

	Annex 4 to the COOMET Recommendation COOMET R/AQ/9:2019 "Recommendations on the evaluation of quality management systems of National metrology institutes/Designated institutes"	
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REGULATION FOR AUDITORS ON A PEER REVIEW OF THE QUALITY MANAGEMENT SYSTEMS OF NATIONAL METROLOGY INSTITUTES/ DESIGNATED INSTITUTES

1. SCOPE

This document specifies requirements for auditors on a peer review of a quality management system of NMIs/DIs as well as their rights, duties and responsibility.

2. NORMATIVE REFERENCES

This document was developed taking into consideration:

ISO 9000, Quality management systems - Fundamentals and vocabulary.

ISO 9001, Quality management systems – Requirements.

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

ISO 17034 General requirements for the competence of reference material producers

ISO 19011, Guidelines for auditing management systems.

CIPM/2007-25 – Recommendation for on-site visits by peers and selection criteria for on-site visit peer reviewers.

3. TERMS AND DEFINITIONS

Terms and definitions used in this Regulation conform to ISO 9000:2015 along with:

Auditor - a person competent for carrying out audit of QMS of NMI/DI.

4. GENERAL PROVISIONS

4.1 Only auditors who have been approved within the framework of the COOMET Quality Forum and have undergone through special training are permitted to conduct a peer review of QMS of NMI/DI.

4.2 Auditors may be specialists of NMI/DI whose qualifications and personal data comply with paragraph 5 of this Regulation.

4.3 The document certifying the competence of the auditor is a certificate issued in accordance with the established procedure.

5. CRITERIA FOR THE SELECTION OF AUDITORS

5.1. General Requirements to Auditors

The selection of auditors is based on the principles of ISO 19011: 2017.

The requirements of this section are mandatory for auditors and are used to select specialists conducting a peer review of QMS of NMI/DI.

COOMET Quality Forum must ensure that the auditors have the necessary experience and are suitably qualified and independent.

5.2. Qualification

The selected candidate nominated as an auditor should normally have a full higher education in the field close to the activity where he performs the peer review.

Candidate before approval from COOMET Quality Forum demonstrate the ability to express his / her ideas and concepts in the quality provision part in the field of calibration and measurement verbally and in written form at least in one of the COOMET working languages (English or Russian).

The candidate appointed as an auditor must be able to demonstrate his/her knowledge and abilities to manage the skills required to perform a peer review in accordance with the recommendations and ISO 19011.

5.3. Independence

The candidate nominated as an auditor must be independent from the NMI/DI which QMS is subject to a peer review as well as from parties interested in the results of the peer review.

5.4. Training

Candidate nominated as an auditor on a peer review of QMS of NMI/DI shall go through a training (educational institutions, seminars, etc.) and relevant test of its results.

The auditor shall know and understand:

- International standards ISO 9001, ISO/IEC 17025;
- If the peer review covers the production of reference materials then the auditor shall have additionally sufficient knowledge and experience with the requirements of ISO 17034;
- International and national metrological rules and norms, methods of calibration and measurements realization;
- Procedure and methods of work performance in the process of an audit (peer review, interview skills, researches, report preparation);
- Competence in these matters shall be demonstrated by means of verbal or written exams or other methods.

5.5. Work experience

Candidates nominated as auditors must have sufficient practical experience of work in NMI/DI and at least two year experience in quality management, quality assurance or QMS auditing related to laboratory activities at the NMI/DI level.

The candidate shall gain experience of conducting a peer review of QMS of NMI/DI by means of participation in at least 3 such peer reviews including analysis of documentation, activity on calibration and report preparation. At the same time, one of such assessments may be an assessment of the NMI/DI with a positive result of trust, in which he participated as the organizer and/or responsible person for the results of this assessment.

An auditor shall permanently maintain his level of competence and develop it by means of:

- Training at advanced development courses;
- Independently upgrade level of his/her professional knowledge;
- Participation in seminars and conferences on issues of quality management;
- Regular participation in peer reviews.

5.6. Personal skills

Candidate nominated as an auditor shall have skill of analysis, ability to apprehend the situation as it is, take the right decision in complex situations, express his/her thoughts verbally and in a written form, be regardful, make up his/her communication based on full mutual respect.

6. RESPONSIBILITIES OF AUDITORS

The responsibilities of auditors include:

- Conducting evaluation of the documentation submitted by the applicant for a peer review of the QMS;
- Performing a functional QMS peer review;
- Compliance with professional courtesy norms and Code of conduct for auditors;
- Orderly and safe processing of documents;
- Ensuring the confidentiality of data obtained;
- Objectivity and impartiality while conducting a peer review of QMS.

7. RIGHTS OF AUDITORS

An auditor has the right to:

- Inquire the data needed to conduct a peer review of QMS from the applicant NMI/DI;
- Apply to the Chairperson of COOMET Quality Forum in case of being under pressure from the interested parties;
- Submit a proposal to the Chairperson of COOMET Quality Forum on improvement of NMI/DI QMS peer review procedures and organization of work.

8. FORMATION OF DATA ON AUDITORS

The COOMET Quality Forum files data containing information on auditors.

9. THE LANGUAGE OF PEER REVIEW

The peer reviews are conducted in COOMET official languages.

10. CODE OF CONDUCT FOR AUDITORS

- Shall perform the trusted duty in a fair and impartial manner;
- Shall not compromise the reputation of COOMET Quality Forum, the auditor and the applicant NMI/DI;
- Shall not disclose to the third party the results of his/her activity or data received in the process of a peer review of QMS, except for cases when a relevant written permission from NMI/DI is obtained;
- Shall not accept direct or indirect rewards from applicant NMI/DI or other persons related to the NMI/DI.
- Shall express his/her opinion as auditor's based only on full confidence of the opinion's accuracy and reliability;
- Shall avoid outbreak of any conflict situation in all the cases and adhere ethics while performing the work;
- Shall keep confidentiality of data received in the process of performing the work;
- Respect the national traditions of the country where a peer review is carried out.