	COOMET Recommendation	
	Content and Rules of Drawing up Documents for CRMs Developed within COOMET	**COOMET R/RM/5:2010**
Endorsed at the 5th meeting of experts on certified reference materials of COOMET member-countries (Sofia, Bulgaria, October 1998), updated and supplemented at the 8th meeting of experts on certified reference materials of COOMET member-countries (Vilnius, Lithuania, October 2002), updated and supplemented at the 14th meeting of COOMET TK 1.12 "CRMs"(Minsk, Belarus, October, 2009) *Approved at the 20th COOMET Committee Meeting (Astana, Kazakhstan, on April 21–22, 2010)*		

1 SCOPE

The present Recommendation is developed in elaboration of Memorandum of understanding on the development and use of certified reference materials for composition and properties of substances and materials within COOMET and establishes general requirements for the content, drawing up and agreement of technical documents for CRMs developed within COOMET (hereinafter referred to as COOMET CRMs).

The Recommendation is developed with due account of provisions of the following documents:

COOMET D1/2006 COOMET Memorandum of understanding

COOMET D3/2008 Memorandum of understanding on the development and use of certified reference materials for composition and properties of substances and materials within COOMET

COOMET D4/2003 COOMET publications. Classification, development, approval and registration. General provisions.

2 REFERENCES

The references for the following normative documents are used in the present Recommendation:

COOMET D2/2006 COOMET Rules of procedure

COOMET R/RM/4:2008 Procedure for joint development, recognition and registration of certified reference materials 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

3 GENERAL PROVISIONS

3.1 The present recommendation covers the following documents, developed in the course of production, testing and certification of COOMET CRMs:

— technical assignment for the development of COOMET CRM;

— report on the production of COOMET CRM (the report on the preparation, testing and certification of COOMET CRM or the report on the confirmation of CRM metrological characteristics);

— certificate (passport) of COOMET CRM;

— instruction for the proper use of CRM.

3.2. Concepts and terms used in technical documentation for COOMET CRMs should be in compliance with those of ISO/IEC Guide 99 [1] and ISO Guide 30 [2].

4 TECHNICAL ASSIGNMENT. CONTENT, DRAWING UP AND AGREEMENT

4.1 Where COOMET CRM is produced by joint development by several countries with a preliminary agreement of the requirements for the CRM to be developed or by CRM development by one of COOMET member-countries with the involvement of the countries, interested in its certification, the Project Coordinator prepares Technical Assignment for the development of COOMET CRM (hereinafter referred to as COOMET CRM TA).

4.2. COOMET CRM TA in the general case should establish:

— intended use of a CRM;

— requirements for the CRM, including:

a) requirements for the material, carrying CRM properties — selection and preparation of the material, ensuring of its homogeneity and stability;

b) requirements for CRM metrological characteristics;

c) procedure for homogeneity and stability testing and determination of CRM validity period;

d) requirements for CRM certification (determination of metrological characteristics) certification programme and procedure (set out in TA or in a separate document), including, *inter alia*, the intended method of establishing certified characteristics and traceability of CRM certification measurement results;

e) safety requirements in CRM production and use;

f) requirements for prepackaging, labeling and packing;

g) requirements for transportation and storage conditions;

— the scheduled stages of CRM development

— the list of documentation for CRM to be developed.

4.3 The requirements, established by COOMET CRM TA, for the certification programme, certification measurement procedures and for the competence of CRM producer and participants of certification measurements should comply with the basic principles of ISO Guide 35 [3], ISO Guide 34 [4] and ISO/IEC 17025 [5]. Certification measurement procedures should ensure the traceability of CRM certified characteristic values to SI units or other internationally accepted units (in the absence of such a possibility, to agreed reference values of these characteristics) in compliance with [6].

COOMET CRM TA may include the programme and procedure of CRM certification (determination of metrological characteristics) in the form of CRM TA section or an annex or stipulate their development in the form of a separate document in the course of CRM production.

4.4 The possibility to develop additional documents, needed to ensure the correct CRM use according to its purpose should be stipulated in the list of the technical documentation to be developed (see p. 3.1 of this Recommendation).

4.5 Where COOMET CRM is produced by joint development by several countries with a preliminary agreement of the requirements for the CRM to be developed, the Project Coordinator agrees the draft COOMET CRM TA with participants of works, as prescribed by routine procedure

within the time stipulated by the working plan of the project; in some cases it is possible to agree upon CRM TA at the meetings COOMET Technical Committee, in which COOMET CRM is being developed. At the stage of COOMET CRM TA agreement the list of participants of certification measurements and the amount of work to be done by each of them should be specified. The agreed programme of works on COOMET CRM production should contain the information on the participants (organizations and participating countries).

4.6 Where COOMET CRM is produced by the development by one of COOMET member-countries with the involvement of the countries, interested in its certification, the Project Coordinator independently prepares the Technical Assignment for the development of a CRM. In the framework of cooperation he circulates among the participants the Programme of certification analyses, containing the requirements, specified in the Technical Assignment. The details on the participants (organizations and participating countries) are given in the form of the Agreed Project.

5. REPORT ON THE PRODUCTION OF COOMET CRM. CONTENT, DRAWING UP AND AGREEMENT.

5.1 The report, containing the information on the completed work in the amount, sufficient to justify the possibility of the recognition of the CRM under consideration as COOMET CRM is issued for the CRM, proposed for the recognition as COOMET CRM [7].

5.2 In case of the recognition as COOMET CRMs of certified reference materials, developed in concert by several countries with due account of preliminary agreed requirements or by one of COOMET member-countries with the involvement of the countries, interested in its certification, the Project Coordinator submits the report on the production, testing and certification of COOMET CRM (hereinafter referred to as report on COOMET CRM development).

5.2.1 The report on COOMET CRM development should, as a rule, contain the following information:

— justification of the necessity, the objective and the main tasks of the works on COOMET CRM production (introduction);

— selection, preparation and investigation of CRM material;

— homogeneity test of the material and the obtained results;

— certification tests, including the justification of the chosen method (scheme) of certification analysis; the information on the certification programme and/or procedure; on the development and certification of measurement procedures; obtained results of certification measurements or the values of calculation data and their evaluation;

— the establishment of the traceability of CRM certified values to SI units or to other accepted units or to agreed reference values;

— stability study of the produced CRM and the determination of the validity period;

— complying with the requirements for prepackaging, labeling and packing.

It is allowed to set out the above mentioned issues in separate sections of the report,

merge together, delete or introduce new sections at the discretion of the author.

5.3 In case of the recognition as COOMET CRMs of certified reference materials, included in the Annex C of MRA, the Coordinator of purposely initiated COOMET project, submits the report on the confirmation of metrological characteristics of these CRMs.

5.3.1 The report on the confirmation of CRM metrological characteristics contains the information on the comparison results within COOMET and/or on publications in international journals and/or

the details of the peer review, submitted by the Project Coordinator in support of calibration and measurement capabilities (CMC).

5.4 CRM accompanying documentation, considered in section 6 of the present Recommendation, should be appended to the report on CRM development.

5.5 The report and CRM accompanying documentation, submitted for the recognition as COOMET CRMs, are subject to metrological examination, conducted by the body of the state metrological service of CRM producing country in compliance with p. 4.3 of COOMET Recommendation R/RM/4:2008.

5.6 The conclusion of the metrological examination, the report and CRM accompanying documentation, submitted for the recognition as COOMET CRMs, are subject to consideration at the meetings of relevant COOMET TCs in compliance with p.p. 5.3 and 5.4 of COOMET Recommendation R/RM/4:2008.

In some cases, upon the decision of the Chairman of COOMET TC 1.12 "CRMs" it is possible to consider the above mentioned documents at the meeting of experts on certified reference materials: COOMET TC 1.12 "CRMs."

6. ACCOMPANYING DOCUMENTATION FOR COOMET CRMs

6.1 Certificate (or passport) and instruction for the use of CRM (if any), containing the information, necessary for COOMET CRM use according to its purpose are the documents, accompanying COOMET CRMs [9]. Without certificate (passport) COOMET CRM is valueless as a means of metrological purpose.

6.2 Certificate (passport) in its content should comply with recommendations of ISO Guide 31 [8] and, as a rule, contain the following information on COOMET CRMs:

— name of the CRM;

— producer and CRM registration number, assigned by certification body [10];

— description of the material;

— intended use of the CRM;

— certified characteristic values, each accompanied by a statement of uncertainty (error);

— methods, used to obtain the characteristic values (with full details where values are dependent on the method of measurement);

— traceability of certified values of characteristics;

— instructions for proper use;

— instructions for appropriate conditions of storage and transportation;

— period of CRM validity;

— safety requirements.

Certificate (passport) of COOMET CRM may include (if appropriate) additional

information on CRM: uncertified (indicative) characteristic values; results, obtained by individual laboratories or methods, etc.

6.3 By the decision of CRM producer (if he considers it necessary) a part of information may be provided separately in the form of instruction for use, containing, in the general case, the following sections:

— general guidelines;

— preparation for use;

— conditions and procedure of use;

— evaluation of measurement results;

— safety requirements;

— conditions of storage and transportation.

6.4 It is allowed to delete or merge together separate sections of COOMET CRM

accompanying documents and to introduce new sections (in this case the section "safety requirements" is compulsory).

6.5 Documentation for COOMET CRMs is prepared by the Project Coordinator in compliance in form and in content with the requirements, specified by the national normative documents operative at the moment of the CRM approval in the country as a national CRM, in working languages of COOMET – Russian and/or English.

7. GUIDELINES FOR REGISTRATION OF DOCUMENTATION FOR COOMET CRMs

7.1 After the CRM is recognized as COOMET CRM at the meeting of COOMET

Committee, the Secretariat of the Chairman of TC 1.12 "CRMs" registers the produced CRM in the Register of COOMET CRMs in compliance with the guidelines of COOMET Recommendation COOMET R/RM/6:200_.

7.2 After the CRM is registered in the Register of COOMET CRMs, the Project Coordinator enters the information on CRM recognition in national documents for this CRM.

As an example the following form of record may be recommended:

"CRM is recognized as the CRM developed within COOMET by the resolution of the meeting of COOMET Committee (_____) , entered in the Register of

(date and venue of the meeting)

COOMET CRMs under No._____ and allowed for use without any restrictions in:

(registration number)

_____".

(the list of COOMET member-countries, which have joined the recognition)

7.3 Upon the completion of CRM development the Project Coordinator:

— fills-in the form of the final project and submits it to the Secretariat of the Chairman of TC 1.12 "CRMs" in compliance with the guidelines of COOMET Recommendation D 2/2006;

— informs the Secretariat of the Chairman of TC 1.12 "CRMs" of the participants of certification analyses and/or the participants of experimental works on CRM comparison for drawing up Certificates of participants of interlaboratory certification and/or experimental works on comparison.

7.4 The Secretariat of the Chairman of TC 1.12 "CRMs" , on the basis of the obtained information, draws up Certificates of participants of interlaboratory certification and/or experimental works on comparison and forwards them to the Project Coordinator.

BIBLIOGRAPHY

1 ISO/IEC Guide 99:2007 International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

2 ISO Guide 30:1992 Terms and definitions used in connection with reference materials

3 ISO Guide 35:2006 Reference materials — General and statistical principles for certification

4 ISO Guide 34:2009 General requirements for the competence of reference material producers

5 ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

6 Metrological traceability of measurement results in chemistry: concepts and implementation — IUPAC recommendations 2009
http://old.iupac.org/reports/provisional/abstract09/debievre_prs.pdf

7 COOMET Recommendation R/RM/4:2008 Procedure for joint development, recognition and registration of certified reference materials within COOMET

8 ISO Guide 31:2000 Reference materials — Contents of certificates and labels

9 ISO Guide 33:2000 Uses of certified reference materials

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