

	Annex B to the COOMET Recommendation COOMET R/AQ/9:2019 "Recommendations on the evaluation of quality management systems of National metrology institutes/Designated institutes" (Annex 3) COOMET R/AQ/13:2019 "Rules and Procedure for the evaluation of the quality management systems of National metrology institutes/Designated institutes"	
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RECOMMENDATIONS

on preparing a written presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes/Designated Institutes (NMIs/DIs)

Introduction

These guidelines are to provide guidance on preparing written (printed) presentations of quality management system (QMS) of NMI/DIs to COOMET Quality Forum.

The document uses the following basic abbreviations:

NMI/DI – National metrology institute/ Designated institute

KCDB – key comparison database

COOMET – Euro-Asian cooperation of national metrological institutions

CIPM - International Committee for Weights and Measures

RM – reference materials

Normative References

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

ISO 17034 General requirements for the competence of reference material producers

General

Presentation shall be given in the form of a written (printed) report.

The presentation should contain information on the activities of the NMI/DI in respect of which it complies with ISO/IEC 17025 (ISO 17034) (hereinafter – the main activity).

The NMI shall declare compliance with ISO/IEC 17025 (ISO 17034 if the NMI/DI is a manufacturer of reference materials) (hereinafter the standard) for activities for the purposes of CIPM MRA.

The presentation should contain information about activities that ensure compliance with the requirements of the standard. The presentation should contain information about the QMS of NMI/DI at the moment and the changes that have occurred since the previous presentation.

Information on the construction, content and presentation presented in this document is advisory in nature and can be expanded and supplemented.

Section 1: Structure of the NMI/DI

1.1. General information

The following data should be presented:

- number of employees inclusive of permanent workers, part-time and temporary contract workers etc.;
- total financing of the NMI/DI including state budget finances, contractual finances, grants etc.;

- number of calibration certificates issued in the last year.

1.2. Policy of Quality

It is advisable to indicate which section of the Quality Manual describes the quality policy of the institute.

1.3. Structure of the NMI/DI

It is recommended that the location of the NMI/DI (city) be indicated, as well as the resources that support the core activities: staff, facilities, equipment, systems and support services needed to manage and carry out the core activities.

The organizational structure of the NMI/DI should be presented in the Annex.

1.4. Structure of the quality management system

1.4.1. Organization and responsibilities

It should be enough to mention, that the guarantee of an efficient implementation within the NMI/DI is the organizational structure of the QMS as shown in the annex. The main characteristics of this organization could be described in terms of the following areas.

1.4.1.1. Management

It is recommended to describe functions of the top management of the NMI/DI. In case of accumulation of multiple functions, those functions should be referred to together with the executive document pursuant to which they are accumulated.

1.4.1.2. Technical departments (laboratories)

It is advisable to state the number of technical departments and laboratories and to whom from the top management they are subordinated and to divide the technical departments (laboratories) according to the types of measurements they perform, e.g. mass, length, electricity etc. If applicable, other metrological divisions should be mentioned as well, e.g. metrology department, testing department, division for fundamental and scientific metrology.

1.4.1.3. Coding of working divisions

Where laboratories and departments are given identification codes, e.g. using numeric or letter coding, it is advisable to explain the principle of coding.

1.4.1.4. Special working groups

In certain cases special working groups may be created to establish QMS documents, various normative documents on calibration and test procedures. Working groups created may correspond to specific areas, e.g.:

- revision of the quality manual,
- basic normative documents,
- calibration procedures,
- internal audit,
- training of personnel,
- uncertainty,
- equipment,
- risks.

1.4.2. Description of main provisions on management of the NMI/DI

Rights and obligations of the management of the NMI/DI should be described as follows:

- director
- deputy directors
- deputy director for quality (where included in the structure of the NMI/DI)

It may be reasonable to handle each level separately. Descriptions concerning heads of technical departments and laboratories should be focused mainly on keeping, maintenance and use of national measurement standards and on internal and external interactions.

1.4.3. Functional subordination

In this part of presentation, the enclosed NMI/DI chart may be referred to.

Section 2: Information on development of the quality management system and implementation of the standards

In this section, we recommend that you specify:

- the start date of the implementation of the quality management system;
- development of quality management system (by years),
- information on certification (if any) of the quality management system for compliance with a certain standard,
- plan to upgrade to a new version of a specific standard

2.1 Documentation of the quality management system

2.1.1 Structure of the documents of the quality management system

It is recommended to indicate that the structure of the quality management system documentation includes:

A: Internal documents:

- Quality Manual. It is advisable to make a brief description what the Quality Manual is composed of, what it applies for and how it shall be authorized.

- Special documents of laboratories/testing centres. Only in case they are not included in the Quality Manual. It is highly advisable to clarify what these documents are for.

- Guidance documents. It is advisable to specify which documents of the NMI/DI shall be considered to be guiding ones: documented procedures, internal standards or other documents.

- Technical documentation. Documents on technical activities: working procedures, calibration or tests instructions etc.

- Administrative documents. Managerial orders etc.

- Forms. Only if available as standalone documents.

B: External documents. These are documents that have not been developed by the NMI/DI itself but are required for maintenance of the quality management system (national standards, procedures, Quality Management System standards, laws, technical publications etc.)

C: Quality reports (internal and external)

It is advisable to enclose the documentation structure of the quality management system as an annex.

This structure is usually represented as a triangle with the Quality Manual on the very top and the layers of normative technical documents in descending order of their importance below.

2.2 Management of quality management system documents

In this section it is recommended to specify how the documents of the quality management system are distributed and controlled.

It is important to specify the distribution and control of electronic documents, if any.

It is also necessary to describe the process of managing NMI/DI records.

2.2.1 Contents of the quality Manual

The content of the quality Manual is given, and each section should correspond to a specific section of the standard.

In General, the quality Guide can contain the following main sections:

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 General requirements
 - 4.1 Impartiality
 - 4.2 Confidentiality
- 5 Requirements to the structure
- 6 Requirements to the resources
 - 6.1 General
 - 6.2 Personnel
 - 6.3 Facilities and environmental conditions
 - 6.4 Equipment
 - 6.5 Metrological traceability
 - 6.6 External products and services
- 7 Requirements to the process
 - 7.1 Review of requests, tenders and contracts
 - 7.2 Selection, verification and validation of methods
 - 7.3 Sampling
 - 7.4 Handling of test or calibration items
 - 7.5 Technical records
 - 7.6 Evaluation of measurement uncertainty
 - 7.7 Ensuring the validity of results
 - 7.8 Reporting on results
 - 7.9 Complaints
 - 7.10 Nonconforming work
 - 7.11 Control of data and information management
- 8 Management system requirements
 - 8.1 Management system documentation
 - 8.2 Control of management system documents
 - 8.3 Control of records
 - 8.4 Actions related to risks and opportunities
 - 8.5 Improvement
 - 8.6 Corrective actions
 - 8.7 Internal audits
 - 8.8 Management Review

It is advisable to number sections of the quality Manual identical to sections of the standard.

2.2.2 For NMI/DI that are manufacturers of reference materials additional sections shall be given on technical and production requirements of ISO 17034.

2.2.3 cross-reference table (specify titles)

Together with the written presentation, it is advisable to provide a table of cross-references in the Annex.

Section 3: Quality management system and calibration capabilities of NMI/DI covered by it

3.1 The NMI/DI declares the services it provides and its calibration capabilities (CMC).

It would be reasonable to refer to the corresponding BIPM KCDB Annex containing CMC data of the NMI/DI under consideration.

Preferably all the information should be presented in the form of tables and must be consistent with the data previously submitted to BIPM.

3.2 It is also advisable to mention the following:

- number of primary standards and corresponding types of measurements;
- number of manufactured, certified (tested) references for composition and properties of substances and materials;

3.3 for calibrations:

- total number of calibration certificates inclusive of certificates for foreign customers covered by CMC data, with BIPM and COOMET logos;
- total number of documents issued to certify RMs etc.

3.4 for international cooperation:

- geography of customers applying for calibrations of standards and measuring instruments;
- participation in Consultative Committees of BIPM;
- number of CMCs included in the database of BIPM,
- number of comparisons included in the database of BIPM etc.

Section 4: Functioning of the quality management system

4.1 Management system documentation

This section is recommended to give a brief description of:

- developed and documented policies and tasks that address issues of competence, impartiality, processes, systems, records, etc. related to the implementation of requirements to achieve the objectives of the NMI/DI;
- safeguards to ensure the perception and implementation of these policies and objectives at all organizational levels of the NMI/DI;
- evidence of fulfillment of NMI/DI obligations in relation to the development and implementation of the quality management system, improving its effectiveness;
- procedures that provide access to all personnel involved in the performance of work within the framework of the main activity, to those parts of the documentation of the quality management system and relevant information that are applicable in the area of its responsibility.

4.2 Control of management system documents

It is recommended to give a brief description of document management (internal and external), which are associated with the implementation of the requirements of a certain standard.

It is recommended to give a brief description of the procedures to ensure that:

- the conformity of the document is confirmed by authorized persons prior to their release;
- documents are periodically reviewed and, if necessary, updated;
- status of changes and current version of documents is indicated;
- the current versions of the applicable documents are available in the places of their use and, where necessary, their distribution is controlled;
- documents are uniquely identified;
- appropriate designation is applied to obsolete documents stored in the archive;
- measures are being taken to prevent the unintentional use of outdated documents.

4.3 Control of records

It is recommended to give a brief description of the procedures for maintaining and keeping legible records to demonstrate that NMI/DI meets the requirements of the standard, implements

the measures required to identify, store, protect, back up, archive, issue, determine the retention period and order of destruction, as well as measures to ensure the confidentiality of the information contained in the records.

4.4 Actions related to risks and opportunities

It is advisable to indicate what risks and opportunities associated with the activities of the NMI/DI are taken into account in order to:

- guarantee that the quality management system can achieve the planned results;
- enhance the ability to achieve the goals and objectives of the NMI/DI;
- prevent or reduce undesirable consequences and possible failures in the laboratory;
- ensure the improvement of the quality management system.

It is also recommended to give a brief description of actions to address these risks opportunities, including their effectiveness, taking into account the proportionality of the possible impact on the reliability of the results of work.

4.5 Improvements

It is recommended to give a brief description of the opportunities identified by the NMI/DI for improvement and the actions taken to this end. For example, analysis of procedures, audit results, assessment of qualifications, feedback from customers, etc.

4.6 Corrective actions

It is useful to note what actions NMI/DI provides in case of non-compliance, for example, actions to manage and correct non-compliance, measures regarding the consequences of non-compliance, etc., as well as the procedure for their documentation.

It is recommended to give a brief description of the assessment of measures to eliminate the cause (s) of non-compliance, as well as actions aimed at ensuring that non-compliance does not occur again, for example, analysis of non-compliance, causes of non-compliance, the effectiveness of any corrective actions taken, updating information about risks, making changes to the quality management system.

4.7 Internal audits

It is recommended to give a brief description of the procedure of internal audits in order to obtain information on the compliance of the quality management system with its own requirements of NMI/DI, for example, audit planning, reporting requirements, storage of records, analysis of the results of previous audits, etc.

4.8 Management Review

It is advisable to provide information on which Chapter of the quality Manual and which procedures of the NMI/DI describe the requirements for the analysis of the quality management system by its management. For example, planning the analysis of the quality management system, the initial data for the analysis of quality management.

Initial data for quality management analysis may include:

- changes in external and internal factors essential for NMI/DI;
- achievement of objectives;
- suitability of policies and procedures;
- activities carried out on the results of the previous analysis of the quality management system;
- results of recent internal audits;
- corrective actions;
- external evaluation;
- changes in the scope and types of work or in the nomenclature of the main activity;
- customer and staff feedback data;
- effectiveness of any improvements made;
- sufficiency of resources;
- outcomes of the evaluation of the credibility of the results of the core activities, etc.

It is advisable to give a brief description of the decisions and measures taken by the analysis of the quality management system, for example, the effectiveness of the quality management system and its processes, improvement of the main activities related to the implementation of the standard requirements, provision of the required resources, assessment of the need for changes, etc.

It is advisable to indicate when the annual analysis was conducted, where it was heard, who conducted it (with the names and positions of the inspectors).