

TITLE OF THE CD (English): Revision: OIML B 10-1 and B 10-2 Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations

TITLE OF THE CD (French): Cadre pour un Arrangement d'Acceptation Mutuelle sur les Evaluations de Type OIML

Original version in: English

TC 3 / SC 5 Co-Secretariat: The United States and the BIML

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Explanatory note

Revising OIML B 10-1 and OIML B 10-2 was decided at the 41st CIML Meeting held on October 2006 in Cape Town (South Africa). Two projects have been registered by the BIML as project p8 and p9 of OIML TC 3/SC 5 *Conformity Assessment*.

Since then, on the basis of the conclusions of the TC 3/SC 5 meeting held in May 2008, it was decided to withdraw OIML B 10-2 mostly due to the fact that OIML D 29 *Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology* and OIML D 30 *Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology* are now available. The appropriate ISO/IEC Standard and the relevant Guide may be now used directly by the OIML Issuing Authorities and the Testing Laboratories.

Consequently, the revision of OIML B 10-1 will be named OIML B 10. It This revision is conducted in parallel with that of OIML B 3 *OIML Basic Certificate System for OIML Type Evaluation of Measuring Instrument* (project p7 of OIML TC 3/SC 5).

The main changes proposed to B 10 are the following:

- To clarify the OIML MAA as an additional tool of the OIML Basic Certificate System, and to consequently revise the structure of the MAA to be aligned with that of OIML B 3;
- To include the operating rules of the Committee on Participation Review and of a Declaration of Mutual Confidence on the basis of OIML MAA 01:2005 and on the experience gained from the first three DoMCs;
- To include the Amendment (2006) to OIML B 10-1;
- 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). It was drawn up on the basis of 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, in particular for the maintenance process of the Declarations of Mutual Confidence, 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.

Considering the changes in the presentation, it was not possible to draw up a marked version of OIML B 10. Consequently, cross-reference tables with OIML B 10-1:2004 have been temporarily added in Annex G in order to facilitate the comparison between the two documents.

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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 10, 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 OIML B 10-1:2004, OIML B 10-2:2004 and the Amendment (2006) to OIML B 10-1:2004.

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 objectives of the OIML Mutual Acceptance Arrangement are:
 - To establish rules and procedures for fostering mutual confidence among participating OIML Member States and Corresponding Members in the results of type evaluations that indicate conformity of measuring instruments and/or modules, under legal metrological control, to OIML metrological and technical requirements and, when included, any agreed upon additional national/regional requirements;
 - To promote the global harmonization, uniform interpretation, and implementation of legal metrological requirements for measuring instruments and/or modules;
 - To promote efficiency in time and cost of national type evaluations and approvals, or recognition of measuring instruments and/or modules under legal metrological control, while achieving and maintaining confidence in the results in support of facilitating global trade of individual instruments;
 - To support countries which do not have their own test facilities.

- 1.2 The OIML MAA is an additional tool available to the OIML Basic Certificate System, that is defined in OIML B 3 OIML Basic Certificate System for OIML Type Evaluation of Measuring Instrument. 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.
- 1.3 The OIML MAA, as the OIML Basic Certificate System, is a voluntary system since OIML Members States and Corresponding Members are free to participate or not.
- 1.4 Participating in a Declaration of Mutual Confidence, as defined in 3.4, does not mean that accepting test data is mandatory. However, once test data is accepted, then there is a legal responsibility to use it.

2 Scope

- 2.1 This Framework for a Mutual Acceptance Arrangement (MAA) establishes the rules for a framework whereby Participants voluntary accept and utilize OIML MAA Type Evaluation Reports (see 3.6), when associated with an OIML MAA Certificate, for type approval or recognition in their national or regional metrological controls.
- 2.2 The implementation of the OIML MAA leads to the establishment of a separate Declaration of Mutual Confidence for each category of measuring instrument. Depending on the relevant OIML Recommendation, modules of measuring instruments may be also included in the Declaration of Mutual Confidence. This Publication provides procedures to establish, operate and maintain a Declaration of Mutual Confidence and for Participants to appeal and resolve issues concerning their participation.
- 2.3 The OIML MAA covers all items defined in the scope of the relevant Declaration of Mutual Confidence for a category of measuring instrument or a module.
- 2.4 OIML B 3 and OIML B 10 are complementary Publications. OIML B 10 identifies supplementary and/or other requirements applicable to the implementation of the OIML MAA.

3 Abbreviations and terminology

In addition to those defined in OIML B 3:XXXX, the following abbreviations and definitions apply:

OIML MAA	OIML Mutual Acceptance Arrangement
DoMC	Declaration of Mutual Confidence
CPR	Committee on Participation Review
MAA Certificate	OIML Certificate issued under the MAA
IP	Issuing Participant
LID	
UP	Utilizing Participant
UP TC	Utilizing Participant Technical Committee (OIML)
01	

3.1 National Issuing Authority

Certifying body or person in an OIML Member State or Corresponding Member that is responsible for national type approval and that issues Type Approval Certificates (VIML, 3.2 [3]) for specific categories of measuring instruments or modules on the basis of examination and testing under its own control.

3.2 National Responsible Body

Organization within an OIML Member State or Corresponding Member that does not conduct type evaluation (OIML B 3, 3.7 [4]) but is responsible for the metrological control of measuring instruments and/or modules.

3.3 OIML Mutual Acceptance Arrangement (OIML MAA)

Framework agreement that commits Participants to accepting and utilizing OIML MAA Type Evaluation Reports issued by other Participants under a particular DoMC, after having established mutual confidence among them through assessment of competence, and to assume any legal responsibility once such reports have been accepted.

3.4 Declaration of Mutual Confidence (DoMC)

Declaration by Participants that they have achieved a voluntary mutual arrangement with regard to type evaluation, for a specified category of measuring instruments, to accept and utilize OIML MAA Type Evaluation Reports issued by Issuing Participants.

3.5 OIML MAA Certificate of Conformity

Document issued under the rules of MAA by an Issuing Participant in a DoMC, providing confidence that the identified type of measuring instrument or module is in conformity with the requirements of the relevant Recommendation, taking into account the exclusions mentioned in the scope of the DoMC, if applicable.

Note: See Annex A.

3.6 OIML MAA Type Evaluation Report

Report, issued by an Issuing Participant in a DoMC, that assesses the conformity of the type of measuring instrument or module to the requirements in the relevant Recommendation (taking into account the exclusions mentioned in the scope of the DoMC, if applicable) and, if applicable, to the national additional requirements included in the scope of the relevant DoMC.

Note: See Annex A.

3.7 MAA Test Report

Test Report as defined in OIML B 3 (3.14) [4] but issued by a Testing Laboratory designated in a DoMC.

Note1: See annex A.

Note 2: An MAA Test Report may contain results of tests and examinations which correspond to the national additional requirements included in the relevant DoMC.

3.8 Partial MAA Test Report

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

3.9 Participant

OIML Issuing Authority and/or National Issuing Authority and/or National Responsible Body of an OIML Member State or Corresponding Members that accedes to a DoMC.

Note: Three categories of Participants exist: Issuing Participants (see 3.9), Utilizing Participants (see 3.10) and Associates (see 3.11).

3.10 Issuing Participant

OIML Issuing Authority as defined in OIML B 3 (3.16) [4] which issues OIML MAA Type Evaluation Reports and MAA Certificates.

3.11 Utilizing Participant

OIML Issuing Authority or National Issuing Authority or National Responsible Body from an OIML Member State that does not issue any OIML MAA Type Evaluation Reports nor MAA Certificates, but which utilizes those issued by Issuing Participants.

3.12 Associate

National Issuing Authority or National Responsible Body from an OIML Corresponding Member that will utilize OIML MAA Type Evaluation Reports issued by Issuing Participants.

3.13 Accreditation (from ISO/IEC 17000, 5.6 [6])

Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

3.14 Conformity assessment (from ISO/IEC 17000, 2.1 [6])

Demonstration that specified requirements related to a product, process, system, person or body are fulfilled.

3.15 Peer assessment (from ISO/IEC 17000, 4.5 [6])

Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group.

Note: Within the MAA implementation, this is the procedure by which agreed upon legal metrology experts assess, against specified requirements, on site, the competence of Testing Laboratories designated by Issuing Participants in a DoMC.

3.16 Audit (from ISO/IEC 17000, 4.4 [6])

Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Note: Audits may be internal or external. Internal audits are supposed to be conducted by the relevant personnel provided that it is not responsible for the activity which is audited. External audits are conducted by third-party bodies.

3.17 Committee on Participation Review (CPR)

Committee responsible for managing a DoMC.

3.18 Applicant

Manufacturer and/or authorized representative who submits an application for an OIML MAA Type Evaluation of a measuring instrument to an Issuing Participant in a DoMC in order to obtain an OIML MAA Type Evaluation Report and an OIML MAA Certificate for that type of instrument.

3.19 Additional national requirement

Requirement that is not included in the relevant OIML Recommendation but is required in order to issue national/regional type approvals, and that has been included in the scope of the DoMC.

4 Conditions for establishment of a DoMC

- **4.1** A DoMC may be established for categories of measuring instruments (including families and modules as appropriate) that are included in the OIML Basic Certificate System (OIML B 3, 2.2 [4]).
- **4.2** In general, one DoMC covers the relevant OIML Recommendation. Nevertheless, in the event that an OIML Recommendation covers several kinds of measuring instruments (e.g. OIML R 117 on dynamic measuring systems for liquids other than water), several DoMCs may be established for the different kinds of measuring systems (e.g. fuel dispensers, measuring systems on trucks, etc.).
- **4.3** At least two Issuing Participants (3.10), preferably from different regions, shall be required in order to establish a DoMC.
- **4.4** The scope of a DoMC is defined by the CPR on the basis of the tests and examinations for which detailed procedures are defined in the appropriate OIML Recommendation, and on the basis of additional national requirements (see 3.19) submitted by the Participants and for which detailed testing procedures have been provided (see 5.4).
- **4.5** Issuing Participants shall designate Testing Laboratories (internal and/or subcontracting) that will be responsible for issuing MAA Test Reports. Those Testing Laboratories shall be assessed either by accreditation or peer assessment using requirements of ISO/IEC 17025 [8] and OIML D 30 [13] for the scope of the DoMC as defined in 4.4.

5 Application for participation in a DoMC

Applications for participation shall be submitted to the BIML through CIML Members or contact persons of Corresponding Members and shall be accompanied by the following information:

- **5.1** For both potential Issuing Participants, Utilizing Participants and Associates:
 - An official letter confirming participation in the MAA and the type of participation (Issuing Participant or Utilizing Participant or Associate);
 - Information about additional tests and examinations required for national type approval that Participants would potentially be willing to include in the scope of the DoMC in such a case, the detailed testing procedures indicated in 4.4 shall be provided to be examined by the CPR (see 5.4);

- **5.2** For potential Issuing Participants only:
 - Information about its competence as defined in 4.2 of OIML B 3 [4];
 - A list of testing laboratories (subcontracting and internal) indicating, for each one, which tests and examinations of the relevant OIML Recommendation and of additional national requirements included in the scope of the DoMC, if applicable, it performs;
 - Information about its type testing capabilities (including those of its designated subcontracting testing laboratories, if any);
 - The certificates of accreditation of the testing laboratories and their most recent accreditation assessment report which includes the relevant scope of the DoMC and enough information that an assessment of the legal metrology aspects of the accreditation can be determined, if accreditation applies;
 - The most recent internal audit of each testing laboratory conducted on the basis of ISO/IEC 17025 [8] and OIML D 30 [13] for the relevant scope of the DoMC;
 - The results of intercomparisons conducted in the relevant field, if any;
 - A copy of the most recent OIML Basic Type Evaluation Report issued for the considered category in the event that the potential Issuing Participant is already an OIML Issuing Authority (OIML B 3, 3.16 [4]) for the relevant category.
- **5.3** The BIML shall send potential Issuing Participants an invoice for the BIML administrative fees related to the review of its application for participation.
- **5.4** In order to issue a national type approval certificate on the basis of an OIML MAA Type Evaluation Report received from another Participant, the National Issuing Authority may be required by national or regional laws and regulations to perform additional evaluations to those defined in the relevant OIML Recommendation.

Participants requiring additional requirements (see 3.19) to be included in the DoMC shall clearly identify them with an explanation and justification, and also reference them along with any necessary additional associated testing procedures and test report format, if appropriate.

Other Participants may choose to carry out these additional evaluations, in addition to the tests and examinations within the relevant OIML Recommendation, in order to provide applicants with "one-stop testing". Performing these additional evaluations is optional for each Issuing Participant. The relevant information shall be submitted to the BIML.

6 Review of application for participation in a DoMC

6.1 **CPR establishment and operating rules**

- 6.1.1 A CPR shall be set up for the purpose of:
 - reviewing the documentation submitted by potential Participants;
 - deciding for which Testing Laboratory a peer assessment shall be conducted and in that case defining the scope of the peer assessment or requesting an extension of the scope of accreditation, if appropriate;
 - validating the scope of the DoMC (see 4.4);

- reviewing the accreditation reports and peer assessment reports of the potential Issuing Participants;
- deciding, in case of a new edition of an OIML Recommendation is included in the DoMC, whether an extension of accreditation (for accredited Testing Laboratories) or a new peer assessment (for non-accredited Testing Laboratories) is necessary;
- validating the candidacies submitted by technical and metrological experts who will
 participate in the assessments of the Testing Laboratories (see 4.5);
- preparing a report based on all information received, including peer assessments when conducted, on the competence of each potential Issuing Participant in the DoMC to be used for the decision on participation (see 6.2);
- establishing, expanding and maintaining the appropriate DoMC;
- proposing to the CIML the deadline after which it will no longer be possible to issue OIML Basic Certificates for the relevant category (see OIML B 3, 11.1).
- 6.1.2 The CPR is composed of:
 - A representative of each Participant in the DoMC;
 - The Secretariat of OIML TC 3/SC 5 *Conformity assessment*;
 - The Secretariat of the TC or TC/SC responsible for the relevant OIML Recommendation;
 - A representative of the BIML, who acts as the CPR Secretariat.
- 6.1.3 The representative in the CPR of each potential Participant is appointed by the CIML Member of the relevant OIML Member State in case of Issuing or Utilizing Participants, or by the contact person of the relevant Corresponding Member for Associates.
- 6.1.4 Generally, one CPR per DoMC is established. Nevertheless, one CPR may be established for several DoMCs if their scopes are similar. In such a case, the CPR may be composed of several representatives of the same Participant to ensure the necessary degree of competence.
- 6.1.5 In the event that several Participants in the same country apply for participation in a DoMC, a representative of each Participant may be designated as CPR member. Nevertheless, only one of them has voting rights in the CPR, as decided by the CIML Member or the contact person of the Corresponding Member.
- 6.1.6 Before a DoMC is signed, a provisional CPR is established with representatives of those potential Participants who have applied for participation. After the DoMC is signed, the definitive CPR is established with a representative of each Participant approved (see 6.2).
- 6.1.7 Decisions in the CPR are considered valid if two-thirds of the votes cast by the CPR members who are granted voting rights are in favour of them. Abstentions and failures to reply do not count as votes cast. *Information: the rule defined in 2.4 of Amendment (2006)* to OIML B 10-1 has been changed to be consistent with that of the draft revision of the Directives for OIML Technical Work applicable to TCs/SCs.

This rule is applicable for decisions both taken at meetings or further to postal consultations.

Representatives of Associates, of the BIML and of TCs/SCs are not granted voting rights.

6.2 Approval of Issuing Participants

6.2.1 When a DoMC is first being established, all potential Participants shall independently review the report drawn up by the CPR.

Each potential Participant shall initially submit its agreement or reservations on the participation of Issuing Participants to the BIML representative on the CPR.

Responses from at least 80 % of the potential Participants shall be received. Each Issuing Participant is accepted providing that at least 80 % of the potential Participants agree on its participation.

6.2.2 Once a DoMC is established, all Participants shall independently review the report on a potential Issuing Participant drawn up by the CPR. At least 80 % of the Participants shall answer concerning the acceptance of the new potential Issuing Participant. Among these answers, 80 % shall be in favour of the acceptance for the new potential Issuing Participant being accepted.

6.3 Admission of Utilizing Participants and Associates

- 6.3.1 Potential Utilizing Participants or Associates who apply for participation and who do not require additional national requirements to be included in the DoMC are automatically accepted, and the CPR's composition is modified consequently to take into account the newly appointed members.
- 6.3.2 In the event that a potential Utilizing Participant or Associate requires additional national requirements to be included in the DoMC, the BIML consults the CPR for the acceptance of these additional national requirements and for decision on conducting any additional necessary assessments for those Issuing Participants wishing to perform the tests according to the additional requirements.

7 Assessments of Testing Laboratories

7.1 The accreditation body that carries out an assessment of a Testing Laboratory of a Participant in a DoMC shall participate in a mutual recognition arrangement among accrediting bodies (regional or international), for instance participation in the ILAC MRA (International Laboratory Accreditation Mutual Recognition Arrangement).

The assessment team shall include at least one technical and metrological expert validated by the CPR (see 7.3).

- 7.2 The peer assessment shall be carried out by a team of experts, including at least one technical and metrological expert validated by the CPR (see 7.3) and at least one expert knowledgeable in assessing quality management systems of testing laboratories on the basis of ISO/IEC 17025 [8]. A lead assessor of an accreditation body as defined in the Memorandum of Understanding signed between ILAC, IAF and the OIML fulfils this latest requirement.
- **7.3** A list of technical and metrological experts validated to serve as assessors for the relevant category of measuring instruments is maintained by the BIML and shall be available on the OIML web site.
- 7.4 An expert that participates in conducting assessments shall not be a CPR member.

- 7.5 The criteria for the qualification of technical and metrological experts are the following:
 - The expert shall have an experience in type evaluation of the relevant category of instrument or module and shall have a good knowledge of the applicable testing procedures;
 - The expert shall not come from a manufacturer of measuring instruments;
 - The expert shall participate in the initial training and periodic training organized by the BIML for maintaining their qualification and in additional training required by the CPR;
 - The expert shall speak good English in order to conduct assessments in English and draw up assessment reports in English.

8 Record of participation

- **8.1** Each accepted Participant shall sign in duplicate a registration form drawn up according to the format defined in Annex C.
- **8.2** The BIML is responsible for making a synthesis of the registration forms (see Annex B) containing the necessary information on the participants, available to the public. This synthesis represents the official registration of the DoMC by the BIML and shall be available on the OIML web site.

The synthesis includes, if appropriate, the additional testing procedures and test report Format as defined in 5.4.

9 Initiation and maintenance of a DoMC

9.1 Each DoMC becomes effective on the date that it is recorded by the BIML. From this date, Issuing Participants shall issue OIML MAA Type Evaluation Reports and MAA Certificates only for the relevant category of measuring instruments as soon as tests and examinations are included in the scope of the DoMC.

In the event that results of tests outside the scope of the DoMC (e.g. results of tests provided by manufacturers) are taken into account in the evaluation, an OIML Basic Type Evaluation Report and an OIML Basic Certificate (OIML B 3, 3.12 and 3.13 [4]) may still be issued by the Issuing Participant. Those results shall be clearly identified in the OIML Basic Type Evaluation Report (OIML B 3, 5.3.4 and 5.5.1 1) [4])

- **9.2** Evaluation and testing of the instrument may be performed for an application received before a DoMC becomes effective, provided that requirements in a) and b) below are fulfilled; however the OIML MAA Type Evaluation Report and the MAA Certificate cannot be issued until the DoMC becomes effective. The requirements are:
 - a) Application for the OIML MAA Type Evaluation Report and the MAA Certificate was received, and examination and testing were performed after the report drawn up by the CPR (see 6.1.1) led to a proposal to accept the potential Issuing Participant.

Note: This means that:

 The assessment of the Testing Laboratory was conducted according to ISO/IEC 17025 [8] either under the accreditation process or under the peer assessment process before the application for the OIML MAA Type Evaluation Report and the MAA Certificate, was received by the potential Issuing Participant; and

- The assessment Report of the Testing Laboratory has been evaluated by the CPR before the application for the OIML MAA Type Evaluation Report and the MAA Certificate, was received by the potential Issuing Participant.
- b) The CPR has formulated a proposal to accept the relevant potential Issuing Participant without any reservations.

The above-mentioned requirements also apply to a new potential Issuing Participant in a DoMC which is already in place.

Information: 9.2 is adapted from OIML MAA 06:August 2007

- **9.3** Issuing Participants are required to undergo internal audits and re-assessments of competence according to the following maintenance process:
 - A review by the CPR, once a year, of an internal report submitted to the BIML. This report shall highlight in particular:
 - Results of comparisons,
 - Changes in personnel, structure and organization;
 - Results of management reviews;
 - Results of internal audits;
 - o Complaints received.

A report Format is presented in Annex D.

- A review by the CPR, every five years, of the accreditation assessment and peer assessment reports of Issuing Participants submitted to the BIML.
- **9.4** Issuing Participants whose Testing Laboratories are peer assessed are responsible for organizing their peer assessments every five years under the conditions defined in 7.2.
- **9.5** Issuing Participants whose Testing Laboratories are accredited are responsible for requesting their national accreditation body to include a technical and metrological expert validated by the CPR (see 7.1) in the assessment team as soon as the scope of the DoMC is included in the assessment.
 - *Note:* Considering a maximum of a five-year renewal period recommended by the ILAC Guidance, all the accredited Testing Laboratories should be able to submit at least one accreditation assessment report which includes the scope of the DoMC.
- 9.6 The maintenance process is summarized on the diagram in Annex E.
- **9.7** The CPR shall report to the Participants in the relevant DoMC on the reviews defined in 9.3 for any possible subsequent actions (see 14.6).
- **9.8** An Issuing Participant may withdraw from a DoMC by giving written notice to the BIML, taking into account all current obligations to applicants for OIML MAA Type Evaluations, and the BIML shall in turn notify all other Participants.

All remaining Participants, however, shall accept and utilize or recognize the OIML MAA Type Evaluation Reports that were issued prior to the withdrawal.

10 Revision of a DoMC

- **10.1** A DoMC may be revised to:
 - Include new Participants;
 - Withdraw Participants;
 - Change the status of participation of certain Participants;
 - Revise its scope (e.g. inclusion of a new edition of the relevant OIML Recommendation, inclusion of new additional national requirements).
- **10.2** The current Participants shall agree upon any changes related to participation on the basis of the rules defined in 6.2 and 6.3.
- **10.3** Revisions related to the scope of the DoMC are under the responsibility of the CPR on the basis of the rules defined in 6.1.7.
- **10.4** In the event that an Issuing Participant is withdrawn from a DoMC, all remaining Participants shall accept and utilize the OIML MAA Type Evaluation Reports that were issued and registered by that Participant prior to withdrawal.

11 Processing an OIML MAA Type Evaluation Report and an MAA Certificate

11.1 Application for an OIML MAA Type Evaluation Report and an MAA Certificate

- 11.1.1 The manufacturer of a type of instrument or module, or an authorized representative of the manufacturer shall apply to an Issuing Participant in the relevant DoMC for an OIML MAA Type Evaluation Report and a MAA Certificate.
- 11.1.2 The application shall include the information listed in 5.1.2 of OIML B 3 [4]. If results of previous type evaluation reports (OIML B 3, 5.1.2 (g)) are provided, they shall come from an OIML MAA Type Evaluation Report.
- 11.1.3 When applicable, the applicant shall also inform the Issuing Participant on which additional tests and examinations he is applying for on the basis of national additional requirements included in the DoMC (see 5.4).

11.2 Consideration for the application by an Issuing Participant

- 11.2.1 The provisions in 5.2 of OIML B 3 [4] apply with the following amendments.
- 11.2.2 Refusing an application for the reason defined in 5.2.2 (a) of OIML B 3 is not applicable because the testing capabilities of the Issuing Participant are clearly defined in the DoMC.
- 11.2.3 Referring to 5.2.5 of OIML B 3, previous test results shall come from OIML MAA Type Evaluation Reports.

11.3 Tests and examinations

- 11.3.1 The tests and examinations for OIML Type Evaluation shall be performed in the Testing Laboratories designated by the Issuing Participant and listed in the relevant DoMC (see 4.5).
- 11.3.2 The test procedures shall be consistent with those described in the relevant Recommendation and/or the additional testing procedures annexed to the DoMC for the national additional requirements included into the scope of the DoMC (see 4.4).

The test procedures may be abbreviated or omitted if the Issuing Participant considers that the conclusions necessary for issuing the OIML MAA Type Evaluation Report may be drawn from a previous OIML MAA Type Evaluation Report.

11.4 Test Report(s)

- 11.4.1 The provisions defined in 5.4.1, 5.4.3, 5.4.4 and 5.4.5 of OIML B 3 [4] apply.
- 11.4.2 Results of tests corresponding to the additional national requirements included in the DoMC may be provided in separate Test Reports, or included in the Test Reports issued for the tests and examinations conducted according to the relevant OIML Recommendation.
- 11.4.3 All the Test Reports will then be included in the OIML MAA Type Evaluation Report issued by the Issuing Participant (see 11.5.1).

11.5 OIML MAA Type Evaluation Report

- 11.5.1 The OIML MAA Type Evaluation Report is prepared by the Issuing Participant according to the Format specified in the relevant OIML Recommendation, and includes all relevant Test Report(s).
- 11.5.2 The provisions in 5.5.2, 5.5.4, 5.5.5, 5.5.6, 5.5.7 and 5.5.8 of OIML B 3 [4] apply to OIML MAA Type Evaluation Reports and Issuing Participants.
- 11.5.3 The OIML MAA logo shall be affixed on the OIML MAA Type Evaluation Report.

11.6 Issue of an MAA Certificate

- 11.6.1 The provisions defined in 5.6.1, 5.6.3, 5.6.4, 5.6.5, 5.6.6 and 5.6.7 of OIML B 3 [4] apply to OIML MAA Certificates, OIML MAA Type Evaluation Reports and Issuing Participants.
- 11.6.2 The MAA Certificate shall be drawn up according to the model given in Annex A of OIML B 3 [3]. It shall be signed by the Issuing Participant and bear the OIML MAA logo.
- 11.6.3 In the event that tests according to the national additional requirements included in the DoMC have been conducted, a letter issued by the Issuing Participant may validate the conformity of the instrument to these requirements. A copy of such a letter shall be sent to the BIML with the MAA Certificate.

12 Registration of an MAA Certificate

The provisions defined in 6 of OIML B 3 [4] apply to MAA Certificates.

13 Use of OIML MAA Type Evaluation Reports

- **13.1** The owner may use an OIML MAA Type Evaluation Report (see 13.2) in support of an application for national or regional type approval, or for gaining approval to put the instrument on the market, in countries that participate in the DoMC; it is the responsibility of the applicant to give evidence upon request that the type presented for approval is identical to that identified in the OIML MAA Type Evaluation Report;
- **13.2** The owner is responsible for providing a Participant, a National Issuing Authority or a National Responsible Body with the original, or a certified copy of, the OIML MAA Evaluation Report.
- **13.3** A Participant that accepts an OIML MAA Type Evaluation Report under the term of the MAA and utilizes it to issue a national type approval certificate shall also assume responsibility for the OIML MAA Type Evaluation Report regarding its national regulation.

14 Appeals, resolution of complaints and disputes

- **14.1** An applicant that has not been accepted to participate in a DoMC may appeal that decision to the CIML Presidium (consisting of the CIML President and two Vice-Presidents).
- **14.2** The BIML shall be contacted in the event of a dispute initiated either by an applicant regarding an OIML MAA Evaluation Report or a Participant in a DoMC regarding the operational procedures of the MAA.
- **14.3** The appropriate CIML Members may represent their Participants involved in a dispute and shall attempt to resolve among themselves any issue that might arise. If the Participants affected are unable to solve an issue, they shall provide a written explanation to the BIML for distribution to the CIML Members representing all other Participants.
- 14.4 A complaint may be submitted to the BIML with documented and substantiated evidence that an OIML MAA Type Evaluation Report was issued by an Issuing Participant on the basis of incorrect technical conclusions or procedures. The BIML shall notify the owner of the Report and all other Participants in the relevant DoMC of the complaint.
- **14.5** Such unresolved disputes and complaints as indicated in 14.3 and 14.4 may be referred to the CIML Presidium. It would consider the matter or refer it for resolution to an appropriate task group consisting of representatives of non-involved Participants.
- **14.6** A Participant that fails over time to respect the obligations of a DoMC may be excluded from further participation upon a resolution in writing agreed upon by other Participants (see 10.2).

15 Modification of a certificate

- **15.1** The provisions defined in 9.1, 9.2 and 9.3 of OIML B 3 [4] apply to OIML MAA Certificates.
- **15.2** The provisions defined in 11.3 of OIML B 3 [4] apply to Issuing Participants.

16 **Revision of an OIML Recommendation**

16.1 Once the revision of a relevant OIML Recommendation has been published, the CPR is responsible for examining the conditions for the inclusion of the new edition in the relevant DoMC, which would lead to revising the scope of the DoMC.

These conditions may require Testing Laboratories to be re-assessed (either by accreditation or peer assessment).

16.2 Once the DoMC has been revised and published, the owner of an OIML MAA Certificate issued on the basis of the previous edition of the relevant OIML Recommendation may apply to have this Certificate updated on the basis of the revised OIML Recommendation.

The provisions of 9.4.2 and 9.4.3 of OIML B 3 [4] apply to Issuing Participants.

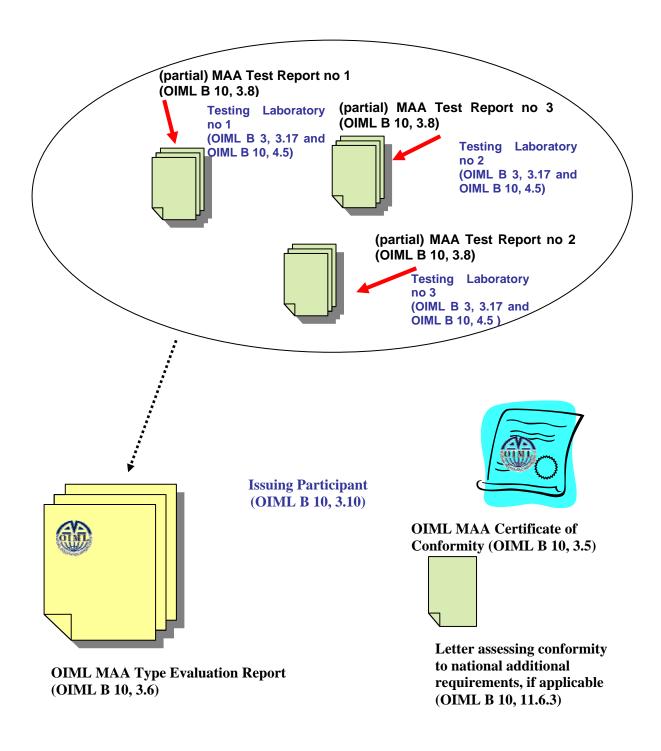
16.3 OIML MAA Certificates may be issued on the basis of the previous Recommendation as long as it remains included in the relevant DoMC.

17 Maintaining the OIML Basic Certificate System in parallel with the MAA

The provisions defined in 11 of OIML B 3 [4] apply.

Annex A - (Informative) Example of the System operation

The following drawing uses the appropriate terminology. References in parentheses refers to the appropriate sections of OIML B 3 [4] and of this Publication.



Annex B - (Mandatory) Publication Form for a DoMC (by the BIML)

To be developed on the basis of the current Publication Form.

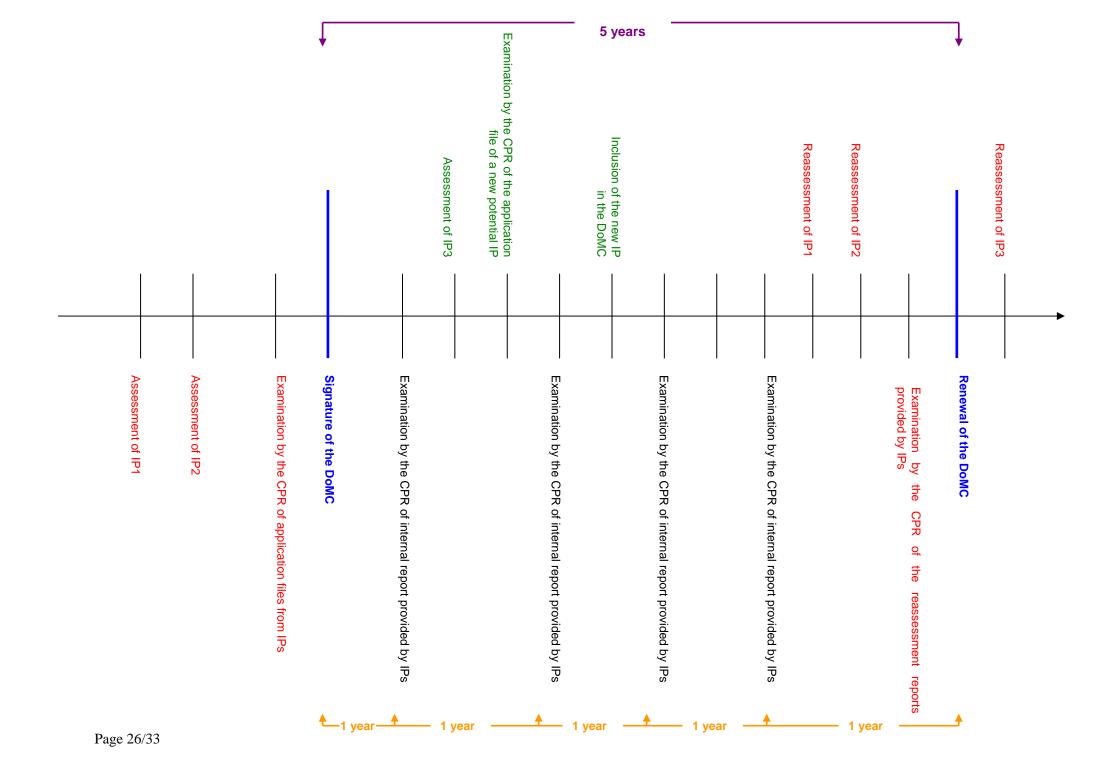
Annex C - (Mandatory) Individual Registration Form of Participants

To be developed on the basis of the current Registration Form.

Annex D - (Mandatory) Periodic Review Report Format

To be developed.

Annex E - (Informative) Summary of the maintenance process of a DoMC



Annex F - (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 3: 200X, "OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments"
- [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"

Annex G - (Temporary annex) Cross-reference tables between OIML B 10-1:2004 and 1 CD

G.1 Cross-reference table OIML B 10-1:2004 / 1CD

Sections in OIML B 10-1:2004	Sections in 1 CD
0.1	Deleted
0.2	Deleted
0.3	Deleted
0.4	Deleted
0.5	Deleted
1.1	2.1 and 2.3 (with editorial changes)
1.2	2.2
1.3	Deleted
1.4	Deleted and provisions included in 3.11 (definition of Associate), in 6.1.3 and 6.1.7 (section 2.3 of Amendment (2006) to OIML B 10-1)
2.1	1.1
2.2	1.1
2.3	1.1
3.1	Deleted
3.2	3.2 of 2 CD (Revision OIML B 3)
3.3	3.6 of 2 CD (Revision OIML B 3)
3.4	3.7 of 2 CD (Revision OIML B 3)
3.5	Deleted
3.6	3.10 of 2 CD (Revision OIML B 3)
3.7	3.12 of 2 CD (Revision OIML B 3)
3.8	3.13 of 2 CD (Revision OIML B 3)
3.9	3.6
3.10	3.1
3.11	3.15 of 2 CD (Revision OIML B 3)
3.12	3.2
3.13	3.16 of 2 CD (Revision OIML B 3)
3.14	Deleted
3.15	3.9 of 2 CD (Revision OIML B 3)
3.16	3.3
3.17	3.4
3.18	3.8
3.19	3.11 (taking into account changes of section 2.1 of Amendment (2006) to OIML B 10-1)
3.20	3.13
3.21	3.12
3.22	3.14
3.23	3.15 (with changes)
3.24	Deleted
3.25	Deleted
3.26	3.16 and 6.1.2

Sections in OIML B 10-1:2004	Sections in 1 CD
4.1	4.1 (with editorial changes)
4.2	4.2 (with editorial changes)
1.2	8 and 5.4 (third paragraph) – with editorial
4.3	changes
	Deleted and replaced by 3.8, 3.9, 3.10 and 3.11
4.4	(wording based on 2.3 of Amendment (2006) to
	OIML B 10-1)
4.5	4.3
4.6 First bullet	4.4 (with editorial changes)
4.6 Second bullet	4.5 (with editorial changes)
4.6 Third bullet	Deleted (see 4.2 of 2 CD (Revision OIML B 3))
4.6.1	7.1 and 6.1.1 (with editorial changes)
4.6.2	7.2, 7.3, 7.4 and 6.1.1 (with editorial changes)
4.6.3	Deleted
4.6.4	Moved to Annexes B and C
4.7	Deleted
4.8	5
4.9	5
4.9.1	5.2 (with editorial changes)
4.9.2	5.1 (with editorial changes)
4.10	6.1.1, 6.1.3 and 6.1.5 (with editorial changes)
4.10.1	6.1.1 (with editorial changes)
4.10.2	Deleted
4.11	6.2 (taking into account section 2.5 of Amendment (2006) to OIML B 10-1 and the voting rules proposed for votes within TCs/SCs in the draft revision of the Directives for the OIML Technical Work) 14.1 (Last sentence of 4.11)
4.12	8 (with editorial changes)
5.1	Deleted
5.2	Deleted
5.3	5.4 – Third paragraph has been deleted
5.4	11.5.1 (with modifications)
5.5.1	11.6 (with modifications)
5.5.2	13.1
5.5.3	11.6.3 and 12
5.6	Deleted
5.7	13.3
5.8	Deleted
6.1	5 (with modifications)
6.2	5.3 - with modifications
6.3	Deleted
6.4	Deleted
7.1	14.2
7.2	14.2
7.3	14.3
7.4	14.5
7.5	14.5
1.5	17.J

Sections in OIML B 10-1:2004	Sections in 1 CD
7.6	14.6
8.1	9.1
8.2	9.3, 9.4 and 9.6 (taking into account the proposals made at the combined R 49/R 60/R 76 CPR meeting in June 2009 concerning the maintenance scheme of a DoMC)
8.3	9.7 (with editorial changes)
8.4	Deleted
8.5	9.8 (with editorial changes)
8.6	Deleted
9.1	10.1 and 10.2 (with modifications)
9.2	16.1 (with modifications)
10	Deleted
References	Annex F
Annex A	Annex B
Annex B	Deleted considering the Publication of OIML D 30
Annex C	Deleted

G.2 Cross-reference table 1CD / OIML B 10-1:2004

Sections in 1 CD	Sections in OIML B 10-1:2004
1.1	2.1, 2.2 and 2.3 (with additions)
1.2	New
2.1	1.1 (partially)
2.2	1.2
2.3	1.1 (partially)
2.4	New
3.1	3.10
3.2	3.12 (with editorial changes)
3.3	3.16
3.4	3.17
3.5	Deleted – see 3.12 of 2 CD (revision OIML B 3)
3.6	3.9 (with modifications)
3.7	New
3.8	3.18 (with modifications)
3.9	New
3.10	New
3.11	3.19 (with modifications)
3.12	3.21 (with modifications)
3.13	3.20 (with modifications)
3.14	3.22 (with modifications)
3.15	3.23 – The definition has been extended
3.16	3.26 (with editorial changes)
3.17	New (replaces 3.24)
3.18	New
4.1	4.1
4.2	4.2
4.3	4.5

Sections in 1 CD	Sections in OIML B 10-1:2004
4.4	4.6 First bullet
4.5	4.6 Second bullet
5	4.9
5.1	4.9.2 (with modifications)
5.2	4.9.1 (with modifications)
5.3	6.2 (with modifications)
5.4	5.3 (with modifications)
	4.6.1, 4.6.2 and 4.10
6.1.1	(with modifications)
6.1.2	3.26 (with modifications)
0.1.2	4.10 (with modifications)
6.1.3	and
0.1.5	2.2 of Amendment (2006) to OIML B 10-1
6.1.4	2.2 of Amendment (2006) to OIML B 10-1 2.2 of Amendment (2006) to OIML B 10-1
0.1.4	4.10 and 2.2 of Amendment (2006) to OIML B 10-1
6.1.5	10-1 (with modifications)
6.1.6	New
0.1.0	
	2.4 of Amendment (2006) to OIML B 10-1
6.1.7	modified according to the voting rules proposed
0.1.7	for votes within TCs/SCs in the draft revision of
	the Directives for the OIML Technical Work
	4.11 First bullet
6.2.1	and
	2.5 of Amendment (2006) to OIML B 10-1
	4.11 Second bullet
6.2.2	and
	2.5 of Amendment (2006) to OIML B 10-1
6.3.1	2.6 of Amendment (2006) to OIML B 10-1 (with
(22	modifications)
6.3.2	New
7.1	4.6.1 (with editorial changes)
7.2	4.6.2 (with modifications)
7.3	4.6.2 (with editorial changes)
7.4	4.6.2 (last sentence)
7.5	7.2 of OIML MAA 01:August 2005
8.1	4.12 (with modifications)
8.2	4.12 (with modifications)
	8.1 (with modifications including the second
9.1	paragraph of Resolution no. 20 of the 43rd
	CIML)
9.2	New (based on OIML MAA 06:August 2007)
	8.2 (with modifications including the proposals
0.2	made at the combined R 49/R 60/R 76 CPR
9.3	meeting in June 2009 concerning the
9.5	maintenance scheme of a DoMC)
	8.2 (with modifications including the proposals
	made at the combined R 49/R 60/R 76 CPR
9.4	meeting in June 2009 concerning the
	maintenance scheme of a DoMC)

Sections in 1 CD	Sections in OIML B 10-1:2004
	8.2 (with modifications including the proposals
0.5	made at the combined R 49/R 60/R 76 CPR
9.5	meeting in June 2009 concerning the
	maintenance scheme of a DoMC)
	8.2 (with modifications including the proposals
	made at the combined R 49/R 60/R 76 CPR
9.6	meeting in June 2009 concerning the
	maintenance scheme of a DoMC)
9.7	8.3 (with editorial changes)
9.8	8.5 (with editorial changes)
10.1	9.1 (with editorial changes)
10.1	9.1 (with editorial changes)
10.2	New
10.4	New
11.1.1	New
11.1.2	New
11.1.3	New
11.2.1	New
11.2.2	New
11.2.3	New
11.3.1	New
11.3.2	New
11.4.1	New
11.4.2	New
11.5.1	5.4 (with modifications)
11.5.2	New
11.5.3	New
11.6.1	5.5.1 (with modifications)
11.6.2	5.5.1 (with modifications)
11.6.3	5.5.1 (with modifications) and 5.5.3
12	5.5.3 (with modifications)
13.1	5.5.2
13.1	New
13.2	5.7
13.5	
	4.11 (last sentence) and 7.2
14.2	7.1
14.3	7.3
14.4	7.4
14.5	7.5
14.6	7.6
15	New
16.1	9.2 (with modifications)
16.2	New
16.3	New
Annex A	New
Annex B	Annex A (with modifications)
	New
Annex C	Will be based on Annex II to
	OIML MAA 01:August 2005
Annex D	New

Sections in 1 CD	Sections in OIML B 10-1:2004
Annex E	New
Annex F	References