



COMMITTEE DRAFT OIML CD1

Date: 17 March 2008

Reference number: B 3/2008/CD1

Supersedes document: N/A

OIML TC 3/SC 5

Title: OIML B 3 *OIML Certificate System for Measuring Instruments*

Co-Secretariat:

- United States
- BIML

Circulated to P- and O-members and liaison international bodies and external organisations for:

- discussion planned at a meeting to be held on 27-30 May 2008
- Additional comments by: 20 June 2008
- vote (P-members only) and comments by

TITLE OF THE CD (English):

Revision OIML B 3

OIML Certificate System for OIML Type Evaluations of Measuring Instruments

TITLE OF THE CD (French):

Système de Certificats OIML pour l'Évaluation de Type OIML des Instruments de mesure

Original version in: English

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IEC, International Electrotechnical Commission
ISO, International Organization for Standardization

Explanatory note

The revision of OIML B 3 was decided at the 41st CIML Meeting held on October 2006 in Cape Town (South Africa). This project has been registered by the BIML as project p7 of OIML TC 3/SC 5 Conformity Assessment.

This revision is conducted in parallel with that of OIML B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* (project p8 of OIML TC 3/SC 5) and OIML B 10-2 *Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations*.

The main changes proposed are the following:

- To clarify the OIML Certificate System as applicable to OIML Type Evaluations on the basis of technical and metrological requirements specified in the relevant OIML Recommendations;
- To add criteria for the designation of OIML Issuing Authorities;
- To improve the issuing and registration conditions of OIML Certificates of conformity;
- To clarify the presentation of an OIML Certificate and of the associated OIML Type Evaluation Report;
- To clarify the link between the OIML Certificate System and the OIML Mutual Acceptance Arrangement;
- To revise and clarify terminology.

The present document constitutes the first Committee Draft (1CD). Some of the critical changes proposed will be discussed at the OIML TC 3/SC 5 Meeting to be held on 27-30 May 2008 at the BIPM (France). Additional written comments will be requested by 20 June 2008.

Based on the conclusions of the OIML TC 3/SC 5 Meeting and additional comments received, it is expected that a Second Committee Draft (2CD) will be developed and circulated among OIML TC 3/SC 5 Members by the end of 2008.

Definitions and references related to the International vocabulary of metrology – Basic and general concepts and associated terms (VIM) have been modified according to the 2007 edition.

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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; the OIML Member States shall implement these Recommendations to the greatest possible extent;

International Documents (OIML D), which are informative in nature and intended to improve the work of the metrological services;

International Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems;

International Guides (OIML G), which are informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are 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 and Guides are published in French (F) and English (E) and are subject to periodic revision.

Additionally, the OIML 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 to metrological authorities, 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 B 3, edition 200X (E) - was developed by the OIML Technical Subcommittee TC 3/SC 5 *Conformity assessment*. It was approved for final publication by the International Committee of Legal Metrology in 200X and supersedes the previous edition dated 2003 and its amendment dated 2006.

OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization's headquarters:

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01 Introduction

~~0.11.1~~ The OIML Certificate System for Type Evaluation of Measuring Instruments (hereafter referred to as the System) is a system for issuing, registering and using OIML Certificates of Conformity (hereafter referred as Certificates) and associated ~~in~~ OIML Type Evaluation Reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of Recommendations of the International Organization of Legal Metrology (OIML). It is a voluntary system and aims to facilitate, accelerate, and harmonize the work of national and regional bodies that approve types of measuring instruments that are subject to state control within OIML Members, or within regions including OIML Members. In the same way, instrument manufacturers, who are required to obtain type approval in some countries in which they wish to sell their products, should benefit from the System through providing evidence that their instruments comply with the requirements of the relevant OIML Recommendations. The System also aims to facilitate initial verification of measuring instruments in countries where type approval is not required, and may help to promote the manufacture, marketing, and use of measuring instruments that comply with OIML requirements for applications that are not subject to legal control.

~~0.21.2~~ General rules for the certification of products, processes, and services have been documented by recognized international organizations (see References). The System allows these general rules and applies them to the type evaluation and certification of measuring instruments. Those who implement and those who participate in the System should promote the observance of the international guidelines on certification and testing.

~~0.31.3~~ A manufacturer or its representative from any country may apply for type evaluation and a Certification to be issued by a designated Issuing Authority in any OIML Member State that participates in the System. Likewise, any Certificate may be accepted and utilized by any national metrology service or national responsible body in any country.

Note: In this Publication, the word “Certificate” means OIML Certificate of Conformity as defined in 3.12. When necessary for its application in Member States, it should be clearly distinguished from product certification or legal certificates as defined by the national certification systems or by the national legislation or regulation.

1.4 An additional tool available to the System is defined in OIML B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (OIML MAA)*. Within the OIML MAA, confidence in test and examination results which are included in the OIML Type Evaluation Report is reinforced by a formal and mandatory evaluation process of Testing Laboratories involved in tests and examinations.

12 **Scope**

~~1.12.1~~ An OIML Certificate of a type of measuring instrument (including a family of instruments, a module or a family of modules) attests to the conformity of that type, as represented by the sample(s) submitted, tested, and examined according to the requirements of the relevant OIML Recommendation.

~~1.22.2~~ A Certificate may be issued only for the categories of measuring instruments (including families of instruments, modules, or families of modules) for which the relevant Recommendation specifies:

- (1) The metrological and technical requirements,
- (2) The test procedures and,
- (3) The ~~Test Report~~ OIML Type Evaluation Report Format.

Concerning families of instruments, modules and families of modules, the relevant Recommendation(s) shall specify what can be considered as a family and/or a module as well as the specific metrological and technical requirements and test procedures applicable to such families/modules.

Note: A list of the categories of instrument concerned, with references to the relevant Recommendations, is maintained by the International Bureau of Legal Metrology (BIML) under the supervision of the International Committee of Legal Metrology (CIML).

~~1.3A Certificate is issued by an Issuing Authority of an OIML Member State.~~

~~The CIML member in a given Member State may designate one or several Issuing Authorities in that State per category of instruments.~~

~~The CIML Member in a given Member State may be responsible for an Issuing Authority in that State.~~

~~1.42.3~~ Member States that choose to implement the System shall ensure that documented procedures for the operation, supervision, and control of the System, including appeals, are established and are consistent with national laws and with the requirements of this Publication.

23 **Abbreviations and terminology**

The following abbreviations and definitions apply:

OIML	International Organization of Legal Metrology
CIML	International Committee of Legal Metrology
BIML	International Bureau of Legal Metrology
Member State	OIML Member State
OIML Members	OIML Member States and Corresponding Members
Certificate	OIML Certificate of Conformity

OIML MAA OIML Mutual Acceptance Arrangement

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~~Type~~ ~~Covers the model of a measuring instrument or its module or modules and also the models of a family of instruments or a family of modules.~~

2.13.1 **Measuring instrument**

Device ~~intended to be~~ used ~~to for~~ making measurements, alone or in conjunction with supplementary device(s). (VIM-~~43~~.1)

2.23.2 **Category of instruments**

Identification or classification of instruments according to unique metrological and technical characteristics that may include the measured quantity, the measuring range, and the principle or method of measurement.

2.33.3 **Family of measuring instruments**

Identifiable group of measuring instruments belonging to the same manufactured type within the same category that have the same design features and metrological principles for measurement but which may differ in some metrological and technical performance characteristics, as defined in the relevant Recommendation.

The concept of a “family” primarily aims to reduce the testing required for OIML Type Evaluation. It does not preclude the possibility of listing more than one family in one Certificate.

2.43.4 **Module**

Identifiable part of a measuring instrument or of a family of measuring instruments that performs a specific function or functions and that can be separately evaluated according to prescribed metrological and technical performance requirements in the relevant Recommendation.

2.53.5 **Family of modules**

Identifiable group of modules belonging to the same manufactured type that have similar design features but may differ in some metrological and technical performance requirements as defined in the relevant Recommendation.

2.63.6 **Type of a measuring instrument or module**

Definitive model of a measuring instrument or module (including a family of instruments or modules) of which all the elements affecting its metrological properties are suitably defined.

2.73.7 **Type (~~pattern~~) evaluation**

Systematic examination and testing of the performance of one or more specimens of an identified type (~~pattern~~) of measuring instrument against documented requirements, the results of which are contained in an evaluation report, in order to determine whether the type may be approved. (VIML 2.5)

3.8 OIML Type Evaluation

A Type evaluation conducted on the basis of the relevant OIML Recommendation, the results of which are contained in an OIML Type Evaluation Report associated with an OIML Certificate of Conformity.

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2.83.9 Examination

(Official) visual inspection of an instrument or device and relevant documentation to ensure that some specified requirements are met.

2.93.10 Conformity

Fulfilment by a measuring instrument type of metrological and technical requirements as specified in the relevant Recommendation.

2.103.11 OIML Certificate System for OIML Type Evaluations of Measuring Instruments

Voluntary system for issuing, registering, and using OIML Certificates of Conformity and their associated OIML Type Evaluation Reports.

2.113.12 OIML Certificate of Conformity

Document issued under the rules of the System by the Issuing Authority providing confidence that the identified type of measuring instrument is in conformity with the requirements of the relevant Recommendation.

Note: In order to avoid any confusion with Certificates issued under the OIML MAA, the OIML Certificates issued under the rules of the System are also designated **OIML Basic Certificates**. Certificates issued under the MAA are designated OIML MAA Certificates.

3.13 OIML Type Evaluation Report

Report, prepared according to the Format specified in the relevant Recommendation that includes the **OIML Test Report(s)** and assesses the conformity of the type of measuring instrument to all the requirements in the relevant OIML Recommendation. The OIML Type Evaluation Report is issued by the OIML Issuing Authority and referred to in the OIML Certificate of Conformity.

3.14 OIML Test Report:

Report issued by each Testing Laboratory, which includes results of tests and examinations, carried out on the basis of the relevant OIML Recommendation during OIML Type Evaluation on an identified sample or identified samples of a given type of measuring instrument.

2.15 Test Report

~~Report, prepared according to the Test Report Format specified in the relevant Recommendation, that gives the results of the examinations and testing carried out during type evaluation on an identified sample or samples of a given type and a conclusion as to whether the sample or samples meet the specified requirements.~~

~~Note: For the implementation of the System, the Test Report constitutes the evaluation report referred to in 2.7.~~

2.133.15 OIML Issuing Authority

~~Certifying body or person in an OIML Member State, designated by its CIML Member, that issues OIML Certificates of Conformity according to the rules of the OIML Certificate System for OIML Type Evaluations of Measuring Instruments.~~

~~Note 1: A CIML Member may be responsible for an Issuing Authority.~~

~~Note 2: A list of all Issuing Authorities in the various Member States is maintained by the BIML and is permanently available to Member States and other interested parties on the OIML web site and on request.~~

~~Note 3: The Issuing Authority that issues OIML Certificates may or may not be the same organization as the national body that issues national type approval certificates and whose responsibilities are governed by national regulations.~~

3.16 Testing Laboratory

~~Any specialized laboratory designated by the OIML Issuing Authority to carry out examination and testing of a sample or samples of a measuring instrument submitted for OIML Type Evaluation, with the OIML Issuing Authority assuming responsibility for the OIML Type Evaluation Report.~~

4 Designation of an OIML Issuing Authority

~~4.1 The CIML member in a given Member State may designate one or several OIML Issuing Authorities in that State per category of instruments.~~

~~The CIML Member in a given Member State may be responsible for an Issuing Authority in that State.~~

~~Note 1: The Issuing Authority that issues OIML Certificates may or may not be the same organization as the national body that issues national type approval certificates and whose responsibilities are governed by national regulations.~~

~~Note 2: A list of all Issuing Authorities in the various Member States is maintained by the BIML and is permanently available to Member States and other interested parties on the OIML web site and on request.~~

~~4.2 An OIML Issuing Authority should demonstrate its competence to issue Certificates and associated OIML Type Evaluation Reports according to the requirements specified in this publication and the relevant Recommendation and in particular that it complies with the requirements in international guidelines on certification, in particular in ISO/IEC Guide 65 "General requirements for bodies operating product certification systems" [7]. The Member State is responsible for evaluating the competence of the OIML Issuing Authority. For~~

instance, such an evaluation may be performed on the basis of accreditations, assessments of the OIML Issuing Authority by the CIML Member or on request of an internal audit report to be submitted by the OIML Issuing Authority to the CIML Member.

35 Processing a Certificate

3.15.1 Application for a Certificate

3.1.15.1.1 The manufacturer of a type or an authorized representative of the manufacturer may apply to a designated OIML Issuing Authority for a Certificate.

3.1.25.1.2 The application shall include the following:

- (a) ~~the~~ name and address of the manufacturer and, if appropriate, of the authorized representative;
- (b) ~~a~~ statement that no concurrent application for OIML ~~†~~Type ~~e~~Evaluation has been made to any other OIML Issuing Authority;
- (c) ~~a~~ description of the type as distinct from other types, and any information related to testing; in the case of a family of instruments or modules, the description of the operation may include, as appropriate, information concerning each instrument or module that belongs to the family;
- (d) ~~a~~ description of the instrument's operation, including the manufacturer's operating instructions; in the case of a module, the description of the modules' operation may include, as appropriate, information concerning the characteristics of the category of instruments of which the module may be part;
- (e) ~~a~~ list of specified manufacturer's documentation, necessary and sufficient for the identification of the type submitted such as parts lists, serial or reference number for electronic components, software programs, etc.;
- (f) a sample or samples, representative of the production envisaged, to be submitted for tests and examinations on the basis of the relevant OIML Recommendation;
- (g) technical documentation to assure that the manufacturer is able to ensure consistent production;
- (~~h~~) if applicable, results of Test ~~†~~Reports of previous OIML ~~†~~Type ~~e~~Evaluation(s) (see 5.3.4).

3.1.35.1.3 The applicants may also submit their own test results, or those of a third party laboratory, in support of the claim that the instruments or modules meet the requirements of the relevant Recommendation (see also 5.3.4).

3.25.2 Consideration for the application

3.2.15.2.1 The OIML Issuing Authority receiving the application shall review it and may request ~~the~~ applicant to provide additional information and documents prior to further processing of the application.

3.2.25.2.2 The OIML Issuing Authority may refuse the application if any of the following apply:

- a) the OIML Issuing Authority is unable to have the necessary tests conducted for the category of instruments concerned;
- b) the type does not correspond to the category covered in the relevant Recommendation;

- c) the information required for the application (including any additional information and documents requested) is incomplete;
- d) other clearly identified reasons.

3.2.35.2.3 In the first case under 5.2.2, the OIML Issuing Authority, however, may refer the applicant to an OIML Issuing Authority in another Member State, which may be capable of conducting the OIML ~~†~~Type eEvaluation, without obligating the latter thereby.

3.2.45.2.4 The OIML Issuing Authority shall inform the applicant in writing of its decision concerning the acceptance or refusal of an application. If the application is refused, the reason shall be given.

Note: The OIML Issuing Authority may also request the applicant to provide any specialized equipment necessary to conduct the tests.

3.2.55.2.5 If the application is accepted, the OIML Issuing Authority shall inform the applicant of the rules of the System and of the number of samples of the type that are required for testing. This number is usually specified in the relevant Recommendation but, if not, it shall be mutually agreed upon by the OIML Issuing Authority and the applicant. In certain cases, the OIML Issuing Authority may be satisfied with the results of Test ~~†~~Reports of a previous OIML ~~†~~Type eEvaluation (see 5.3.4) and, therefore, it may not be necessary to test new samples of the type. The OIML Issuing Authority, however, shall obtain evidence that the type for which a Certificate is requested is identical to the previously evaluated type. If previous test results are accepted, the Test-Type Evaluation Report or accompanying document shall indicate which previous results were accepted and utilized.

3.2.65.2.6 In the case of a family of instruments or modules, the OIML Issuing Authority shall inform the applicant of the identity and number of instruments or modules of the family that are to be submitted for testing according to the requirements specified in the Relevant Recommendation.

3.2.75.2.7 For modules, the OIML Issuing Authority shall inform the applicant which instruments or simulation setup may be necessary to enable testing according to the requirements specified in the relevant Recommendation.

3.2.85.2.8 The OIML Issuing Authority shall inform the applicant of the fee for application, an estimate of the fees for OIML ~~†~~Type eEvaluation and issuing the Certificate, and the exact amount of the registration fee. The fees for testing and issuing Certificates and OIML Type Evaluation Reports shall be determined according to national practice, and fees for registration shall be determined by the CIML.

3.2.95.2.9 The Issuing Authority shall inform the applicant in writing of the approximate time necessary to draw up a Test Report and complete the type evaluation.

3.35.3 Tests of conformity

3.3.15.3.1 The tests for OIML ~~†~~Type eEvaluation shall be performed in the Testing ~~†~~Laboratories ~~designated by the Issuing Authority that accepted the application~~. These laboratories shall comply with the requirements in international guides or standards on testing, such as in ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” [8] and other relevant guides and publications. OIML publications concerning the type evaluation processes shall also be observed.

3.3.25.3.2 It is recommended that the competence of the testing laboratory, which performs the test of conformity, be assessed by a body within a national accreditation system, by peers, or by other means.

The assessment team utilized shall include at least one member who is an expert in legal metrology for the relevant category of measuring instruments or devices.

Note: Within the OIML MAA a formal evaluation is mandatory and the conclusions reviewed by an ad-hoc Committee.

3.3.35.3.3 The test procedures shall be consistent with those described in the relevant Recommendation.

3.3.45.3.4 The test procedures may be abbreviated or omitted if the Issuing Authority considers that the conclusions necessary for issuing the Certificate and the OIML Type Evaluation Report may be drawn from a previous type evaluation, provided that they were carried out according the requirements of 3.3.45.3.1 and 3.3.25.3.2 above. Where applicable, relevant test results of the manufacturer or a third-party testing laboratory may be considered. The conditions under which such test results may be considered shall be specified by documented requirements of the OIML Issuing Authority. Results issued from tests performed by manufacturers shall be clearly identified in the OIML Type Evaluation Report and OIML Test Reports (see 5.5.1 and 5.4.1).

5.4 OIML Test Report(s)

5.4.1 The Testing Laboratory responsible for tests according to the relevant Recommendation shall issue an OIML Test Report. In case there are several Testing Laboratories responsible for testing, each Testing Laboratory is responsible for issuing an OIML Test Report which includes the results of test it was responsible for. All the Test Reports will then be included in the OIML Type Evaluation Report issued by the OIML Issuing Authority (see 5.5). In the event that the OIML Issuing Authority is responsible for all the tests and examinations, an OIML Type Evaluation Report only may be issued.

5.4.2 The OIML Test Report shall give, as appropriate, the results of the various tests and examinations obtained for samples of the type. It shall include at least the following:

- a) name and address of the Testing Laboratory with a statement of compliance with the guidelines mentioned in 5.3.1 giving details of any accreditation, peer assessment, or assessment by other means;
- b) reference (number and year of edition) to the relevant Recommendation;
- c) identification of the type (e.g. reference to specific designation);
- d) reference (number and year of edition) to the relevant Recommendation;
- e) identification of specific samples tested;
- f) for each test or examination, dates of testing;
- g) for each test or examination, place of testing;
- h) for each test or examination, name of the person responsible for it;
- i) for each test or examination, the environmental conditions, if appropriate;

- j) for each test or examination, information concerning the instrument or the simulation setup used for testing, especially in the case of a module or family of modules;
- k) examination and test results;
- l) for each test and examination, a conclusion as to whether the samples meet the relevant requirement of the appropriate Recommendation;

5.4.3 The OIML Test Report shall be dated, signed, and provided with a unique identification number by the responsible person or persons of the Testing Laboratory that performed the tests.

5.4.4 The OIML Test Report shall be in English.

Note: In some cases, translation of the OIML Test Report into additional languages other than English or French may assist in national or regional interpretation and implementation.

3.45.5 OIML Type Evaluation Report Test Report

3.4.15.5.1 ~~The Test Report~~ OIML Type Evaluation Report shall give, as appropriate, the results of various tests and examinations obtained for samples of the type and shall be drawn up in the format provided in the relevant Recommendation. It shall include at least the following:

- a) name and address of the OIML Issuing Authority which is responsible for issuing the report with a statement of compliance with the requirements mentioned in 4.2, if available;
- ~~a)~~ b) name and address of the laboratory or laboratories identified according to the specific tests performed, with a statement of compliance with the guidelines mentioned in 3.3.15.3.1 giving details of any accreditation, peer assessment, or assessment by other means;
- ~~b)~~ c) reference (number and year of edition) to the relevant Recommendation;
- ~~b)~~ d) identification of the type (e.g. reference to specific designation, description, external and internal photographs, marking, software, inscriptions, specifications, etc. including, if applicable, the accuracy class); in the case of a family of instruments or a module or family of modules, additional information according to 3.1.25.1.2 shall be provided;
- ~~e)~~ e) identification of the specific samples tested; ~~in the case of a family of instruments or modules, identification of the specific samples tested with a justification of their selection;~~
- f) justification of the selection of samples, in particular in case of a family of instruments or modules or if specific requirements are mentioned in the relevant OIML Recommendation;
- ~~e)~~ g) identification of any authorized and agreed upon adjustments or modifications made to the sample or samples during the testing;
- ~~f)~~ h) name and address of the manufacturer;
- ~~g)~~ i) name and address of the applicant for the Certificate;
- j) information defined in 5.4.2 from f) to l) which may be included by annexing the relevant OIML Test Reports;

~~k) identification of test results from manufacturers which have been taken into account, if applicable;~~

~~e) dates of testing;~~

~~f) place of testing;~~

~~g) information concerning the instrument or the simulation setup used for testing, especially in the case of a module or family of modules;~~

~~h) examination and test results;~~

~~d) general conclusion as to whether the samples meet the requirements of conform to the relevant Recommendation;~~

~~Note: In some countries, a distinction is usually made between test results (recorded measurement results) and evaluation (judgment and conclusions on the test results). In this System, the Test Report includes both kinds of information, and the users of a Test Report will have to take this into account, when necessary.~~

e)m) annexed listing of the manufacturer's documentation submitted with the application for a Certificate and used for identification of the type submitted (see 3.1.25.1.2).

~~3.4.25.5.2~~ The ~~Test Report~~OIML Type Evaluation Report shall be dated, signed, and provided with a unique identification number by the responsible person or persons of the ~~laboratory~~OIML Issuing Authority that performed the ~~OIML Type Evaluation~~. ~~The OIML logo may be affixed on the OIML Evaluation Report~~OIML Type Evaluation Report.

~~Note: The OIML logo can be used to avoid any confusion with any evaluation report issued by a national authority on the basis of OIML requirements (which cannot bear the OIML logo).~~

~~3.4.35.5.3~~ The ~~Test Report~~OIML Type Evaluation Report shall be in English ~~and/or French~~.

~~Note: In some cases, translation of the Test Report~~OIML Type Evaluation Report into additional languages other than English or French may assist in national or regional interpretation and implementation.

~~3.4.45.5.4~~ The OIML Issuing Authority shall keep on file a copy of the ~~Test Report~~OIML Type Evaluation Report and the information provided with the application (see also ~~3.4.5~~5.5.5). By agreement with the applicant, the tested samples may be kept by the OIML Issuing Authority, the Testing Laboratory(ies), or the applicant, the decision taking into account the size and, if appropriate, the commercial value of those samples.

~~3.4.55.5.5~~ In a declaration of the conformity of the type, the following apply:

- a) if it is concluded that the samples meet all the requirements of the Recommendation, a Certificate shall be issued in accordance with ~~3.55.6~~;
- b) if the samples do not meet requirements, the applicant shall be informed in writing of the reason for the failure, and the ~~Test Report~~OIML Type Evaluation Report shall be given to the applicant, if requested.

~~3.4.65.5.6~~ In subsequent applications, the applicant may submit a new application with samples of a modified or newly identified type. New tests may be conducted but may be limited to those requirements for which the previous type was found not to comply only if evidence

provided supports the conclusion that the instrument's performance for all other requirements is not likely to have been affected by the modification of the type. If the application applies to a type for which a Certificate has already been issued, the procedure in 6.79.1 applies.

3.4.75.5.7 Fees for type evaluation and testing shall be collected in accordance with the national practice.

3.55.6 Issue of a Certificate

3.5.45.6.1 If the type is found to conform to all the requirements of the relevant Recommendation, a Certificate shall be issued after the completion of the type evaluation.

3.5.25.6.2 The Certificate shall be drawn up according to the model given in Annex A. It shall be signed by the OIML Issuing Authority, ~~and may also be signed by the CIML Member, if the latter is not the Issuing Authority and if this is permitted by national practice. The BIML shall be informed whether the signature of the CIML Member is required. The signature of the CIML Member, who is not the Issuing Authority, is only intended to confirm the identity of the designated Issuing Authority and that this designation has not been cancelled (see 6.3 for other responsibilities of the CIML Member).~~ It shall bear the OIML logo.

3.5.35.6.3 The Certificate shall be in English or French and, if appropriate, also in the national language of the OIML Issuing Authority (see the *Note* under 3.4.35.5.3).

3.5.45.6.4 The Certificate shall have a unique reference number established according to the form specified in Annex B, indicating the following:

- a) the relevant Recommendation with the year of publication;
- b) the ISO country code [12] of the Member State in which the Certificate was issued, supplemented by the indication of the numbering of the OIML Issuing Authority for the category of instruments concerned in that Member State;
- c) the year of issue;
- d) a sequential two-digit number.

3.5.55.6.5 The Certificate shall also include the identification number ~~or numbers~~ of the associated ~~Test Report~~ OIML Type Evaluation Report(s) as indicated in Annex A.

3.5.65.6.6 The Certificate and the associated ~~Test Report~~ OIML Type Evaluation Report(s) shall be given to the applicant, who then becomes their owner. The OIML Issuing Authority shall keep a copy of the Certificate and the ~~Test Report~~ OIML Type Evaluation Report.

3.5.75.6.7 The fees for issuing the Certificate shall be collected in accordance with the national practice.

46 Registration of a Certificate

4.16.1 The OIML Issuing Authority shall send a copy of each Certificate it issues to the BIML for registration either directly or via its CIML Member (according to the agreement between the

Authority and the Member) ~~(see also 3.5.2). An electronic-~~The copy of each Certificate shall also be sent to the BIML in ~~the an electronic~~ format specified by the latter.

~~4.26.2~~ The BIML shall send the owner of the Certificate an invoice for the registration fee. ~~A Certificate shall be registered only after the fee has been collected.~~ Alternatively, the registration fee may have been included in the fees charged for issuing the Certificate (see ~~3.5.65.6.7~~), in which case the invoice for the registration fee shall be sent to the OIML Issuing Authority concerned, upon its request.

~~4.3~~The BIML shall send a confirmation of the registration and a copy of the Certificate to the owner and a copy of the Certificate to all ~~CIML Members and all OIML corresponding Members.~~

~~4.46.3~~ Certificates are available on the OIML web site. In addition, ~~P~~periodically, the BIML shall inform the Member States and other interested parties of the registration of Certificates, through appropriate publications including the OIML Bulletin, and shall make lists of registered Certificates available on the OIML web site.

57 Use of Certificate - Recognition of test results and acceptance of a Certificate

~~5.17.1~~ The owner may use a registered Certificate and its associated ~~Test Report~~OIML Type Evaluation Report as follows:

- a) in support of an application for type approval in any country or group of countries; it is the responsibility of the applicant to give evidence upon request that the type presented for approval is identical to that identified on the Certificate;

Note: If requested by the regional or national approval authority, the complete ~~Test Report~~OIML Type Evaluation Report shall be presented by, or on behalf of, the owner together with the Certificate.

- b) in support of the presentation of an individual instrument for initial verification in a country in which type approval is not required; it is the responsibility of the applicant to give evidence upon request that the instrument presented for verification is of the type that is identified on the Certificate;
- c) to inform buyers, users, and other interested parties that the type of measuring instrument (represented by the tested samples) was found to conform to the requirements of the relevant Recommendation.

Note: Such evidence of conformity (and the name of the OIML Member State in which the Certificate was issued) may be referred to or included in e.g. manufacturer's catalogues and other marketing literature (however, see ~~5.27.2~~ and ~~5.37.3~~).

~~5.27.2~~ It is the obligation of the manufacturer that has been granted a Certificate to produce individual instruments that conform to those submitted for type evaluation; however, a Certificate shall not be used as proof of conformity of an individual instrument with the requirements of the relevant Recommendation. In particular, neither the reference number of the Certificate nor any other reference to the OIML (e.g. the OIML logo) shall be affixed to an individual instrument.

~~5.37.3~~ Apart from the mention of the Certificate's reference number with the name of the OIML Member State in which the Certificate was issued (see ~~5.17.1~~), partial quotation of the

Certificate or of the associated ~~Test Report~~OIML Type Evaluation Report is not permitted, though they may be reproduced in full.

5.47.4 The legal metrology service (or other responsible body) to which the application for type approval is made should take into consideration the Certificate and ~~the its~~ associated ~~Test Report~~OIML Type Evaluation Report to the extent that is possible. The legal metrology services of OIML Members should especially consider the advantages that may result from the recognition of Certificates and the acceptance of the reported test results in facilitating, accelerating, and harmonizing the processes of national or regional type approval.

5.57.5 OIML Members are encouraged to adopt mechanisms to recognize and accept ~~Test Report~~OIML Type Evaluation Reports accompanied by Certificates through appropriate measures. ~~See also OIML B 10-1 [4] including various bilateral or multilateral mutual acceptance arrangements.~~

68 Supervision and control

6.18.1 General

The CIML shall supervise the implementation of the general rules, their adaptation to changing needs, and the formulation of additional rules that may be necessary for the effective operation of the System.

6.28.2 Appeals

6.2.18.2.1 Each Issuing Authority shall have documented procedures for accepting, considering, and resolving appeals against decisions.

6.2.28.2.2 A CIML Member may act as a technical advisor and may request assistance from the BIML, the responsible OIML Technical Committee or Subcommittee, and/or the CIML in resolving technical issues associated with appeals and disputes of decisions of an Issuing Authority in his or her country.

6.38.3 Role of CIML Members

In addition to the various tasks described in this publication, it is the responsibility of CIML Members to carry out the following:

- a) designate ~~an OIML Issuing Authority~~ies that is competent to issue Certificates according to the requirements specified in this publication and the relevant Recommendation and that complies with the requirements in international guidelines on certification, in particular in ISO/IEC Guide 65 “General requirements for bodies operating product certification systems” [8];
 - b) promptly inform the BIML of the establishment of (or change in) any OIML Issuing Authority in his or her country; including any cancellation of designation;
 - c) provide the OIML Issuing Authorities (and via them the testing laboratories) in his or her country with current information concerning the operation of the System;
- ~~d) also sign the Certificates if he or she is not the Issuing Authority and if this is permitted by the national practice, and inform the BIML as to whether his or her signature is required. This signature is only intended to confirm the identity of the designated Issuing Authority and that this designation has not been cancelled.~~

6.48.4 Misuse of a Certificate by its owner

~~6.4.18.4.1~~ The BIML shall consult the CIML Member of the Member State in which a Certificate was issued when documented and substantiated evidence is presented that the Certificate is being used by its owner in a manner contrary to the requirements of clause 57. Depending on the conclusions of the consultation, the BIML shall both inform other Member States and interested parties accordingly and also directly inform the owner that continued misuse of the Certificate will lead to corrective actions being taken by the CIML that could result in the Certificate being de-listed by the BIML.

~~6.4.28.4.2~~ In the event of de-listing, the BIML shall notify the owner of the Certificate, inform the Member States and any other interested parties, and publish a notice in appropriate publications including the OIML Bulletin and the OIML web site.

6.58.5 Certificate issued on the basis of wrong conclusions

The BIML shall consult the CIML Member of the Member State in which a Certificate was issued when documented and substantiated evidence is presented indicating that the tests providing the basis for issuing the Certificate were performed or interpreted incorrectly. Depending on the results of the consultation, ~~the~~ BIML may de-list the Certificate and shall also inform the owner and other Member States and interested parties accordingly. In such cases, the conditions under which the fees for the tests and for the issue of the Certificate are reimbursed shall be determined by an agreement between the OIML Issuing Authority, or the CIML Member of the Member State involved, and the owner.

6.6 Revision of a Recommendation

~~6.6.1~~ After revision of the relevant Recommendation for a given category of measuring instrument(s) for which Certificates may be issued, the responsible OIML Technical Committee or Subcommittee shall declare, and the CIML shall confirm, whether instruments complying with the previous relevant Recommendation are also deemed to comply with the revised Recommendation.

~~6.6.2~~ If the instruments are declared to comply with the revised Recommendation, an owner of a Certificate provided in accordance with the previous Recommendation may apply for a Certificate referring to the revised Recommendation. A new Certificate shall be issued to the owner by the relevant Issuing Authority for a specified fee and shall be registered at no charge by the BIML.

~~6.6.3~~ If the instruments are declared as not necessarily complying with the revised Recommendation, the owner may apply for a new Certificate according to the revised Recommendation by submitting the same type or modified type for evaluation according to the procedure indicated in 3.3. The tests required for issuing a new Certificate, however, may be abbreviated according to 3.3.4.

~~6.6.4~~ After the publication date of a revised Recommendation, the CIML may declare a specific transition period during which it is possible to apply for a Certificate that may be issued based on the previous Recommendation.

9 Modification of a certificate

6.7.1 Revision of a Certificate

6.7.19.1.1 It may be necessary to amend an issued and registered Certificate for reasons such as:

- a) to correct an error made by the applicant or the OIML Issuing Authority; or
- b) to modify the Certificate upon request of its owner, in particular when the certified type has been modified.

In such cases, the OIML Issuing Authority shall amend the Certificate using the same reference number as for the initial Certificate, indicating in addition the revision number (Revision 1, Revision 2, etc. together with ~~the a~~ statement explaining the reason for the amendment – See 9.1.2. “This revision replaces the preceding one”) and a new date, if appropriate. Depending on the efforts required and the reasons put forward for amending the Certificate, the OIML Issuing Authority may decide if the owner shall pay an additional fee or not for issuing the amended Certificate. A registration fee equal to that of the registration of an initial Certificate shall be required to be paid to the BIML for an amended Certificate.

9.1.2 ~~-A~~ at the beginning of the amended Certificate, a statement shall summarize the reason for the amendment, for instance by using one the following:

- This revision replaces Certificates numberand; or
- This revision consist of a supplement to Certificates numberand

9.1.3 In order to facilitate the use of Certificates by other countries, the number of amendments to a Certificate shall be limited to three. In case further amendments are requested, a complete new Certificate shall be issued. The OIML Type Evaluation Report associated with the Certificate may include previously existing Test Reports provided that existing test and examination results are applicable.

9.1.4 Depending on the request for amending a Certificate, the OIML Issuing Authority is responsible for determining the list of tests and examinations to be performed on the instrument modified. See also 5.5.6.

9.1.5 In case an amended Certificate is issued to correct an error, at the same time as an amended Certificate is registered, the previous Certificate shall be deleted from the lists maintained by BIML.

9.2 Withdrawal of a Certificate

9.2.1 The owner of a registered Certificate may request the BIML to withdraw that Certificate from the lists maintained by the latter for reasons other than those indicated in 8.5 and 9.1 (e.g. the instruments are no longer manufactured). In this case, the BIML shall delete the registration from the OIML web site and inform the Member States and other interested parties of the withdrawal in the same way as described in 6.3 for the registered Certificates.

~~6.6.6~~ If a Recommendation has been replaced by a revised edition, a correction of an error according to 6.7.1 a) may be made on a Certificate based on the previous Recommendation. No other revisions of Certificates based on a Recommendation that has been replaced by a revised edition may be made after the transition period referred to in 6.6.4.

~~6.6.7 At the same time as an amended Certificate is registered, the previous Certificate shall be deleted from the lists maintained by BIML.~~

~~6.7 Withdrawal of a Certificate~~

~~The owner of a registered Certificate may request the BIML to withdraw that Certificate from the lists maintained by the latter for reasons other than those indicated in 6.5 and 6.7 (e.g., the instruments are no longer manufactured, a single Certificate has been issued for a family of instruments, etc.). In this case, the BIML shall proceed in the same way as described in 4.4 for the registered Certificates.~~

6.99.3 Transfer of a Certificate

~~6.9.19.3.1~~ A new owner of a company may apply to the original OIML Issuing Authority for the transfer of a Certificate previously owned by the purchased company provided that:

- a) the same type ~~(model)~~ will continue to be produced by the new owner;
- b) the new owner is also in possession of all of the technical documentation and equipment necessary to continue the production of the identified type ~~(model)~~;
- c) the new owner is authorized by the previous owner of the Certificate.

~~6.9.29.3.2~~ The Issuing Authority shall review the application and documentation indicated in ~~6.9.19.3.1~~ and shall decide whether the new owner is competent to continue the production of the previously evaluated type ~~(model)~~. If the decision is favorable, then a new Certificate may be issued based on the previous type evaluation with an identification of its new owner. The necessary fee for the transfer of ownership will be decided on by the OIML Issuing Authority.

~~6.9.39.3.3~~ The transferred Certificate will be transmitted to BIML for registration and the latter will charge the usual fee. The Certificate registered under the name of the previous owner is withdrawn.

9.4 Issuing Additional Certificates

~~9.4.1~~ A new applicant may apply to the original Issuing Authority to issue an Additional Certificate to the one previously issued to the original applicant provided that:

- a) the additional applicant will produce the same type of measuring instrument;
- b) the additional applicant is also in possession of all of the technical documentation and equipment necessary to continue the production of the identified type;
- c) the additional applicant is authorized by the original applicant of the Certificate.

~~9.4.2~~ The Issuing Authority shall review the application and documentation indicated in 9.3.1 and shall decide whether the additional applicant is competent to produce the previously evaluated type. If the decision is favorable, then the Additional Certificate may be issued based on the previous type evaluation. The necessary fee for issuing the Additional Certificate will be decided on by the OIML Issuing Authority.

~~9.4.3~~ The Additional Certificate will be transmitted to BIML for registration and the latter will charge the usual fee.

9.5 Revision of an OIML Recommendation

~~9.5.1~~ After revision of the relevant Recommendation for a given category of measuring instrument(s) for which Certificates may be issued, the owner of a Certificate issued on the

basis of the previous edition of the relevant OIML Recommendation may apply for updating his Certificate on the basis of the revised OIML Recommendation.

9.5.2 When reviewing the application, the OIML Issuing Authority is responsible for determining, depending on the modifications implemented in the revised Recommendation, whether the type complies with the revised Recommendation and, if applicable, defining the additional tests and examinations to be performed.

9.5.3 Upon successful completion of any additional tests and examinations, a new Certificate shall be issued to the owner by the relevant OIML Issuing Authority. The registration by the BIML is performed according to 6.

9.5.4 After the publication date of a revised Recommendation, a transition period of two years is established during which it is possible to apply for a Certificate that may be issued based on the previous Recommendation. No other Certificates based on a Recommendation that has been replaced by a revised edition may be issued after this transition period.

7References

- [1]OIML D-19: 1988, "Pattern evaluation and pattern approval"
- [2]VIM: 1993, "International vocabulary of basic and general terms in metrology"
- [3]VIML: 2000, "International vocabulary of terms in legal metrology"
- [4]"Framework for a mutual acceptance arrangement on OIML type evaluations (MAA)" (Draft OIML Document, 2003)
- [5]ISO/IEC Guide 2:1996, "Standardization and related activities—General vocabulary"
- [6]ISO/IEC Guide 58:1993, "Calibration and testing laboratory accreditation systems—General requirements for operation and recognition"
- [7]ISO/IEC Guide 61:1996, "General requirements for assessment and accreditation of certification/registration bodies"
- [8]ISO/IEC Guide 65:1996, "General requirements for bodies operating product certification systems"
- [9]ISO/IEC 17025:1999, "General requirements for competence of testing and calibration laboratories"
- [10]"Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations" (Draft OIML Document, 2003)
- [11]WTO TBT Agreement, "Agreement on technical barriers to trade"
- [12]ISO 3166 1:1997, "Codes for the presentation of names of countries and their subdivisions—Part 1: Country codes"

Annex A - (Mandatory) General Model for a Certificate

A.1 The Certificate issued by an Issuing Authority shall be either identical to the General Model presented in this Annex or based on that model, including the essential elements.

The French version of this publication provides the same general model in French. Bilingual Certificates in which the text is in English or French and another language may be issued.

A.2 Specific model Certificates for certain categories of instruments, including families and/or modules, may be developed by the OIML Technical Committee or Subcommittee that is responsible for developing and maintaining the relevant Recommendation. A model Certificate thus developed shall be consistent with the model presented here and shall be included in the relevant Recommendation.

A.3 The logo of the Issuing Authority may be placed on the Certificate according to national rules.

OIML Certificate Format to be developed later.

Annex B - (Mandatory)

Reference Number of a Certificate

B.1 The reference number of a Certificate is divided into the following parts:

- a) the number and year of the edition of the relevant Recommendation as specified in the latest published list of Recommendations included in the System;
- b) a two-letter code indicating the Member State in which the Certificate was issued in accordance with the ISO country codes [12]- as indicated in B.2 - along with the number indicating the specific Issuing Authority beginning with 1 (Example 1) and in the order as designated by the CIML Member; and
- c) the last two figures of the year of issue of the Certificate followed by its two-digit sequential number for that particular year for each Issuing Authority.

Note 1: If one of the Issuing Authorities in a Member State ceases to issue Certificates, its “serial number” shall not be allocated to any other Issuing Authority.

Note 2: Provisionally, the sole Issuing Authority may continue to use its country code without indicating the serial number “1” for Certificates issued in 2003. However, as soon as a second Issuing Authority is identified in a Member State and registered by the BIML, the first Issuing Authority shall add “1” to its country code (e.g. in the case of Example 2 the first Issuing Authority in country “BB” shall be changed for “BB1” in all future certificates.

Note 3: For amended Certificates, the same reference number shall be used as for the initial Certificate (see 9.1).

Figures to be completed.

B.2 ISO country codes for Member States [12]

Albania	AL	Kazakhstan	KZ
Algeria	DZ	Kenya	KE
Australia	AU	Republic of Korea	KR
Austria	AT	Macedonia	MK
Belarus	BY	Monaco	MC
Belgium	BE	Morocco	MA
Brazil	BR	Netherlands	NL
Bulgaria	BG	New Zealand	NZ
Cameroon	CM	Norway	NO
Canada	CA	Pakistan	PK
China	CN	Poland	PL
Croatia	HR	Portugal	PT
Cuba	CU	Romania	RO
Cyprus	CY	Russian Federation	RU
Czech Republic	CZ	Saudi Arabia	SA
Denmark	DK	Republic of Serbia	RS
Egypt	EG	Slovakia	SK
Ethiopia	ET	Slovenia	SI
Finland	FI	South Africa	ZA
France	FR	Spain	ES
Germany	DE	Sri Lanka	LK
Greece	GR	Sweden	SE
Hungary	HU	Switzerland	CH
India	IN	Tanzania	TZ
Indonesia	ID	Tunisia	TN
Islamic Republic of Iran	IR	<u>Turkey</u>	<u>TR</u>
Ireland	IE	United Kingdom	GB
Israel	IL	United States of America	US
Italy	IT	<u>Zambia</u> <u>Vietnam</u>	<u>ZMVN</u>
Japan	JP		

Annex C - (Informative)

Summary of the tasks of an OIML Issuing Authority

- C.1 This Annex summarizes the tasks of the OIML Issuing Authority included in the text of this publication in order to assist them in understanding their central role in implementing the System.
- C.2 The OIML Issuing Authority carries out the following tasks:
- ~~a)~~d) designates the laboratory(ies) that is(are) competent to carry out the necessary examinations and tests of the submitted type (of measuring instrument) and prepares the Test Report(s) of the results;
 - ~~b)~~e) ensures that the testing laboratory(ies) is(are) competent according to requirements compatible with ISO/IEC 17025 [9]:1999, ~~“General requirements for the competence of testing and calibration laboratories;~~
 - ~~e)~~f) ensures that the application and test procedures reflect the current System requirements;
 - ~~d)~~g) _____ specifies documented conditions under which the manufacturer’s or third party’s test results may be considered;
 - ~~e)~~h) reviews the results of type evaluation included in the OIML Test Report(s);
 - i) issues the OIML Type Evaluation Report;
 - ~~f)~~j) for a successful evaluation, issues a Certificate for the type (of measuring instrument) to the applicant;
 - ~~e)~~k) _____ for an unsuccessful evaluation, notifies the applicant in writing of the deficiencies in performance of the type (of measuring instrument);
 - ~~h)~~l) submits (directly or via its country’s CIML Member according to the mutual agreement between the two) the Certificate to the BIML for registration;
 - ~~i)~~m) _____ maintains active liaison with its CIML Member, whenever appropriate; and
 - ~~j)~~n) makes available documented procedures for accepting, considering, and resolving appeals against decisions.

Annex D - (Informative) **Bibliography**

- [1] OIML D 19: 1988, "Pattern evaluation and pattern approval"
- [2] ISO/IEC Guide 99: 2007, "International vocabulary of metrology – Basic and general concepts and associated terms (VIM)"
- [3] VIML: 2000, "International vocabulary of terms in legal metrology"
- [4] OIML B 10-1: 2004, "Framework for a mutual acceptance arrangement on OIML type evaluations"
- [5] ISO/IEC Guide 2: 2004, "Standardization and related activities - General vocabulary"
- [6] ISO/IEC 17000: 2004, "Conformity assessment – Vocabulary and general principles"
- [7] ISO/IEC Guide 65:1996, "General requirements for bodies operating product certification systems"
- [8] ISO/IEC 17025:2005, "General requirements for competence of testing and calibration laboratories"
- [9] ISO/IEC Guide 68: 2002, "Arrangements for the recognition and acceptance of conformity assessment results"
- [10] OIML B 10-2: 2004, "Checklists for issuing authorities and testing laboratories carrying out OIML type evaluations"
- [11] WTO TBT Agreement, "Agreement on technical barriers to trade"
- [12] ISO 3166-1: 2006, "Codes for the presentation of names of countries and their subdivisions - Part 1: Country codes"
- [13] Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology (Draft OIML Document - OIML TC 3/SC 5 project p5 - 2CD:2007)
- [14] Guide for the application of ISO/IEC 17025 to assessment of Testing Laboratories involved in legal metrology testing (Draft OIML Document - OIML TC 3/SC 5 project p4 - 2CD:2006)