

BASIC
PUBLICATION

**Amendment
(2012)
to OIML B 10**
Edition 2011 (E)

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 (MAA)

Amendment (2012) to OIML B 10 Edition 2011 (E)



ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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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. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

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

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

This publication – reference Amendment (2012) to OIML B 10:2011 (E) – was approved for final publication by the International Committee of Legal Metrology at its 47th meeting in Bucharest, Romania, in October 2012. The text in this Amendment supersedes the text in the respective sections of OIML B 10:2011.

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

1 Introduction

The revision of OIML B 10 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* was approved by the CIML at its 46th meeting in 2011. At the same meeting the Committee also approved a new work item for OIML TC 3/SC 5, namely to include appropriate conditions for the registration of Manufacturers' Testing Laboratories (MTLs) under a DoMC, as an amendment to, or revision of, OIML B 10.

Considering the effort necessary to completely revise this Publication again, TC 3/SC 5 chose to draw up an Amendment to B 10 that will be incorporated into B 10 at the time of its next revision.

2 Amendment (2012) to OIML B 10:2011 (E)

2.1 Section 1.5

This section is added to B 10:2011 as a new section.

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).

2.2 Section 3.9

This section is replaced as follows.

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).

2.3 Section 3.19

This section is added to B 10:2011 as a new section.

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.

2.4 Section 4.4

This section of B 10:2011 is replaced as follows.

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.

2.5 Section 4.5

This section is added to B 10:2011 as a new section.

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 MTL¹. 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.

¹ 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).

2.6 Section 5.2

This section of B 10:2011 is replaced as follows.

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.

2.7 Section 9.1

This section of B 10:2011 is replaced as follows.

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]).

2.8 Section 10.1

This section of B 10:2011 is replaced as follows.

A DoMC may be revised to:

- include new Participants and/or Testing Laboratories,
- withdraw Participants and/or Testing Laboratories,
- change the participation status of certain Participants, or
- revise its scope (e.g. inclusion of a new edition of the relevant OIML Recommendation, inclusion of new additional national requirements).

2.9 Section 11.5.4

This section is added to B 10:2011 as a new section.

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.

2.10 Section 13.4

This section is added to B 10:2011 as a new section.

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.