

BASIC

**OIML B 10**

PUBLICATION

Edition 2011 (E)  
including changes in  
the 2012 Amendment

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Framework for a Mutual Acceptance Arrangement  
on OIML Type Evaluations

Cadre pour un Arrangement d'Acceptation Mutuelle  
sur les Évaluations de Type de l'OIML

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OIML B 10 Edition 2011 (E)



ORGANISATION INTERNATIONALE  
DE METROLOGIE LEGALE

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INTERNATIONAL ORGANIZATION  
OF LEGAL METROLOGY

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**BIML note concerning the integration of the  
2012 Amendment to OIML B 10:2011**

The modifications to OIML B 10:2011 contained in the 2012 Amendment are included in this consolidated edition of B 10. For reference, they are summarized below. Both the original publication (B 10:2011) and the 2012 Amendment are available for consultation in the “Superseded” part of the OIML Publications catalog on [www.oiml.org](http://www.oiml.org).

Clause	Change	Clause	Change	Clause	Change
1.5	New section	3.9	Modified	3.19	New section
4.4	Modified	4.5	New section	5.2	Modified
9.1	Modified	10.1	Modified	11.5.4	New section
13.4	New section				

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

International Recommendations, Documents 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 2011 (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 at its 46th Meeting in Prague, Czech Republic in October 2011. It supersedes OIML B 10-1:2004, OIML B 10-2:2004 and the Amendment (2006) to OIML B 10-1:2004. At its 47th Meeting in Bucharest, Romania in October 2012 the CIML approved an amendment to B 10:2011. The changes contained in this amendment are included in the present text.

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:

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

## 1 Introduction

1.1 The objectives of the OIML Mutual Acceptance Arrangement (MAA) 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 offer a viable alternative to countries for which no test facilities are available.

1.2 The OIML MAA is an additional tool to the OIML Basic Certificate System, which is defined in OIML B 3 *OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments*. 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. 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, commits in principle the Participants to accept and use MAA Evaluation Reports issued by Issuing Participants.

1.5 Where an MAA Type Evaluation Report contains test results from an MTL, the participants in a DoMC may accept the results on a voluntary basis (see section 13.4).

## 2 Scope

2.1 This Framework for a Mutual Acceptance Arrangement (MAA) establishes the rules for a framework whereby Participants voluntarily 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 Declaration of Mutual Confidence for each category of measuring instruments. Depending on the relevant OIML Recommendation, modules of measuring instruments may also be 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 instruments 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, Chapter 3, the following abbreviations and definitions apply:

OIML MAA	OIML Mutual Acceptance Arrangement on Type Evaluations
DoMC	Declaration of Mutual Confidence
CPR	Committee on Participation Review
MAA Certificate	OIML Certificate issued under the MAA
IP	Issuing Participant
UP	Utilizing Participant
TC	Technical Committee (OIML)
TC/SC	Technical Subcommittee (OIML)

#### 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 national/regional 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, in principle, 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

#### 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 the 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 additional national 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 registered in a DoMC

*Note1:* See Annex A.

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

### **3.8 participant**

OIML Issuing Authority and/or National Issuing Authority and/or National Responsible Body of an OIML Member State or Corresponding Member 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).

### **3.9 Issuing Participant**

participant (as defined in 3.8) that issues OIML MAA Type Evaluation Reports and MAA Certificates and that utilizes those issued by other Issuing Participants.

*Note:* An Issuing Participant is always also a Utilizing Participant (as defined in 3.10).

### **3.10 Utilizing Participant**

participant (as defined in 3.8) from an OIML Member State that does not issue any OIML MAA Type Evaluation Reports or MAA Certificates, but that utilizes those issued by Issuing Participants

### **3.11 associate**

participant (as defined in 3.8) from an OIML Corresponding Member willing to utilize OIML MAA Type Evaluation Reports issued by Issuing Participants

### **3.12 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

### **3.13 conformity assessment (from ISO/IEC 17000, 2.1 [6])**

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

**3.14 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 requested by Issuing Participants to be registered in a DoMC.

**3.15 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.

**3.16 Committee on Participation Review (CPR)**

committee responsible for managing a DoMC

**3.17 applicant**

manufacturer and/or authorized representative submitting an application for an OIML MAA Type Evaluation of a measuring instrument or module 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

**3.18 additional national requirement**

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

**3.19 Manufacturer's Testing Laboratory (MTL)**

A Testing Laboratory (OIML B 3, 3.16 [4]) of a manufacturer (OIML B 3, 3.17 [4]) that is designated by an OIML Issuing Participant, and registered in a DoMC, that performs specific tests under controlled supervision (as defined in 4.5) or as a third party (subcontracting) laboratory of an Issuing Participant.

*Note:* An MTL may conduct tests for the parent company and/or for other companies. The requirements for controlled supervision (as defined in 4.5) apply if tests are performed for the parent company. Otherwise the MTL is considered as a third-party (subcontracting) Testing Laboratory, in which case the requirements for third-party laboratories must be satisfied.



## **4 Conditions for establishment of a DoMC**

Anyone may submit a request to launch a DoMC through the BIML, which will forward the request to the CIML. The decision to launch a DoMC is made by the CIML. The BIML will report annually to the CIML on the status of the MAA implementation.

**4.1** In general, one DoMC covers the relevant OIML Recommendation.

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** At least three Participants, preferably from different regions, shall be required in order to establish a DoMC. At least two of them must be Issuing Participants (3.9).

**4.3** 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 3.18) submitted by the Participants and for which detailed testing procedures have been provided (see 5.4).

**4.4** Issuing Participants shall apply for the registration of Testing Laboratories (internal and/or subcontracting) that will be responsible for issuing Test Reports that will be utilized in MAA Type Evaluation Reports. In addition to its internal and/or subcontracting Testing Laboratories, an Issuing Participant may, under the provisions of 4.5, register one or more MTLs, the test results of which are to be utilized. All Testing Laboratories shall be assessed either by accreditation (see 3.12) or shall be included in the scope of the peer assessment of the corresponding Issuing Participant (see 3.14) using requirements that comply with ISO/IEC 17025 [8] and OIML D 30 [12] for the scope of the DoMC as defined in 4.3. In either case, the assessment process must comply with the requirements established in section 7.

**4.5** In addition to 4.1 through 4.4 the following applies for MTLs.

**4.5.1** In order to address potential conflicts of interest the MTL shall operate under the controlled supervision of at least one Issuing Participant that is identified in the DoMC. In the case where two or more Issuing Participants want to make use of the same MTL, this must be clearly stated in the DoMC and the Issuing Participant responsible for the supervision of the MTL must also be identified (see 4.5.5). The supervision includes at least the following safeguards:

- a) the Issuing Participant has clear and documented instructions (quality system procedures) for the MTL concerning the test program and the equipment under test (EUT);
- b) the Issuing Participant has clear and documented instructions (quality system procedures) for the MTL in the case that the EUT fails before the test program is finished;
- c) the Issuing Participant is informed when the MTL starts and finishes the agreed tests;
- d) the Issuing Participant or an authorized representative is allowed to make short-notice visits to the manufacturer's site to witness tests performed at the MTL as considered necessary by the Issuing Participant;
- e) after finishing the tests, the Issuing Participant may request that the EUT tested by the MTL be submitted to its internal and/or subcontracting laboratory for re-tests (spot checks) that the Issuing Participant considers necessary; for these re-tests the Issuing Participant may - with the applicant's consent - use another Issuing Participant's registered laboratory;
- f) an MTL shall not subcontract testing.

4.5.2 The Issuing Participant shall exercise a controlled supervision as defined in 4.5.1. The safeguards and actions to be taken in the case of EUT failure have to be documented by written procedures in the quality management systems of both the manufacturer and the Issuing Participant, and their effectiveness is subject to regular surveillance audits as part of the accreditation assessment or peer assessment according to 9.3.

4.5.3 In order to ensure sufficient independence and impartiality of the MTL as part of a larger organization (company) the quality manual and other supporting documents of the organization shall demonstrate that there are suitable provisions that ensure that the MTL's personnel are free from any undue commercial, financial or other pressures which might influence their technical judgement. In particular, the following is mandatory:

- a) the MTL is a clearly defined organizational unit (OU) within the company, or part of such an OU, where procedures exist that define the specific responsibilities of the MTL and the interactions between the MTL and other OUs of the company;
- b) there is an organizational chart that shows the existence of the MTL and its position in the organizational structure;
- c) the MTL staff members, including the head of the MTL, are identified and their competences and responsibilities are described;
- d) there is evidence that the head of the MTL is free of any responsibilities or other pressures which may influence his/her technical judgement, and that he/she is responsible to a member of the top management in all technical conclusions.

4.5.4 The suitability and effectiveness of the procedures described in 4.5.1 through 4.5.3 are evaluated as part of the ISO/IEC 17025 accreditation or included in the scope of the peer assessment of the corresponding Issuing Participant (see OIML D 30 [12]).

4.5.5 Several Issuing Participants may designate the same MTL<sup>1</sup>. In this case, upon agreement among the Issuing Participants, one of them may be identified in the corresponding DoMC as the principal one that is responsible for the procedures and information required according to 4.5.1 through 4.5.4. Nevertheless, the remaining Issuing Participants in the DoMC still retain responsibility for confirming that the procedures and information required according to 4.5.1 through 4.5.4 are satisfied prior to utilizing the MTL.

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<sup>1</sup> Example: In the DoMC the MTL of manufacturer X is listed as an (additional) test laboratory of IP1 and IP2. IP1 is identified as the principal one that is responsible for the supervision and control of the MTL according to 5.2. If manufacturer X applies for type evaluation of a new instrument to IP1, then IP1 is responsible for ensuring that the entire process follows the procedures and requirements laid down in 4.5. If manufacturer X applies for type evaluation of another new instrument to IP2, then IP2 must also ensure that the entire process follows the procedures and requirements laid down in 4.5, the difference being that IP2 may make use of the previous information that IP1 has already provided to the CPR (e.g. information about results of intercomparisons, or other information according to 5.2).

## 5 Application for participation in a DoMC

Applications for participation shall be sent to the relevant CIML Member or contact person of Corresponding Members, who is responsible for submitting them to the BIML. Applications shall be accompanied by the following information:

### 5.1 For both potential Issuing Participants, Utilizing Participants and Associates:

- a) an official letter confirming participation in the MAA and the type of participation (Issuing Participant or Utilizing Participant or Associate);
- b) 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 4.3 shall be provided to be examined by the CPR (see 5.4).

### 5.2 For potential Issuing Participants only:

- a) information about its competence as defined in 4.2 of OIML B 3 [4];
- b) a list of all Testing Laboratories (internal, subcontracting and MTLs) 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;
- c) information about its type testing capabilities (including those of its registered subcontracting Testing Laboratories and MTLs, if any);
- d) in the case of an MTL: the procedures between the Issuing Participant and the MTL to manage the controlled supervision according to 4.5.1;
- e) in the case of accreditation, the certificate(s) of accreditation of the Testing Laboratories and their most recent accreditation assessment report(s) 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;
- f) the most recent internal audit of each Testing Laboratory (whether it is accredited or not) conducted on the basis of ISO/IEC 17025 [8] and OIML D 30 [12] for the relevant scope of the DoMC;
- g) the results of intercomparisons conducted in the relevant field, if any;
- h) 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 3:2011, 3.15 [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 national requirements (see 3.18) 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 4.3);
- reviewing the accreditation reports and peer assessment reports of the potential Issuing Participants;
- deciding, in case 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 4.4);
- 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 [4]).

The CPR may identify and propose to the relevant OIML TC/SC the necessary modifications to be implemented in the revision of the relevant OIML Recommendation to clarify the testing procedures.

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 the 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 and a representative of each Participant is 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 having voting rights are in favor of them. Abstentions and failures to reply do not count as votes cast. This rule is applicable for decisions, both taken at meetings or further to postal consultations.

6.1.8 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 provided 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 favor of the acceptance of the new potential Issuing Participant.

## **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 a decision on conducting any additional necessary assessments for those Issuing Participants wishing to perform the tests according to the additional national 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 the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement).

The assessment team shall include at least one technical and metrological expert validated by the CPR (see 7.3) for at least one of the surveillance assessments which covers the scope of the DoMC within the accreditation renewal cycle.

**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].

*Note:* A lead assessor of an accreditation body as defined in the Memorandum of Understanding signed between ILAC, IAF and the OIML fulfils this last 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 for that category of measuring instruments.

**7.5** The criteria for the qualification of technical and metrological experts are the following:

- The expert shall have sufficient 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 be an employee of a manufacturer of measuring instruments.
- The expert shall demonstrate sufficient experience in assessing on the basis of IEC 17025. This experience may be demonstrated through participation in training organized by the BIML or equivalent training organized by national accreditation bodies or by being a qualified assessor from a national accreditation body and, if applicable, participation in additional training required by the CPR.
- The expert shall have good spoken and written skills in English in order to conduct assessments 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 only OIML MAA Type Evaluation Reports and MAA Certificates for the relevant category of measuring instruments as soon as they perform tests and examinations that are included in the scope of the DoMC.

In the event that results of tests outside the scope of the DoMC are taken into account in the evaluation, an OIML Basic Type Evaluation Report and an OIML Basic Certificate (OIML B 3:2011, 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 3:2011, 5.3.4 and 5.5.1 [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) 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.

**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 summary report submitted to the BIML. This report shall highlight in particular, for the relevant scope of the DoMC:
  - a) results of comparisons,
  - b) changes in personnel, structure and organization;
  - c) results of management reviews;
  - d) results of internal audits;
  - e) 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.

Considering a maximum of a five-year renewal period recommended by the ILAC Guidance, a technical and metrological expert validated by the CPR for the appropriate scope shall, at least once over the renewal cycle, participate in the accreditation assessment team.

**9.6** The maintenance process is summarized in 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, and possibly suggest any subsequent actions (see 14.6).

## **10 Revision of a DoMC**

**10.1** A DoMC may be revised to:

- include new Participants and/or Testing Laboratories;
- withdraw Participants and/or Testing Laboratories;
- 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 wishes to withdraw from a DoMC, the Issuing Participant shall give notice to the BIML of its intention, but shall meet all current obligations to customers before actual withdrawal.

If the Issuing Participant is withdrawn from a DoMC at the proposal of the CPR, any ongoing applications shall be completed under the conditions defined by the CPR. These conditions should take into account the fact that tests and examinations may have already started.

In both cases, the BIML shall in turn notify all other Participants. All remaining Participants shall, however, accept and utilize or recognize the OIML MAA Type Evaluation Reports that were issued and registered prior to the 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 an 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 which additional tests and examinations he is applying for on the basis of additional national requirements included in the DoMC (see 5.4).

### **11.2 Consideration of 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 5.2.3 (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 5.3.5 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 of the Issuing Participant registered in the relevant DoMC (see 4.4).

*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 additional national requirements included in the scope of the DoMC (see 4.3).

*11.3.3* 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 the 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.

*11.5.4* In the event that test results from an MTL are utilized, this must be prominently stated and the respective tests identified at the beginning of the OIML MAA Type Evaluation Report, together with the designation of the MTL as registered in the respective DoMC.

### **11.6 Issuance 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 [4]. 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 additional national 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 Type Evaluation Report.

**13.3** In the event that questions arise during the review of an MAA Type Evaluation Report received (including the test data), a Participant shall consult the relevant Issuing Participant for clarification of the matter and take any further appropriate actions. In case the test data are not accepted, written justification for denial shall be sent to the relevant Issuing Participant and the manufacturer. The Issuing Participant may subsequently appeal this decision according to the procedure defined in 14.

**13.4** OIML MAA Type Evaluation Reports that contain test results from an MTL may be accepted by Issuing Participants or Utilizing Participants in the DoMC on a voluntary basis. In the event that test results from an MTL are not accepted, a justification or explanation is not required.

## **14 Appeals, resolution of complaints and disputes**

**14.1** A potential Participant in a DoMC that has not been accepted 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 for OIML Type Evaluation regarding an OIML MAA Type 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 9.3.2 and 9.3.3 of OIML B 3 [4] apply to Issuing Participants.

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

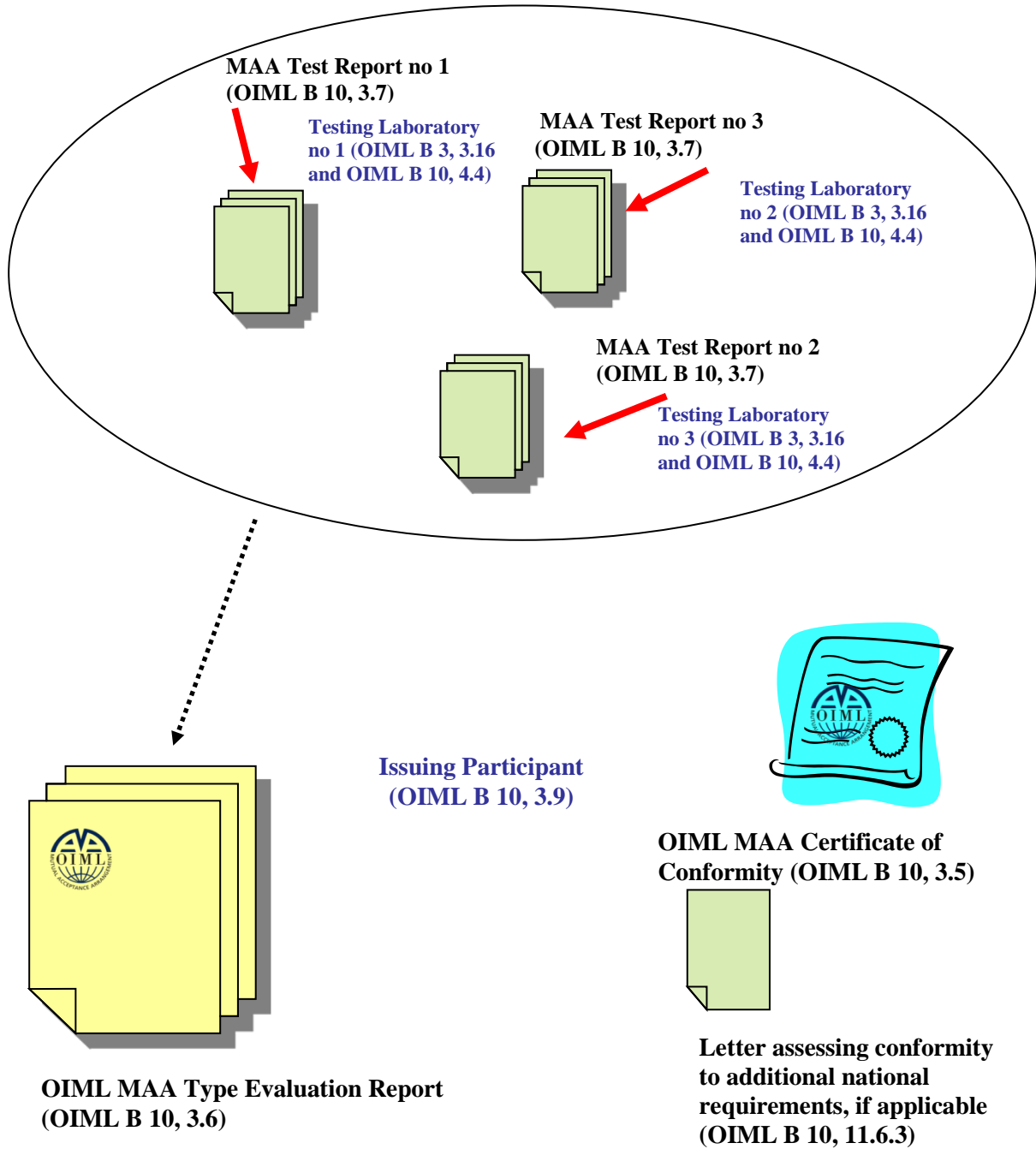
## **17 Maintaining the OIML Basic Certificate System in parallel with the MAA**

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 refer to the appropriate sections of OIML B 3 [4] and of this Publication.



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



**[Number of the relevant OIML Recommendation] Declaration of Mutual Confidence**

**Rev. X**

Revision	Date of revision	Nature of the revision
Rev.0		
Rev.1		
.....		

**1. Relevant OIML Recommendation:**

OIML R XX [*title*] – Edition 20XX

**2. Items in Recommendation not covered (if applicable)**

### 3. Issuing Participants and their Testing Laboratories

State	Issuing Participant	Testing Laboratories

### 4. Range of evaluation capability

This document defines a synthesis of the testing capabilities established on the basis of the internal testing facilities of the Testing Laboratories.

The use of external testing facilities (e.g. by subcontracting) may lead to higher capabilities.

Manufacturers are invited to contact the Testing Laboratories for any additional detailed information.

*[Names of the various Issuing Participants]*

*[Associated testing capabilities] These are to be defined in the format accepted by the relevant CPR.*

### 5. Additional national/regional requirements

State	Name of requirement	Requirements and applicable test procedure reference document

Conformity to these above-mentioned requirements may be evaluated by the following Issuing Participants and their Testing Laboratories:

State	Issuing Participant	Testing Laboratory(ies)

#### 6. Means used for establishing mutual confidence in the competence of Testing Laboratories

State	Means of establishing mutual confidence	
	Accreditation	Peer assessment

#### 7. Participation

The Participants indicated below have signed the DoMC to accept and utilize Test Reports and Certificates issued by the above-mentioned Issuing Participants in their national type approval program for the category of instruments specified in 1. This DoMC has been established in accordance with the requirements of OIML B 10 (20XX) *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*.

State	Identity of Participants and Associates	Status of participation	Date of participation

**8. Specific provisions** (if applicable)

**9. BIML receipt**

Date recorded at the BIML:



## Annex C - (Mandatory)

### Individual Registration Form of Participants



#### REGISTRATION OF A PARTICIPANT

**in a Declaration of Mutual Confidence (DoMC)**

1. **Relevant OIML Recommendation: OIML R XXX [title] – Edition 2XXX**
  
2. **Country:**
  
3. **References of the Participant:**

Name	Address	Contact Person

4.  **Issuing Participant**                       **Utilizing Participant**                       **Associate**

**5. In case the signatory is an Issuing signatory,**

**Name and address of Testing Laboratory(ies)**

*(if different from the Issuing Signatory):*

.....  
.....

**6. Items of the OIML Recommendation which are not covered by the DoMC according to the CPR decision**

.....  
.....

**7. Additional national requirements requested by the Participant and included in the DoMC**

.....  
.....

**8. Additional national requirements included in the DoMC to be performed by the Participant (in case the signatory is an Issuing Participant)**

.....  
.....

**9. Testing capabilities of the Testing Laboratory(ies)**

*(to be defined in the format accepted by the relevant CPR)*

.....  
.....

On the basis of the CPR Report dated [date], [name of the Participant] decided to sign the [reference of the relevant OIML Recommendation] DoMC to accept and utilize Test Reports and Certificates issued by other Participants in its national type approval program for the category of instruments specified in 1. The DoMC is established in accordance with the requirements of OIML B 10 Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations dated 20XX.

Date:

Signature:

[Name of the responsible person]

[Position of the responsible person]

**Annex D - (Mandatory)**  
**Periodic Review Report Format**

OIML MAA



**Periodic review of the participation in a  
 Declaration of Mutual Confidence (DoMC)**

1. **Relevant OIML Recommendation: OIML R .... – Edition .....**
  
2. **Country:**
  
3. **References of the Participant:**

Name	Address	Contact Person

4. **Name and address of Testing Laboratory <sup>2</sup>**

*(if different from the Issuing Signatory):*

.....  
 .....

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<sup>2</sup> For the case of countries with more than one Testing Laboratory, one report must be filled for each laboratory.

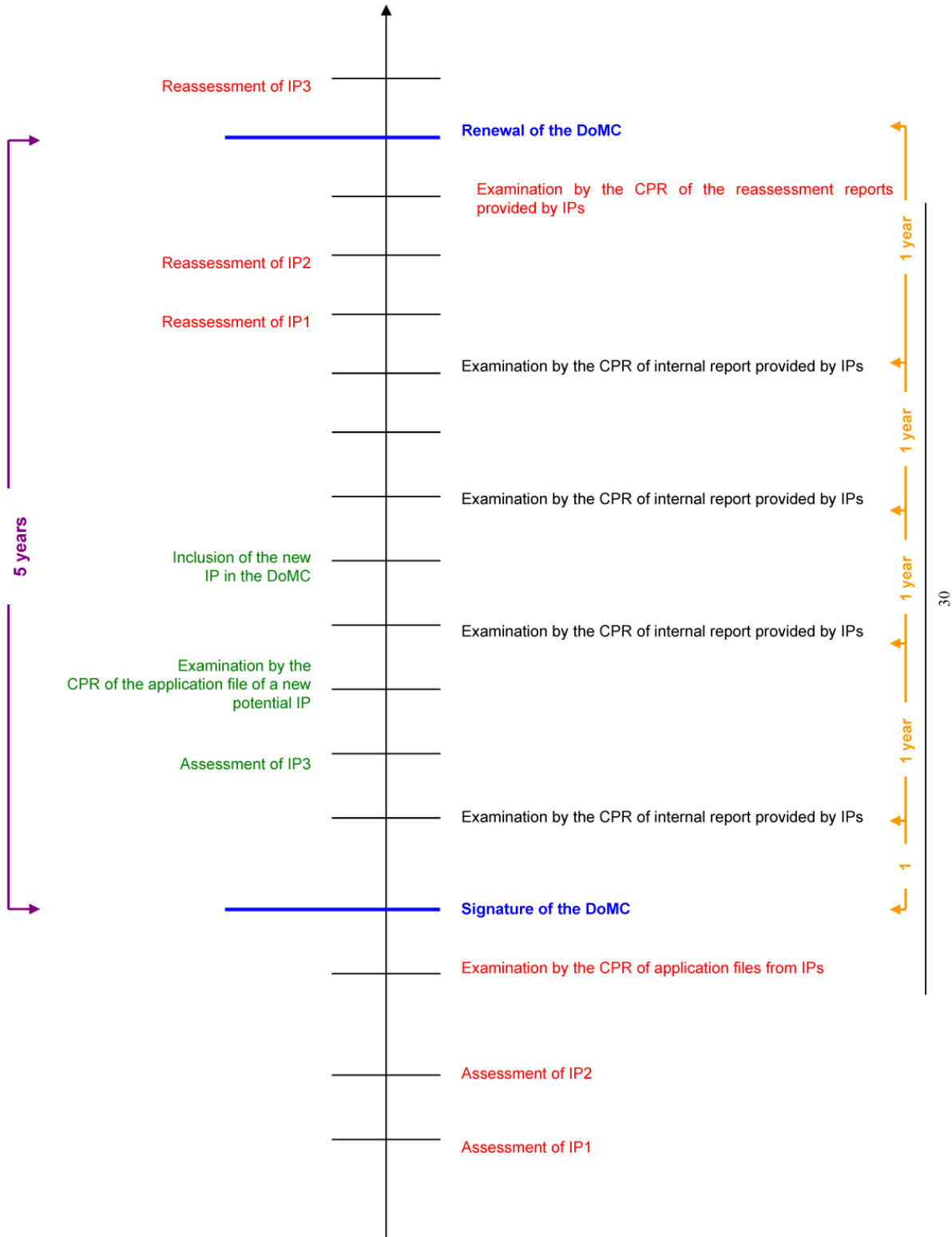
**5. Information provided for review (B 10 – paragraphs 9.3 to 9.5)**

<b>Item</b>	<b>File name (if relevant)</b>
Results of management reviews	
Results of internal audits	
Changes in personnel, structure and organization	
Complaints received	
Results of comparisons	
Accreditation assessment or peer assessment report(s)	

**Date:****Signature:**

## 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 3:2011, “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” (this Guide is under revision and is expected to be published as ISO/IEC Guide 17065)
- [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] ISO 3166-1: 2006, “Codes for the presentation of names of countries and their subdivisions - Part 1: Country codes”
- [11] OIML D 29: 2008 “Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology”
- [12] OIML D 30: 2008 “Guide for the application of ISO/IEC 17025 to assessment of Testing Laboratories involved in legal metrology testing”