

إجراء مراجعة نظام إدارة الجودة
Quality Management System Review Procedure

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1. Propose

This document specifies the procedure for reviewing the quality management systems (QMSs) of GULFMET National Metrology Institutes (NMIs) and Associates - Designated Institutes (DIs) within the framework of the review of calibration and measurement capabilities (CMCs) declared by GULFMET Member NMIs and DIs for the purpose of recognition under the global CIPM Mutual Recognition Arrangement (MRA). This document is based on CIPM MRA, corresponding JCRB resolutions.

TC-QS has a mandate to monitor QMS 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-QS has become the GULFMET platform to perform QMS review by peers. Within the framework of TC-QS, 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-QS of all the documents from institutes in their country that are requested by TC-QS.

Furthermore, TC-QS submits recommendations and information to GULFMET GA about:

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

2. Review criteria

GULFMET has adopted ISO/IEC 17025 as the reference standard to cover calibration and measurement activities under the CIPM MRA.

CMCs involving Certified Reference Materials (CRMs) related to the CCQM must be covered by a quality management system fulfilling the requirements of ISO / IEC 17034 in combination with ISO/IEC 17025. All declared CMCs shall be covered by the QMS.

2.1 The requirements of the CIPM MRA, regarding the QMS, are detailed in CIPM MRA G-12 (QMS in the CIPM MRA).

GULFMET 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-QS as specified in this document are considered by GULFMET as equivalent means for institutes to demonstrate confidence in the operation of their QMS.

2.2 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” (MC-210205-05-02) and meet the requirements of A3 of CIPMMRA-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-QS;
- the relevant excerpts from assessment reports, especially those concerning findings, must be made available to TC-QS by way of annual reports.

2.3 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 17034 (where applicable);
- institutes are to arrange for on-site peer review visits by themselves in compliance with the provisions of GULFMET “Guide for on-site visits by peers in the framework of CIPM MRA” (MC-210205-05-02) 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” (MC-210205-05-02-1) issued to peer reviewed institute;
- if the template of the “Template of the final peer review record” (MC-210205-05-02-1) 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.

2.4 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 GULFMET KCs or SCs.
- 3- Knowledge of the institute’s capabilities through active participation in GULFMET activities.
- 4- Participation in scientific and training activities, study visits by peers and consultations with technical experts from other RMOs.

In addition to the periodic actions, demonstration of competence and capability may require visits and examination of procedures by an NMI and/or by peers selected by GULFMET (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-QS 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 GULFMET or other RMO technical TCs.
- lack of publications on scientific work in the areas covered by CMCs.

Peer reviews of this kind shall be carried out according to the GULFMET Guide for on-site visits by peers in the framework of CIPM MRA inclusive the Final Record template.

3. Review procedure and timetable

3.1 Within the framework of the review of CMCs, institutes first must present their QMS in TC-QS through the so-called ‘Initial QMS presentation’. In the case where the QMS is accepted, institutes must report about the status of their QMS on an annual basis and are re-evaluated after 3 years.

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

- a. Initial QMS presentation;
- b. Annual reports;
- c. QMS re-evaluation.

3.2 Initial QMS presentation

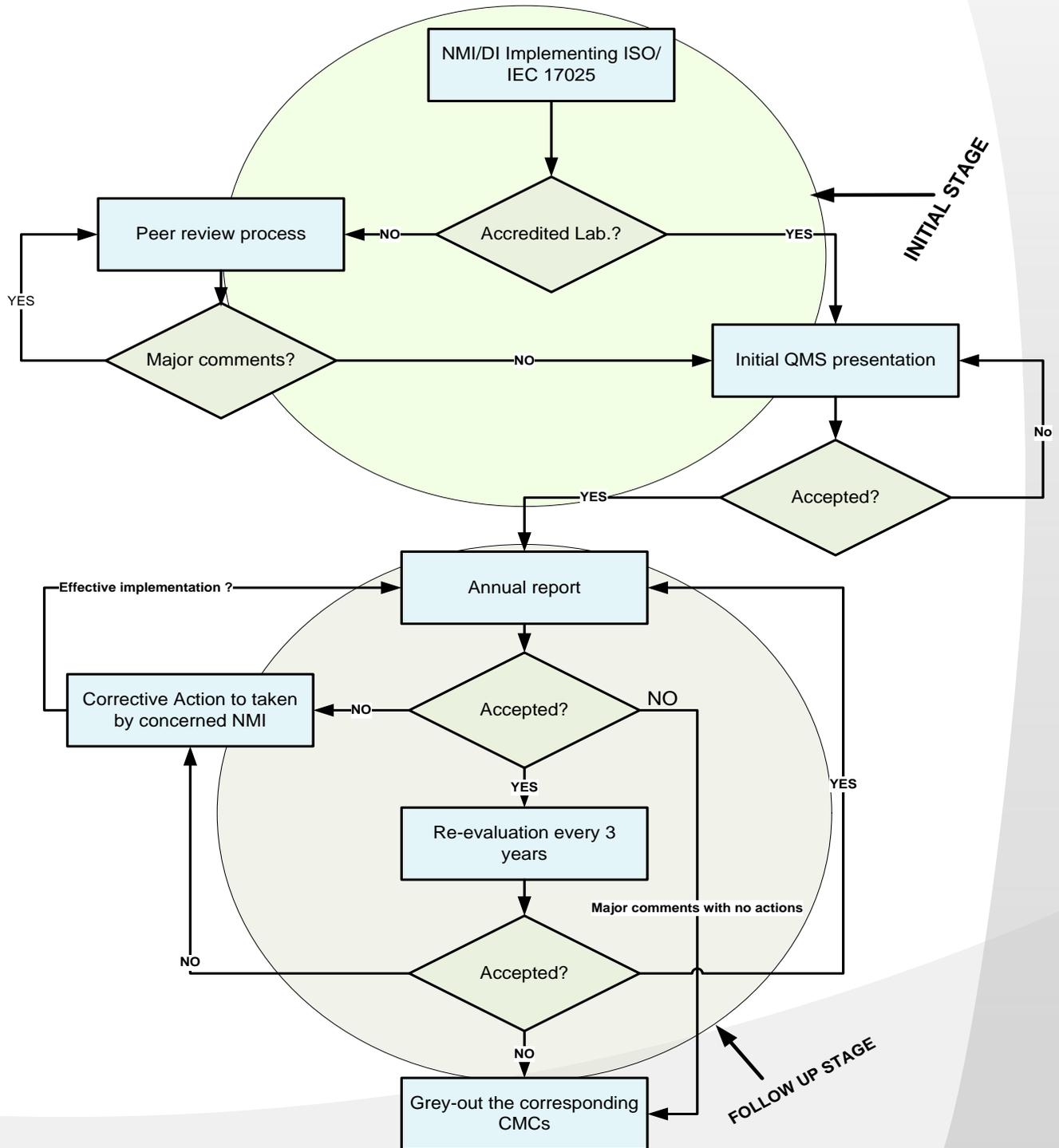
As explained above, each institute, constituting the national metrological infrastructure of each country, has to present their QMS to the other participants of TC-QS. According to the “Guideline for initial QMS presentation” (MC-210205-05-03), each institute has to prepare a written document detailing the required information and give an oral presentation following this specific guideline. The initial presentations of the QMS of DIs to TC-QS must be done directly by the responsible person of the DI and not through its NMI. The written documentation is focused on the organization 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 Quality Management System review procedure strong points of the organization, thus facilitating reciprocal learning and a better understanding of the operation of the QMS.

The written documentation is first reviewed by the selected reviewers that prepares comments.

Following the oral presentation during the plenary meeting of the TC-QS, all the participants can raise questions.

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

3.3 Process Map – GULFMET Overview QMS Review Procedure



4 weeks before the TC-QS meetings:

The TC-QS 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.

Between 4 weeks before the TC-QS meeting:

The reviewers review the documents and send their written comments to the TC-QS Chair and the TC-QS Secretary.

Before one-week TC-QS meeting:

The compilation of documents and written comments from the reviewers are presented to the TC-QS Secretary for detailed analysis and the summary is presented to the contact persons during the TC-QS meeting.

Within 2 weeks after the TC-QS 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-QS meetings:

The contact person of the country sends the answers and information directly to the reviewer.

Within 8 weeks after the TC-QS meetings:

The reviewer accepts or refuses the supplied complementary information and in each case informs the TC-QS Chair and Secretary.

The results of the review will be reported to GULFMET Secretary

At the end of the oral presentation and the subsequent discussion, the TC-QS 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 TC-QS meeting:

- the QMS is fully accepted with no unanswered questions or outstanding deficiencies. The TC-QS members 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 TC-QS members and NMI/DI representatives (TC-QS members 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-QS 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 TC-QS members 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-QS 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 GULFMET President).

This review process leads to an update of the “Overview table (MC-210205-05-01-1)” which is a document containing the status of the QMS evaluation regarding initial and re-evaluation presentations.

3.4 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”, even if a re-evaluation is planned.

This does not apply if an initial presentation is planned. In case of DIs the QMS annual reports must be prepared and presented by themselves. Analysis of the documentation is performed by selected reviewers of the TC-QS.

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 shall be submitted by the TC-QS representative and shall be reported in the minutes of the TC-QS;
- 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 GULFMET President) is made by the TC-QS Chair.

3.5 QMS re-evaluation presentation

The same timetable applies for the QMS re-evaluation as for initial QMS presentation. Within 3 years, after the initial QMS presentation any institute registered with TC-QS must present the QMS for reevaluation. Under exceptional circumstances only might the re-evaluation be postponed. Reevaluation presentations of the QMS of DIs to TC-QS are made directly by the responsible person of the DI.

The re-evaluation presentation has to be prepared in accordance with the “Guideline for QMS re-evaluation presentation” (TC-133007-02).

Related documents

TC-153604-02	Guideline for Quality Committee (TC QS) Technical Work
MC-210205-05-03	Guideline for initial QMS presentation
TC-133007-02	Guideline for QMS re-evaluation presentation
MC-210205-05-04	Guideline for QMS annual report
MC-210205-05-02	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
G-TCQ-PRC-001	EURAMET Quality Management System review procedure

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