Guideline for Initial QMS Presentation

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Introduction

This TC-Quality guideline is applicable for NMIs and Designated institutes who have not yet presented their Quality Management System (QMS) to TC-Quality.

The initial QMS presentation consists of written documentation and an oral presentation. Part A of this guideline contains the requirements for the QMS written documentation, 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.

Timetable

For the complete timetable of the review of initial presentations, please see "Quality Management System review procedure" (G-TCQ-PRC-001).

The electronic version of the initial presentation document shall be sent to the TC-Q secretary at least 4 weeks prior to the TC-Q meeting. Electronic versions of the oral presentation shall be provided to the TC-Q secretary no later than the day of the presentation as planned at the TC-Q meeting agenda.

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Part A: Guideline for written documentation

NMIs who have declared their QMS to be compliant with ISO/IEC 17025:2017 and (where applicable) ISO 17034:2016 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.

Information	Objective	Guidance
Information on the national metrology system.	To provide insight into 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 the centralized or decentralized system (in the case of a decentralized system indicate which institutes are involved and the requirements imposed on these institutes), the national metrology legislation and the procedure for designation of institutes within the CIPM MRA[1]. The role of the institute in the respective NMS should be highlighted.
The quality policies and objectives. Detailed organogram of the NMI. QMS processes and steering mechanisms in the organization (e.g. communication processes, role of NMI management, people/functions involved, policies). Current accreditations.	To identify the responsibilities and to obtain evidence of competence, impartiality and consistent operation of the NMI and a well implemented QMS supported by the NMI management.	**Chapter 2: Presentation of the QMS** 2.1 Quality policies and 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 about role of management). 2.4. Current accreditations (if applicable).

[1] CIPM-MRA-D-06 Designated Institutes participating in the CIPM MRA (https://www.bipm.org/utils/common/documents/CIPM-MRA/CIPM-MRA-D-06.pdf)

Information	Objective	Guidance
Detailed table of documents (including revision dates)	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
Comprehensive list of general, administrative and technical procedures, including their reference, title and date.	To obtain a reasonable knowledge of the real development of the QMS.	3.2 List of general and administrative procedures 3.3 List of technical procedures
Table of cross-references: ISO/IEC 17025 versus the documentation of the management system.	To check the implementation of ISO/IEC 17025 standard.	3.4 Table of cross-references (The template proposed in document G-TCQ-TMP-004-Table_of_cross_references_17025).
List of calibration capabilities covered by the QMS (also including reference materials produced by the laboratory, where applicable).	To check the coherence between the QMS and services offered. Evidence that CMCs are covered by the QMS.	**Chapter 4: QMS and calibration measurement capabilities covered by QMS** Declare whether all the services corresponding to the CMCs 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. Information about number of certificates per year issued for each field.
QMS procedure(s) of improvement. Provide information about the way improvement is achieved.	To obtain information about the activity of the QMS.	**Chapter 5: QMS life** 5.1 Improvement Information about the improvements implemented and the way improvement is achieved.

Information	Objective	Guidance
QMS Procedure to seek and analyze customer feedback. Describe how customer feedback is analyzed and used to improve the management system, laboratory activities and customer services. Provide this information for the past 3 years, including the current year (if possible).	To obtain information about the activity of the QMS.	5.2 Service to the customer (monitoring of positive and negative feedback and consecutive measures) Summarize the results of the customer feedback analysis and provide a summary of its use to improve the management system, laboratory activities and customer services, in case such improvements have been necessary. Note: Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.
Number of customer complaints per year (including complaints related to reference materials where applicable) and the way they are processed. Provide this information for the past 3 years, including the current year (if possible).	To obtain information about the activity of the QMS.	5.3 Complaints Indicate the number of customer complaints per year, explain briefly what they were about (using broad and descriptive categories) and indicate how complaints are dealt with in order to ensure that they are resolved. Also indicate the approximate number of calibration certificates issued per year (in order to establish the relation between number of complaints, non-conformities etc. and the number of certificates).

Information	Objective	Guidance
Number of non-conformities per year (including non-conforming work related to reference materials where applicable) and the way they are processed. Provide this information for the past 3 years, including the current year (if possible).	To obtain information about the activity of the QMS.	5.4 Non-conforming work Indicate the number of non-conformities, explain briefly what they are about (using broad and descriptive categories) and indicate how corrective actions are followed up in order to ensure their effectiveness.
Internal audits (including ISO 17034 audits where applicable): number, dates, activity and people involved, including number of non-conformities per audit. Indicate whether non-conformities have been resolved or not. Provide this information for the past 3 years (if possible).	To obtain information about the activity of the QMS.	5.5 Internal audits Provide information about the dates of internal audits, the activity (scope of the audit), the functions and names of people involved, the number of non-conformities per audit and indicate whether the non-conformities have been resolved or not. In case of internal audit with an external expert, please report it in this section including the affiliations and expertise of an external expert.
External audits (including ISO 17034 audits where applicable): number, dates, activity and people involved, including number of non-conformities per audit. Indicate whether non-conformities have been resolved or not.	To obtain information about the activity of the QMS.	5.6 External Reviews Provide a table showing the dates of external audits (peer reviews and accreditations), the activities (scope of the audit), the functions, names of people involved and affiliations, the number of non-conformities per audit and indicate whether the non-conformities have been resolved or not.

Information	Objective	Guidance
Management reviews (including reviews related to ISO 17034 where applicable): date(s), people attending, contents and summary of the outcome. Provide this information for the past 3 years (if possible).	To obtain information about the activity of the QMS.	5.7 Management reviews Report general information about the management review(s), provide date(s), people attending, contents and a short summary of the outcome.
Information about the relevant changes made in the QMS and QMS documentation in order to comply with the requirements of ISO 17034.	To check the implementation of the requirements of ISO 17034.	**Chapter 6: Further information on ISO 17034 implementation for reference materials (RMs)** (where applicable) 6.1 Implementation of ISO 17034 requirements. Explain how differences between ISO 17034 and ISO/IEC 17025 requirements are dealt with.
List of general and technical procedures concerning the production of RMs (including approval and revision dates).	To obtain a reasonable knowledge of the real development of the QMS related to ISO 17034.	6.2 List of general and administrative procedures (if considered to be necessary to fulfil additional requirements of ISO 17034 and if applicable) 6.3 List of technical procedures required to fulfil additional requirements of ISO 17034 (if applicable)
Table of cross-references: ISO 17034 versus the documentation of the management system.	To check the implementation of ISO 17034 standard.	6.4 Table of cross-references for ISO 17034 requirements (if applicable) (The template proposed in document G-TCQ-TMP-005-Table_of_cross_references_17034).

Information	Objective	Guidance
In the case where specific activities (e.g. production) are subcontracted, indicate how the quality is assured and how the subcontractor is evaluated.	To check the fulfillment of ISO 17034 requirements related to subcontracting.	6.5 Subcontracting[2] Report whether the subcontractor(s) comply(ies) with relevant ISO 17034 requirements and how this is assessed.

[2] CIPM 2005-09 Subcontracting of measurements under the CIPM MRA (https://www.bipm.org/utils/common/documents/CIPM-MRA/CIPM-MRA-Subcontracting.pdf)

Part B: Guideline for oral presentation

The presentation should concentrate as much as possible on 'how' problems related to the implementation of the QMS are dealt with.

In the case of 'decentralized systems' (when two or more institutes in a country are responsible for maintaining national measurement standards), the representative(s) of the individual institutes shall carry out the oral presentation (see the QMS review procedure G-TCQ-PRC-001 point 5.2.). Items to be addressed during the oral presentation:

1. Addressing the national metrology system This should be brief, because this item is already covered in the QMS written documentation, however it should set the scene and provide an overview to set the rest of the presentation in context. Especially, the role of the institute in dissemination of traceability on national level shall be clarified.
2. Addressing documentation part and ISO/IEC 17025:2017 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: • QMS steering mechanisms *(people involved, responsibilities, communication processes, role of management)*; • improvement *(process information)*; • service to the customer *(mechanisms for monitoring customer satisfaction)*; • information about non-conforming work and complaints (especially with regard to the way they are processed); • information about internal audits; • information about external reviews • information about management reviews.
3. Addressing ISO 17034 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, together with information about the process.
4. **Addressing (solutions found for) risks, opportunities, planned and implemented actions with respect to them for improvement** Addressing e.g. the identified risks, related opportunities for improvement.