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|---|--|---------------------------------|
|  | <b>Annex 11 to the COOMET Recommendation</b><br><b>COOMET R/AQ/13:2019 "Rules and Procedure for the evaluation of the quality management systems of National metrology institutes/Designated institutes"</b> |                                 |
|   | Document of COOMET Quality Forum<br>Document code: <b>QSF-doc_003r_anx11</b>   | Pages: 2<br>Version: 28.03.2019 |

## RECOMMENDATIONS FOR THE PREPARATION OF AN ANNUAL REPORT ON THE NMI/DI QMS

### RECOMMENDATIONS for the preparation of an annual report on the quality management system of National metrology institutes/Designated institutes according to the ISO/IEC 17025 /ISO 17034 for CIPM MRA purposes

This recommendation is a supplement to QSF-doc.003r\_anx10 and is intended for the preparation of an annual report of the quality management system of NMI/DI.

The form of the report should comply with QSF-doc.003r\_anx10.

#### Section 0 includes information about the status of CMCs covered by the NMI/DI QMS

*Example of filling in the table of Section 0*

| Fields and relevant COOMET Technical committees |                                    | Is the field covered by the QMS? (Y/N) | Are CMCs Published? (Y/N, number) | Are CMCs in the review stage? (Y/N, number) | Are CMCs in the review stage covered by the QMS? (Y/N) |
|---|------------------------------------|--|-----------------------------------|---|--|
| EM  | TC 1.3 «Electricity and Magnetism» | Y                                      | 5                                 | 2   | Y  |
| L   | TC 1.5 «Length and angle»          | N                                      | N                                 | 1   | N  |
| ...   | ...                                | ...                                    | ...                               | ...   | ...  |
| Total:  |                                    |  | 5 lines                           | 3 lines                                     |  |

The information of the table should demonstrate that all CMCs published or submitted to the review process (being in whatever review stage) are covered by the QMS.

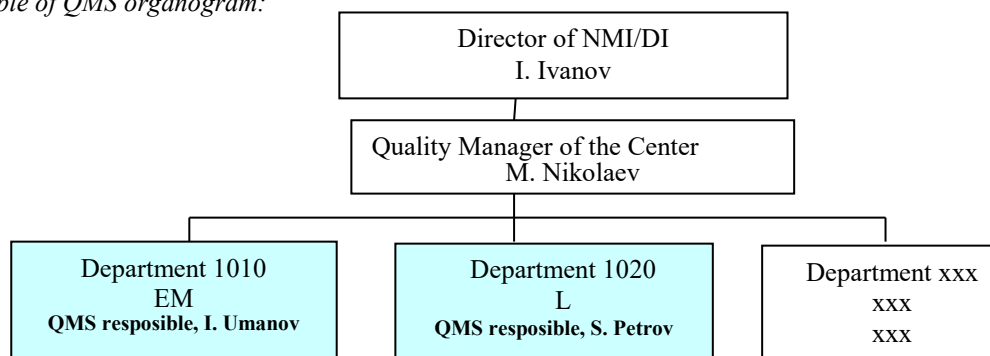
**Section 1** includes changes and supplementations of QMS according to the requirements of ISO/IEC 17025 and/or ISO 17034 to the certified reference materials (CRM).

#### **1.1. Description of the structure including the position of the managing staff of NMI/ DI.**

Changes in the structure and the position of managing staff of NMI/DI should be indicated in "Reporting information". The changes should be set off in another ink. If there are no any changes then a special note should be made.

It is necessary to give the reference to the number of Appendix 1 and the Appendix 1.1 to the present report in the column "Comments". Appendixes 1 and 1.1 should contain the current structure of NMI/DI and QMS organogram showing the position and name of managing staff of NMI, the organization departments of NMI/DI with relevant fields and the position of the quality managing staff. The departments where fields are covered by the QMS should be set off in another ink

Example of QMS organogram:



Comments: 1010 – department .....

## 2. Quality management system (QMS management, processes and technical requirements)

Specific changes put into action should be specified in "Reporting information". If there are no changes then a special note should be made.

QMS documents, which have been changed accordingly, should be specified in "Comments" or there should be a link to Appendix 2 to this report.

## 3. Calibration and measurement capabilities (CMCs)

"Reporting information" should contain a total amount of modified CMC lines and measuring categories by which the new, deleted, modified and/or greyed out CMC data have been published for reporting year. If there are no changes then a special note should be made.

If there are any changes then "Comments" should contain a reference to the number of Appendix 3 of this report which should be arranged as in a table.

Example of filling in the table

| Field of Measurement |                           | CMCs, Number of lines (modified) |         |     |          |            |
|----------------------|---------------------------|----------------------------------|---------|-----|----------|------------|
|                      |                           | Total                            | Deleted | New | Modified | Greyed out |
| L                    | Length                    | 4                                | 1       | 2   | 1        | -          |
| EM                   | Electricity and magnetism | 11                               |         | 4   | 2        | 5          |
| QM/4                 | Gases                     | 7                                | 1       | 6   |          |            |
| ...                  | .....                     | ...                              | ...     | ... | ...      | ...        |
| Total:               |                           | 22                               | 2       | 12  | 3        | 5          |

Comments. If there are new CMCs then there should be a list of calibration documents with titles, identification numbers and dates of approval.

## 4. Comparisons (including the interlaboratory comparisons)

The total amount of carried out comparisons should be specified in "Reporting information" (including interlaboratory comparisons). It is necessary to make an appropriate note of the absence.

Number of comparisons ranged by categories (key, complementary, pilot and other international, national, etc.) should be specified in "Comments".

## 5. Calibration certificates

The total amount of calibration certificates as well as those which have CIPM MRA logo and those ranged by measuring categories should be specified in "Reporting information". If there are no changes then a special note should be made.

## 6. CRM certificates

The total amount of CRM certificates as well as those which have CIPM MRA logo and those ranged by measuring categories should be specified in "Reporting information". If there are no changes then a special note should be made.

## 7. Complaints (claims)

The number of complaints (claims) should be specified in "Reporting information". If there are no changes then a special note should be made. In case of complaints (claims) it is necessary to report the category of complaints or make a reference to Appendix 4 of this report.

## 8. External audits

The number of external audits (peer reviews by COOMET, audits of accreditation body and other governing body) should be specified in "Reporting information". If there are no changes then a special note should be made.

In case of external audits' existence, it is necessary to specify in "Comments" the organization, which carried out the audit or make reference to Appendix 5 of this report and specify technical experts, auditors who are attracted from other Regional Metrological Organization (RMO).

Appendix 5 of this report should be arranged as in a table mentioned below including the type of audit, field of measurement where the audit was carried out, date of the audit, affiliation of auditor and/or technical experts and their qualification.

*Example of filling in the table*

| Identification of the external audit | Date of the external audit | Name of the auditor(s)/technical experts, specialization | Affiliation (NMI, country) | Qualification  |
|--------------------------------------|----------------------------|--|----------------------------|----------------|
| Peer review by COOMET in electricity | 02 – 04 April 2018         | Mr. Ivanov, Electricity                                  | VNIIM, Russia              | Leading expert |

## 9. Internal audits

The number of internal audits (planned and carried out) and the number of departments related to NMI/DI and subjected to internal audits should be specified in "Reporting information".

Paragraphs of ISO/IEC 17025 and ISO 17034 subjected to internal audits should be specified in "Comments".

## 10. Non-conformities

The total number of non-conformities of Section 1, which were detected (internal audits, peer reviews by COOMET, complaints (claims), comparisons including the interlaboratory comparisons, should be specified in "Reporting information". If there are no changes then a special note should be made.

In case of non-conformities they shall be mentioned in "Comments" or a reference shall be made to Appendix 6 of this report where non-conformities are specified.

Appendix 6 of this report is filled as a table to specify paragraphs of ISO/IEC 17025 and/or ISO 17034 with non-conformities, a number of non-conformities and a type of audit during which non-conformities were established.

*Example of filling in the table*

| Paragraphs of ISO/IEC 17025 and/or ISO 17034 | Number of non-conformities | Type of audits        |
|--|----------------------------|-----------------------|
| paragraph 6.2.2 of ISO/IEC 17025             | 1                          | Peer review by COOMET |

## 11. Results of corrective actions

The existence of planned corrective actions according to the discovered nonconformities mentioned in paragraph 10 Section 1 shall be specified in "Reporting information" or a reference shall be made to Appendix 7 of this report. It is necessary to inform in detail about the corrective actions caused by the unacceptable results of key or supplementary comparisons.

## 12. Management review

The date of QMS annual management review should be specified in "Reporting information".

It is necessary to make a reference in "Comments" to Appendix 8 of this report where the structure of the report, assessment of the results of QMS functioning, types of actions which are proposed to improve QMS shall be given.

*Example of filling in the reporting data related to Section 1*

| <i>Title</i>   | <i>Reporting information</i>   | <i>Comments</i>  |
|--|--|--|
| 1. Description of the structure including the position of the managing staff of NMI/DI | A new department SRD-7 is created.<br>Mr. Petrov has been appointed a Deputy director since  | Appendix 1 « NMI/DI structure »<br>Appendix 1.1 «Organogram of NMI/DI QMS »  |
| 2. Quality management system (QMS management, processes and technical requirements)    | Three QMS documents were revised.<br><br>There are no changes.   | Appendix 2 «List of QMS documents» or QM 001-20XX<br>«Quality Manual»,<br>ES XX-20XX « Procedure for QMS documents management»                       |
| 3. Calibration and measurement capabilities (CMCs)                                     | Total - 22 including:<br>Deleted – 2<br>New- 12<br>Modified – 3<br>Greyed out - 5  | Appendix 4. Calibration and measurement capabilities (CMCs)<br>List of calibration methods for new CMCs.<br>List of measurement methods for new CMCs |
| 4. Comparisons (including interlaboratory comparisons)                                 | The total number of carried out comparisons – 5.   | EM - Key –1<br>L – Supplementary - 3<br>QM – Pilot – 1   |
| 5. Calibration certificates  | Total – 5 000, among them those which have CIPM MRA logo – 210, including those to the following measuring categories:<br>30-length<br>80- thermometry<br>25- acoustics<br>35- photometry<br>40- electricity | Please do not include a information about verification certificate in statistics.  |
| 6. CRM certificates  | Total - 2179 among them those which have CIMP MRA logo - 186 to the measuring category "gases".  |  |
| 7. Complaints (claims)   | No   |  |
| 8. External audits   |  | Peer reviews by COOMET<br>Appendix 5   |
| 9. Internal audits   | ISO/IEC 17025:<br>planned - 8<br>carried out - 8<br>checked - 8 departments  | All paragraphs of ISO/IEC 17025  |
|  | ISO 17034:<br>planned - 3<br>carried out - 3   | All paragraphs of ISO 17034  |
| 10. Non-conformities   | ISO/IEC 17025:<br>4 (internal audit);<br>External audit - no   | Appendix 6 «Information about non-conformities»  |
|  | ISO 17034:<br>4 (internal audit)   |  |

| <i>Title</i>                      | <i>Reporting information</i>  | <i>Comments</i>   |
|-----------------------------------|---|---|
| 11. Results of corrective actions | <i>The corrective actions are elaborated according to the detected non-conformities</i> | <i>Elaborated corrective actions were carried out completely.</i> |
| 12. Management review             | XX.XX.20XX  | Appendix 8. «Management review»                                   |

*Comments. In any case the Appendixes should be listed in the order specified in the form (if there is no appendix, it shall not be given).*

**Section 2 – Main problems occurred during the year and/or main improvements.**

**1. Problems (risks) –** what problems arose during the year (it is necessary to consider all paragraphs of ISO/IEC 17025 and ISO 17034).

*Example: while carrying out calibration of measurement standards in NIMs of other countries the calibration certificates did not contain the information about traceability to international SI units.*

**2. Improvements –** it is necessary to declare that the main significant changes aimed at the improvements were fulfilled (it is necessary to consider all paragraphs of ISO/IEC 17025 and ISO 17034).

*Examples:*

*There are changes in the structure – a new measurement laboratory was established.*

*New documents on the procedures of preparing gas mixture were developed and implemented.*

### **Section 3 – Declaration**

The NMI/DI hereby declares that all requirements of the relevant QMS standards were duly fulfilled during the year (the reported period), e.g. internal audits, management reviews etc. These elements are to be reviewed in detail during actions of external auditing on site.

Appendix: (give all the Appendices referred to so far).

Signature of an authorized body with an indication of the position, date.

Contact person (name, surname, phone number, e-mail).