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The use of certified reference materials in fields covered by metrological control exercised by national services of legal metrology. Basic principles

Utilisation des matériaux de référence certifiés dans les domaines couverts par le contrôle métrologique exercé par les services nationaux de métrologie légale. Principes de base

OIML D 18 Edition 2008 (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

- **International Recommendations (OIML R),** which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D),** which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;
- **International Guides (OIML G),** which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B),** which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

This publication - reference OIML D 18, edition 2008 (E) - was developed by the OIML Technical Subcommittee TC 3/SC 3 *Reference materials*. It was confirmed by the International Committee of Legal Metrology in 2008 with an update of Annex A: Bibliography in order to take into account the most recent edition of the VIM (edition 2007).

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Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

The use of certified reference materials in fields covered by metrological control exercised by national services of legal metrology. Basic principles

0 Scope

This International Document sets out guidelines for the development of legal requirements applicable to certified reference materials (CRMs) used in the framework of metrological activities covered, in conformity with national laws, by the metrological control and supervision exercised by national services of legal metrology.

Note: National laws may specify the fields of activity in which the metrological control and supervision of measuring instruments, standards, measurement procedures, etc., shall be exercised by the bodies of the national metrological service or other authorized organizations [A.l]. In this International Document, the abbreviation SMCS is used to refer to the state metrological control and supervision that cover such fields.

It is recommended that the principles set out in this International Document be implemented in the development of OIML publications and in the activities of national legal metrology services.

This International Document has been developed taking into consideration the general concepts expressed in ISO/REMCO and OIML publications concerning the use of CRMs as standards in metrological activities. Account has also been taken of concepts set out in other OIML publications establishing general metrological requirements and rules such as the competence of legal metrology services, the fields covered by state metrological control [A.l], legal requirements and type approval procedures [A.2], the principles of establishing standards and traceability [A.3, A.4], etc.

This International Document is also based on ISO/REMCO Guides 30 to 35 (see Annex A) and supplements these Guides with a view to facilitating a wider use of reference materials in SMCS.

1 General concepts

CRMs are widely used in metrological activities which, according to national laws, may be related to the fields covered by the SMCS, e.g. the verification and calibration of measuring instruments and control of measurement procedures as well as measurements connected with health protection, veterinary medicine, safety, trade and stock control of goods and material resources, financial settlements, etc. When used for such purposes, CRMs also become the object of metrological control and supervision.

In this connection, this International Document specifies the minimum content of technical procedures that form the elements of metrological control and supervision applied to CRMs. CRMs allowed for use in the field of SMCS should undergo these procedures, which may be modified or expanded in national regulatory documents taking into account any specific features and experience of practical work in various countries.

The question of whether or not a particular CRM is related to the field covered by SMCS may present a certain difficulty. When examining this question it is useful to take into consideration the intended metrological use of the CRM as indicated, for example, in its certificate. From this point of view, the metrological functions of the CRM may serve as a criterion and be summarized as follows:

- the use of the CRM as a standard to verify, calibrate and test measuring instruments;
- the use of the CRM to certify measurement procedures and/or to determine their uncertainties in the course of measurement; and
- the use of the CRM to calibrate measuring instruments in the course of measurement procedures.

The question of relating the particular CRM to a field covered by SMCS may be resolved on the basis of information on whether the relevant measuring instruments or measurement procedures are related to this field.

The OIML International Document D 12 *Fields of use of measuring instruments subject to verification* [A.5] may serve as a useful guide in resolving this question. Among similar fields OIML D 12 mentions official (state) activity, medicine (including the preparation and control of medicines), environmental protection, safety, etc. and gives pertinent comments and specific details.

2 Terminology

The terminology used in this Document is in line with:

- the *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM) [A.13];
- the *International vocabulary of terms in legal metrology* (VIML) [A.14]; and
- relevant ISO publications.

In relation to reference materials, the following definitions apply.

2.1 Reference material (RM)

Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. (VIM 5.13).

2.2 Certified reference material (CRM)

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. (VIM 5.14).

3 General requirements for certified reference materials

3.1 CRMs may be used in the fields covered by the SMCS provided that they comply with certain metrological, technical and administrative requirements set by the national services of legal metrology.

Note: 1) The three kinds of requirements recommended below for CRMs are in line with the provisions specified for measuring instruments by the OIML International Document D 3 Legal qualification of measuring instruments [A.2].

2) By decision of the national service of legal metrology, CRMs delivered by national organizations and foreign CRMs may be allowed for use in the field covered by the SMCS under the same conditions or under different, but clearly specified, conditions.

3.2 The metrological requirements applicable to a given CRM include, primarily, establishing:

- the list of the standardized metrological characteristics of the CRM to be determined;
- the format for their presentation; and
- the requirements for the measuring means and methods applied for certification (characterization) of the CRM, for the content of the CRM's certification programs and procedures, etc.

3.3 The technical requirements applicable to a given CRM include, for example, establishing:

- the form of issue (production) of the CRM;
- the list of technical documents for the initial and subsequent issue of the CRM; and
- the requirements applicable to the packing of the CRM at the time of supply to the user, etc.

Note: In establishing the metrological and technical requirements, the recommendations of ISO Guides 30 [A.6], 31 [A.8] and 35 [A.9] should be taken into account.

3.4 The administrative requirements for a CRM include, normally, establishing:

- the specification of metrological activities in which the CRM is intended to be used;
- the requirements for the nature and format of documents accompanying the CRM when supplied to the user;
- the kinds and methods of control of the metrological characteristics of the CRM in the course of its use (if necessary); and
- the details of registration for identification of specimens or batches of the CRM, etc.

Note: In establishing the administrative requirements, the recommendations of ISO Guide 33 [A.10] should be taken into account.

3.5 When developing a CRM, the relevant metrological, technical and administrative requirements may be included in advance in the specifications assigned for the development of the CRM or in more general requirements or in other document of this kind, prepared at the initial stage of the work.

3.6 The requirements applicable to certified reference materials allowed for use in a field covered by the SMCS may be set out in a regulatory document of legal metrology, or a national standard or guide, developed according to the provisions of both this International Document and other international, regional or national relevant regulatory documents.

4 Metrological control of the compliance of certified reference materials with legal requirements

4.1 According to relevant OIML provisions, the metrological control of measuring instruments normally consists of a set of operations, including:

- the evaluation or testing of specimens of the type of measuring instrument and its approval;
- the verification (initial, periodic and others) or calibration of measuring instruments; and
- the metrological supervision of the issue and use of measuring instruments and the conditions of their use, etc.

As for the metrological control of CRMs, all these operations are not always justified and may be limited, for example, to:

- the evaluation of the first lots of CRMs and the type approval of CRMs by a competent authority of the national service of legal metrology; and
- the periodic control of the certified values of CRMs or the periodic verification of the CRMs of the approved type (Note: by analogy with material measures, this operation applies to CRMs which can be used for a long time and are not destroyed during their use, for example, CRMs of electric, magnetic and optical properties of materials, CRMs of radioactive properties of substances, etc.);
- the analysis and evaluation of the results of the stability test of the certified characteristics of the CRMs, performed either by the producer or by the user after the CRM type has been approved;
- the control of production of lots of the approved CRMs, for example through licensing the CRMs producers; and
- the metrological supervision of compliance with the requirements applicable to the issue and use of CRMs.

4.2 It is appropriate to specify the ways (form, content and order) according to which the metrological control of CRMs must be exercised in a regulatory document of the national service of legal metrology.

4.3 The main purpose of the metrological control is to establish the compliance of CRMs with the metrological, technical and administrative provisions (legal requirements) as specified in clause 3 of this International Document.

4.4 The compliance of a CRM with legal requirements is evaluated during the type approval of the CRM. Preceding the decision on the approval of the CRM, the condition of its issue should be examined to make sure that legal requirements have been fully taken into account and reflected in the technical documents on the CRM in question. In performing such an examination the following documents must be considered:

- the technical assignment or specifications for the issue of a CRM; and
- the CRM certification program or procedure, the specimens of the CRM certificate or documents;
- supplied to the user together with specimens of the CRM or other documents specified by the administrative requirements referred to in sub-clause 3.4 of this International Document.

Notes: 1) One of conditions of correct certification of a CRM is the use of measuring instruments covered by metrological control for this purpose.

2) If a CRM is intended for use as a measurement standard in a hierarchic traceability chain, then measurement standards standing higher in the traceability chain should be used as means of certification as specified in OIML D 5 [A.3].

The examination may include a general or detailed familiarization with the CRM preparation procedure and with the manufacturing supervision of the compliance with the requirements of technical documents. In this case the competence of a CRM producer may be evidenced by their accreditation according to ISO Guide 34 [A.16] when the national body approving this CRM set down such a condition.

4.5 The type of the CRM is approved by a competent authority of the national service of legal metrology based on the positive results of the examination according to sub-clause 4.4 of this International Document.

4.6 The type approval may be accompanied by the issue of a "certificate of the CRM type approval" or by granting the CRM producer the right to apply the type approval mark on the documents accompanying the supply of the CRM to the user. The format of the certificate and the mark are established by the authority approving the type of CRM.

4.7 The validity period of the certificate of type approval may be limited with a possibility to be extended, provided that no new requirements impeding the use of the CRM in accordance with its purpose appear during this period.

Note: Modifications in the rules for the verification of instruments or in regulatory documents for test and control methods specifying the use of a CRM may constitute such impediments.

4.8 The metrological control of CRMs in the course of their use (see note to sub-clause 4.1) may be exercised through periodic verification or certification by metrological bodies having the relevant responsibility. The rules of verification and the specification of necessary measurement standards should be established when the type of the CRM is approved.

4.9 The metrological control of subsequent lots of approved CRMs which, in particular, are not subject to periodic verification may be exercised through a licensing which usually involves a periodic control by the producer of conformity with the requirements of the technical documents on the CRM, when new lots are issued.

4.10 Together with the metrological control as specified in sub-clauses 4.4 to 4.9 of this International Document, it is necessary to envisage a metrological supervision of the observance of legal requirements in the course of the CRM's issue and use, exercised by the metrological supervision bodies of the national service of legal metrology. The content and order of metrological supervision should be specified in the national regulatory document referred to in sub-clause 4.2. In so doing, it is useful to bear in mind the provisions of the OIML International Document D 9 [A..12].

4.11 National services of legal metrology, together with producers of CRMs, are encouraged to organize or participate in international comparisons of CRMs used in the fields covered by the SMCS.

4.12 National legal metrology services in the countries concerned are encouraged to conclude agreements of mutual recognition of CRM type approval certificates so as to use these CRMs without any difficulties after their purchase or sale.

Note: The Mutual Recognition Arrangement of the CIPM (14 October 1999) signed by national metrology institutes may include CRMs used in the field covered by the SMCS.

Annex A
Bibliography

A.1	OIML D 1:2004	Elements for a Law on Metrology.
A.2	OIML D 3:1979	Legal qualification of measuring instruments.
A.3	OIML D 5:1982	Principles of the establishment of hierarchy schemes for measuring instruments.
A.4	OIML D 8:2004	Measurement Standards. Choice, recognition, use, conservation and documentation.
A.5	OIML D 12:1986	Fields of use of measuring instruments subject to verification.
A.6	ISO Guide 30:1992/Amd 1:2008	Terms and definitions used in connection with reference materials.
A.7	ISO/IEC Guide 2:2004	Standardization and related activities - general vocabulary.
A.8	ISO Guide 31:2000	Reference materials - contents of certificates and labels.
A.9	ISO Guide 35:2006	Reference materials - general and statistical principles for certification.
A.10	ISO Guide 33:2000	Uses of certified reference materials.
A.11	OIML D 16:1986	Principles of assurance of metrological control.
A.12	OIML D 9:2004	Principles of metrological supervisions.
A.13	OIML V 2-200:2007	International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM), 3rd Edition.
A.14	OIML V 1:2000	International vocabulary of terms in legal metrology (VIML).
A.15	ISO Guide 32:1997	Calibration in analytical chemistry and use of certified reference materials.
A.16	ISO Guide 34:2000/Cor 1:2003	General requirements for the competence of reference material producers.