

	COOMET Recommendation	COOMET R/RM/4:2023
	Procedure for Joint Development, Approval and Registration of Certified Reference Materials within COOMET	
<p><i>Approved at the 18th COOMET Committee meeting (Kharkiv, Ukraine, 15–16 May 2008) updated and amended: at the 34th COOMET Committee meeting (23-24 May 2023, Astana, Kazakhstan & online)</i></p>		

1. SCOPE

This Recommendation is developed in the elaboration of Memorandum of Understanding on the Development and Use of Certified Reference Materials of Composition and Properties of Substances and Materials within COOMET (COOMET Document D3/2008) and establishes the procedure for joint development, approval and registration of certified reference materials within COOMET (hereinafter referred to as COOMET CRMs). Recommendation is developed in view of the following documents¹:

COOMET D1/2022 COOMET Memorandum of understanding;

COOMET D4/2022 COOMET publications. Classification, development, approval and registration. General provisions.

2. REFERENCES

In this Recommendation, references are made to the following publications¹ and International Standards:

COOMET D2/2021 COOMET Rules of procedure;

COOMET D5/2021 Model Regulations for COOMET Structural Bodies;

COOMET R/RM/5:2010 Contents and rules of drawing up documents for CRMs developed within COOMET;

COOMET R/RM/6:2010 Register of certified reference materials for composition and properties of substances and materials developed within COOMET. Basic principles;

COOMET R/RM/22:2020 Form and content of COOMET certificate for reference materials for composition and properties of substances and materials;

COOMET I/RM/2:2023 Register of Certified Reference Materials of composition and properties of substances and materials, developed within COOMET;

ISO Guide 30:2015 Reference materials — Good practice in using reference materials;

ISO Guide 31:2015 Reference materials – Contents of certificates, labels and accompanying documentation;

ISO Guide 35:2017 Reference materials – Guidance for characterization and assessment of homogeneity and stability;

ISO 17034:2016 General requirements for the competence of reference material producers.

¹ When using this publication, it is advisable to check the year of approval of the referenced publications on the website www.coomet.org (section "COOMET Publications") or the portal www.coomet.net (section "Publications").

3. GENERAL PROVISIONS

3.1. COOMET certified reference materials are certified reference materials (CRMs) of composition and properties of substances and materials developed jointly by the countries cooperating within COOMET and registered in the Register of certified reference materials developed within COOMET (the Register of COOMET CRMs).

3.2. COOMET CRMs are applied in COOMET participating countries without additional research in bilateral or multilateral economic and scientific-technical cooperation.

3.3. The procedure for the application of COOMET CRMs in COOMET participating countries is established in accordance with the existing national regulations and/or documents; in their absence - in accordance with COOMET publications.

3.4. The following CRMs may be submitted as COOMET CRMs:

- CRMs developed by several countries in concert according to the preliminarily agreed requirements;
- CRMs developed by one of COOMET participating countries with the involvement of the interested countries in determining the metrological characteristics of a certified reference material;
- CRMs related to the implementation of the CIPM MRA and published in the KCDB Database of the International Bureau of Weights and Measures (hereinafter referred to as BIPM KCDB).

Notes:

1) *The CIPM MRA is an agreement on the mutual recognition of national standards, calibration and measurement certificates issued by national metrological institutes.*

2) *The BIPM KCDB is a free web resource and web platform (<https://www.bipm.org/kcdb/>) related to the implementation of the CIPM MRA.*

3.5. Only CRMs with state status (certified or approved) in the Coordinator's country in the joint development of COOMET CRMs, or in the country of the CRM developer with the participation of other countries in determining its metrological characteristics, are proposed as COOMET CRMs.

3.6. The development of COOMET CRMs is carried out according to the agreed COOMET projects of the COOMET Work Program performed taking into account the provisions of the COOMET Document D2.

3.7. The rules and methods for determining the metrological characteristics of CRMs and other technological and methodological procedures used in the development of COOMET CRMs are established by the relevant technical documents agreed by the participants in the work.

4. PROCEDURE FOR THE DEVELOPMENT OF CERTIFIED REFERENCE MATERIALS WITHIN COOMET

4.1. The development of CRMs within COOMET normally includes the following stages:

a) preparation of the form for the proposed Project (Appendix 1 to the COOMET Document D2) indicating detailed information on the content of the proposed work;

b) approval of the Project and preparation of the form for the agreed Project (Appendix 2 to the COOMET Document D2);

c) drawing up and approval of the working plan, containing the stages, dates, and the parties responsible for each stage;

d) performance of works in accordance with the agreed work plan of cooperation, obtaining CRMs of state status (certified or approved);

e) examination of materials for the development of CRMs (see clause 4.3);

f) review and approval of the results of the works at the meetings of COOMET Technical Committees (COOMET TCs) coordinating them or by correspondence.

g) expert assessment on the possibility of COOMET CRMs approval by TC 1.12 "Reference materials" (hereinafter referred to as TC 1.12).

4.2. In the course of the COOMET CRM development, the working plan under clause 4.1 b) should contain the following stages:

- the appointment of a Coordinator (when CRMs are developed by several countries in concert);

Note – the Coordinator of the COOMET Project, which provides for the participation of countries interested in determining the metrological characteristics of CRMs, is a representative of the country of the author of the CRM development.

- development and adoption of specification for the development of CRMs, including a program for determining the metrological characteristics of CRMs;
- works on the preparation and testing of the CRM material, and work on the program for determining the metrological characteristics of CRMs;
- drawing up the report and draft documents for the developed CRMs in compliance with COOMET Recommendation R/RM/5;
- preparation of a draft COOMET CRM Certificate in accordance with COOMET Recommendation R/RM/22.
- submission of a set of documents for CRMs for examination to the Secretariat of TC 1.12 and, if necessary, to the relevant COOMET TCs.

4.3. The Secretariat of TC 1.12 examines the materials for the development of CRMs created within COOMET for compliance with the availability and completeness of the set of documents, and the correctness of the draft COOMET CRM Certificate in accordance with the COOMET Recommendation R/RM/22. The Secretariat of TC 1.12 prepares a decision (recommendation) for the submission of CRMs to the meeting of TC 1.12 for an expert assessment.

4.4. The expert assessment of the possibility of COOMET CRMs approval is carried out by the Members of TC 1.12 at the meeting of TC 1.12 or by correspondence.

In the course of an expert assessment, the compliance of the submitted materials on the CRM development and the accompanying documentation for CRMs with the requirements of the technical specification and/or other technical documentation with the provisions of ISO Guide 30; ISO Guide 31; ISO Guide 35; ISO 17034, as well as the procedure for developing CRMs with the requirements specified in the Recommendation, is established.

In the case of an expert assessment at a meeting of TC 1.12, the decision is considered positive if more than half of the Members of TC 1.12 with an active status voted for its adoption (taking into account the requirements for the quorum of the meeting in accordance with clause 5.3.7 of the COOMET Document D5). In case of an equal number of votes, the vote of the Chairman of TC 1.12 is decisive.

In the case of an expert assessment among the Members of TC 1.12 by correspondence, the decision is considered positive if more than half of the Members of TC 1.12 with an active status voted for its adoption (voting of the Members of TC 1.12 with a temporary status of "TC member-observer" in accordance with clause 5.3.7 of the COOMET Document D5 is optional). In case of an equal number of votes, the vote of the Chairman of TC 1.12 is decisive.

The assessment results are made in the form of a decision of TC 1.12.

A positive decision is the basis for the approval of COOMET CRMs (see clause 5.1).

A negative decision is the basis for the termination of work and completion of the COOMET Project in accordance with the established procedure within which the CRM development was carried out (if necessary). The Project Coordinator and the TC Chairman shall be notified.

5. PROCEDURE FOR APPROVAL AND REGISTRATION OF COOMET CRMs

5.1. The decision on the approval and registration of CRMs in the Register of COOMET CRMs is made at the meeting of the COOMET Committee by voting among the Members of the COOMET Committee, and is recorded in the Minute of the meeting on the basis of a positive decision on the result of an expert assessment by the Members of TC 1.12 in accordance with clause 4.4.

5.2. The procedure for registration in the Register of COOMET CRMs of CRMs developed jointly by several countries according to previously agreed requirements, and CRMs developed by one of the COOMET participating countries with the participation of other interested countries in determining the metrological characteristics of CRMs:

5.2.1. The documents prepared by the Project Coordinator in accordance with clause 4.2 of this Recommendation and the decision (recommendation) of the Secretariat of TC 1.12 on the submission of CRMs (see clause 4.3) are considered at the meetings of the corresponding COOMET TCs or the Coordination is carried out with the Members of COOMET TCs by correspondence.

5.2.2. The chairmen of the COOMET TCs submit the Minutes of the COOMET TC meeting on the possibility of registering the submitted CRMs as COOMET CRMs and the List of these CRMs to COOMET TC 1.12 "Reference Materials".

5.2.3. The Secretariat of TC 1.12 organizes expert assessment of materials for CRMs among the Members of TC 1.12. If the CRM is developed within TC 1.12, the stages of work under clauses 5.2.2 and 5.2.3 may be combined.

5.2.4. The Secretariat of TC 1.12 compiles the complete List of CRMs approved for registration as COOMET CRMs and recommended for approval by the COOMET Committee, and submits it to the COOMET Secretariat with a corresponding draft decision before the meeting of the COOMET Committee.

5.2.5. Approval of the COOMET CRMs is carried out by the decision of the COOMET Committee in accordance with clause 5.1.

5.3. The procedure for the registration in the Register of COOMET CRMs of CRMs related to the implementation of the CIPM MRA and published in the BIPM KCDB.

5.3.1. The state metrological institution of the country that has published CRMs in the BIPM KCDB initiates consideration of the set of documents among the Members of the COOMET TC. If necessary, a COOMET Project is opened (taking into account the requirements of the COOMET Document D2). The consideration is carried out by the Members of COOMET TC, which is responsible for CRMs published in the BIPM KCD, by correspondence.

5.3.2. The set of documents includes national documents for CRMs approved in accordance with the procedure established by the state, a draft COOMET Certificate for the CRM issued in accordance with COOMET Recommendation R/RM/22. If necessary, Members of COOMET TC can request comparison reports, as well as other additional information.

5.3.3. The COOMET TC Secretariat summarizes the results of consideration of the set of documents, and prepares a final decision on the possibility of registering the submitted CRMs as COOMET CRMs and the List of these CRMs submitted by the COOMET TC Chairman to TC 1.12.

5.3.4. The further procedure of works conforms to clauses 5.2.2-5.2.5.

5.4. The Secretariat of TC 1.12 assigns a registration number to this CRM in accordance with COOMET R/RM/6 and enters information about the CRM into the Register of COOMET CRMs (Information Material COOMET I/RM/2) and the COOMET CRM database based on the decision of the COOMET Committee on the approval of COOMET CRMs.

5.5. TC 1.12 submits information on the assigned numbers of COOMET CRMs in the Register of COOMET CRMs within a month after the meeting of the COOMET Committee to the Chairman of COOMET TC (within which COOMET CRMs have been developed) and Members of TC 1.12.

5.6. The Secretariat of TC 1.12 updates, as required, the information in the Register of COOMET CRMs, taking into account the requirements of the COOMET Recommendation R/RM/6, and annually submits an updated version of the COOMET Information Material I/RM/2 for approval at the meeting of the COOMET Presidential Council.

INFORMATION

Recommendation COOMET R/RM/4:2023

1. Development coordinator:

Urals Scientific Research Institute of Metrology – branch of the Federal State Unitary Enterprise "All-Russian Scientific Research Institute of Metrology named after D.I. Mendeleev"

2. COOMET project: 857/RU/22

3. The recommendation was updated and approved at the 34th COOMET Committee meeting (2023).

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