	COOMET Recommendation	COOMET R/RM/22:2024
	Form and Content of the COOMET Certificate for Certified Reference Materials for Composition and Properties of Substances and Materials	
<p><i>Approved at the 23th COOMET Committee online meeting (Nizhny Novgorod, Russia, June 5 –6, 2013) updated and amended: at the 30th COOMET Committee online meeting (September 24, 2020) at the 36th COOMET Committee meeting (Tashkent, Uzbekistan, June 4-5, 2024)</i></p>		

1. SCOPE

The Recommendation establishes the form and content of the COOMET certificate for certified reference materials¹ (CRMs) for composition and properties of substances and materials, issued by National Metrology Institutes (NMIs) and Designated Institutes (DIs) of COOMET member-countries (hereinafter referred to as the CRM certificate).

The Recommendation may be used by RM producers that are not NMIs/DIs of COOMET member-countries in the preparation and issuance of certificates for CRMs developed and approved within COOMET as COOMET CRMs.

Note – The Recommendation does not apply to the type approval certificate provided by GOST 8.315².

2. REFERENCES

This Recommendation makes reference to the following international documents and publications of COOMET³:

ISO 33401 "Reference materials – Contents of certificates, labels and accompanying documentation";

Note – This Recommendation does not cover the product information sheet required by ISO 33401.

ISO Guide 35 "Reference materials – Guidance for characterization and assessment of homogeneity and stability";

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

ISO 17034 "General requirements for the competence of reference material producers";

GOST 8.315 "GSI. Certified reference materials for composition and properties of substances and materials. Basic principles";

COOMET R/RM/6 "Register of certified reference materials for composition and properties of substances and materials, developed within COOMET. Basic Principles";

COOMET R/RM/5 "Content and rules of drawing up documents for CRMs, developed within COOMET";

ISO 6141 "Gas analysis – Requirements for certificates for calibration gases and gas mixtures."

CIPM MRA-P-11 "Overview and implementation of the CIPM MRA" version 1.2.

¹ This document covers only certified reference materials, CRMs.

² In GOST 8.315, the document accompanying a reference material is referred to as "reference material passport".

³ For dated references, only the edition cited applies; for undated references, the latest edition applies (including any amendments). The year of approval of COOMET publications can be found on the website www.coomet.org.

3. GENERAL

3.1 The CRM certificate is a document accompanying the CRM and contains information necessary and sufficient for the correct use of the CRM.

3.2 The form and content of the CRM certificate has been developed taking into account the provisions of ISO 33401.

3.3 The use of the recommended form of the CRM certificate unifies the documentation accompanying the CRM and facilitates the work on the external audit of the quality management system of NMIs/DIs for compliance with the requirements of ISO 17034.

4. FORM AND CONTENT OF THE CRM CERTIFICATE

4.1 The form of the CRM certificate is given in Annex 1.

4.2 The CRM certificate shall contain the following sections:

- full name, abbreviation, logo of the RM producer (if any) that issued the CRM certificate, its contact details; COOMET logo (see note 1); CIPM MRA logo (see note 1); other logos (if necessary);
- title of the document;
- name and registration number of the CRM;
- code/index of the CRM (if any), batch (copy) number;

Note - The batch number may be indicated by a letter designation.

- description of the material;
- intended use;
- certified value¹ of a measurand(s) with an expanded uncertainty statement²;
- CIPM MRA statement (see note 1);
- storage and transportation conditions;
- measurement method(s) for method-dependent measurands (if relevant);
- metrological traceability;
- minimum representative sample size (if relevant)³;
- shelf life;
- commutability (if relevant);
- instructions for handling and use;
- management system.

The following information is required:

- number of pages and total number of pages;
- certificate version (unique document version number or document approval date) indicating the date of issue of the batch/copy of the CRM;
- position, initials, surname and signature of the head of the RM producer that approved the CRM certificate or an authorized person.

It is recommended to include the following sections in the CRM certificate:

- measurement methods for method-independent measurands;
- health and safety information and/or instruction;
- information for reviewing the material safety data sheet (if necessary).

¹ Instead of the terms "сертифицированное значение", "сертификация", the use of the terms " аттестованное значение", "аттестация" is allowed.

² The expanded uncertainty of the certified value includes sources related to the characterization, homogeneity, and stability of the CRM.

³ It is allowed to refer the section as "Information on homogeneity", indicating, where appropriate, the degree of RM homogeneity with respect to the property of interest to ensure, that it is fit for purpose.

The CRM certificate may additionally contain the following information:

- reference values and/or additional details (cannot be used for calibration or ensuring metrological traceability);
- legal notice;
- set of supply;
- reference to the certification report.

Notes

1. COOMET logo is inserted only for CRMs issued by NMIs of COOMET member-countries, Quality Management System of which is recognized by Quality Forum of COOMET for compliance with the requirements of ISO 17034 and/or for CRMs approved as COOMET CRMs. The CIPM MRA logo and the CIPM MRA statement is inserted only by NMIs/DIs if CRMs are characterized in accordance with the measurement and calibration capabilities listed in the KCDB database or CRMs are included in the KCDB. In cases where a small percentage of the items reported in the certificates of the calibration and measurement services are not covered by CMCs published in the KCDB, then those items shall be clearly noted as not being supported by the CIPM MRA.

2. The registration number may be the number in the COOMET Register of CRMs, the number in the national register of CRMs or another number that allows searching for CRMs in various databases, including the database of the International Bureau of Weights and Measures (BIPM).

3. The CRM index or others can be indicated as the CRM code.

4. In the section "Measurement method(s)" it is recommended to indicate the measurement method(s) used to determine the certified value.

5. The date of CRM certification corresponds to the date of CRM issue.

4.3 The CRM certificate is issued by the RM producer.

4.4 When filling out the sections of the CRM certificate, it is necessary to follow the provisions of ISO 33401 and the recommendations set out in the interlinear sections of the CRM certificate and the notes given in Annex 1.

4.5 An example of the CRM certificate is given in Annex 2.

4.6 When issuing the CRM certificate for the composition of gas mixtures, it is recommended to follow the provisions set out in ISO 6141.

The CRM certificate form (recommended)



*)

Logo of the RM producer
Logo of the accreditation body (if necessary)



*)

Name, address, telephone, fax, e-mail of the RM producer, website

CERTIFICATE

name of the certified reference material
registration number

Code/index: _____ batch (copy) number: _____

(the batch number may be indicated by a letter designation)

Description: _____
(material data, aggregate state, design, dispersity, if necessary, type of packaging, etc.)

Intended use: _____

Certified value of a measurand with an expanded uncertainty statement**): _____

(measurand, certified value, expanded uncertainty, coverage factor, confidence level)

The certified value and expanded uncertainty of the certified value of the certified reference material are established in accordance with the provisions of ISO Guide 35.

CIPM MRA statement*)

This certificate is consistent with the calibration and measurement capabilities that are included in Appendix C of the CIPM MRA drawn up by the CIPM. Under the CIPM MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in the KCDB (for details see <https://www.bipm.org/kcdb/>). The CIPM MRA logo and this statement attest only to the measurement(s) applied for determining the certified values on the certificate

Storage and transportation conditions: _____

Measurement method: _____

*(measurement method(s) used to determine the certified value;
in the measurement of method-dependent measurands, indication of the method used is mandatory)*

Homogeneity: _____

*(minimum representative sample size (where appropriate),
brief information on homogeneity, etc.)*

Stability: _____

Metrological traceability: _____

Commutability _____
(details are provided where information on commutability is required)

Shelf life: _____
(it is allowed to state the shelf life)

Batch/copy release date: _____
(date, month, year)

Instructions for handling and use: _____

Safety requirements: _____
(a reference to the availability of a safety data sheet is possible)

Additional information *):** _____
(information on reference values, etc.)

Set of supply: _____
(number of copies, supply unit, information on package and accompanying documents)

Management system: _____
(information on the compliance of producer's quality management system with the requirements of ISO 17034, ISO/IEC 17025; on the organization that conducted the QMS assessment)

Certificate version: _____
(unique certificate number or date of approval of the certificate with the validity period of the certificate confirming the validity of the metrological characteristics of the CRM)

Signatures of certifying officers:

Expert(s):

Position of expert(s)
of the RM producer

_____ *signature*

_____ *initials, surname*

Head:

Position of the head
of the RM producer
or authorized person

_____ *signature*

_____ *initials, surname*


Seal place


This certificate may not be reproduced except in full. Any publication or reproduction of an extract of this certificate requires permission in writing from RM producer, which issued this certificate.

CRM certificate
batch (specimen) No.____
page __ of ____

Notes



*) The logo  and the CIPM MRA statement may be represented on the title page of the CRM certificate, provided that NMIs/DIs has calibration and measurement capabilities in the KCDB to characterize the CRM or the CRM of NMIs/DIs is included in the KCDB.

The logo  may be represented on the title page of the CRM certificate, provided the CRM is issued by NMIs/DIs from COOMET member-countries, the Quality Management System of which is recognized by the Quality Forum of COOMET for compliance with the requirements of ISO 17034 and/or CRMs are approved as COOMET CRMs.

**) Instead of the terms "сертифицированное значение", "сертификация" the use of the terms "аттестованное значение", "аттестация" is allowed.

***) In section "Additional information" the information according to p. 5.4 of ISO 33401, p. 6.2 of COOMET R/RM/5 may be provided.

Example of the CRM certificate



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CERTIFICATE
CERTIFIED REFERENCE MATERIAL
FOR COMPOSITION OF POTASSIUM DICHROMATE
COOMET CRM 0112-2017-RU
(GSO 2215-81)

Batch number: 17

Description: the certified reference material is an orange-red powder. The certified reference material is supplied in plastic bottles 30 cm³ each containing 5 g of material. Each bottle is additionally placed in a plastic bag with a ZIP-Lock. The certified reference material is potassium dichromate reagent of "extra pure" grade, additionally recrystallized according to MA 04-03-223-2011 "GSO 2215-81. Procedure of manufacturing CRMs for composition", approved in 2011 by UNIIM.

Intended use: certified reference material is intended for:

- transfer of the unit of the base substance mass fraction to certified reference materials and chemical reagents by the oxidation-reduction reaction;
- calibration of measurement instruments, control of metrological characteristics during testing of measurement instruments, including those for the purpose of pattern approval; graduation of measurement instruments;
- certification of measurement procedures and accuracy control of measurement procedures in the course of their application.

Certified value of a measurand with an uncertainty statement:

Certified characteristic	Certified value	Expanded uncertainty, with k=2, P=95%
Mass fraction of potassium dichromate, %	99,992	0,017

The certified value and expanded uncertainty of the certified value of the certified reference material are established in accordance with the requirements of ISO Guide 35 and the principles of ISO/IEC Guide 98-3:2008 "Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)."

CIPM MRA statement

This certificate is consistent with the calibration and measurement capabilities that are included in Appendix C of the CIPM MRA drawn up by the CIPM. Under the CIPM MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in the KCDB (for details see <https://www.bipm.org/kcdb/>). The CIPM MRA logo and this statement attest only to the measurement(s) applied for determining the certified values on the certificate.

Storage and transportation conditions: Transportation of the certified reference material is allowed by any type of transport, provided the integrity of the certified reference material is ensured.

Transportation is allowed only in packages.

The certified reference material should be stored in its original container at the premises with an ambient temperature of (20 ± 10) °C and a relative humidity of no more than 80% in the absence of contact with aggressive media.

Measurement method: metrological characteristics of the certified reference material are determined by coulometric titration according to the document MA 03-223-2011 "GSO 2215-81. The programme and procedure of the determination of metrological characteristics", approved in 2013 by UNIIM.

Homogeneity: the homogeneity study of the certified reference material is conducted in accordance with the requirements established in *ISO Guide 35:2017 "Reference materials – Guidance for characterization and assessment of homogeneity and stability."* The standard uncertainty due to heterogeneity of 0.003% is taken into account in the calculation of the expanded uncertainty of the certified value of the certified reference material.

Metrological traceability: traceability of the certified value of the certified reference material is ensured by direct measurements on State primary measurement standard of mass (molar) fraction and mass (molar) concentration of a component in liquid and solid substances and materials based on coulometry, GET 176-2013, calibration and measurement capabilities of which are recognized in the framework of international key comparisons and included in the database of international key comparisons of International Bureau of Weights and Measures (Institute service identifier: 1.1-01).

Shelf life: 5 years.

Batch release date: batch No. 17, September 30, 2019.

Instructions for handling and use:

General guidelines

The certified reference material is supplied to the user in packaging and in a complete set in accordance with the certificate. The completeness, integrity of package and presence of markings and labels are checked by external examination. The package should be free of damage, resulting in the break of air tightness.

CRMs with expired shelf life are not allowed for use.

Application procedure

Measurement conditions:

- | | |
|--------------------------------------|--------------------|
| - ambient air temperature, °C | from 18 to 28, |
| - relative air humidity, not more, % | 80, |
| - atmospheric pressure, kPa | from 84,0 to 106,7 |

Preparation for use

Out of the bottle in which the certified reference material for composition of potassium dichromate of the 1st order is supplied, pour the material into a clean dry weighing beaker (as per GOST 25336-82) and close the bottle with a lid. To prevent possible contamination of the main mass of the certified reference material, the weighed portions should be taken only from the weighing beaker. The remainder of the material should not be poured into the bottle.

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The selected weighed portion is dried during 2 hours at a temperature of $(105 \pm 2) ^\circ\text{C}$ and then cooled in a desiccator to an ambient temperature.
The weighed portion is weighed on analytical balance according to the operational documentation.

Safety requirements: Premises for work with the CRM should be equipped with general supply and exhaust mechanical ventilation; dusty areas should be equipped with exhaust ventilation; measurement procedures with the CRM should be carried out in a laboratory fume hood.
When working with the preparation, personal protective equipment (respirators, protective glasses, rubber gloves) should be used, and personal hygiene rules should be observed. Do not allow the CRM to enter upon mucous membranes and skin.

Additional information: The certified reference material is recognized as a COOMET CRM by the decision of the 27th meeting of the COOMET Committee and included in the Register of COOMET CRMs under **COOMET CRM 0112-2017-RU**.

Set of supply: a copy of the certified reference material in a plastic bottle with a capacity of 30 cm³ with a label, additionally insulated in a plastic bag with a ZIP-Lock; the certified reference material certificate.

Management system: UNIIM quality management system complies with the requirements of ISO/IEC 17025 (Certificate of recognition of the quality management system No. QSF-R47 issued February 15, 2017, by the COOMET Quality Forum) and ISO 17034:2016 "General requirements for the competence of reference material producers" (Certificate of recognition of the quality management system No. QSF-R62 issued October 2, 2019, by the COOMET Quality Forum).

Certificate version: September 30, 2019.

Signatures of certifying officers:

Expert (s):

*Position of expert (s)
of CRM producer*

signature

initials, surname

Head:

*Position of the head
of RM producer
or authorized person*

signature

initials, surname

Seal place

This certificate may not be reproduced except in full. Any publication or reproduction of an extract of the certificate requires permission in writing from UNIIM that issued this certificate.

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INFORMATION

Recommendation COOMET R/RM/22:2024

1. Development coordinator: TC 1.12 «Reference Materials»
2. COOMET project: **893/RU/23**
(Coordinator: UNIIM - Affiliated Branch of the D. I. Mendeleyev Institute for Metrology, Russia)
3. The Recommendation was updated and approved at the 36th COOMET Committee meeting (2024).

Since this COOMET Recommendation has an organizational and methodological content, and reflects procedural issues of COOMET activities in performing work on the development of COOMET CRMs, this Recommendation should be implemented by all participants in cooperation within COOMET.