1. Subject

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). This document is based on CIPM MRA, corresponding JCRB resolutions and EURAMET Guide 8 (see reference [1]). Throughout this guideline the word 'institutes' refers to both NMIs and A-DIs.

2. Introduction

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 Appendix C of the MRA. This review (see [1]) 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 Guide 34 at institutes and share and develop knowledge on ISO/IEC 17025 and ISO Guide 34.

TC-Q has a mandate to monitor QS life through annual reports and, when necessary, through on-site visits by peers (see TC-Q Terms of Reference, par. 1e) 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.

Within the framework of TC-Q, the Contact Person is the point of contact within a country and is in charge of:

- dissemination of information to the institutes within the country;
- supervision of collection and dissemination to TC-Q of all the documents from institutes in their country that are requested by TC-Q.

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

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

3. Organisation

According to the Terms of Reference of TC-Q [2], the specific structure of TC-Q is based around a chairperson, secretary, steering committee and a plenary meeting. The secretary helps with the organisation of meetings and the documentation. The steering committee prepares the work before the plenary meeting. Its membership is on a voluntary basis whereby members are approved by the chairperson and the plenary meeting.

TC-Q operates by consensus whenever possible. When votes have to be taken, the simple majority is required, with a quorum given by TC-Q Chairman and one-third of the Contact persons.
4. 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 Guide 34 in combination with ISO/IEC 17025. All declared CMCs shall be covered by the QMS.

4.1 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 assessed by an accreditation body fulfilling the requirements of ISO/IEC 17011 and should be a signatory to the ILAC MRA or
- a QMS following ISO/IEC 17025 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.

4.2 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 par. 2.3 of [3] and meet the requirements of CIPM 2007-25 [4], 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.

4.3 Additional guidelines for self-declared institutes:

- the QMS should undergo an on-site peer review visit covering both the management and technical requirements of ISO/IEC 17025 and/or ISO Guide 34 (where applicable);
- institutes are to arrange for on-site peer review visits by themselves in compliance with the provisions of EURAMET “Guide for on-site visits by peers in the frame work of CIPM MRA” (see [3]) usually using external reviewers;
- if the template of the Final Record as per [3] 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.

4.4 In addition to the requirements on QMS specified above the review process may also take into account the following.
1. CMCs have been established as a result of published scientific work in impacted and refereed international journals, etc.
2. Piloting CC KCs or EURAMET KCs or SCs.
3. Knowledge of the institute’s capabilities through active participation in EURAMET projects and activities.
4. Participation in scientific and training activities, study visits by peers and consultations with technical experts from other RMOs.

4.5 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, EMRP projects etc.

Peer reviews of this kind shall be carried out according to the EUROMET Guide for on-site visits by peers in the frame work of CIPM MRA [3] inclusive the Final Record template.

5. Review procedure and timetable

5.1 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. So, the review process and procedure consists of three parts:

a. Initial QMS presentation;

b. Annual reports;

c. QMS re-evaluation.

5.2 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 the guideline “Initial QMS presentation” [5], 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 Guide 34 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**

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Event Description</th>
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<tbody>
<tr>
<td><strong>4 weeks before the TC-Q meetings:</strong></td>
<td>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 will be regarded as a ‘yellow card’, which will be sent to the EURAMET Chairman and will be interpreted as a lack of confidence in the quality management system.</td>
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<tr>
<td><strong>Between 4 weeks before the TC-Q meeting and the TC-Q meeting:</strong></td>
<td>The reviewers review the documents and send their written comments to the Chairman and the Secretary.</td>
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<tr>
<td><strong>TC-Q SC meeting and TC-Q plenary meeting:</strong></td>
<td>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.</td>
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<tr>
<td><strong>Within 2 weeks after the TC-Q meetings:</strong></td>
<td>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).</td>
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<tr>
<td><strong>Within 6 weeks after the TC-Q meetings:</strong></td>
<td>The contact person of the country sends the answers and information directly to the reviewer.</td>
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<tr>
<td><strong>Within 8 weeks after the TC-Q meetings:</strong></td>
<td>The reviewer accepts or refuses the supplied complementary information and in each case informs the TC-Q Chairman and Secretary. The results of the review will be reported to EURAMET Secretary.</td>
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At the end of the oral presentation and the subsequent discussion, the TC-Q Chairman 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 sufficient 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 laboratory 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 Chairman).

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.

5.3. Annual report
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” [6], 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 nevertheless 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, then a request to JCRB to grey-out the corresponding CMCs (via EURAMET Chairman) is made by the TC-Q Chairman.

5.4. QMS re-evaluation presentation
The same timetable applies for the QMS re-evaluation as for initial QMS presentation. Within a maximum of 6 years, the regular time being 5 years, after the initial QMS presentation any institute registered with TC-Q must re-present the QMS. Re-evaluation presentations of the QMS of A-DIs to TC-Q are made either directly by the responsible person of the A-DI or within the presentation of the corresponding NMI in absence of any representative of the A-DI(s) – the choice between these 2 options has to be reported by the contact person concerned to the TC-Q Secretariat at least 4 months before the relevant TC-Q meeting. The latter case of a unified presentation is available only to A-DIs accredited by a signatory to the ILAC MRA under the condition that technical experts
used in accreditation are disclosed in the presentation. If those experts do not meet the criteria given in 4.2 the A-DI is required to have a separate presentation at the next TC-Q meeting – the decision is to be made by TC-Q. The re-evaluation presentation has to be prepared in accordance with the “Guideline for QMS re-evaluation presentation” [7].

The same review procedure and timetable is applicable as for initial QMS presentation.

6. References

[1] EURAMET Guide no 8 “EURAMET procedures and review criteria for CMCs”.
[3] EURAMET Guide for on site visits by peers in the frame work of CIPM MRA.