

EURO-ASIAN COOPERATION
OF NATIONAL
METROLOGICAL INSTITUTIONS

COOMET



ЕВРО-АЗИАТСКОЕ СОТРУДНИЧЕСТВО
ГОСУДАРСТВЕННЫХ
МЕТРОЛОГИЧЕСКИХ УЧРЕЖДЕНИЙ

КООМЕТ

RECOMMENDATION

Procedure for the Assessment of Quality Management Systems in National Metrology Institutes

Astana, 2008

The present Recommendation determines the procedure for the assessment of quality management systems in National Metrology Institutes (NMI) of COOMET Member states by for the purpose of realizing the Mutual Recognition Arrangement for National Measurement Standards and of Calibration and Measurement Certificates issued by National Metrology Institutes (MRA).

The NMI Quality Measurement System (QMS) assessment is made by auditors and technical experts the COOMET QS-Forum.

Before realization of an assessment of quality management systems by auditors and technical experts the COOMET QS-Forum NMI represents to QS-Forum Technical Committee written and conference presentations NMI QMS then the QS-Forum Technical Committee makes a decision on readiness NMI for realization external audit.

Written and conference presentation

Written and conference presentations of the NMI QMS are made in accordance with the time schedule of the COOMET QS-Forum.

It is recommended, in order to prepare the conference presentation the NMI QMS, to use the procedural document of COOMET: “Recommendations for conference presentations at the COOMET QS-Forum of the Quality Management System in National Metrology Institutes (NMI QMS)”.

One month before the conference presentation, the NMI presenting its Quality Management System to the COOMET QS-Forum spreads the written presentation among the QS-Forum Technical Committee members of the COOMET. It is recommended, in order to prepare the written presentation of the MNI QMS, to use the procedural document of COOMET: “Recommendations for preparing the presentations the Quality Management System in National Metrology Institutes (NMI QMS)”.

If the members of the Technical Committee have no objections to the presented document, the Secretariat of the COOMET QS-Forum includes the conference presentation the submitted NMI QMS in the Agenda of the COOMET QS-Forum session.

The NMI submitting its QMS to the COOMET QS-Forum for the conference presentation prepares handouts of the presentation materials for each member of the Technical Committee.

After realization of conference presentation, the COOMET QS-Forum Technical Committee makes a decision QS-Forum Technical Committee on readiness NMI for realization of external audit NMI QMS about what enters the name in the protocol of session TC QF COOMET.

NMI Quality Measurement System Assessment by the auditors and technical experts of the COOMET QS-Forum

The NMI Quality Measurement System assessment will be carried out after realization of written and conference presentations is direct in National Metrology Institutes on the corresponding application for external audit, by the COOMET QS-Forum at the National Metrology Institute (Appendix 1) and in accordance with the time schedule approved by the COOMET QS-Forum (Appendix 2).

The assessment is made by auditors and technical experts authorized by the COOMET QS-Forum.

The auditor and technical experts for the assessment of the QMS of a specific NMI is notified by the Chairman of the COOMET QS-Forum Technical Committee.

The notified auditor and technical experts must be a citizens of a country other than the country of the inspected NMI.

When choosing technical experts for the NMI QMS assessment it is recommended to be guided by the field of activity of the given NMI, by the submitted CMC tables and by the technical competence of the expert, as well as by economical reasons.

When choosing technical experts for the NMI QMS assessment it is recommended to use the document of The Joint Committee of Regional Metrology Organizations and BIPM (JCRB) "Recommendations for Selection Criteria for Peers Conducting On-site Visits and Guide to the Need for On-site Visits" (Appendix 3)

The COOMET QS-Forum Technical Committee Chairman informs the NMI about the forthcoming inspection and about the personal content of the technical experts group. The NMI has a right to turn down the nominated auditors and technical experts if the reasons are sufficiently.

When making the assessment, the auditors and technical experts must follow the COOMET document "Recommendations for the assessment of the Quality Management Systems in National Metrology Institutes". Auditors and technical experts at realization of an assessment also should observe confidentiality concerning data checked NMI.

The NMI to be inspected must send to the COOMET QS-Forum Technical Committee the following documents one month prior to the scheduled date:

- § Application for the external assessment of the QMS (Appendix 3);
- § Quality Manual;
- § Effectiveness analysis of the QMS made by the top management for the last year;
- § List of documents on the uncertainty calculation;
- § Procedures of calibration (methods of calibration) demonstrating the calculation of the budget of uncertainty on all prospective CMC-tables. In case of the same

documents (for example, on various ranges of measurements) representation or 1-2 documents is supposed at the applicant's choice.

The documents are prepared in Russian (if necessary, their English translation may be attached).

The National Metrology Institute presenting its QMS for the assessment must provide complete information about its QMS at the place of assessment, as well as its complete QMS documents. Internal QMS documents of the NMI may be in the language of the applicant's country.

The technical experts while realizing the assessment may demand from the NMI to realize a specific metrological procedure ensuring the traceability from the measurement standards recognized by the BIPM.

The work related to the assessment is made at the expense of the applicant. The duration of the assessment must not exceed three days not including the time necessary for experts' journey.

The assessment is made in accordance with Assessment Schedule (see Appendix 4).

All nonconformities that will be revealed by the experts during the QMS assessment are to be recorded in special Protocols (Appendix 5). Specific nonconformity with references to the corresponding article of Standard ISO/IEC 17025 and ISO Guide 34 (in case of reference materials) and opinion of the applicant on this nonconformity must be recorded in these Protocols.

Each technical expert must prepare the report on the results during the assessment (Appendix 6) and transmit it to the auditor.

The report must contain the detailed description of the following points:

- § Compliance with what items of the Standard ISO/IEC 17025 and ISO Guide 34 (in case of reference materials) was assessed by the given expert.
- § What subdivisions of the NMI he assessed.
- § If any metrological inspections were made, it is necessary to specify them along with the results of measurement.
- § What incompliance was found and what proposals for their elimination were made.
- § Proposals as to the possibility to approve (disapprove) the NMI QMS.

In addition, the technical expert may give in written recommendations for improving the NMI QMS.

The auditor on the basis of the technical experts' reports draws up the report on the external assessment (Appendix 7) and sends to the inspected NMI and to the COOMET QS-Forum Technical Committee. This report should be attached by corresponding technical experts reports.

The NMI sends its action plan within one month after receipt and study of report to the COOMET QS-Forum Technical Committee for the elimination of nonconformities.

The COOMET QS-Forum Technical Committee gives a decision about the NMI QMS assessment results and presents it to the COOMET QS-Forum for

consideration. Voting on the assessment results is to be processed on the COOMET QS-Forum Technical Committee meeting.

The COOMET QS-Forum, upon receipt of positive results of the NMI QMS assessment, presents to the NMI the COOMET Confirmation of NMI QMS Recognition (Appendix 8). The Confirmation is valid for maximum 5 years.

The Confirmation may be withdrawn if the measures specified in the action plan have not been taken in due time. The QS-Forum Technical Committee may temporarily withdraw the validity of the COOMET Confirmation until the QMS-Forum decision. He presents corresponding information to the NMI Manager. Action of the certificate renews after representation and consideration TC QF of the data about discrepancies. In proved cases TC QF COOMET the decision on cancellation of the on a recognition, on what is corresponding information to the NMI Manager. In case of cancellation of the certificate on recognition procedure of recognition renews in full.

NMI annually not later March presents to the QS-Forum Technical Committee an annual report (Appendix 9) about QMS stay and acting. In case of changes in QMS NMI also presents the notice of changes.

The secretary of Technical committee directs annual report NMI to two members TC QF on consideration. Members TC QF within two weeks consider them and direct the conclusion to Secretary TC QF and NMI. Secretary TC QF COOMET conducts monitoring annual reports NMI COOMET (the Appendix 10).

The inspection control

The inspection control is spent behind all QMS NMI, recognized Confirmation TC QS-forum COOMET.

The inspection control can be scheduled (not less often than a once in five years) and off-schedule (in case of significant changes in QMS NMI).

Secretary TC QS-forum COOMET prepares plans of the inspection control over the ending of validity of the certificate on recognition and agrees with NMI terms of their carrying out.

The inspection control is spent by written presentation NMI, external audit under the reduced program approved by Chairman TC QS-forum, and conference presentation on QS-Forum COOMET (one presentation for all NMI of the countries-members COOMET).

In case of negative results at carrying out of the inspection control the Technical committee has the right to make a decision on stay or cancellation of action of the certificate on recognition.