	COOMET Recommendation	COOMET R/RM/22:2020
	Form and Content of COOMET Certificate for Reference Materials for Composition and Properties of Substances and Materials	
<p><i>Agreed at the 17th meeting of COOMET Technical Committee 1.12 "Reference Materials" (Braunschweig, Germany, October 2012)</i></p> <p><i>Approved at the at the 23th COOMET Committee online meeting (Nizhny Novgorod, Russia, 5 –6 June 2013)</i></p> <p><i>Updated at the 25th meeting of TC 1.12 "Reference Materials" into online format (10 September 2020).</i></p> <p><i>Approved at the 30th COOMET Committee online meeting (24 September 2020)</i></p>		

This Recommendation establishes the form and content of COOMET certificate for reference materials¹ (RMs) 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 RM certificate).

This Recommendation may be also used by RM producers from COOMET member-countries, which are not NMIs/NIs, during the preparation and issue of certificates for reference materials, developed and approved within COOMET as COOMET RMs.

Note – This Recommendation does not apply to the certificate of RM type approval, specified by GOST 8.315².

The Recommendation is based on the principles, set out in the following documents. For the dated references only specified edition of reference document should be used. For the undated references the last edition should be used (including all corrections).

ISO Guide 31 "Reference materials – Contents of certificates, labels and accompanying documentation";

Note – This recommendation does not cover the product information sheet, required by ISO Guide 31.

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";

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".

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".

1 GENERAL

1.1 RM certificate is a document, which accompanies a reference material and contains the information, necessary and sufficient for correct RM use.

1.2 The form and content of RM certificate is developed with due account of the provisions of ISO Guide 31.

1.3 The use of the recommended form of RM certificate harmonizes the documentation, accompanying reference materials and facilitates the work on external audit of NMIs/DIs quality management system for conformity with the requirements of ISO 17034.

2 FORM AND CONTENT OF RM CERTIFICATE

2.1 The form of RM certificate is given in Annex 1.

2.2 RM certificate shall contain the following sections:

- full name, abbreviation, logo of RM producer (if any), which issued RM certificate, its contact details; COOMET logo (see Annex 1); CIPM MRA logo (see Annex 1); other logos (where appropriate);

- title of the document;

- name of the reference material, RM registration number;

- code/index of the reference material (if any), number of the batch/specimen;

- description of the material;

- intended use;

- certified value¹ of a measurand and associated uncertainty;

- conditions of storage and transportation;

- measurement method(s) for method-dependent measurands (where appropriate);

- metrological traceability;

- minimum representative sample size (where appropriate)²

- period of validity;

- commutability (where appropriate);

- instructions for handling and use;

- management system.

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

² 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 following information is mandatory:

- page number and the total number of pages;
- certificate version (unique identifier of the document version or the date of the document approval), indicating the date of issue of RM batch/specimen;
- position, initials, surname and signature of the head of the organisation (or authorised person) - CRM producer, which approved the certificate.

It is recommended that the following sections be included in RM certificate:

- measurement method(s) for method-independent measurands;
- health and safety information and/or instruction.

RM certificate may additionally contain the following information:

- indicative values and/or additional details;
- legal notice;
- a set of supply;
- reference to a certification report.

Notes:

1. COOMET logo is inserted only for RMs, issued by National Metrology Institutes (NMIs) of COOMET member-countries, Quality Management System of which is recognized by Quality Forum of COOMET and/or for RMs, approved as COOMET RMs. CIPM MRA logo is inserted only by NMIs/DIs, when RM is included in CIPM MRA Database, CMCs.

2. COOMET RM Register number, RM national register number or another number, enabling the RM search in various data bases, including the data base of the International Bureau of Weights and Measures (BIPM), may be indicated as registration number

3. RM index, etc, may be used as RM code.

4. In the section "Measurement method (s)" it is recommended to indicate measurement method (s), used in the determination of RM certified value.

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

2.3 RM certificate is issued by RM producer.

2.4 When filling out the sections of RM certificate it is necessary to follow the provisions of ISO Guide 31 and the recommendations set out under the lines of the sections of RM certificate and in notes, provided in Annex 1.

2.5 The example of RM certificate is given in Annex 2.

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

**The form RM certificate
(recommended)**



*)

Logo of RM producer



*)

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

CERTIFICATE

**name of the reference material
registration number**

Code/index of the material: _____ **batch (specimen) number:** _____

Description of the reference material _____
(material data, aggregate state, design, dispersity, etc.)

Intended use: _____

Certified value of a measurand with uncertainty statement):** _____
(measurand, certified value, expanded uncertainty, coverage factor, confidence level)

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

Conditions of storage and transportation: _____

Measurement method (s):

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

Information on homogeneity: _____

*(minimum representative sample size,
brief information of homogeneity study, etc.)*

Metrological traceability: _____

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

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

Period of validity: _____
(it is allowed to state the expiration date)

Instructions for handling and use: _____

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

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

A set of supply: _____
(number of specimens, supply unit, information on package and accompanying documents)

Date of batch/specimen release: _____
(date, month, year)

Management system: _____
(information on the conformity of producer's quality management system with the requirements of ISO 17034, ISO/IEC 17025, on the organization, which conducted peer review of QMS)

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

Signatures of certifying officers:

Expert (s):

Position of expert (s)
of RM 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 this certificate requires permission in writing from RM producer, which issued this certificate.

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

Notes:



*) The logo  may be represented on the title page of RM certificate, provided the reference material of NMI/DI is included in CIPM MRA Database, CMCs.

The logo  may be represented on the title page of RM certificate, provided the RM is issued by the NMI/DI from COOMET member-countries, Quality Management System of which is recognized by Quality Forum of COOMET and/or RM is approved as COOMET RM.

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

***) In section "Additional information" the information according to p. 5.4 of ISO Guide 31, p. 6.2 of COOMET R/RM/5 may be provided.

Example of RM certificate



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CERTIFICATE
CERTIFIED REFERENCE MATERIAL
FOR COMPOSITION OF POTASSIUM DICHROMATE
GSO 2215-81

Batch number: 17

Description: certified reference material is 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 uncertainty statement:

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

Certified value and expanded uncertainty of the certified value of certified reference material are established in conformity 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)".

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batch No. 17
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Conditions of storage and transportation: Transportation of certified reference material is allowed by any means of transport, provided the integrity of the certified reference material is ensured.

Transportation is allowed only in packages.

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, not exceeding 80% in the absence of contact with aggressive media.

Measurement method: metrological characteristics of 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.

Information on homogeneity: homogeneity study of certified reference material is conducted in conformity with requirements, established in *ISO Guide 35:2017 "Reference materials –Guidance for characterization and assessment of homogeneity and stability"*. Standard uncertainty due to inhomogeneity, equal to 0,003 %, is taken into account in the calculation of the expanded uncertainty of the certified value of certified reference material.

Metrological traceability: metrological 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).

Period of validity: 5 years.

Instructions for handling and use:

General guidelines

Certified reference material is delivered to the user in a package and in a complete set in accordance with a certificate. Completeness, integrity of package and availability of marking and label are checked by external examination. The package should be free of damage, resulting in the break of air tightness.

CRMs with expired lifetime 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 certified reference material for composition of potassium dichromate of the 1st order is supplied , pore out material into a clean dry weighing beaker (as per GOST 25336-82) and close the bottle with a cover. To prevent possible contamination of the basic mass of the certified reference material, the test portions should be taken only out of the weighing beaker. The remainder of the material should not be poured into the bottle.

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The collected test portion is dried during 2 hours at the temperature of (105 ± 2) °C and then cooled in a dessicator to an ambient temperature.

The collected test portion is weighed on analytical balance according to operational documentation.

Safety requirements: The premises at which work with the preparation is carried out should be equipped with general supply and exhaust mechanical ventilation; in places of greatest dusting local suction should be provided; analysis of the preparation 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. Avoid preparation contact with mucous membranes and skin.

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

A set of supply: a specimen of certified reference material in a plastic bottle with a capacity of 30 cm³ with a label, additionally isolated by a polyethylene bag with ZIP-Lock; certified reference material certificate.

Date of batch release: batch N 17, 30 September 2019.

Management System: Quality Management System of UNIIM complies with the requirements of ISO/IEC 17025 (Confirmation of Recognition of Quality Management System No. QSF-R47 is issued on 15 February 2017 by COOMET Quality Forum) and ISO 17034:2016 "General requirements for the competence of reference material producers" (Confirmation of Recognition of Quality Management System No. QSF-R62 is issued on 02 October 2019 by COOMET Quality Forum).

Certificate version: 30 September 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 this certificate requires permission in writing from UNIIM, which issued this certificate.

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