SIM QSTF Procedure for the Review and Approval of the Quality Management Systems

Introduction

Implementation of the CIPM MRA has delegated the responsibility to review the quality management systems (QMSs) to the Regional Metrology Organizations (RMOs). Thus, SIM is responsible to review and to approve the QMS operated by its member National Metrology Institutes (NMIs) and their Designated Institutes (DIs) and to report on their acceptance to the Joint Committee of the RMOs and the BIPM (JCRB). This responsibility has been assigned by SIM Council to the SIM Quality System Task Force (QSTF) [see SIM-09]. QMS approval by SIM QSTF is required to support CMC claims, however since it is not limited to this purpose any NMI in the SIM region may present a QMS related to their measurement services for QSTF approval.

1. Purpose

The purpose of this document is to describe the processes and requirements of the SIM QSTF for the review and approval of a QMS related to a measurement service.

2. Scope

This document applies to any NMI in the SIM region, even if it is not a signatory of the CIPM MRA. This document applies to all QMSs submitted by NMI/DIs. This document also applies to the review of a QMS submitted by the BIPM and an international intergovernmental organizations (IGO), or their DI, that is a signatory to the CIPM MRA and requests approval by SIM.
Measurement services include calibration and measurement capabilities, reference material and certified reference material production and proficiency testing activities.

3. On Site Peer Review and/or Assessment[1]

3.1. The QMS operated by the NMI/DI must conform to appropriate requirements of ISO/IEC 17025 for calibration and testing laboratories; ISO 17034 for reference material producers (RMPs); or ISO/IEC 17043 for proficiency testing providers. Conformance can be demonstrated by peer reviews with a self-declaration or with an appropriate accreditation.

3.2. The QSTF requires the QMS to undergo an on-site peer review/assessment prior to and within 18 months of March 1st for QMS presentation to the QSTF at the mid-term meeting or September 1st for QMS presentation to the QSTF at the SIM Week meeting. If approval is delayed due to a planned presentation being deferred, outside of the presenter's control, to a subsequent QSTF meeting, the 18-month requirement may be waived by the Chair.

3.3. NMI/DIs are to arrange for on-site peer reviews/assessment of their QMS consistent with CIPM guidelines. Reviewers must be competent in the areas and standards they assess and should meet the criteria detailed in Appendix A of CIPM MRA-G-12, Quality management systems in the CIPM MRA, which includes required and desirable characteristics for the education and experience of peer reviewers in the technical field relevant to the CMCs being reviewed.

3.4. For accredited NMI/DIs, an accreditation assessment may be acceptable to the QSTF depending on the extent of the assessment and the qualifications of the assessors involved. Monitoring or surveillance visits, which are part of the accreditation process, may not suffice as peer reviews for the purposes of the QSTF since they often lack depth and breadth, and consequently do not provide necessary information to the QSTF on which to base their decision.

3.5. Normally the peer review team should be composed of reviewers from institutes other than the one being reviewed. In the case of

[1] The SIM Quality System Task Force acknowledges the growing use of remote and hybrid (mixed in-person and virtual) peer reviews or assessments. Organizations seeking approval by the QSTF for a quality system based on a peer review conducted either partially or entirely in a remote modality should evaluate the associated risks and consider guidance outlined in the QSTF's "Guidance for performing and conducting remote assessments at National Metrology Institutes and Designated Institutes with the SIM Regional Metrology Organization"

large NMIs with many qualified reviewers external to the actual unit being reviewed, reviewers internal to the NMI but independent and outside the management chain of the unit being reviewed might also be acceptable to the QSTF. NMIs using internal reviewers for their on-site peer reviews must be approved for this by the QSTF. In evaluating such requests the QSTF would consider whether the proposed process presented by the NMI would provide independent reviewers with strong qualifications. Once approval is achieved, the NMI will need to continue to demonstrate the independence and qualifications of their on-site peer reviewers on a continuing basis. NIST (USA), INTI (Argentina) and INMETRO (Brazil) have received approval by the QSTF to use qualified internal reviewers.

3.6. The on-site peer review report should cover the requirements of ISO/IEC 17025, ISO 17034 or ISO/IEC 17043. The report should include the information specified in Appendix A of CIPM MRA-G-12, Quality management systems in the CIPM MRA, as well as:

- Scope of the review (e.g. CMC tables);
- Standards used including version;
- Dates of the review;
- Findings, recommendations, actions taken and their results, and/or action plans to be taken;
- An explanation of any significant differences of opinion between the reviewer and metrology institute; and
- Conclusions of the reviewer(s) related to the conformance of the QMS to appropriate standards and its effectiveness in supporting the capabilities/CMCs.

4. Meetings and Submission Requirements

4.1. A meeting announcement, including deadlines for the submission of the documentation, will be sent by the QSTF Chair or Secretariat at least eight (8) weeks prior to the meeting. Meeting are generally held during SIM Week (held between Sept and Nov) and at the mid-term (held between March and May).

4.2. For a QMS that has not previously been approved, NMI/DIs shall submit their documentation, in the format required by the QSTF templates, to the QSTF Secretariat at least six (6) weeks in advance of the meeting.

4.3. For a QMS that has previously been approved by the QSTF, the NMI/DIs shall submit their documentation, in the format required by the QSTF templates, to the QSTF Secretariat at least four (4) weeks in advance of the meeting.

4.4. NMI/DIs may choose to present their QMS as a whole or in parts, but must clearly specify which measurement services are included in the presentation (e.g. CRMs produced, PT analysed, CMC tables, scope of accreditation).

4.5. NMI/DIs must make their QMS documentation, in its original language, available to the SIM QSTF. They must submit, in full and in English, the Submission Template (QSTF-1), the Checklist for Submission of QMS for Review by QSTF (QSTF-3).[2]

4.6. NMI/DIs must provide names and biographies of the reviewers demonstrating that they meet the criteria detailed in Appendix A of CIPM MRA-G-12, Quality management systems in the CIPM MRA.

4.7. A summary of the submitted documentation will be presented at a QSTF meeting by a knowledgeable representative of the NMI/DI. QSTF-2 is an option tool for the presentation.

4.8. The SIM QSTF must satisfy itself that, through its review process, the QMS operated by the NMI/DI is effective and conforms to the applicable requirements.

4.9. In addition to the requirements regarding the QMS, the review process may also take into account:

- knowledge of the NMI/DI's capabilities through active participation in SIM projects and activities;
- other available knowledge and experience, such as scientific and quality related publications; and
- participation in scientific and training activities, visits and consultation with technical and quality experts from other RMOs.

4.10. The following special considerations apply to accredited laboratories:

[2] https://www.nist.gov/pml/sim-quality-system-documentation

- The claimed capabilities/CMCs uncertainty must not be smaller than the accredited uncertainties documented in the scope of accreditation.
- The NMI/DI must submit the name of the accreditation body, the period covered by the accreditation, and the names and bios of the technical assessors who were involved in the assessment of the institute's capabilities.
- The accreditation body must operate according to ISO/IEC 17011 and shall be a signatory to the ILAC MRA.

4.11. An NMI/DI presenting a QMS for re-approval by the QSTF must provide all the documentation specified in QSTF-3, including evidence of the "vitality" of the CMCs. Such evidence may include the kind of information listed in 4.9, and/or documentation of:

- when the CMCs were last updated;
- performance on key or other comparisons;
- related publications;
- training of key personnel;
- improvements to services;
- personnel, facility or equipment changes that might affect the delivery of CMCs;
- management changes that might affect the delivery of CMCs; and/or
- customer feedback regarding the delivery of CMC services.

4.12. If considered necessary, the SIM QSTF may request that an additional on-site peer review be undertaken, in order that the NMI/DI may demonstrate confidence and capability in their claimed CMCs.

5. Monitoring of approved QMS

5.1. The SIM QMS review process includes on-going monitoring of the quality management system of the NMI/DIs. Each NMI/DI shall promptly notify the SIM QSTF Chair and Secretariat of any major changes that affect its approved measurement services, the validity of its accreditation or self-declaration status, or the coverage of its declared CMCs.

5.2. Each NMI/DI having an approved QMS will submit an annual report to document significant changes that have occurred that might affect the continued delivery of those CMCs. The annual report (template on the QSTF website) must be sent to the QSTF Chair and Secretariat by January 31st of the following year.

5.3. Upon notification of significant changes, the SIM QSTF Chair will take appropriate action.

6. Re-approval of QMS and Vitality of Published CMCs

6.1. Approved quality management systems must be reviewed and re-approved within five (5) years by the QSTF. [i]

6.2. Re-approvals of a QMS have the same requirement as original approvals.

6.3. In addition, re-approvals a QMS also require evidence accumulated over the last several years supporting the existence of a robust quality management system including regular internal audits, management reviews, customer feedback, nonconformities and corrective actions, appropriate record keeping, action plans to address noted deficiencies and the results of actions taken, and related items.

Revision History

Version	Authors	Date	Comments
1	QSTF	2018-03-19	Initial approval – created based on clauses of SIM-09 v10 that were extracted in the approval of SIM-09 v11
1.1	Georgette Macdonald	2018-03-20	Clause 3.5: Correction of typo – IMETRO replaced by INMETRO
1.2	Andrew Conn	2023-05-05	Footnote to section 3.0 acknowledging the growing use of remote and hybrid peer reviews and assessments & replacing references to Section 3 of CIPM 2007-25, Recommendations for On-Site Visits by Peers and Selection Criteria for On-Site Peer Reviewers with Appendix A of CIPM MRA-G-12, Quality management systems in the CIPM MRA.

[i] JCRB Resolution 29/2 …It is the responsibility of the RMO TC for QMS review to establish the continued validity of all published CMC's covered by the quality management system, taking into account all supporting technical evidence, including participation in comparisons. If the TC for QMS review is not satisfied that a particular CMC remains valid then it initiates a process of greying out the CMC in question.

JCRB Resolution 28/2 The JCRB resolves that the QMS must be in place prior to the acceptances of the CMC's must be according to ISO/IEC 17025 (and ISO Guide 34 for CRM's) in line with the requirements for calibration laboratories.