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OIML TC 3/SC 5

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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 in October 2010 (dates and venue to be confirmed)
- ☒ Comments by: 30 April 2010
- ☐ vote (P-members only) and comments by

TITLE OF THE CD (English):

Revision OIML B 3

OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments

TITLE OF THE CD (French):

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

Original version in: English

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ISO, International Organization for Standardization

Explanatory note

Revising 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 simplify the issuing and registration conditions of OIML Certificates of conformity;
- To clarify the layout 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 second Committee Draft (2CD). It was drawn up on the basis of the discussions on the 1CD, the conclusions of the OIML TC 3/SC 5 Meeting held on 27-30 May 2008 at the BIPM (France) - please refer to the minutes dated 16 July 2008. Additional comments from CPR Members on guidelines to the manufacturer for the use of the Evaluation Report have also been taken into account.

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.

The title has been changed to “OIML **Basic** Certificate System for OIML Type Evaluation of Measuring Instruments” to make a clear distinction with the OIML MAA and in order to emphasize the concept that the MAA is an additional tool to the OIML Basic Certificate System. Consequently, the structure of the revised OIML B 10 is similar to that of the revised OIML B 3. The revised OIML B 10 defines only those requirements which are different from the revised OIML B 3 or not applicable.

The Test Report as defined in 2.12 of OIML B 3:2003 has been renamed to the OIML Basic Type Evaluation Report (see 3.13) since it is issued by the OIML Issuing Authority and includes the conclusions on the conformity of the sample tested to the requirements of the relevant OIML Recommendation.

The Test Report as defined in 3.14 and 5.4 is now issued by an internal or a subcontracting Testing Laboratory of the OIML Issuing Authority. In the event that several subcontracting Testing Laboratories are involved in type testing, several Test Reports may be issued. Afterwards, they are all included in the OIML Basic Type Evaluation Report.

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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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1 Introduction

- 1.1 The OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments (hereafter referred to as the System) is a system for issuing, registering and using OIML Basic Certificates of Conformity (hereafter referred as Certificates) and associated 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 legal control within OIML Member States and Corresponding Members, or within regions including OIML Member States and Corresponding 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 that provides evidence that their instrument type or design complies with the requirements of the relevant OIML Recommendations. The System may also 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.
- 1.2 The OIML Basic Certificate System requires a Type Evaluation of sample(s) of measuring instruments which should be representative of the production. The type is defined on the basis of the information defined in 5.1.2. However the Type Evaluation conducted within the System does not include any formal evaluation to establish that the type is representative of the intended production. Such an evaluation, and the assessment of the conformity of the produced instruments to the certified type, may be addressed in other OIML Publications.
- 1.3 General rules for the certification of products, processes, and services have been documented by recognized international organizations (see [7] in Annex E). The System takes these general rules into account 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.
- 1.4 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 Basic 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.

- 1.5 An additional tool available to the System is defined in OIML B 10 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* (OIML MAA). Within the OIML MAA, confidence in test and examination results that are included in the OIML MAA Type Evaluation Report is reinforced by a formal and mandatory evaluation process of Testing Laboratories involved in tests and examinations.
- 1.6 OIML B 3 and OIML B 10 are complementary Publications. OIML B 3 defines the general requirements for the implementation of the OIML Basic Certificate System. OIML B 10 identifies additional and/or other requirements applicable to the implementation of the OIML MAA.

2 Scope

- 2.1 An OIML Basic Certificate issued for 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 - to the requirements of the relevant OIML Recommendation.
- 2.2 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 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)

(The last part of the note has been deleted considering Resolution no. 19 of the 43rd CIML Meeting)

Reminder of Resolution no. 19:

As soon as an OIML Recommendation, including the Test Report Format (which is now called OIML Basic Type Evaluation Report) is published, the relevant OIML Recommendation is automatically included in the OIML Basic Certificate System. The Bureau will publish the appropriate information on the web site.

If a new version of an OIML Recommendation is published, the earlier version is maintained in the OIML Basic Certificate System or in the relevant OIML DoMC, together with the new version.

A comparison document between the two versions, drawn up by the appropriate TC/SC Secretariat, is no longer required.

Note: The last part of the Resolution results in withdrawing the requirement defined in 6.6.1 of OIML B 3: 2003.

- 2.3 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.

3 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 Basic Certificate of Conformity
OIML MAA	OIML Mutual Acceptance Arrangement

3.1 Measuring instrument

Device used for making measurements, alone or in conjunction with supplementary device(s). (VIM 3.1)

3.2 Category of instruments

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

3.3 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.

3.4 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.

3.5 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.

3.6 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.

3.7 Type evaluation

Systematic examination and testing of the performance of one or more specimens of an identified type 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)

Note 1: Measuring instruments could here include modules as defined in 3.4.

Note 2: The word “certified” used in this Publication should be understood as “conformity to the relevant OIML Recommendation” (e.g. certified type).

Note 3: Evaluation reports include a Test Report as defined in 3.13 3.14 or partial Test Reports as defined in 3.15.

3.8 OIML Type Evaluation

Type evaluation conducted on the basis of the relevant OIML Recommendation.

3.9 Examination

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

3.10 Conformity

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

Note: See note 2 of 3.7.

3.11 OIML Basic Certificate System for OIML Type Evaluations of Measuring Instruments

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

3.12 OIML Basic Certificate of Conformity

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

Note: If the additional rules defined in OIML B 10 are also met, the Certificates issued are called “OIML MAA Certificates of Conformity”.

3.13 OIML Basic Type Evaluation Report

Report, issued by the OIML Issuing Authority (see 3.16) that assesses the conformity of the type of measuring instrument or module to all the requirements in the relevant Recommendation.

Note: See Annex C.

3.14 Test Report

Report issued by a Testing Laboratory, that includes results of tests and examinations carried out on the basis of the relevant OIML Recommendation during OIML Type Evaluation on identified sample(s) of a given type of measuring instrument or module.

Note: See annex C.

3.15 Partial Test Report

Test Report that does not include results of all the tests specified in the relevant OIML Recommendation

3.16 OIML Issuing Authority

Certifying body or person in an OIML Member State, designated by its OIML Member, that issues OIML Basic Certificates of Conformity and OIML Basic Type Evaluation Reports according to the rules of the OIML Basic Certificate System.

Note: See annex C.

3.17 Testing Laboratory

Any laboratory designated by the OIML Issuing Authority to carry out examination and testing of sample(s) of a measuring instrument or module submitted for OIML Type Evaluation.

Note 1: Testing laboratories may be internal laboratories of OIML Issuing Authorities, third-party laboratories or manufacturers' laboratories.

Note 2: The OIML Issuing Authority, and not the Testing Laboratory, is responsible for issuing the OIML Basic Type Evaluation Report.

Note 3: See annex C.

3.18 Designer

Company or person legally responsible for the design of the measuring instrument and/or a module.

3.19 Manufacturer

Company or person legally responsible for producing measuring instruments and/or modules which conform to the certified Type.

3.20 Applicant

Manufacturer and/or authorized representative who submits an application for an OIML Basic Type Evaluation of a measuring instrument to an OIML Issuing Authority in order to receive an OIML Basic Type Evaluation Report and an OIML Basic Certificate for that type of instrument.

Note: After the issuing of the Certificate, the applicant becomes the owner of the Certificate.

4 Designation of an OIML Issuing Authority

- 4.1** The CIML Member in a given Member State may designate one or more OIML Issuing Authorities in that State per category of instruments.

Note 1: The CIML Member may be a member of the staff of an Issuing Authority in a given Member State.

Note 2: 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 3: 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] *(For information: this Guide is under revision and will become ISO/IEC 17065 “Conformity assessment - Requirements for certification bodies certifying products, services and processes”)*.

The Member State is responsible for evaluating the competence of the OIML Issuing Authority.

Note: 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 behalf of the CIML Member, or at the request of an internal audit report to be submitted by the OIML Issuing Authority to the CIML Member.

5 Processing a Certificate

5.1 Application for a Certificate

- 5.1.1** The manufacturer of a type, or an authorized representative of the manufacturer, may apply to a designated OIML Issuing Authority for a Certificate.
- 5.1.2** 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 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 lists of (electronic) devices (OIML D 11, 3.2 [14]) and sub assemblies (OIML D 11, 3.3 [14]), serial or reference number for electronic components, software programs, etc.;
 - (f) information on, or details of, the sample(s), representative of the production envisaged, to be submitted for tests and examinations on the basis of the relevant OIML Recommendations;
 - (g) if applicable, results of Test Reports of previous OIML Type Evaluation(s) (see 5.3.5).
- 5.1.3 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 5.3.40).

5.2 Consideration for the application by the Issuing Authority

- 5.2.1 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.
- 5.2.2 When the applicant submits test results as defined in 5.1.3, the Issuing Authority is not required to accept them.
- 5.2.3 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 or module concerned;
 - b) the type does not correspond to the category or module 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.
- 5.2.4 In the first case under 5.2.3, the OIML Issuing Authority may, however, refer the applicant to an OIML Issuing Authority in another Member State, which may be capable of conducting the OIML Type Evaluation, without obligating the latter thereby.
- 5.2.5 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.
- 5.2.6 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 Evaluation (see 5.3.5) and, therefore, it may not be necessary to test new sample(s) 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 OIML Type Evaluation Report or accompanying document shall indicate which previous results were accepted and utilized.

- 5.2.7 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 of the family or modules that are to be submitted for testing according to the requirements specified in the Relevant Recommendation.
- 5.2.8 For modules, the OIML Issuing Authority shall inform the applicant which equipment or simulation setup may be necessary to enable testing according to the requirements specified in the relevant Recommendation.
- 5.2.9 The OIML Issuing Authority shall inform the applicant of the fee for application, an estimate of the fees for OIML Type Evaluation and issuing the Certificate, and the exact amount of the BIML registration fee. The fees for testing and issuing Certificates and OIML Type Evaluation Reports shall be determined according to national practice, and BIML fees for registration shall be determined by the CIML.
- 5.2.10 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.

5.3 Tests and examinations

- 5.3.1 The tests and examinations for OIML Type Evaluation shall be performed in the Testing Laboratories. 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 (e.g. OIML D 30 [13]).
- 5.3.2 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 appropriate Committee.

- 5.3.3 The test procedures shall be consistent with those described in the relevant Recommendation.
- 5.3.4 Where applicable, relevant test results of the manufacturer 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 Basic Type Evaluation Report (see 5.5.1).
- 5.3.5 The test procedures may be abbreviated or omitted if the Issuing Authority considers that the conclusions necessary for issuing the Certificate and the OIML Basic Type Evaluation Report may be drawn from a previous type evaluation, provided that they were carried out according the requirements of 5.3.1 and 5.3.2 above. The conditions under which such test results may be considered shall be specified by documented requirements of the OIML Issuing Authority. If tests have been abbreviated or omitted, it shall be clearly indicated in the OIML Basic Type Evaluation Report (see 5.5.1).

5.4 Test Report(s)

- 5.4.1 The Testing Laboratory conducting tests according to the relevant Recommendation shall issue a Test Report. In case there are several Testing Laboratories conducting such tests, each Testing Laboratory shall issue a Test Report which includes the results of the tests it has conducted.
- 5.4.2 All the Test Reports will then be included in the OIML Basic Type Evaluation Report issued by the OIML Issuing Authority (see 5.5).
- 5.4.3 Each 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 category as defined in the relevant OIML Recommendation (e.g. check weigher, fuel dispenser);
 - d) identification of the type or the family (e.g. commercial name or number);
 - 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 who conducted the test or examination;
 - i) for each test or examination, the environmental conditions, if appropriate;
 - j) for each test, a description of the test facilities;
 - k) 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;
 - l) examination and test results including considerations on measurement uncertainties and a statement on traceability, as appropriate;
 - m) for each test and examination, a conclusion (pass/fail) as to whether the samples meet the relevant requirement of the appropriate Recommendation;
- 5.4.4 The Test Report shall be dated, signed, and provided with a unique identification number by the responsible person of the Testing Laboratory who authorizes the report.
- 5.4.5 The Test Report shall be in English and shall not bear any OIML logo.

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

5.5 OIML Basic Type Evaluation Report

Note: The OIML Basic Type Evaluation Report is prepared according to the Format specified in the relevant OIML Recommendation, and includes all the relevant Test Report(s).

- 5.5.1 The OIML Basic 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;
 - 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 5.3.1 giving details of any accreditation, peer assessment, or assessment by other means;
 - c) reference (number and year of edition) to the relevant Recommendation;
 - d) identification of the category (e.g. check weigher, fuel dispenser);
 - e) identification of the type (e.g. reference to specific designation, description of the instrument, 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 5.1.2 shall be provided;
 - f) identification of the specific samples tested;
 - g) 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;
 - h) identification of any authorized and agreed upon adjustments or modifications made to the sample or samples during the testing;
 - i) name and address of the manufacturer;
 - j) name and address of the applicant for the OIML Basic Certificate;
 - k) Test Report(s);
 - l) identification of test results from manufacturers which have been taken into account, if applicable;
 - m) general conclusion as to whether the samples conform to the relevant Recommendation;
 - n) annexed listing of the manufacturer's documentation submitted with the application for an OIML Basic Certificate and used for identification of the type submitted (see 5.1.2).
- 5.5.2 The OIML Basic Type Evaluation Report shall be dated, signed by the responsible persons (e.g. evaluator and supervisors according to OIML D 29 [12]) of the OIML Issuing Authority that performed the OIML Type Evaluation, and provided with a unique identification number.
- 5.5.3 The OIML logo shall be affixed on the OIML Basic Type Evaluation Report.
- 5.5.4 The OIML Basic Type Evaluation Report shall be in English.

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

- 5.5.5 The OIML Issuing Authority shall keep on file a copy of the OIML Basic Type Evaluation Report and the information provided with the application (see also 5.5.6). 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.
- 5.5.6 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 5.65.6;
 - b) if the samples do not meet requirements, the applicant shall be informed in writing of the reason for the failure, and the OIML Type Evaluation Report shall be given to the applicant, if requested.
- 5.5.7 In the event that the samples failed a previous evaluation, 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 9.1 applies.
- 5.5.8 Fees for type evaluation and testing shall be collected in accordance with the national practice.
- 5.6 Issue of an OIML Basic Certificate of Conformity**
- 5.6.1 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.
- 5.6.2 The Certificate shall be drawn up according to the model given in Annex A. It shall be signed by the OIML Issuing Authority. It shall bear the OIML logo.
- 5.6.3 The Certificate shall be in English and, if appropriate, also in the national language of the OIML Issuing Authority (see the *Note* under 5.5.4).
- 5.6.4 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.
- 5.6.5 The Certificate shall also include the identification number of the associated OIML Basic Type Evaluation Report as indicated in Annexes A and B.
- 5.6.6 The Certificate and the associated OIML Basic Type Evaluation Report shall be given to the applicant, who then becomes their owner. The OIML Issuing Authority shall keep a copy of the Certificate and the OIML Basic Type Evaluation Report. (See 6 for registration by the BIML).

- 5.6.7 The fees for issuing the Certificate shall be collected in accordance with the national practice.
- 5.6.8 The official date from which an OIML Basic Certificate can be issued by an OIML Issuing Authority for a given OIML Recommendation is the date on which all the relevant parts (see 2.2) have been uploaded on the OIML web site (see 10).

6 Registration of a Certificate

- 6.1 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). The copy of each Certificate shall be sent to the BIML in an electronic format specified by the latter.
- 6.2 The BIML shall send the owner of the Certificate an invoice for the registration fee. Alternatively, the BIML registration fee may have been included in the fees charged for issuing the Certificate (see 5.6.7), in which case, upon the request of the OIML Issuing Authority concerned, the invoice for the BIML registration fee shall be sent to the Authority..
- 6.3 Certificates are available on the OIML web site. In addition, 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.

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

- 7.1 An OIML Basic Certificate of conformity does not bestow any form of legal international approval.
- 7.2 The owner may use a registered Certificate and its associated OIML Basic Type Evaluation Report as follows:
- a) in support of an application for national or regional 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 OIML Basic 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 7.4 and 7.5).

- 7.3** If requested by the regional or national authority, the owner is responsible for providing it with the original, or a certified copy of, the complete OIML Basic Evaluation Report.
- 7.4** It is the moral 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.
- 7.5** 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 7.1), partial quotation of the Certificate or of the associated OIML Type Evaluation Report is not permitted, though they may be reproduced in full.
- 7.6** The legal metrology service (or other responsible body) to which the application for national or regional type approval is made should take into consideration the Certificate and its associated OIML Basic 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.
- 7.7** OIML Members are encouraged to adopt mechanisms to recognize and accept OIML Basic Type Evaluation Reports accompanied by Certificates through appropriate measures. See also OIML B 10 [4].

8 Supervision and control

8.1 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.

8.2 Appeals

- 8.2.1** Each Issuing Authority shall have documented procedures for accepting, considering, and resolving appeals against decisions.
- 8.2.2** 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.

8.3 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 OIML Issuing Authorities;

- b) promptly inform the BIML of the establishment of (or change in) any OIML Issuing Authority and its contact person 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.

8.4 Misuse of a Certificate by its owner

- 8.4.1 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 77. 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.
- 8.4.2 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.

8.5 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.

9 Modification of a certificate

9.1 Revision of a Certificate

- 9.1.1 It may be necessary to revise 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 a statement explaining the reason for the amendment – See 9.1.2) and a new date, if appropriate. 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 At the beginning of the revised Certificate, a statement shall indicate that the Certificate replaces the previous version(s) and summarize the reason(s) for the revision.

The revised Certificate shall indicate references to all the OIML Basic Evaluation Reports that have been used to determine conformity, including those attached to previous version(s) where still valid.

- 9.1.3 When revising a Certificate, the OIML Issuing Authority is responsible for determining the list of tests and examinations to be performed on the modified instrument. See also 5.5.7.

- 9.1.4 In case a revised Certificate is issued to correct an error, the previous Certificate shall be deleted from the lists maintained by the BIML when the revised Certificate is registered.

9.2 Transfer of a Certificate

- 9.2.1 When the name or address of the applicant is requested to be changed by a new applicant, the new applicant shall apply to the original OIML Issuing Authority for the transfer of the Certificate provided that the new applicant is also in possession of all of the technical documentation as defined in 5.1.2, and the existing OIML Basic Evaluation Report.

The OIML Issuing Authority should make any necessary inquiry to ensure the validity of the transfer.

- 9.2.2 The transferred Certificate will be transmitted to the BIML for registration and the latter will charge the applicable fee.

9.3 Issuing Additional Certificates

- 9.3.1 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 the new applicant is also in possession of all the technical documentation as defined in 5.1.2, and of the existing OIML Basic Type Evaluation Report.

The OIML Issuing Authority should make any necessary inquiry to ensure the validity of the application.

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

9.4 Revision of an OIML Recommendation

- 9.4.1 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.

- 9.4.2 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.

- 9.4.3 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.

10 Inclusion of an OIML Recommendation in the System

As soon as an OIML Recommendation, including the OIML Basic Evaluation Report Format is published, the relevant OIML Recommendation is automatically included in the OIML Basic Certificate System.

The BIML is responsible for publishing the appropriate information on the OIML web site. This information includes the date on which the new or revised OIML Recommendation first appears on the OIML web site.

If a new version of an OIML Recommendation is published, the earlier version is maintained in the OIML Basic Certificate System together with the new version as long as the CIML does not decide to withdraw the earlier version from the System.

11 Specific provisions after withdrawing an OIML Recommendation from the System when a Declaration of Mutual Confidence (OIML B 10, 3.4 [4]) is set up for this Recommendation

- 11.1** For a given OIML Recommendation that is included in a Declaration of Mutual Confidence, the OIML Basic Certificate System and the OIML MAA are maintained in parallel until the CIML decides to withdraw the relevant Recommendation from the System.
- 11.2** When the CIML has decided to withdraw the relevant Recommendation from the System, a two-year period is allowed before the withdrawal from the System becomes effective. After this period, no OIML Basic Certificates may be issued on the basis of the relevant Recommendation except under the conditions defined in 11.3.
- 11.3** When the CIML has decided to withdraw the relevant Recommendation from the System and in the event that an applicant requests a revision of an OIML Basic Certificate based on the same version of the Recommendation, which has been subsequently covered by the MAA, the revised OIML Basic Certificate may be issued by the original OIML Issuing Authority – even if it is not an Issuing Participant (OIML B 10, 3.9 [4]) – or by an Issuing Participant in the relevant Declaration of Mutual Confidence.

Annex A - (Mandatory) Format for a Certificate

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

Bilingual Certificates in which the text is in English or another language may be issued.

A.2 This Format constitutes the first two pages of the Certificate. Additional pages shall be included in the Certificate to define the essential technical and metrological characteristics of the measuring instrument. A specific Format for these additional pages may be available in the relevant OIML Recommendation.

A.3 In addition to the OIML logo (see 5.6.2), the logo of the Issuing Authority may be placed on the Certificate according to national rules.

A.4 The kind aims to define the type of the Certificate (see 9):

- Initial Certificate;
- Revised Certificate;
- Transfer of a Certificate;
- Additional Certificate for a new applicant.

Examples:


- a) **Kind of Certificate:** Initial Certificate
- b) **Kind of Certificate:** This Certificate cancels the Certificate no.
- c) **Kind of Certificate:** This Certificate revises the Certificate no. to add a new type of load cells
- d) **Kind of Certificate:** This Certificate revises the Certificate no. to change the temperature range of the instrument
- e) **Kind of Certificate:** This Certificate transfers the ownership of the Certificate no. to
- f) **Kind of Certificate:** This Certificate extends the ownership of the Certificate no. to

A.5 Since the Reference Number of the Certificate (see Annex B -) includes the category only through the number of the OIML Recommendation, the module shall be clearly identified in the Certificate in the event that the Certificate concerns a module. This identification shall be made in the heading “designation of the module”.

Examples:

- a) **Designation of the module:** Indicating device
- b) **Designation of the module:** Electronic printer

A.6 The identification of the certified Type shall be defined as it is indicated on the instrument (marking) and shall be identical to that defined in the OIML Basic Evaluation Report.

	
OIML Member State	OIML Certificate no.
OIML BASIC CERTIFICATE OF CONFORMITY	
Kind of Certificate The present Certificate	
Issuing Authority Name: Address: Person responsible:	
Applicant Name: Address:	
Manufacturer Name: Address:	
Identification of the certified type <i>(the detailed characteristics will be defined in the additional pages)</i>	
Designation of the module <i>(if applicable)</i>	
<p>This Certificate attest the conformity of the above identified Type (represented by the sample(s) identified in the OIML Basic Evaluation Report) with the requirements of the following Recommendation of the International Organization of Legal Metrology (OIML):</p> <p style="text-align: center;">OIML R Edition (year):</p> <p>For accuracy class <i>(if applicable)</i>:</p> <p style="text-align: center;">Page ... of ... pages</p>	

OIML Certificate no.	
<p>This Certificate relates only to metrological and technical characteristics of the Type of measuring instrument covered by the relevant OIML Recommendation above-identified.</p> <p>This Certificate does not bestow any form of legal international approval.</p>	
<p>The conformity was established by the results of tests and examinations provided in the associated OIML Basic Type Evaluation Report(s)</p> <p>No.dated that includespages</p> <p>No.dated that includespages</p> <p>No.dated that includespages</p> <p>.....</p>	
<p>Identification, signature and stamp</p> <p>The OIML Issuing Authority</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>Date:</p>	
<p><i>Important note:</i> Apart from the mention of the Certificate's reference number and the name of the OIML Member States in which the Certificate is issued, partial quotation of the Certificate and of the associated OIML Basic Evaluation Report(s) is not permitted, although either may be reproduced in full</p>	
<p>Page ... of ... pages</p>	

Annex B - (Mandatory)

Reference Number of a Certificate

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 [11] 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 the Recommendation is published in separate parts, the number as defined in a) consists of the generic number of the Recommendation (without indication of the parts) and the year of Publication related to the part which defines the requirements (in general Part 1 or Parts 1 & 2).

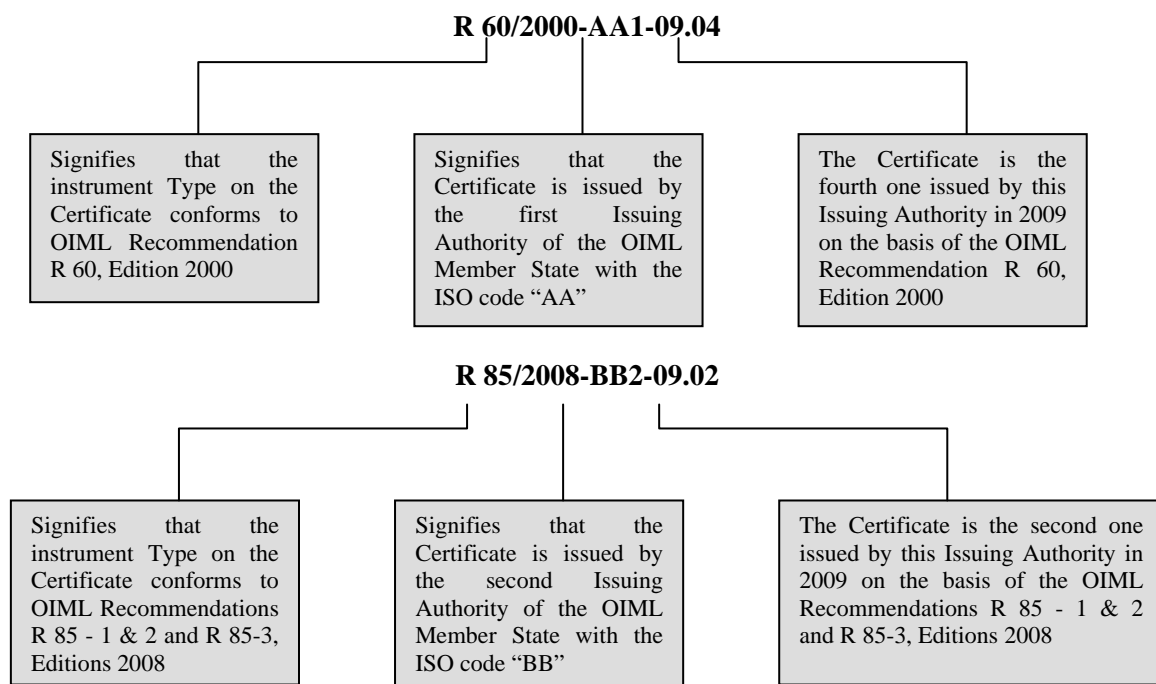
Example: R 76/2006

Note 2: 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 3: As soon as a first Issuing Authority is designated in a Member State and registered by the BIML, this first Issuing Authority is identified by its country code associated to the serial number “1” (e.g. AA1). When a second Issuing Authority is registered in the same country, it is identified by the same country code associated to the serial number “2” (e.g. AA2).

Note 4: For revised Certificates, the same reference number shall be used as for the initial Certificate (see 9.1).

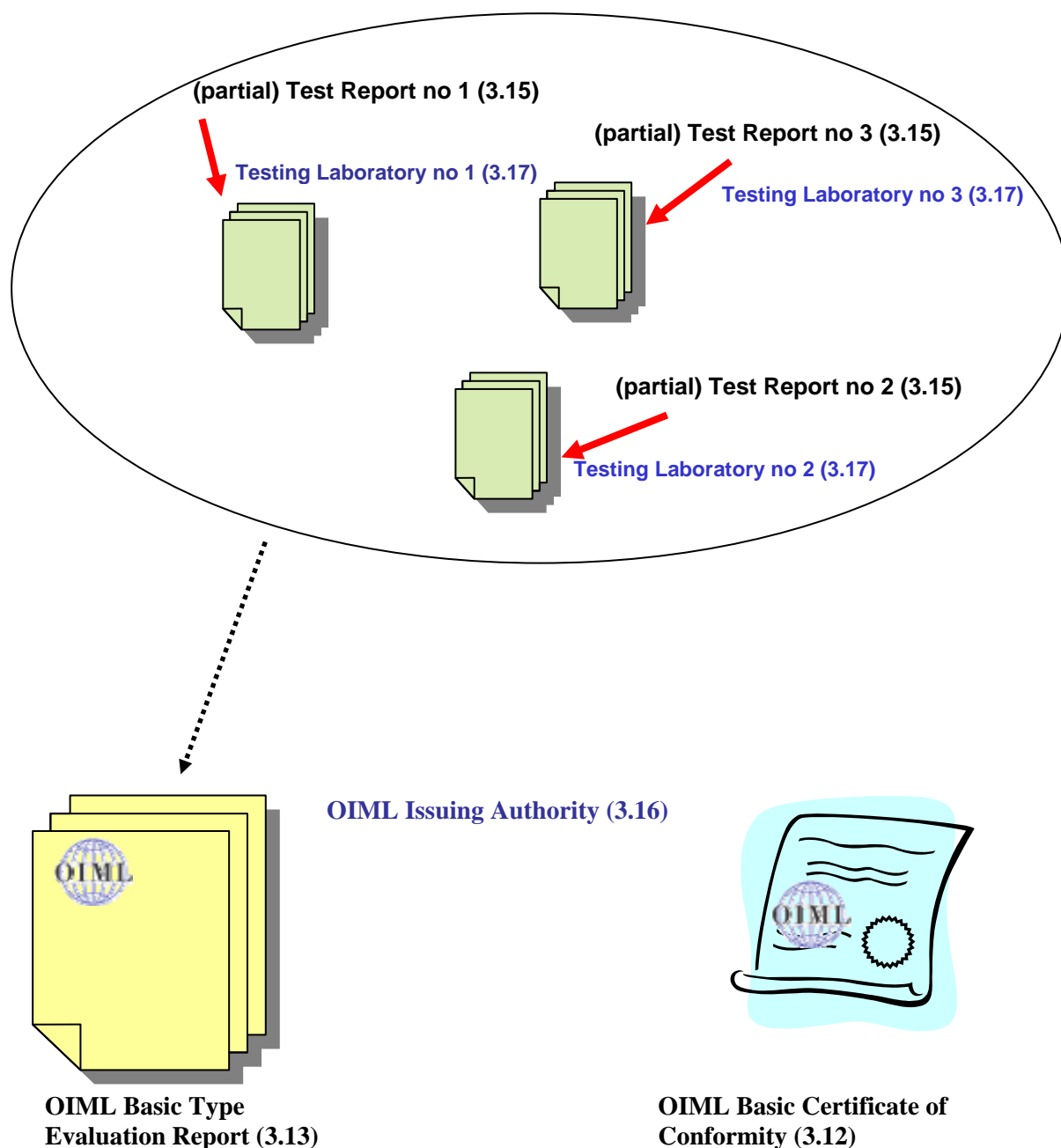
Example 1



Annex C - (Informative)

Example of the System operation

The following drawing uses the appropriate terminology. References in parenthesis refers to the definitions in 3.



Annex D - (Informative)

Summary of the tasks of an OIML Issuing Authority

D.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.

D.2 The OIML Issuing Authority carries out the following tasks:

- 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;
- e) ensures that the testing laboratory(ies) is(are) competent according to requirements compatible with ISO/IEC 17025 [8]
- f) ensures that the application and test procedures reflect the current System requirements;
- g) specifies documented conditions under which the manufacturer's test results may be considered (see 5.3.4) and under which tests are abbreviated or omitted (see 5.3.5);
- h) reviews the results of tests and examinations included in the Test Report(s);
- i) issues the OIML Basic Type Evaluation Report;
- j) for a successful evaluation, issues a Certificate for the type (of measuring instrument) to the applicant;
- k) for an unsuccessful evaluation, notifies the applicant in writing of the deficiencies in performance of the type (of measuring instrument);
- 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;
- m) maintains active liaison with its CIML Member, whenever appropriate; and
- n) makes available documented procedures for accepting, considering, and resolving appeals against decisions.

Annex E - (Informative)

Bibliography

- [1] OIML D 19: 1988, "Pattern evaluation and pattern approval"
- [2] V 2-200: 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: 200X, "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] WTO TBT Agreement, "Agreement on technical barriers to trade"
- [11] ISO 3166-1: 2006, "Codes for the presentation of names of countries and their subdivisions - Part 1: Country codes"
- [12] OIML D 29: 2008 "Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology"
- [13] OIML D 30: 2008 "Guide for the application of ISO/IEC 17025 to assessment of Testing Laboratories involved in legal metrology testing"
- [14] OIML D 11: 2004 "General requirements for electronic measuring instruments"