Introduction

This TC-Quality guideline is applicable for NMIs and Designated institutes 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.

Timetable

The complete timetable of the review of QMS re-evaluation presentation is presented in "Quality Management System review procedure" (G-TCQ-PRC-001).

The electronic version of the re-evaluation 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.

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.
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/Dis and NMIs/DIs 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 centralised or decentralized system (in the case of a decentralised system, indicate which institutes are involved and the requirements imposed on these institutes), e.g. 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.
In the case where changes have been implemented since the initial QMS presentation, these changes must be reported with regard to the following topics: Detailed organogram of the NMI/DI. QMS processes and steering mechanisms in the organisation (e.g. communication	To identify the changes with regard to responsibilities and to obtain evidence of competence, impartiality and consistent operation of the NMI/DI and a well implemented QMS supported by the NMI/DI management.	**Chapter 2: Presentation of the QMS** 2.1 Quality policies and objectives. 2.2 Structure of NMI/DI (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).

[1] https://www1.bipm.org/documents/20126/43742162/CIPM-MRA-P-13.pdf

Information	Objective	Guidance
processes, role of NMI/DI management, people/functions involved, policies). Current accreditations		2.4. Current accreditations (if applicable).
Detailed table of contents of the quality manual or QMS-document structure (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 or QMS-document structure
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, including their reference, title and date.	To obtain a reasonable knowledge of the real development of the QMS.	3.3 List of ISO/IEC 17025 / ISO17034 related non-technical procedures (e.g., complaints, non-conforming work, subcontracting etc.) (Partly accredited or fully accredited NMIs/DIs do not have to provide this information). 3.4 List of technical procedures (information is not expected from NMIs/DIs for accredited fields if the scope of these accredited fields has not changed).
Table of cross-references: ISO/IEC 17025 versus the documentation of the management system.	To check the implementation of ISO/IEC 17025.	3.5 Table of cross-references

Information	Objective	Guidance
		(The template proposed in document G-TCQ-TMP-004-Table_of_cross_references_17025 may be used). (Information shall not be provided by partly accredited or fully accredited NMIs/DIs).
Information about fields and subfields in which the NMI/DI is providing CMCs.	To check the coherence between the QMS and services offered. Evidence that CMCs are covered by the QMS.	**<u>Chapter 4:</u> QMS and covered calibration measurement capabilities** Declare whether all the services corresponding to the CMCs approved by the EURAMET Technical Committees or still under review, 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. Total number of certificates per year.
QMS procedure(s) for improvement. Provide information about the way improvement is achieved. Indicate what improvements have been made during the past 4/5 years with regard to the continuous improvement procedure.	To obtain information about the improvement of the QMS.	**<u>Chapter 5:</u> QMS life** 5.1 Improvement Report about implemented improvements with regard to the way improvement is achieved.
Indicate what improvements have been made during the past 4/5 years with	To obtain information about the improvement of the QMS.	5.2 Service to the customer (monitoring of positive and negative feedback and consecutive measures)

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regard to the service to the customer procedure		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, etc.
Number of customer complaints per year (including complaints related to production of reference materials where applicable) and the way they are processed.	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).
Number of non-conformities per year (including non-conforming work related to production of reference materials where applicable) and the way they are processed.	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	To obtain information about the activity of the QMS.	5.5 Internal audits Provide information about number of internal audits, the activities (scope of the audits using broad and descriptive

Information	Objective	Guidance
number of non-conformities per audit. Indicate whether non-conformities have been resolved or not.		categories), required qualification 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 (peer review), please report it in this section including the affiliations and expertise of an external expert. Please report also the metrological field and if the audit was done on site or remotely.
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 (metrological field of the audit), the functions, names and required qualification of people involved and affiliations, the number of non-conformities per audit and indicate whether the non-conformities have been resolved or not. Please report also if the peer review was done on site or remotely.
Management reviews (including reviews related to ISO 17034 where applicable): date(s), people attending, contents and summary of the outcome.	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	Objective	Guidance
Information about the relevant changes made in the QMS and QMS documentation during the past 4/5 years related to RMs and ISO 17034.	To obtain information about the implementation of the requirements ISO 17034.	**<u>Chapter 6:</u> 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. Include a statement as to whether or not ISO 17034 and RM production activities are applicable to your institute. Detail the relevant points and changes during the past 4/5 years.
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 may be used).
In the case where specific activities related to RMs (e.g. production) are subcontracted, indicate how the quality is assured and how the subcontractor provider is evaluated.	To check the fulfillment of ISO 17034 requirements related to subcontracting.	6.5 Subcontracting within ISO 17034 Report whether the subcontractor(s) comply(ies) with the relevant ISO 17034 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.

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 as stated in the "Quality Management System review procedure" (G-TCQ-PRC-001).

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 summary of the metrology system within the country as a whole in order to provide an overview.
2. Addressing documentation part and ISO/IEC 17025:2017 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 NMI/DI management) • implemented improvements during the past 4/5 years with regard to continuous improvement (process information), internal audits, onsite visits by peers, management reviews, service to the customer, non-conforming work, complaints and corrective actions
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 and information about the process.
4. Addressing (solutions found for) risks, opportunities, planned and implemented actions with respect to them for improvement, e.g., addressing the identified risks, related opportunities for improvement.

Related Documents

G-TCQ-PRC-001	Quality Management System review procedure
G-TCQ-TMP-004	Table of cross references 17025
G-TCQ-TMP-005	Table of cross references 17034
CIPM MRA-P-13	Participation in the CIPM MRA: National Metrology Institutes, Designated Institutes, International organizations