Guideline for QMS Re-evaluation Presentation

Issue 1

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Contents

1. Introduction

This TC- QUALITY guideline is applicable for National Metrology Institutes (NMIs) and Designated Institutes (DIs) who have to present their Quality Management System (QMS) for re-evaluation within TC- QUALITY.

The QMS presentation consists of written documentation and an oral presentation. Part A of this guideline contains the requirements for the QMS written documentation to be provided, whilst Part B includes the requirements for the oral presentation.

Throughout this guideline the word 'NMI' is taken to include both NMIs and Designated institutes.

2. Timetable

For the complete timetable of the review of QMS re-evaluation presentation, please see Quality Management System review procedure – TCQP 06

The electronic version of the re-evaluation document shall be sent to the TC- QUALITY secretary at least 4 weeks prior to the TC- QUALITY meeting. Electronic versions of the oral presentation shall be sent to the TC- QUALITY secretary at least 2 working days prior to the TC- QUALITY meeting.

Part A: Guideline for written documentation

NMIs who have declared their QMS to be in compliance with ISO/IEC 17025 and (where applicable) ISO Guide 34 are required to provide documented information about their QMS according to the table below.

It is suggested that the written documentation for each NMI be presented in 6 chapters (preferably in a single Word or PDF file). For each chapter, the same title as indicated in the 'Guidance' column should be used.

With regard to the information to be provided, some changes have been made, within the paragraphs 3.3, 3.4 and 3.5, between accredited NMIs and NMIs with self-declaration. See the guidance column at paragraphs 3.3, 3.4 and 3.5 for more information.

Information	Objective	Guidance
Information about changes to the national metrology system during the past 4/5 years.	To provide insight into the changes to the metrology infrastructure of the country and check the possible consequences for the QMS(s) to be implemented.	**Chapter 1: Information on national metrology system** Provide information about changes to the centralized or decentralized system (in the case of a decentralized system, indicate which institutes are involved and the requirements imposed on these institutes), e.g. the national metrology law and the procedure for appointing national measurement standards.
In the case where changes have been implemented since the initial QMS presentation, these changes must be reported with regard to the following topics: The quality policy. The quality objectives. Detailed organogram of the NMI. QMS processes and steering mechanisms in the organization.	To identify the changes with regard to responsibilities and the implementation of the QMS.	**Chapter 2: Presentation of the QMS** 2.1 Quality policy (Including quality objectives). 2.2 Structure of NMI (Including organogram showing key staff, their names and their roles). 2.3 QMS structure (Including QMS processes and steering mechanisms).

Information	Objective	Guidance
Detailed table of contents of the current quality manual (including dates of revisions over the past 4/5 years).	To obtain a reasonable knowledge of the real development of the QMS.	Chapter 3: Information on QMS development and ISO/IEC 17025 implementation 3.1 Table of contents of the quality manual
Relevant QMS issues from annual reports.	To obtain a reasonable knowledge of the real development of the QMS and to identify the changes in the QMS during the past 4/5 years.	3.2 Annual reports and QMS development Report in detail about the major QMS developments during the past 4/5 years as indicated in the annual reports.
Comprehensive list of general, administrative and technical procedures, work instructions and forms including their reference title, version number and issue date including their reference, title and date.	To obtain a reasonable knowledge of the real development of the QMS.	3.3 List of general and administrative procedures (Partly accredited or fully accredited NMIs do not have to provide this information). 3.4 List of technical procedures, work instructions and forms. (Information does not have to be provided by NMIs for accredited fields if the scope of these accredited fields has not changed).
Table of cross-references: ISO/IEC 17025 versus quality documentation.	To check the implementation of ISO/IEC 17025.	3.5 Table of cross-references (Partly accredited or fully accredited NMIs do not have to provide this information).
Information about role of top management. Information about the way continuous improvement is achieved. Information about service to the customer (monitoring of customer satisfaction and feedback measures).	To check the implementation of the new requirements of the second edition of ISO/IEC 17025.	3.6 Implementation of new requirements of ISO/IEC 17025

Information	Objective	Guidance
List of calibration capabilities covered by the QMS (including reference materials where applicable).	To check the coherence between the QMS and services offered. Evidence that CMCs are covered by the QMS.	**Chapter 4: QMS and covered calibration measurement capabilities** Declare whether all the services corresponding to the CMCs approved by the GULFMET Technical Committees or still under discussion, are covered by the QMS (accredited QMS where applicable). If not, please indicate which services are not yet covered by the QMS and explain the status of implementation.
Indicate what improvements have been made during the past 4/5 years with regard to the complaints procedure.	To obtain information about the improvement of the QMS.	**Chapter 5: QMS life** 5.1 Complaints Report about implemented improvements with regard to the handling and solving of complaints.
Indicate what improvements have been made during the past 4/5 years with regard to the non-conforming work procedure.	To obtain information about the improvement of the QMS.	5.2 Non-conforming work Report about implemented improvements with regard to the handling and solving of non-conforming work.
Indicate what improvements have been made during the past 4/5 years with regard to the internal audit procedure.	To obtain information about the improvement of the QMS.	5.3 Internal audits Report about implemented improvements with regard to performing internal audits.
Indicate what improvements have been made during the past 4/5 years with regard to the management review procedure.	To obtain information about the improvement of the QMS.	5.4 Management reviews Report about implemented improvements with regard to performing management reviews.

Information	Objective	Guidance
Information about the relevant changes made in the QMS and QMS documentation during the past 4/5 years related to CRMs and ISO Guide 34.	To obtain information about the activity of the QMS related to CRMs and ISO Guide 34.	**Chapter 6: Further information on ISO Guide 34 implementation for reference materials (CRMs)** (where applicable) 6.1 Implementation of ISO Guide 34 requirements Include a statement as to whether or not ISO Guide 34 and CRM activities are applicable to your institute. Detail the relevant points and changes during the past 4/5 years. Explain how differences between ISO Guide 34 and ISO/IEC 17025 requirements are dealt with.
In the case where specific activities related to CRMs (e.g. production) are subcontracted, indicate how the quality is assured and how the subcontractor is evaluated.	To check the fulfillment of ISO Guide 34 requirements in case of subcontracting.	6.2 Subcontracting within ISO Guide 34 Report whether the subcontractor(s) comply(ies) with the relevant ISO Guide 34 requirements and how this is assessed.

Part B: Guideline for oral presentation

During the presentation, the TC- QUALITY members present should be invited to ask as much as possible about 'how' problems related to the implementation of the QMS are dealt with. A real, interactive two-way communication stimulates fast(er) learning from each other.
The oral presentation should be carried out by one person representing all the institute(s) of the country and covering the QMS of all the institutes involved in their countries.

Items to be addressed during the oral presentation:

1. Addressing the national metrology system Addressing the changes in the national metrology system during the past 4/5 years. This should be brief because this item is already covered in the QMS-documentation supplied. Provide a brief summary of the metrology system within the country as a whole in order to provide an overview.
2. Addressing documentation part and ISO/IEC 17025 management and technical Requirements This should be brief with no 'repeat-presentation' of items dealt with in the QMS written documentation, but highlighting 'how' requirements are implemented and interpreted. The presentation should explain the process, especially: o QMS steering mechanisms (people involved, responsibilities, communication processes, role of top management); o continuous improvement (process information); o service to the customer (mechanisms for monitoring customer satisfaction); o implemented improvements during the past 4/5 years with regard to internal audits, management reviews, non-conforming work, complaints and corrective actions.
3. Addressing ISO Guide 34 management and technical requirements (where applicable) This should be brief with no 'repeat-presentation' of items dealt with in the QMS documentation already supplied, but highlighting 'how' requirements are implemented and interpreted and information about the process.
4. Addressing points waiting for implementation
5. Addressing weak and strong points
6. Addressing (solutions found for) problems encountered