can raise questions.

Timetable/review procedure for initial QMS presentation, re-evaluation presentation and annual report is following:

4 weeks before the TC-Q meetings:
The TC-Q Secretary shall receive all the documents.
All the documents are allocated to reviewers. Each document will have two reviewers.
In the case where documents are not submitted at least 4 weeks in advance, this can be regarded as an indication for a lack of confidence in the quality management system (see section 4.5).

Between 4 weeks before the TC-Q meeting and the TC-Q meeting:
The reviewers review the documents and send their written comments to the TC-Q Chair and the TC-Q Secretary.

TC-Q SC meeting and TC-Q plenary meeting:
The compilation of documents and written comments from the reviewers are presented to the Steering committee for detailed analysis and the summary is presented to the contact persons during the plenary meeting.

Within 2 weeks after the TC-Q meetings:
Questions are sent to the contact person of the country directly by the reviewer (all participants can send their questions to the reviewer who collects the questions and forward them to the contact person).

Within 6 weeks after the TC-Q meetings:
The contact person of the country sends the answers and information directly to the reviewer.

Within 8 weeks after the TC-Q meetings:
The reviewer accepts or refuses the supplied complementary information and, in each case, informs the TC-Q Chair and Secretary. The results of the review will be reported to EURAMET Secretary.

At the end of the oral presentation and the subsequent discussion, the TC-Q Chair asks the audience for a formal approval of the QMS in question: whether all the points have been addressed by the presenting institute and if “the attending Contact Persons have sufficient confidence in the QMS presented and its ability to fulfil the requirements of the CIPM MRA”. As a result of the analysis of the documentation and oral presentations, there may be three outcomes at the end of the plenary meeting:

- the QMS is fully accepted with no unanswered questions or outstanding deficiencies (Contact Persons at the plenary meeting have full confidence in the QMS and its ability to fulfil the requirements of the CIPM MRA);
- the QMS is accepted with minor comments to be dealt with between the selected TC-Quality SC members and corresponding Contact Persons (Contact Persons at the

plenary meeting have sufficient confidence in the QMS and its ability to fulfil the requirements of the CIPM MRA);

- the QMS is not accepted, further actions are required. These actions are reported in the minutes and in the "Status of review" table which is a document issued after each TC-Q meeting containing for each NMI/DI the history: of initial presentations, of re-evaluation presentations and of pending actions (related to initial presentation and re-evaluations). In this case Contact Persons do not have sufficient confidence in the QMS and its ability to fulfil the requirements of the CIPM MRA. This can also be the case when a QMS is not yet fully implemented. In this case the institute concerned is required to submit a final implementation report and TC-Q has to decide whether an additional oral presentation or an on-site peer review is required. Failing to observe the agreed deadlines in completion of the actions will result in a request to JCRB to grey-out the corresponding CMCs (via EURAMET Chair).

This review process leads to an update of the "Overview table" which is a document containing the status of the QMS evaluation regarding initial and re-evaluation presentations.

4.2. Annual reporting

The same timetable applies for the annual reports as for initial QMS presentation. Each institute with an approved QMS has to prepare an annual report according to the "Guideline for QMS annual report" (G-TCQ-PRC-002), even if a re-evaluation is planned. This does not apply if an initial presentation is planned. In case of A-DIs the QMS annual reports must be prepared by themselves but submitted via their respective national TC-Q contact person. Analysis of the documentation is performed by selected reviewers of the Steering Committee. No oral presentation takes place. During the plenary meeting participants can raise questions.

As a result of the analysis of the documentation, there will be one of three outcomes at the end of the plenary meeting:

- the annual report is accepted; no additional action is necessary;
- the annual report is accepted, but some clarification/information is required; the clarification/information required is requested directly by a responsible member of the SC to the Contact Person of the country concerned (bilateral action) and the questions will be reported in the minutes of the SC;
- the annual report is not accepted as it is. Actions are required and these are reported in the minutes. If the actions and their results are satisfactory, then the annual report will be approved. If the actions or their results are not satisfactory, the case shall be investigated by appropriate means (see section 4.5). In case the lack of confidence is confirmed, a request to JCRB to grey-out the corresponding CMCs (via EURAMET Chair) is made by the TC-Q Chair.

4.3. QMS re-evaluation presentation

The same timetable applies for the QMS re-evaluation as for initial QMS presentation. Within 5 years, after the initial QMS presentation any institute registered with TC-Q must present the QMS for re-evaluation. Under exceptional circumstances only might the re-evaluation be postponed. Re-evaluation presentations of the QMS of A-DIs to TC-Q are made directly by the responsible person of the A-DI.

The re-evaluation presentation has to be prepared in accordance with the "Guideline for QMS re-evaluation presentation" (G-TCQ-PRC-004).

Related documents

G-PRM-TOR-010	Terms of Reference Technical Committee for Quality (TC-Q)
G-OPS-PRC-005	Guideline for initial QMS presentation
G-OPS-PRC-004	Guideline for QMS re-evaluation presentation
G-TCQ-PRC-002	Guideline for QMS annual report
G-TCQ-PRC-006	Guide for on-site visits by peers in the framework of CIPM MRA
CIPM MRA-G-12	Quality management systems in the CIPM MRA: Guidelines for monitoring and reporting