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<b>Annex 11 to the document «Recommendation. The Rules and Procedure for the Evaluation of Quality Management Systems In National Metrology Institutes»</b>		

## RECOMMENDATION for the annual report preparation of Quality Management System of NMI

This recommendation is a supplement to QSF-doc.003r\_anx10 and intended for the annual report preparation of Quality Management System of NMI.

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

### Section 0 includes information about a status of CMCs covered by QMS of NMI.

*Example of fill in the table of Section 0*

Fields and relevant COOMET Technical committees		Field covered by the QMS (Y/N)	CMCs published (number(s))	CMCs in the review stage? (number(s))	CMCs in the review stage covered by the QMS? (Y/N)
EM	TC 1.3 «Electricity and Magnetism»	Y	5 lines	2 lines	Y
L	TC 1.5 «Length and angle»	Y	N	1 line	Y
....	.....				
Total:			5 lines	3 lines	

The information of the table of Section 0 should demonstrate that all CMCs published or submitted to the review process (being in whatever review stage) are covered by the QMS (which means in particular that they have associated technical procedures).

### Part A

Part A includes the requirements of ISO/IEC 17025 as to changes and management of QMS.

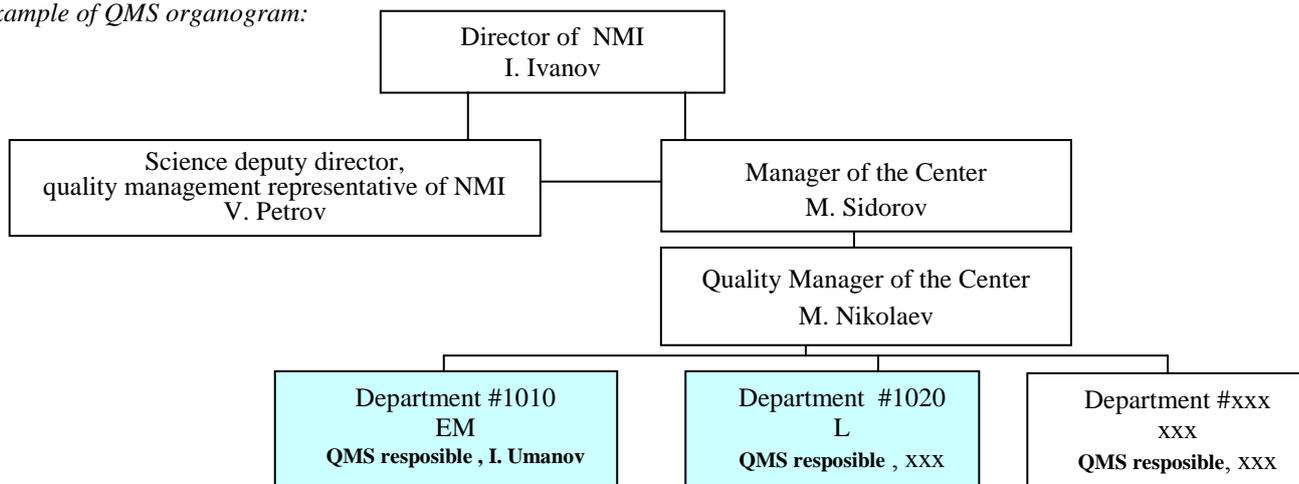
#### Section 1A – Changes and supplementations of QMS.

##### 1. Structure description including the position of managing staff of NMI.

The changes in the structure and the position of managing staff of NMI 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 number of the Appendix 1A and the Appendix 1A.1 to the present report in the column "Comments". Appendixes 1A and 1A.1 should contain the current structure of NMI and QMS organogram showing the position and name of managing staff of NMI, the organization departments of NMI with relevant fields and the position of the quality managing staff.

Example of QMS organogram:



Comments: 1010 – department .....

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

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

QMS documents which have been accordingly changed should be specified in “Comments” or there should be a link to the Appendix 2A 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 any changes then a special note should be made.

If there are any changes then “Comments” should contain a reference to the number of Appendix 3A of this report which should be arranged as in a table mentioned below:

Example of fill in the table of Appendix 3A

Field of Measurement		CMCs, Number of lines				
		Total	Deleted	New	Modified	Greyed out
L	Length	4	1	2	1	-
EM	Electricity and magnetism	11		4	2	5
...	.....	...	...	...	...	...
Итого:		15	1	6	3	5

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

## 4. Comparisons

The total amount of carried out comparisons should be specified in “Reporting information”. 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 ranged by measuring categories should be specified in “Reporting information”. If there are no any changes then a special note should be made.

*Example of fill in of the reporting data related to Section 1A*

<b>Title</b>	<b>Reporting information</b>	<b>Comments</b>
1. Procedure description including the position of the managing staff of NMI.	New department “SRD-7” was set up. Petrov V.P. was appointed as a deputy director of calibration.	Appendix 1A. NMI structure. Appendix 1A.1 QMS organogram.
2. Quality system (QMS management, processes and technical requirements)	Two QMS documents were revised.	QM 001-20XX «Quality Manual», ES XX-20XX «Enterprise’s standard. Management procedure .....» or Appendix 2A
3.CMCs	Total - 15 including: Deleted – 1 New- 6 Modified – 3 Greyed out - 5	Appendix 3A. CMCs
4. Comparisons	24	EM - Key –1 L - Supplementary - 3 QM -Pilot -1
5.Calibration certificates	Total – 5 000 as well as those which have CIPM MRA logo – 210 including to the following measuring categories: 30-length 80- thermometry 25- acoustics 35- photometry 40- electricity	Please ,do not include a type of calibration certificate in statistics

## Section 2A – QMS management

### 1. Customer complaints.

The number of customer complaints should be specified in “Reporting information”. If there are no any changes then a special note should be made.

In case of complaints it is necessary to report the category of complaints or make a reference to Appendix 4A of this report in “Comments”.

### 2 Internal audits.

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

ISO/IEC 17025 points which were detected by internal audits should be specified in Comments”.

### 3 External audits

The number of external audits should be specified in “Reporting information”. If there are no any 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 a reference to Appendix 4A of this report.

Appendix 4A of this report should be arranged as in a table mentioned below including the field of measurement where the audit carried out and the results of audit.

Identification of external audit	Date of audit	Name of auditor(s)	NMI' name, country	Qualification

#### 4 Non-conformities

The number of non-conformities of points 1, 2 and 3 Section 2A which were detected (complaints, results of internal and external audits) and of the results of the interlaboratory comparisons should be specified in “Reporting information”. If there are no any changes then a special note should be made.

In case of non-conformities it is necessary to make a reference in “Comments” or make a reference to Appendix 4A of this report.

#### 5 Results of corrective actions

The existence of planned corrective actions according to discovered nonconformity mentioned in point 4 Section 2A should be specified in “Reporting information” or make a reference to Appendix 6A of this report. It is necessary to inform in detail about the corrective actions caused by the unacceptable results of key or supplementary comparisons..

#### 6 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 7A of this report where should be an assessment of the results of QMS functioning, types of actions which are proposed to improve QMS.

*Example of fill in of the reporting data related to Section 2*

<b>Title</b>	<b>Reporting information</b>	<b>Comments</b>
<i>Customer complaints</i>	<i>no</i>	
<i>Internal audits</i>	<i>Planned – 14 Carried out – 14 Inspected – 7 departments</i>	<i>All points of ISO/IEC 17025</i>
<i>External audits</i>	<i>1</i>	<i>National accreditation body Appendix 4A.</i>
<i>Non-conformities</i>	<i>12</i>	<i>Appendix 5A. Data of detected non-conformities</i>
<i>Results of corrective actions</i>	<i>The corrective actions are elaborated according to the detected non-conformities</i>	<i>Elaborated corrective actions were carried out completely. The corrective actions are effective. Appendix 6A.</i>
<i>Management review</i>	<i>XX.XX.20XX</i>	<i>Appendix 7A.</i>

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

### Section 3A – Main problems occurred during the year and/or main improvements.

**1 Problems** – the type of problems have been arisen during the year (it is necessary to examine all points of ISO/IEC 17015 standard).

*Example: while carrying out the 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 directed to the improvements were fulfilled (it is necessary to examine all points of ISO/IEC 17015).

*Example.*

*New documents of calibration procedure are carried out and implemented in a correct way.*

*There are departments' changes – a new department was established..*

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

Signature of responsible body by indicating the position, date.

Chargeable person (name, surname, phone number, e-mail)

#### **Section 4A – Declaration**

The NMI hereby declares that all the requirements of the relevant QMS standards have been 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 spot.

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

Signature of responsible body by indicating the position, date.

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

#### **Part B.**

Part B includes the requirements of ISO Guide 34 to the certified reference materials (CRMs) - an information of implemented activities.

#### **Section 1B – Development and change of QMS and Quality Manual .**

##### **1. Description of QMS structure including the position of managing staff of NMI.**

The changes in the structure and the position of managing staff of NIMs should be specified in “Reporting information”. The changes should be marked out. If there are no any changes then a special note should be made.

It is necessary in “Comments” to refer to the Appendix number of a current report where the current structure of NMI and also the QMS organogram are given.

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

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

QMS documents which have been accordingly changed should be specified in “Comments”.

### 3. Measurement capabilities (CMCs)

“Reporting information” should contain a total amount of 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 any changes then a special note should be made.

In case of changes “Comments” should contain a reference to the number of Appendix of this report which should be arranged as in a table mentioned below:

*Example of fill in the table of Appendix 2B*

Field of Measurement		CMCs, Number of lines				
		Total	Deleted	New	Modified	Greyed out
L	Length	4	1	2	1	-
EM	Electricity and magnetism	11		4	2	5
...	.....	...	...	...	...	...
Итого:		15	1	6	3	5

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

### 4. Comparisons

The total amount of carried out comparisons should be specified in “Reporting information”. If there are no any changes then a special note should be made.

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

### 5. Certificates (CRM).

The total amount of the certificates should be specified in “Reporting information”. If there are no any changes then a special note should be made.

The number of the certificates covered by CMC data which are ranged by measuring categories should be specified in “Comments”.

*Example of fill in of the reporting data related to Section 1B*

Title	Reporting information	Comments
1. Procedure description including the position of the managing staff of NMI.	Managing staff – not changed QMS responsible persons – there are some changes (see Appendix 1A). QM XXXX-20XX “Production of reference materials of gas mixture. Quality manual” The production of reference materials of gas mixture is performed by department XXXX of NMI.	Appendix 1B. NMI structure, QMS organogram.
2. Quality system (QMS management, processes and technical requirements)	Two QMS documents were revised.	PMC XXX – 2010 « Procedure of measurement carrying-out. Procedure of quantity assessment of molar fraction ..... by the method...», ES XX-20XX « Enterprise’s standard. Procedure of...»

3.CMCs	There is new one line in the CMC data table by the measuring category “gases”.	Appendix 2B. CMCs. Appendix 3B. List of procedures covering the new CMCs.
4. Interlaboratory comparisons	1	Pilot -1(natural gas)
5. Certificates (CRM)	50	Covered by CMC data -2 including to the following measuring categories: 3-gas mixtures
6. Additional information (should be fill in by NMI if necessary)		

## Section 2B – QMS management

### 1 Customer complaints.

The number of customer complaints should be specified in “Reporting information”. If there are no any changes then a special note should be made.

In case of complaints it is necessary to report the category of complaints in “Comments”.

### 2 Internal audits.

The number of internal audits wherewith the requirements of ISO Guide 34 are fulfilled (planned and performed) and the number of departments related to NIM and subjected to internal audits should be specified in “Reporting information”. If there are no any changes then a special note should be made.

ISO Guide 34 points which were detected by internal audits should be specified in “Comments”.

### 3 External audits

The number of external audits should be specified in “Reporting information If there are no any 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 a reference to Appendix 4A of this report.

Appendix 4A of this report should be arranged as in a table mentioned below including the field of measurement where the audit carried out and the results of audit.

Identification of external audit	Date of audit	Name of auditor(s)	NMI’ name, country	Qualification

In case of external audits’ existence it is necessary to specify in “Comments” the organization which carried out the audit or make a reference to Appendix 4A of this report.

Appendix 4A of this report should be arranged as in a table mentioned below including the field of measurement where the audit carried out and the results of audit.

Identification of external audit	Date of audit	Name of auditor(s)	NMI' name, country	Qualification

#### 4 Non-conformities

The number of non-conformities of points 1, 2 and 3 Section 2A which were detected (complaints, results of internal and external audits) and of the results of the interlaboratory comparisons should be specified in "Reporting information". If there are no any changes then a special note should be made.

In case of non-conformities it is necessary to make a reference in "Comments" to Appendix number of this report where the certain non-conformities and points of ISO Guide 34 according to which the non-conformities were detected should be reported.

#### 5 Results of corrective actions

The existence of planed corrective actions according to discovered nonconformity mentioned in point 4 Section 2B should be specified in "Reporting information". If there are no any changes then a special note should be made.

The existence of planed corrective actions according to discovered nonconformity mentioned in point 4 Section 2A should be specified in "Reporting information" or make a reference to Appendix 6A of this report. It is necessary to inform in detail about the corrective actions caused by the unacceptable results of key or supplementary comparisons..

#### 6 Management review

The date of QMS annual management review of NMI in compliance with the requirements of ISO Guide 34 should be specified in "Comments". If there are no any changes then a special note should be made.

It is necessary to make a reference in "Comments" to Appendix number of this report where should be reported the structure of QMS management review and the estimation of the results of QMS functioning.

#### Example of fill in of the reporting data related to Section 2

<i>Title</i>	<i>Reporting information</i>	<i>Comments</i>
<i>Customer complaints</i>	<i>no</i>	
<i>Internal audits</i>	<i>Planed – 12 Carried out – 12 Inspected – 17 departments of NMI</i>	<i>All points of ISO Guide 34</i>
<i>External audits</i>	<i>1</i>	<i>Appendix 4B</i>
<i>Non-conformities</i>	<i>12</i>	<i>Appendix 4B. Data of detected non-conformities</i>
<i>Results of corrective actions</i>	<i>The corrective actions are elaborated according to the detected non-conformities</i>	<i>Elaborated corrective actions were carried out completely. The corrective actions are effective.</i>

<i>Management review</i>	<i>XX.XX.20XX</i>	<i>Appendix 6B. Structure of the review and the assessment of the effectiveness</i>

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

**Section 3B – Main problems occurred during the year and/or main improvements.**

**1 Problems** – the type of problems have been arisen during the year (it is necessary to examine all points of ISO Guide 34).

*Example: there were any information about traceability in the documents.*

**2 Improvements** – it is necessary to declare that the main significant changes directed to the improvements were fulfilled (it is necessary to examine all points of ISO Guide 34).

*Example.*

*New documents of production procedure of gas mixture were carried out and implemented in a correct way.*

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

Signature of responsible body by indicating the position, date.

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