Guidelines for the Submission of Information to the SIM QSTF for the Review of Quality Management Systems

Version 1.0

Approved on 11 September 2020

NOTE: "This document is a guide only on how to fill out the QSTF-1 template and provide a convention for file naming. It is not a template. The templates to be used are QSTF-1, QSTF-3 and (optional) QSTF-4."

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Introduction & Instructions on how to use this guide

Presenters should familiarize themselves with SIM-09 and QSTF-00 as they prepare for presentations before the QSTF. Organizations seeking QSTF approval are required to complete and submit QSTF-1 & QSTF-3, along with the necessary supporting documents, as a part of their submission package.

Please look over the submission templates (QSTF-1 and QSTF-3) and consider every clause carefully. Fill in all sections that apply and remove subsections that are not relevant in the templates. The instructions in this guide are indicated in red; information that should be entered within the QSTF-1 template is marked blue. Be aware that the text appearing in this guide is designed to serve as an example and demonstrate the content and the level of detail that is expected. **It should NOT simply be copied into your QSTF-1 submission.**

Please also add any relevant information pertaining to your INSTITUTION that you deem relevant.

How to organize the electronic documentation package

Please save all documents under the following structure:

- Folder name: {INSTITUTION}_QS_Date in year, month, day format). As an example, the folder name for NRC of Canada would be: [**NRC_QMS_2020-07-31].** *If you wish to submit any of the documents as a separate document, please follow the similar naming convention.*

The files **QSTF-1** and **QSTF-3** must be in the main folder. In addition, 7 subfolders should be named as such:

1. Peer reviews *(include reports there and action plans)*
2. Reviewed CMCs
3. Internal Audits *(include reports there and action plans)*

4. Management Review
5. Quality monitoring records *(where you include other Action logs/Corrective Action Request/Risk and Opportunities/Complaints etc…)*
6. Bios
7. Vitality *(for 5-Year reviews only)*

How to send the electronic documentation to the SIM QSTF Secretary

Submit your documentation to the SIM QSTF Secretary by email or other electronic means, as appropriate, before the submission deadlines. Document submission deadlines are provided to QSTF representatives via email at least eight weeks prior to each meeting (QSTF-00, section 4).

Title Page

The title page could include:

- The name and logo of the NMI or DI

1. Quality System Structure

1.1 Quality System Management Goals/Objectives

In this section, the NMI/DI should describe how it has committed to the implementation of the goals/objectives, the implemented standard, and requires all staff related to calibration and measurement services to familiarize themselves with the policies described in the current issue of the Quality manual or the associated processes & procedures. Staff must also ensure that their conduct conforms to the above-mentioned policies and procedures.

1.2 Quality System Management Policies, Roles and Responsibilities

In this section, the NMI/DI should describe how the quality system ensures that its calibration and measurements services comply with the specified requirements of standard implemented. Quality-related activities are governed by written procedures, where applicable, with emphasis on the following:

- Impartiality and confidentiality
- Non-Conformity works
- Data control
- Risk and opportunities
- Selection and monitoring of suppliers of materials and services that affect the quality of service;
- Procedures ensuring the safe and confidential handling, packaging, storing, and delivery of materials;
- Procedures to establish and monitor calibration and measurement processes;

- Regular internal audits and management reviews;
- Continuous improvement of the effectiveness of the quality system
- Effective corrective actions for dealing with client complaints and other instances of non-conformance as well as follow-up to formulate preventive action procedures; and appropriate techniques to monitor quality and seek clients feedback.]

Scope

[This policy applies to all functions of the calibration and measurement services.]

Roles and Responsibilities

[Calibration and measurement services personnel who manage, perform and verify work that has an effect on quality are responsible for the implementation of the quality system.

[The Quality System Coordinator is responsible for ensuring that the quality system is implemented, properly documented and maintained. The Quality System Coordinator may delegate certain responsibilities to appropriate staff.]

Quality Management System Documentation Structure

The NMI/DI should describe how the Quality System is designed around the following document structure:

- quality management system documentation;
- quality system files;
- published standards;
- statutory regulations;
- training and qualification records of calibration and measurement services personnel;

- correspondence and agreements with clients;
- internal audits and follow-ups;
- complaints, follow-ups and client's feedback;
- quality system reviews; and
- documentation of the output from operating procedures and calibration or measurement operating procedures.

1.3 Organizational Chart

The Organizational Chart would appear in the text or in an appendix. If it is a separate document, the file name should be the following:
[: {NMI/DI}_OrgChart]

2. Quality Management System Implementation

2.1 Customer Feedback Management

2.2 Managing Customer Complaints

2.3 Management of Nonconforming Work

[{INSTITUTION} should describe how calibration and measurement services records and investigates client feedback, complaints and nonconforming work.

Statistics

[Since {Date}: {#}]

Related Procedures, or Process

[:{INSTITUTION_Procedures for complaints/nonconformity works/ Feedback}]

2.4 Corrective Actions (ISO/IEC 17025:2017 [8.7] and ISO 17034:2016 [8.9])

[{INSTITUTION} calibration and measurement services implements corrective actions when the evaluation of a non-conformance indicates it could recur or that {INSTITUTION} calibration and measurement services are not in compliance with quality system policies and procedures.]

2.5 Actions to address Risks and Opportunities and Improvement

The risks and opportunities associated with laboratory activities should be considered to ensure that the management system achieves its intended results, improve opportunities to achieve the purpose and objectives of the laboratory; prevent or reduce desired impacts and potential breaches of activities.

[Since {Date}: {#} Actions to address risks and opportunities {Describe Action to address risks and opportunities}, carried out and reviewed for effectiveness {Date}]

Scope

[This action applies to the {INSTITUTION} calibration and measurement services.]

Related Procedures or Process

[name: {INSTITUTION_Procedures for action to address risks and opportunities}]
and/ or Risk Matrix.

3. Audits, Assessments and/or Peer Reviews

3.1. Internal Audits (ISO/IEC 17025:2017 [8.8] and ISO 17034:2016 [8.7]) (For ISO 17034:2016: a procedure is required.)

[{INSTITUTION} carries out internal audits to determine whether the calibration and measurement services' activities, and documented policies and procedures meet the requirements of the quality system and are effective in achieving the stated quality objectives.]

[When auditing calibration procedures, every effort is made to balance the need for a conflict of interest-free process with the need to ensure the participation of auditors with the highest level of technical knowledge in order to compare the written calibration procedures to the internationally validated methods.]

Scope

[This policy applies to internal audits for the quality system.]

Responsibilities

[The ……. is responsible for:

- scheduling and coordinating internal audits,
- maintaining audit records,
- initiating corrective actions on the basis of the audit results,
- communicating audit results.
- specifying qualification requirements of internal auditors and coordinating training activities for internal auditing.]

[The …….. authorizes the Quality System Coordinator to schedule and coordinate internal audits and to initiate corrective actions. The …….. also identifies areas of importance for auditing, reviewing audit results and for monitoring results of corrective action.]

[Calibration and measurement services have documented procedures for planning and implementing internal audits. These audits verify compliance of quality and technical activities and results, with the requirements of the quality system.]

[The …… proposes an audit plan for approval by the……. .]

[Internal audits are conducted by qualified personnel who are independent of the activity audited.]

[Records are maintained of all audits. Audit findings are documented and communicated to the accountable personnel as well as to the …….. for timely, corrective action.]

Summary of Current Cycle of Internal Audits

Scope	Audit dates	Main findings	Committed Dates for resolving the nonconformities

3.2 Management Reviews (ISO/IEC 17025:2017 [8.9] and ISO 17034:2016 [8.6])

[{INSTITUTION} Quality System and its calibration and measurement activities are reviewed at sufficient intervals to ensure their continuing suitability and effectiveness in satisfying ISO/IEC 17025; ISO 17034:2016 stated quality policy and objectives].

Scope

[This policy applies to all activities within the calibration and measurement services].

Responsibilities

[The {INSTITUTION} Management Team reviews the Quality Management System for calibration and measurement activities.]

Formal audit action items and corrective action items are included, when appropriate, as agenda items for {INSTITUTION} Management Team meetings.

[Minutes of the review meetings are maintained to ensure that actions arising from the reviews are discharged as required.]

Frequency

[Management reviews are held in planned intervals.]

Reviews

"NMIs/DIs must make sure to cover all the elements of ISO/IEC 17025:2017 and if applicable ISO 17034:2016 and any other standards they comply to (e.g. ISO/IEC 17043:2010)"

[: {INSTITUTION_Guidelines for management review}]

Summary of recent Management Reviews

[for example, include minutes. Some NMIs /DIs may records the results of…"the results of their MR in a different way.}

Describe the main results of at least the last management review.

3.3 On-site Peer Reviews or Assessments

Please give the status of assessment process and the date of the Assessment Report. Please attach a copy of the Assessor's report. Please include a **clear** statement about the scope of the assessment (which parts of the Standard were taken into consideration).

Five-year re-approvals require a recent on-site peer review or external assessment. The date of the assessment needs to be clearly indicated.

: {Institution's_Assessment Report}

4. Evidence of Vitality

You may wish to describe this evidence in the document, as well as include filenames for additional files. Refer to QSTF-00 section 4.11. Examples of vitality include:

1. Improvements to services
2. Changes to staff and equipment
3. Successful participation in inter-comparisons.
4. Participation in RMO Projects and Activities
5. Participation in Training Activities.
6. Visits and consultations with technical experts from other NMIs or RMOs

5. Appendices

List of Calibration and Measurement Capabilities (CMCs) covered by the QMS under Review { INSTITUTION_CMCList}]

Bios of Internal Assessors

Bios of Peer Reviewers