A Comparative Analysis of OIML Documents and Russian Rules on the Use of Reference Materials

Narine G. Oganyan and Vladimir I. Dobrovolskiy

Abstract The article analyzes the compliance of Russian legal documents with the Recommendations of the International Organization of Legal Metrology regarding the use of reference materials in the fields covered by the state control and supervision. The problem of ensuring the quality of measurement results is relevant for each laboratory, performing measurements in any fields of activity. In addition to a reliable and proven measurement method, a decisive role in obtaining comparable results is played by reference materials. In order to ensure the traceability of measurements, a reference material must be certified. Certified reference materials are obligatory for the state metrological control and supervision of the quality and safety of food and pharmaceutical products, quality of measurements in clinical laboratories, environmental safety, etc. Considering the important role of reference materials in the process of ensuring the uniformity of measurements in analytical laboratories, this study can contribute to the promotion of ideas for improving the Russian legislative framework in the relevant area.

Keywords Certified reference material · CRM production · CRM type approval · CRM expertise · State metrological control and supervision · Legal requirements

Abbreviations

GSO	Approved type of reference material
OIML	International Organization of Legal Metrology
RF	Russian Federation
RM	Reference material

N. G. Oganyan (✉) · V. I. Dobrovolskiy
All-Russian Scientific Research Institute of Physicotechnical and Radio Engineering Measurements (VNIIFTRI), Moscow Region, Russia
e-mail: oganyan@vniiftri.ru

V. I. Dobrovolskiy
e-mail: mera@vniiftri.ru

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CRM Certified reference material
BIPM International Bureau of Weights and Measures

Introduction

A decision on the conformity of products to their quality requirements is primarily based on the sufficient accuracy of measurement results provided by analytical laboratories [1–3]. Therefore, every laboratory, regardless of the field of its activity, should be aware of the need to ensure the quality of its measurement results. Over the past decades, an agreement has been reached between experts from various countries on how the required quality of measurements can be achieved. The starting point undoubtedly involves the choice of a reliable and proven method. However, this cannot be considered a sufficient basis for comparing the results obtained in various laboratories. In order to ensure the comparability of the results, it is necessary to ensure the metrological traceability of these measurements [1, 4]. In analytical laboratories, a decisive role in this issue is played by references in the form of chemicals, which are called reference materials (RMs). RMs are used for the verification, calibration, and validation of methods, assessment of measurement uncertainties, and quality control. In addition, it should be kept in mind that a particular RM can be used only for one measurement purpose, for example, for calibration or product quality control [5].

According to the international metrological vocabularies JCGM 200:2012, ISO/IEC Guide 99:2007, and RMG 29–2013 [6–8], a certified reference material (CRM) is a "reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures". According to the metrological vocabulary RMG 29–2013, operating within the Russian Federation (RF): "a certified reference material is a reference material, accompanied with the documentation issued by an authoritative body, which indicates one or more values of a certain property with the appropriate measurement accuracy characteristics (uncertainties) and traceability, which are established using reasonable procedures." Therefore, the CRM definition is fully consistent with the foreign analogues.

As can be seen from the RM and CRM definitions, in order to ensure the traceability of measurements, without which it is impossible to pass the accreditation procedure by any measuring laboratory for a compliance with the requirements of ISO/IEC17025:2017 [9, 10], laboratories need to use CRMs.

It is obvious that laboratories have to use CRMs in such areas, as the quality and safety of food and pharmaceutical products, quality of measurements in clinical laboratories, environmental safety, etc., where ensuring the uniformity of measurements is regulated by the State in accordance with the requirements of the Federal Law of June 26, 2008 No. 102-FZ [11]. In addition, laboratory specialists should know and understand how to correctly select RMs for their measurements and that

not all samples, offered on the market, are produced with the same quality level. It is important to ensure that any used CRM is developed and characterized in a technically sound manner. Generally, detailed information about homogeneity and stability studies, certification methods, as well as uncertainties and deviations in the declared RM values is available from a reliable producer and this information may be used to assess their reliability. As indicated above, a CRM must be accompanied with a certificate (or other identical document) that includes the evaluated uncertainty associated with the assigned value. The criteria for the competence of CRM producers, recognized at the interstate level, are determined by ISO 17034:2016[1] [12, 13].

It is clear that the practice of RM production and use differs from country to country. Therefore, it is extremely risky to leave this issue without appropriate state regulation. For this purpose, within the framework of the International Organization of Legal Metrology (OIML), the Document OIML D18 [14] was developed, formulating legal requirements for RMs, used in metrological activities in accordance with the national legislation. OIML D18 is based on the General principles regarding the use of RMs as measuring standards, which are provided in both ISO/REMCO and OIML publications. The document defines the minimum content of technical procedures that form the elements of the state metrological control and supervision applied to RMs. If necessary, procedures, depending on the specifics and practical experience in a particular country, may be changed and extended in national regulatory documents.

As we have already defined, the traceability of measurements in the field covered by the state control and supervision should be ensured by using CRMs.

How to Determine Whether the RMs Used Are Within the Scope of State Control and Supervision

In practice, this is often a difficult problem. According to OIML D18 [14], when considering whether the used RM is within the scope of state control and supervision or not, it is advisable to use the information specified in the CRM Certificate on the intended metrological use, such as:

- using the CRM as a measuring standard for verification, calibration and testing of measuring instruments;
- using the CRM to standardize measurement procedures and/or to determine their uncertainties while measuring;
- using the CRM for calibration of measuring instruments in measurement procedures.

Information on whether relevant measuring instruments or measurement procedures are in the field covered by the state metrological control and supervision or

[1] *Note*: In the RF, GOST R ISO 17034-2021 [12] State Standard, forced in December 2021, has not yet commonly used by RM producers.

not may be used to determine whether this CRM is covered by the state metrological control and supervision. A useful guidance in resolving this issue may be a list of the fields covered by the state regulation, whose legal documents provide specific details. The Document OIML D 12[2] [16] may be a useful guidance.

Thus, according to the international documents, in the RF, relevant legal documents determine both fields covered by the metrological control and supervision and a list of measurements related to these fields, according to which it is possible to determine whether the CRM is included in the legislative fields.

Necessary Criteria for the Compliance of a CRM with the Requirements

The necessary conditions for the use of CRMs in the fields covered by the state metrological control and supervision are their compliance with the specified metrological, technical, and administrative requirements, established in the country. Three types of requirements developed on the basis of OIML D3 [17] recommended and adapted for CRMs are provided below.

Metrological requirements include:

- list of CRM metrological characteristics to be determined;
- format of their presentation;
- requirements for measuring instruments and methods used in determining the metrological characteristics of CRMs, requirements for the content of CRM certification programs and procedures, etc.

Technical requirements include:

- CRM product form;
- list of accompanying technical documents for the initial and subsequent CRM production;
- requirements for packing and marking of the CRM delivered to the user, etc.

Administrative (legal) requirements for CRMs include:

- list of metrological activities, where the CRM is intended to be used;
- requirements for the type and format of documents accompanying the CRM, when delivered to the user;
- if necessary, designation of types and methods to control CRM metrological characteristics in the process of its use;
- details of the state registration in order to identify CRM or CRM batches, etc.

[2] *Note*: In the RF, the fields covered by the state metrological control and supervision are laid in the Federal Law of June 26, 2008 No. 102-FZ [9], and the list of measurements related to the scope of the State Control for Measurement Uniformity Assurance are laid in the Government Decree dated November 16, 2020 No. 1847 [15].

During the development of some CRMs, metrological, technical, and administrative requirements may be preliminary included in the project prepared at the initial stage of works.

In addition, the requirements to CRMs, authorized for the use in the field of the state metrological control and supervision, may be set out in the relevant regulatory document on the legislative metrology or a state standard.[3]

It is evident that, similar to any measuring standard or instrument, CRMs, approved for the use in the fields covered by the state metrological control and supervision, are also subject to the state metrological control and supervision [14].

CRM Metrological Control

The main purpose of metrological control is to ensure the compliance of CRMs with metrological, technical, and administrative (legal) requirements specified above.

A reasonable question is "What should be taken into account for metrological control to make sure the compliance of a CRM with the legal requirements?"

According to the relevant OIML provisions, the metrological control of measuring instruments normally includes the evaluation or testing of samples of a measuring instrument type and its approval, the verification (initial, periodic and other) or calibration of measuring instruments, the metrological supervision of the issue and use of measuring instruments and the conditions for their use, etc. In the case with CRM, all these operations are not always justified and may be limited [14] to the following operations, which can be represented schematically (Fig. 1):

At the same time, it is advisable to indicate in the regulatory document of the National Service of Legal Metrology, which ways (form, content, and procedures) the metrological control of a CRM shall be implemented.

According to the foregoing, type approval is one of the ways for the metrological control of used CRMs, in which the compliance of a CRM to legislative requirements is assessed (to make an examination). Before making a decision about the approval of the CRM type, it is necessary to make sure that the legal requirements are fully taken into account and reflected in the technical documentation of the CRM:

- performance or target specification for the CRM production;
- CRM certification program or procedure, CRM certificate model or another identical document;
- documents, accompanying the CRM when delivered to the consumer, or other documents specified by administrative requirements.

To conduct the expertise, it is also important to assess whether measuring instruments used to establish the certified CRM values are covered by the metrological control and whether the measuring standards used are higher in the traceability

[3] *Note*: In the RF, on the basis of the Federal Law dated June 26, 2008 No. 102-FZ [9], only approved type of RMs are allowed to use in the field covered by the State metrological control and supervision.

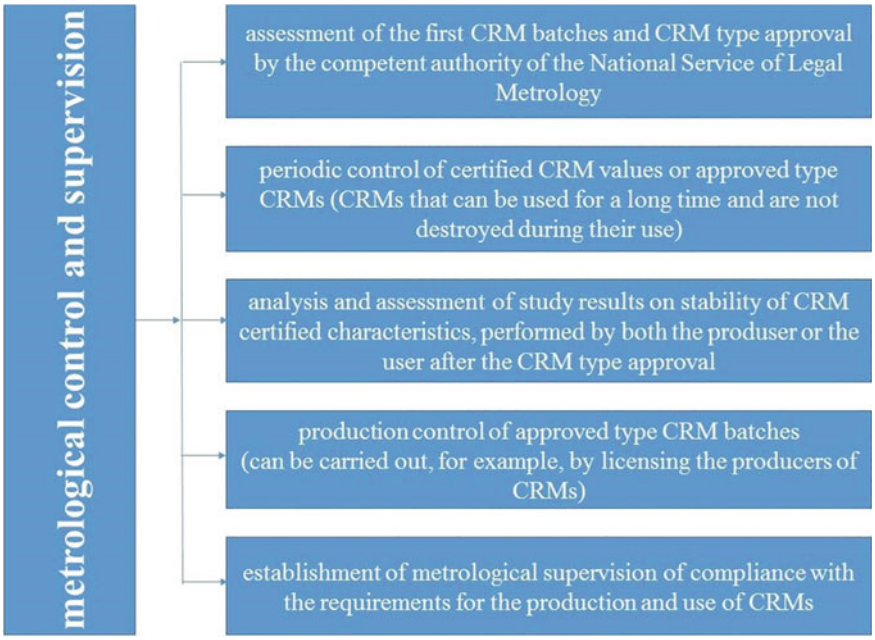

Fig. 1 Set of operations on the CRM metrological control and supervision, according to the provisions of OIML

chain [18]. The expertise may be general or detailed, including introduction to the CRM preparing procedure and production supervision of the compliance with the requirements of technical documents. In the latter case, it is possible to confirm the competence of the CRM producer by the accreditation procedure in accordance with the requirements of ISO 17034:2016 [12], provided that the national authority has established this possibility.[4]

Based on the positive results of assessing the compliance of a CRM with the established requirements, the type of CRM is approved by the competent authority of the National Service of Legal Metrology. When approving the CRM type, rules for verification and certification of the necessary standards should be established. The type approval may be accompanied by both the issuance of a "CRM type approval certificate" and the authorization of the CRM producer to stamp a type approval mark on the accompanying CRM documents.[5] The model of the certificate and/or mark

[4] *Note*: In the RF, on the basis of the Order of the Ministry of Industry and Trade dated August 28, 2020 No. 2905 [19], in terms of a CRM compliance assessment, the test procedure of RM have been established, including the examination of documentation.

[5] *Note*: In the RF, based on the Order of the Ministry of Industry and Trade dated February 03, 2015 No. 164 [20], the approved type of the CRM gets the status of the State Reference Material (SRM/GSO), is issued the "RM type approval Certificate," the relevant information is included in the State Register of Approved Types of Reference Materials of the Federal Information Fund of Measurement Uniformity Assurance.

are established by the authority that approves the CRM type. The validity of the type approval certificate may be limited with the possibility to extend. The extending is possible provided that during the validation period no new requirements to use the CRM in accordance with its purpose have been established (such restrictions may be the changes in the rules for calibration of measuring instruments or in the regulatory documents on test and control methods determining the use of the CRM).

The use of CRMs may be metrologically controlled by the relevant authorized metrological bodies by means of periodic verification or certification. The subsequent batches of CRMs of approved type, which, in particular, are not subject to periodic inspection, may be metrology controlled through licensing, which usually includes periodic monitoring by the producer of CRM compliance with the technical documentation when producing new batches. When developing regulatory documents of the national legal metrology service, it is important to take into account the recommendations of ISO Guide 33:2015 [21] to establish administrative (legal) requirements and the recommendations of ISO Guide 30:2015, ISO Guide 31:2015, and ISO Guide 35:2015 [22–24], for metrological and technical requirements. It should be noted that all these Guides are translated into Russian and approved for the use in the Russian Federation [25–27].

In addition, the National Service of Legal Metrology should clearly define the conditions (the same or different) applicable to imported CRMs, as well as for their admission to use in the fields covered by the state metrological control and supervision.[6]

Thus, the conditions for admission to the use of domestic and imported CRMs in the fields covered by the state metrological control and supervision are clearly established in the Russian Federation.

As might be expected, it is impossible to be limited only to the metrological control of CRMs used in the field of the state metrological control and supervision. Along with the metrological control described above, it is necessary to provide for the metrological supervision of compliance with the legislation requirements for the production and use of CRMs, which is entrusted to the metrological supervision bodies of the National Service of Legal Metrology.

The content and procedure of the metrological supervision shall be specified in the relevant national regulatory document. Here, it is recommended to take into account the provisions of the International Document OIML D 9[7] [29].

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[6] *Note*: In the RF, on the basis of the Federal Law dated June 26, 2008 No. 102-FZ [9], in the field covered by the state technical regulation, regardless of the RM producing country, only approved type reference materials are allowed to be used.

[7] *Note*: In the RF, the content and procedure for the metrological control/supervision is established in the Decree of the Government of the Russian Federation dated June 29, 2021 No. 1053 [28].

It should also be noted that the full information on legal documents, including related to use of RMs in the Russian Federation, may be find on the official website of the Federal Information Fund for Measurement Uniformity Assurance.

According to the document OIML D1 [30], us a rule, when detecting violations of the rules and misfits during the control of the market and production process by the metrological supervision, to take coercive action, fixed at the legislative level.[8]

In order to confirm the reliability of the obtained results, national legal metrology services, together with CRM manufacturers, are recommended to organize and/or participate in international comparisons of CRMs used in areas covered by the scope of the state metrological control and supervision. National Services of Legal Metrology in the respective countries are encouraged to sign agreements on the mutual recognition of CRM type approval certificates for removing technical barriers. For example, the list of CRMs used in the field covered by the state metrological control and supervision, may include the corresponding CRMs from the database of the International Bureau of Weights and Measures (BIPM), in accordance with the Agreement CIPM MRA [31] on the mutual recognition of standards and calibration certificates, signed by national metrological institutes.[9]

Conclusion

Thus, as shown by the conducted comparative analysis, the Russian legal framework regarding the use of reference materials in the fields covered by the state technical regulation was developed and approved in accordance with the OIML documents.

Nevertheless, some issues remain to be finalized.

1. No clear procedure is available for rules and regulations on the confirmation of the CRM producer competence. The absence of the "RM competent producer" status leads to the absence of such an important RM term in the country as a CRM. That is, the producer is not authorized to issue the legitimate RM Certificate to assign to the RM the status of the CRM. At the bottom of this, an additional stage of testing for the purpose of the type approval by an authorized body arises. In fact, if the decision about type approval is positive, the RM is given the status of a GSO (State Reference Material), bypassing the status of a CRM, and entered in the Register of Approved Types of Reference Materials. This approach complicates and greatly increases the duration of RM type approval procedure for their admission to the scope of the state technical regulation. The development of rules and regulations on the confirmation of the RM producer competence will let the level of RM production and simplify the RM type approval procedure to raise in a couple of years.

[8] *Note*: In the RF, the coercive actions have not been developed and are not laid legally in relation to violations and inconsistencies of the CRM with the data specified in the Type Approval Certificate.

[9] *Note*: The Russian Federation regularly participates and conducts such international comparisons within the framework of the Agreements between the Interstate Council on Standardization, Metrology and Certification (ISC) of the Commonwealth of Independent States (CIS) and the Euro-Asian Cooperation of State Metrological Institutions regional metrological organization (COOMET). It should be noted that this area is in a constant process of development and improvement.

2. Moreover, no coercive actions are applied to producers and suppliers of CRMs, established at the legislative level. It is suggested that, in the case of detecting a significant non-compliance of CCO/GSO with the established requirements, which is caused by the systematic negligence of the CRM producer/supplier, an extreme coercive action be applied as leverages on the CRM producer/suppliers. In addition, the "GSO" status should be disqualified and the CRM producer and/or supplier should receive the status of "unfair" or "incompetent", with the inclusion of this information in the relevant state information database (for example, add a special column in the register of GSO approved types).

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