

Annex A to the COOMET Recommendation

COOMET R/AQ/9:2019 "Recommendations on the evaluation of quality management systems of National metrology institutes/Designated institutes" (Annex 2)

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 giving an oral presentation at the COOMET Quality Forum of the quality management systems of National metrology institutes/
Designated institutes (NMIs/DIs)

This document applies for National metrology institutes/ Designated institutes (hereinafter referred to as NMI/DI) and provides guidance on preparing an oral presentation of the quality management system (hereinafter referred to as Presentation).

A.1 General

These Guidelines define the order and the procedure of giving an oral presentation of the QMS of an NMI/DI before initial or periodic peer review by COOMET Quality Forum.

Initial and periodic oral presentations shall be arranged in accordance with the schedule of COOMET Quality Forum.

The Presentation shall be given in form of an oral report together with accompanying computer files.

The Presentation shall contain information regarding activities of the NMI/DI, its current QMS and changes thereof that took place since the previous Presentation.

Layout, contents and method of representation described in this Document are facultative and may be extended and supplemented.

A. 2 Initial oral presentation of the QMS

What questions are worth to be dealt with?

At the very beginning of the Presentation one should explain what a specific institute focuses on, what is its place within the national metrological framework, what are the types of measurements it is responsible for and present the organizational chart of the NMI/DI.

A.2.1 Information on the NMI/DI's QMS documentation.

The message should be "brief", free of citations of QMS documentation items; however the main aspects of that documentation should be emphasized.

In this part of presentation, the documentation triangle may be demonstrated again, and the main aspects covered by the documentation may be described in 3 to 4 files.

A.2.2 Information on compliance with managerial and technical requirements according to ISO/IEC 17025.

General requirements include:

- impartiality;
- confidentiality;

Requirements to the structure include:

- management responsibility;
- area of activity;
- organizational structure;
- authorized personnel.

Requirements to the resources include:

- personnel;
- facilities and environmental conditions;
- equipment;
- metrological traceability;
- externally provided products and services.

Requirements to the process include:

- review of requests, tenders and contracts;
- selection, verification and validation of methods;
- sampling;
- handling of test or calibration items;
- technical records;
- evaluation of measurement uncertainty;
- ensuring the validity of results;
- reporting on results;
- complaints;
- nonconforming work;
- control of data and information management.

Management system requirements include:

- management system documentation;
- control of management system documents;
- control of records;
- actions to address risks and opportunities;
- improvement;
- corrective actions:
- internal audits;
- management reviews.
- A.2.3 Requirements of ISO/IEC 17025 that are currently being implemented within NMI/DI (have not been implemented yet).

This information should also be appropriate here due to provisions of Clause A.2.2.

A.2.4 Requirements of ISO 17034 that have not been implemented yet or are just being implemented.

Number of produced reference materials.

A.2.5 Information on trends of development of the quality management system of the NMI/DI. Only a short chronological overview should be appropriate here.

A.2.6 Strong and weak points of the quality management system

Strong points should be increased efficiency of operations, improved organization of work, satisfaction of customers and personnel and wage rise.

Weak points meanwhile should be staff reduction, bureaucracy, increased expenses for administrative and professional activities.

A.2.7 Problems occurring during the implementation of the quality management system and ways to their solution.

A.3 Periodic Oral Presentation

Information about activities of the NMI/DI

A.3.1 Information about the change of the NMI/DI activities

- A.3.1.1 position of the NMI/DI within the national metrological framework, types of measurements it is responsible for;
 - A.3.1.2 functions of the institute in the field of metrology, e.g.:
 - developing, researching, establishing, keeping, maintaining and comparing national measurement standards;
 - assuring traceability of measurement standards to international standards and national standards of other countries;
 - calibration of measuring instruments;
 - developing normative, methodical and organizational documents to provide uniformity of measurements;
 - developing and certifying measurement procedures; performing metrological work within international and regional organizations and in the course of bilateral cooperation;
 - holding metrological technical committees and secretariats;
 - developing concepts, metrological working programmes etc.

A.3.1.3 Personal:

- total number of employees of the NMI/DI, including personnel responsible for calibration, manufacturing of reference materials (RMs), in the event that NMI/DI performs this types of work;
- number of employees having higher academic degree (doctors, candidates of science etc.);
- mean age of employees;
- number of employees under the age of 33 etc.
- A.3.1.4 Organizational structure of the NMI/DI with indication of units involved in calibration and manufacturing of RMs.
- A.3.1.5 Facilities: accommodation of the NMI/DI, its total area, including areas associated with calibrations etc.
- A.3.1.6. Measurement standards: number of primary and secondary standards, total and for different types of measurements etc.
- A.3.1.7 Reference materials: number of manufactured and certified references of composition or properties of substances and materials.

A.3.1.8 Documents issued by the NMI/DI for metrological works:

- 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.

A.3.1.9 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.

A.3.2 Quality Management System

A description of the QMS should include an overview of NMI/DI QMS (ISO 9001, a.o.), QMS for calibrations (ISO/IEC 17025) and QMS for RMs (ISO 17034), dynamics of QMS, range of problems and prospective development of QMS.

A.3.2.1 The overview of the NMI/DI QMS shall cover basic QMS issues:

- quality policy;
- organizational structure of QMS;
- hierarchy of QMS documents.

A.3.2.2 Quality Manual of the NMI/DI

- list of national QMS regulations that are harmonized with relevant international documents (only basic ones should be mentioned);
- QMS procedures developed in the period under review;
- training of personnel: advanced training courses, practical studies etc.;
- internal and external audits: programs, schedules, reports etc.;
- complaints;
- corrective actions;
- list of criteria for evaluation of activities in the field of the quality of calibration works.

A.3.2.3 Quality Manual for reference materials (if necessary)

- procedure for developing and approving RMs;
- procedure for processing RMs purchase applications;
- procedure for internal audits of the QMS.

A.3.2.4 Evolution of the QMS for each year within the period under review:

- changes in quantity of CMCs registered in the database of BIPM;
- evolution in developing calibration procedures;
- evolution in developing and manufacturing RMs, if applicable;
- evolution in training calibration specialists;
- dynamics of audits and changes in the number of nonconformities identified;
- implementation of requirements of ISO/IEC 17025 regarding continual improvement of effectiveness of the QMS.

A.3.2.5 Problems of the QMS.

A.3.2.6 Prospective development of the QMS