BASIC
PUBLICATION

OIML B 10-1

Edition 2004 (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

OIML B 10-1 Edition 2004 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Contents

Foreword

The *OIML Certificate System for Measuring Instruments* was introduced in 1991 to facilitate harmonizing approval procedures and lowering costs associated with the international trade of measuring instruments subject to legal control. The *System* provides the possibility for a manufacturer to obtain an OIML Certificate and a Test Report indicating that a given instrument type complies with the requirements of relevant OIML International Recommendations that are applicable within the *System*.

The *System* was established to take into account the general principles applicable to testing, certification, conformity assessment, accreditation and related subjects as laid down by other International Organizations such as ISO, IEC and ILAC. A decision of the Tenth International Conference of Legal Metrology in 1996 confirmed and enhanced these objectives and also included reference to the WTO in the context of the TBT Agreement. In 2002 the *System* was revised (OIML B 3 (formerly P 1): *OIML Certificate System for Measuring Instruments* - Edition 2003) to extend the scope of application to categories of measuring instruments including families of measuring instruments, modules, and families of modules.

OIML Certificates and Test Reports may be provided by OIML Member States that have established Issuing Authorities responsible for processing applications by manufacturers that request certification of their instrument types.

This *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*, or MAA, has been developed to further enhance the climate for mutual confidence and recognition of test results between OIML Members by providing a means whereby national metrology services can more directly assess testing and certification capabilities through internationally accepted means, such as laboratory accreditation and peer review. The MAA is designed to do this in an efficient manner that minimizes the need for multiple independent bilateral arrangements between Members. By accommodating certain agreed upon additional requirements, beyond those in the relevant OIML Recommendation, the MAA is designed to potentially expand the customer base of testing laboratories, and provide instrument manufacturers the "one-stop-testing" they desire. While OIML Certificates and Test Reports will continue to be accepted by national metrology services on a voluntary basis, the MAA is intended to greatly strengthen the commitment of the signatories.

This publication - reference OIML B 10-1 Edition 2004 (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 2003.

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0 Introduction

0.1 The International Organization of Legal Metrology (OIML) was established in 1955 as an intergovernmental body (treaty) dedicated to harmonizing the national metrology regulations of its Member States. Its administrative headquarters is the International Bureau of Legal Metrology (BIML) located in Paris, France. The International Committee of Legal Metrology (CIML), which is comprised of one representative from each Member State, provides oversight and supervision of the technical activities of the OIML.

0.2 Technical Committees within the OIML develop International Recommendations for specific categories of measuring instruments. OIML Recommendations provide the characteristics and performance requirements for measuring instruments and include the examination and test procedures used to evaluate the performance requirements and a Test Report Format for reporting the results of a type evaluation. After achieving a consensus within the originating Technical Committee and the CIML, OIML Recommendations are approved by the CIML for publication.

0.3 In 1991, the *OIML Certificate System for Measuring Instruments* (The *System*) was introduced. It provides a means by which an Issuing Authority designated by a participating Member State may issue Test Reports validated by an OIML Certificate. No obligation exists for OIML Member States to accept or recognize such Test Reports and associated OIML Certificates. These Test Reports with Certificates, however, may be presented by their owners (e.g. manufacturers) as evidence of conformity with the requirements of the relevant OIML Recommendation for the purposes of applying for type approval or initial verification in another OIML Member State.

0.4 A consensus has developed globally among legal metrologists that an effective means for eliminating and avoiding technical barriers to trade for measuring instruments may be achieved through harmonizing the performance requirements for measuring instruments under legal metrological control and mutual arrangements to accept and utilize type evaluation results. For this purpose, it was recognized that a mutual arrangement could be established among national bodies responsible for the legal metrological control of such instruments.

0.5 After extensive discussions, representatives of interested OIML Member States concluded that OIML Recommendations and the *System* could provide the basis for developing a voluntary mutual arrangement among Participants to accept and utilize reports of type evaluations that were reviewed and transmitted by participating Issuing Authorities. The mutual arrangement would be applied in the national and regional type approval or recognition programs of participating states. An important prerequisite for establishing such an arrangement would be achieving mutual confidence in the testing and certification capabilities among Participants.

1 Scope

1.1 This Framework for a Mutual Acceptance Arrangement (MAA) establishes the rules for a voluntary framework whereby Participants within OIML Member States and Associates within Corresponding Members accept and utilize Test Reports, as defined in 3.8, when validated by issuing of an OIML Certificate, for type approval or recognition in their relevant national or regional metrological control programs, and/or for issuing subsequent OIML Certificates. The MAA covers all items in the OIML Test Report for which detailed procedures are prescribed in the Recommendation. OIML Issuing Authorities and the Testing Laboratory or Laboratories that they utilize or supervise are all subject to evaluation of competence under this Arrangement. Of special note, OIML Issuing Authorities that also perform testing or examination within their organization are subject to the same evaluation of competence as Testing Laboratories for these activities.

1.2 The implementation of this MAA is through the establishment of a separate "Declaration of Mutual Confidence" (DoMC) for each category of instruments. Procedures are provided for establishing, operating, and terminating a DoMC and for Participants to appeal and resolve issues concerning their participation.

1.3 A DoMC shall not be legally binding; however, Participants shall have an obligation to cooperate in the implementation, improvement, and clarification of all provisions according to this Mutual Arrangement.

1.4 Issuing Authorities and/or National Responsible Bodies of OIML Corresponding Members may voluntarily take part in a DoMC as Associates by indicating in writing their willingness to accept and utilize Test Reports. Associates do not participate in the Committees on Participation Review.

2 Objectives of the Mutual Acceptance Arrangement

2.1 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 the conformity of measuring instruments, under legal metrological control, to OIML metrological and technical requirements and, when included, any agreed upon additional requirements.

2.2 To promote the global harmonization, uniform interpretation, and implementation of legal metrological requirements for measuring instruments.

2.3 To promote efficiency in time and cost of national type evaluations and approvals or recognition of measuring instruments under legal metrological control while achieving and maintaining confidence in the results in support of facilitating global trade of individual instruments.

3 Terminology

Note: A reference is provided in parenthesis after the definition of the term to indicate the applicable definition or comparable definition in references [1], [2] or [3].

3.1 OIML Recommendation

Publication addressing categories of measuring instruments or devices that includes metrological and technical performance requirements, a test procedure for evaluating conformity to the requirements, and a Test Report Format.

3.2 Category of instruments

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

3.3 Type of measuring instrument

Definite model of the category of instruments to which it conforms.

3.4 Type evaluation

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

3.5 Type approval

Decision of legal relevance, based on the evaluation report, that the type of a measuring instrument complies with the relevant statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time. (VIML 2.6)

3.6 Conformity

Fulfillment by the measuring instrument type of specified requirements. (ISO/IEC Guide 2, 12.1)

3.7 OIML Certificate of conformity

Document issued by an OIML Issuing Authority indicating that the identified measuring instrument type is in conformity with the requirements of the applicable OIML Recommendation.

3.8 OIML Test Report

Report which accompanies an OIML Certificate of Conformity under the OIML Certificate System.

OIML B 3 (formerly P 1): *OIML Certificate System for Measuring Instruments,* Edition 2003, subclause 2.12:

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

Note: The OIML Test Report shall always be accompanied by the OIML Certificate of Conformity which validates it.

3.9 Test Report

In the present publication, "Test Report" means a report comprised of the OIML Test Report (see 3.8) and, when applicable, a complementary Test Report containing test results for any agreed upon additional requirements.

Note 1: The Test Report gives the results of the examinations and testing carried out during type evaluation on an identified sample or samples of a given type and a conclusion as to whether the sample(s) meet the specified requirements.

Note 2: The Test Report constitutes the evaluation report referred to in 3.4.

Note 3: The complementary Test Report may be validated by a letter from the OIML Issuing Authority.

3.10 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 (see VIML 3.2) for specific categories of measuring instruments on the basis of examination and testing under its own control.

3.11 OIML Issuing Authority

Certifying body in an OIML Member State, designated by its CIML Member, that issues OIML Certificates of Conformity for a particular category of instruments.

Note: The OIML Issuing Authority may or may not be the same organization as the National Issuing Authority whose responsibilities are governed by national regulations. When the term "Issuing Authority" is used in this document without being further qualified, both "OIML Issuing Authority" and "National Issuing Authority" are assumed.

3.12 National Responsible Body

Organization within an OIML Member State or Corresponding Member that does not conduct type evaluation but is responsible for the metrological control of measuring instruments, including the approval or recognition of specific types of measuring instruments for national use.

3.13 Testing Laboratory

Principal laboratory including any necessary specialized laboratory or laboratories designated by the Issuing Authority to carry out examination and testing of a sample or samples of a measuring instrument submitted for type evaluation, with the principal laboratory assuming responsibility for the evaluation results reported.

See *Note* under 3.11.

3.14 Testing

Act of carrying out technical operations that consists of determining the metrological and technical characteristics of an instrument according to specified procedures. (ISO/IEC Guide 2, 13.1)

3.15 Examination

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

3.16 Mutual Acceptance Arrangement (MAA)

Framework agreement that commits Participants to accepting and utilizing Test 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.

3.17 Declaration of Mutual Confidence (DoMC)

Attestation by Participants that they have achieved a voluntary mutual arrangement with regard to type evaluation to accept and utilize Test Reports, which include results of examinations and testing, issued by other Participants for a specified category of measuring instrument.

3.18 Participant

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

3.19 Associate

National Issuing Authority and/or National Responsible Body of an OIML Corresponding Member that voluntarily takes part in a DoMC by indicating in writing its willingness to accept and utilize Test Reports.

Note: Associates receive information from, but do not participate in, the Committee on Participation Review.

3.20 Conformity assessment

Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled. (ISO/IEC Guide 2, 12.2)

3.21 Accreditation

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (ISO/IEC Guide 2, 12.11)

3.22 Peer assessment

Procedure by which one or more agreed-upon legal metrology experts assess, against specified requirements, on site, the competence of the Testing Laboratory or Laboratories designated by a participating Issuing Authority in the category of measuring instruments covered in a DoMC.

3.23 Internal audit

Systematic examination against specified requirements by personnel, not being directly responsible for the activity, to determine whether activities related to an agreed arrangement are implemented effectively and are suitable to achieve the stated objectives.

3.24 Customer

Manufacturer and/or an authorized representative who submits an application for type evaluation of a measuring instrument to an Issuing Authority participating in a DoMC in order to receive a Test Report and OIML Certificate for that instrument type.

3.25 Applicant

Issuing Authority or National Responsible Body that applies to be a Participant in a particular DoMC.

3.26 Committee on Participation Review

Committee, composed of one expert representing Participants of each Member State and one representative from the BIML, established for each DoMC to carry out tasks specified in 4.6 and 4.10.

4 Requirements for establishing a DoMC

4.1 Instruments included

Only those measuring instruments that are a part of the *OIML Certificate System* may be specified in a DoMC under this arrangement.

4.2 Number of declarations per instrument category

Only one DoMC shall exist for each category of instruments; that is, one that encompasses all or some of the applicable instruments or devices covered by an OIML Recommendation. The format for establishing a DoMC is given in Annex A.

4.3 Record of a declaration

The specific category of measuring instruments that are covered by a DoMC shall be recorded according to the format in A.1. A Participant shall indicate in A.1 which additional tests specified in A.2 they have successfully demonstrated their competence to perform.

4.4 Types of Participants

A Participant in a DoMC may be:

a) A body that issues OIML Test Reports that are validated by an OIML Certificate issued by the OIML Issuing Authority in that country, which may or may not be the same body, and that accepts and utilizes Test Reports issued by other Participants in that DoMC.

Note: This type of Participant may include one OIML Issuing Authority and one or more National Issuing Authorities per Member State.

b) A National Responsible Body or an Issuing Authority that does not issue OIML Test Reports under a particular DoMC, but accepts and utilizes Test Reports issued by other Participants mentioned in a).

Note: For those OIML Issuing Authorities that choose to participate and are not National Issuing Authorities, then both the OIML Issuing Authority and the National Issuing Authority shall participate.

4.5 Minimum number of Issuing Authorities

At least two Issuing Authorities as described in 4.4 (a), preferably from different regions, shall be required to establish a DoMC.

4.6 Assessments of Issuing Authorities and Testing Laboratories

Prior to establishing a DoMC for a specific category of instruments:

- The Committee on Participation Review shall identify the list of tests for which detailed procedures are prescribed in the appropriate Recommendation, and the list of additional tests to be optionally performed by the Participants. These lists will be used to establish the scope of assessment of competences of the Issuing Authorities and Testing Laboratories. OIML TCs/SCs should be invited to consider removing or making more explicit the examination procedures or other inadequately defined procedures in the appropriate Recommendations.
- The Issuing Authorities as described in 4.4 (a) that also perform testing or examination within their organizations, and all of the Testing Laboratories that they use in conjunction with a particular DoMC, shall be assessed either by accreditation or peer assessment using criteria that comply with ISO/IEC 17025 for the scope of assessment as determined above.
- The OIML Issuing Authorities that validate the Test Reports shall conduct internal audits using criteria that comply with ISO/IEC Guide 65. If the OIML Issuing Authority is the same as the Issuing Authority in the second bullet above, it shall in addition be assessed as required in the second bullet.

The costs for carrying out the assessments of the Issuing Authorities and Testing Laboratories is to be borne by the body that is being assessed.

4.6.1 The accreditation body that carries out an assessment of the laboratory or laboratories of an Applicant for participation in a DoMC shall participate in a mutual recognition arrangement among accrediting bodies in the participating Member States or within regions that include

the intended Participants in a proposed or existing DoMC as, for example, participation in the ILAC MRA ("International Laboratory Accreditation Cooperation Mutual Recognition Arrangement"). In accrediting a Testing Laboratory, the assessment team shall include at least one member who is an expert in legal metrology for the category of instruments or devices covered. The Committee on Participation Review shall be consulted regarding the qualifications of the expert selected.

4.6.2 The peer assessments shall be carried out by a team of experts, including at least one legal metrology expert in the category of instruments covered and at least one expert knowledgeable in the requirements of "quality systems". Such experts shall be appointed and mutually agreed upon by the relevant Committee on Participation Review (see 4.10). A list of qualified persons for peer assessment for a specific category of instruments shall be maintained by the BIML according to recommendations and criteria approved by Participants. An expert that participates in conducting a peer assessment shall not be a member of the Committee on Participation Review.

4.6.3 Model assessment requirements according to ISO/IEC Guide 65 for Issuing Authorities and of the assessment requirements according to ISO/IEC 17025 for Testing Laboratories are briefly outlined in Annex B. "Checklists" that may be used for such internal audits and assessments are given in OIML B 10-2 *Checklists for Issuing Authorities and Testing Laboratories carrying out OIML type evaluations* [8].

Note: The criteria for an accreditation, a peer assessment, or an internal audit should be consistent with any approved, relevant OIML Documents on the application of relevant ISO/IEC Standards and Guides.

4.6.4 The means used for establishing mutual confidence shall be indicated in A.3.

4.7 Supplementary means for Testing Laboratories to demonstrate competence

The means of establishing and maintaining confidence in the competence of Testing Laboratories as specified in 4.6 may be supplemented by some, but not necessarily all, of the following actions:

- Exchange of information regarding national capability for testing;
- Exchange of information on training of Issuing Authority and Testing Laboratory personnel; and
- Exchange of test data.

Any supplementary means used for establishing mutual confidence shall be indicated in A.3.

4.8 Notification of decisions

After a decision to establish a DoMC, potential Participants shall notify the BIML through their CIML Member of their intention. In turn, the BIML shall inform all other OIML Member States of this intention so that the latter may also consider participating.

4.9 Application for participation

Application for participation in a DoMC shall be submitted to the BIML and shall be accompanied by the information in 4.9.1 and 4.9.2.

4.9.1 For a body of type (a) in subclause 4.4 that intends to review and transmit Test Reports in a DoMC:

- The Applicant shall submit for information the report of the results of the most recent internal audit according to requirements prepared by the Committee on Participation Review using as a model the "Checklists" [8] for ISO/IEC Guide 65 or, if available, a certificate of accreditation covering the scope of the DoMC. A completed questionnaire must also be provided on "National Capabilities for Type Testing" for which a generic form is provided in Annex C;
- For all Testing Laboratories to be utilized by the Applicant that use accreditation as the means for demonstrating competence, the Applicant shall submit a certificate of accreditation for the Testing

Laboratories that includes the scope of the DoMC and enough information that an assessment of the legal metrology aspects of the accreditation can be determined. The composition and qualifications of the assessment team must be provided.

- For all Testing Laboratories to be utilized by the Applicant using peer evaluation as the means for demonstrating competence, the Applicant shall submit the reports of the results of the most recent internal audits and, if available, a certificate of accreditation covering part of the scope of the DoMC or other evidence of competence. These reports shall be according to requirements prepared by the Committee on Participation Review using as a model the "Checklists" [8] for ISO/IEC 17025, and shall include enough information that an assessment of the legal metrology aspects of the accreditation can be determined;
- A report may be submitted on the results of the participation in intercomparisons, if any, of relevant testing by any of the designated Testing Laboratories; and
- The proposed expert to serve on the Committee on Participation Review shall be identified by the CIML Member and agree to participate in the work of the committee.

4.9.2 For all Applicants in a DoMC:

- If additional evaluations are required in the regulations of the Applicant's country, they shall be clearly identified or referenced along with the associated test methods and test report format, if required, in a completed table as given in A.2 (see also 5.3); and
- The proposed expert to serve on the Committee on Participation Review shall be identified by the CIML Member.

4.10 Reviewing participation

A Committee on Participation Review shall be established for the purpose of reviewing the documentation submitted by potential Participants, of establishing the scopes of peer assessment when necessary, of establishing lists of experts for conducting peer assessments and participating in accreditations, of preparing reports on the qualifications of potential Participants, and for any other purpose required for establishing, expanding, and maintaining the appropriate participation in a DoMC. It shall be open to one expert from each OIML Member State, appointed by the CIML Member to represent all of the Participants from that Member State, in each established DoMC or representing each potential Participant in a DoMC being established.

4.10.1 For an Issuing Authority as described in 4.4 (a) that applies for participation in a DoMC, the committee shall carry out the following tasks:

- Review the information submitted in the application;
- Accept without further assessment the valid report on the accreditation of a Testing Laboratory within the scope of the DoMC;
- Decide, based on the internal audit report (appropriately constructed Checklist), on the scope of the necessary peer assessment of a Testing Laboratory of an Applicant that has not been accredited;
- Select, when necessary, the expert or experts that will conduct a peer assessment of the Testing Laboratory;
- Prepare a report, based on all information received including peer assessments when conducted, on the competence of an Applicant for distribution to all Participants and other potential Participants in a DoMC to be used for a decision on participation; and
- Review the requirements for a customer to apply for national type evaluation and approval that shall be consistent with the requirements of subclause 3.1 of OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* [1].

4.10.2 For a potential Participant that intends only to accept and utilize Test Reports, and for an Associate, the committee shall review the requirements for a customer to apply for national type evaluation and approval or recognition. Application requirements shall be consistent with the requirements of subclause 3.1 of OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* [1].

4.11 Approval of participation

- When a DoMC is first being established, all potential Participants shall independently review the reports on all other potential Participants prepared by the Committee on Participation Review, and all other potential Participants shall independently agree that each potential Participant meets the requirements in order that it be accepted as a Participant. The potential Participants shall originally submit their findings to the BIML representative on the committee, who will transmit all findings to the others only after all findings have first been submitted.
- Once a DoMC is established, all Participants shall independently review the report on a potential Participant prepared by the Committee on Participation Review, and all Participants must agree that the potential Participant meets the requirements in order that it be accepted as a Participant.

An appeal of a decision is covered in clause 7.

4.12 Record of participation

After establishing mutual confidence, the accepted Issuing Authorities and National Responsible Bodies shall sign as Participants and, thereby, execute a DoMC, according to the format contained in A.4, that is then placed on record with the BIML. The CIML Member or other governmental official may sign to confirm the participation of the indicated OIML Member State.

5 Requirements for implementing a DoMC

5.1 Commitment of Participants

Participants in a DoMC shall commit their participation according to A.4. Each Participant shall agree to implement reciprocity with regard to all other Participants in accepting and utilizing or recognizing the Test Reports and Certificates prepared according to the relevant OIML Recommendation and any additional test requirements having been reviewed and transmitted by other Participants.

5.2 Information for customers

A Participant as described in 4.4 (a) shall provide the following documented information to potential customers (instrument manufacturers or their representatives):

- The procedures for a manufacturer (or authorized representative) of a measuring instrument or device to apply for a Test Report prepared according to the requirements for type evaluation of the category of measuring instruments covered in the DoMC;
- The necessary information and documentation that a manufacturer (or authorized representative) shall submit regarding identifying the measuring instrument type to be evaluated;
- The identity of the Testing Laboratory or laboratories that will carry out the examination and testing;
- The extent of type evaluation that will be conducted;
- The approximate fees and time schedule required for the preparation of Test Reports; and
- The identity of participating OIML Member States that have agreed to accept and utilize the Test Reports in their national or regional metrological control programs and their requirements for type approval or recognition.

Note: The appropriate requirements of clause 3 *Processing of a Certificate* of OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* [1] should be followed, especially 3.1.2 regarding the required documentation identifying the instrument type submitted in the application for type evaluation.

5.3 Additional requirements and evaluations

In order to issue a national type approval certificate on the basis of a Test Report received from another Participant, the Issuing Authority may be required by national or regional laws and regulations to perform additional evaluations to those required in the relevant OIML Recommendation.

A Participant requiring any additional type evaluations shall clearly identify them with an explanation and justification and also reference them along with any necessary additional associated test methods and the

test report format in A.2. Such references shall be updated promptly after any change in these requirements.

These additional evaluations shall be included in the scope of the DoMC when accepted by the Committee. Additional evaluations may be proposed, in particular for the following cases:

- Testing at severity levels different than those specified in the OIML Recommendation (e.g., testing to different EMC severity levels);
- The OIML Recommendation does not provide adequately detailed testing procedures (e.g., software testing); or
- The national regulation contains testing and other requirements for characteristics not covered by the OIML Recommendation (e.g., tests for resistance to sand or zinc in water for water meters).

Other Participants may choose to carry out these evaluations, in addition to the tests within the corresponding OIML Recommendation, in order to provide customers with "one-stop-testing". Performing these additional tests is optional for each Participant.

5.4 Preparation of the Test Report

The Test Report shall be prepared either by the Principal Testing Laboratory or by the responsible Issuing Authority. If prepared by the Principal Testing Laboratory, it shall be reviewed by the responsible OIML Issuing Authority. It shall be completed according to the Test Report Format of the applicable OIML Recommendation and shall clearly identify the instrument evaluated and those responsible for carrying out type evaluation, especially the principal laboratory and any specialized laboratories utilized. For those Participants who choose to do so, the Test Report may include the results of evaluations carried out at the request of the customer and according to the additional requirements of some Participants.

5.5 Transmission and use of a Test Report

5.5.1 The Issuing Authority shall transmit the Test Report to the customer in the following ways:

- With an OIML Certificate of Conformity, prepared according to the rules established in OIML B 3 (ex P 1) [1]; and
- With a letter validating the complementary Test Report, if any.

5.5.2 The customer that receives the Test Report with the Certificate and letter, if obtained, then may use it (them) in an application for national or regional type evaluation in another country.

5.5.3 The Issuing Authority shall send a copy of each Certificate and letter it issues to the BIML for registration according to the rules in 4.1 of OIML B 3 (ex P 1) [1].

5.6 Consultations on a Test Report

In the event that questions arise during the review of a Test Report received, a Participant shall consult the Participant responsible for transmitting the Test Report for clarification of the matter and take any necessary further actions that may be required. In all cases, the customer shall be informed clearly of the details of any such consultations.

5.7 Responsibility for the Test Report

A Participant that accepts a Test Report under the terms of the MAA and utilizes it to issue a national or OIML Certificate of Conformity shall also assume responsibility for the Test Report according to national regulation.

5.8 Collaborations of Participants

Representatives of each Participant in a DoMC shall collaborate, as applicable, in the following efforts:

- To mutually accept and utilize Test Reports as received;
- To make non-confidential information pertaining to all type evaluations available upon request, or as agreed upon, to other Participants;
- To maintain the confidentiality of proprietary information;
- To monitor the capability and competence of their Testing Laboratories;
- To achieve and maintain competence for determining conformity to requirements when reviewing Test Reports; and

- To provide active participation in any technical revisions of relevant OIML Recommendations.

6 Role of the BIML

6.1 After being informed, the BIML shall promptly announce a decision to initiate a DoMC. The BIML shall receive the information specified in 4.9 from an OIML Member State, through its CIML Member, of its intention to participate in a proposed or an existing DoMC.

6.2 The BIML shall assist the Committee on Participation Review in its responsibilities and assume necessary administrative roles in facilitating a DoMC. Administrative fees, approved by the CIML, may be imposed and collected by the BIML to recover costs associated with the various identified tasks assumed. Operational expenses for administering the MAA Program are elaborated in a separate document [12].

6.3 The BIML shall prepare periodic reports for CIML Members indicating the number of Certificates issued to customers by Member States that utilized Test Reports under this arrangement. Each Participant in a specific DoMC shall provide the BIML the necessary information as the basis for this report.

6.4 The BIML shall be responsible for monitoring and maintaining records of all Declarations of Mutual Confidence and shall also provide, upon request, information on current activities to any interested party in an OIML Member State through its CIML Member. Information about the MAA shall be published periodically in the OIML Bulletin.

7 Resolution of complaints and disputes

7.1 The BIML shall be contacted in the event of a dispute initiated either by a customer regarding a Test Report or a Participant regarding the operational procedures of this *Framework for a Mutual Acceptance Arrangement*. The BIML will also provide, if requested, an interpretation or clarification of the intent of the Arrangement.

7.2 An Applicant that has not been accepted to participate in a DoMC may appeal that decision.

7.3 The CIML Members may represent the Participants involved in a dispute and shall attempt to resolve among themselves any issue that might arise. If the Participants affected are unable to resolve an issue, they shall provide a written explanation to the BIML for distribution to the CIML Members representing all other Participants.

7.4 A complaint may be submitted to the BIML with documented and substantiated evidence that a Test Report was prepared, reviewed, or transmitted by a Participant on the basis of incorrect technical conclusions or procedures. The BIML shall notify the owner of the documentation and all other Participants in a DoMC of the complaint.

7.5 Such unresolved disputes and complaints as indicated in 7.3 and 7.4 may be referred to the CIML Presidium (consisting of the CIML President and two Vice-Presidents). The Presidium would consider the matter or refer it for resolution to an ad hoc task group of CIML Members consisting of representatives of non-involved Participants.

7.6 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 all other Participants.

8 Initiation, maintenance and termination

8.1 Each DoMC established according to Annex A shall become effective on the date that it is recorded by the BIML.

8.2 In order to be active in a DoMC, Participants shall be required to undergo internal audits and re-assessments of competence according to the following schedule:

- Issuing Authorities shall produce a report on their internal audits according to appropriately constructed "Checklists" [8] or accreditation reports at least once every two years;
- Testing Laboratories that are accredited shall undergo surveillance as required by the accreditation body and be re-accredited at least once every four years; and
- Testing Laboratories that undergo on-site peer assessment shall produce a report on an internal audit according to appropriately constructed "Checklists" [8] at least once every two years for surveillance and shall be subject to a peer re-assessment at least once every four years.

8.3 The reports shall be submitted to the relevant Committee on Participation Review, which shall review them and report to the Participants the need for any possible subsequent actions (see 7.6).

8.4 A DoMC shall not be legally binding although Participants agree to cooperate in its implementation, improvement, and clarification of provisions.

8.5 A Participant may withdraw from a DoMC by giving written notice to the BIML taking into account all current obligations to customers for type evaluation, and the BIML shall in turn notify all other Participants. All remaining Participants, however, shall accept and utilize or recognize the Test Reports that were prepared, reviewed, and transmitted by the Issuing Authority of the Participant prior to withdrawal.

8.6 OIML TCs/SCs will be invited to develop technical interpretation guides to clarify certain aspects of Recommendations under their responsibility as matters are brought to their attention by Participants in a DoMC.

9 Amendment

9.1 A DoMC may be reviewed and amended when necessary to incorporate changes in technical or administrative requirements that do not conflict with this document. All current Participants in a DoMC shall agree upon any specific changes.

9.2 The detailed requirements for participation in a DoMC shall be reviewed after an OIML Recommendation on which it is based is revised. After such a review, amendments to a DoMC may be required.

10 Revision

Revisions of this document shall be the responsibility of OIML TC 3/SC 5, and shall be approved by the CIML.

References

[1] OIML B 3 (ex P 1) (2003), OIML Certificate System for Measuring Instruments (Second Edition)

[2] OIML V 1 (2000), International Vocabulary of Terms in Legal Metrology (VIML)

[3] ISO/IEC Guide 2 (1996), Standardization and related activities - General vocabulary

[4] ISO/IEC 17025 (1999), General requirements for the competence of testing and calibration laboratories

[5] ISO/IEC Guide 58 (1993), Calibration and testing laboratory accreditation systems - General requirements for operation and recognition

[6] ISO/IEC Guide 61 (1996), General requirements for assessment and accreditation of certification/registration bodies

[7] ISO/IEC Guide 65 (1996), General requirements for bodies operating product certification systems

[8] OIML B 10-2 (2004), Checklists for Issuing Authorities and Testing Laboratories carrying out OIML type evaluations

[9] ILAC Document G 10 (1996), Harmonized procedures for surveillance and reassessment of accredited laboratories

[10] ISO/IEC 17040 (2001), General requirements for peer assessment of conformity assessment bodies

[11] ISO/IEC CD 17000, Conformity assessment - General vocabulary

[12] OIML B 10-3 (2004), Document on MAA implementation (to be separately developed and approved by the CIML)

ANNEX A

Format for a Declaration of Mutual Confidence (DoMC)

Relevant OIML Recommendation (4.1, 4.2): .....

Items in Recommendation not covered (1.1): .....

Note: All reference numbers are to clauses in OIML B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations.*

A.1 Specific measuring instrument or device category covered (4.3)

State	Issuing Authority	Principal Testing Laboratory	Range of evaluation capability (class, measuring range, etc.*)

* for accredited Laboratories, the scope of accreditation (4.9.1).

A.2 Additional requirements, where applicable (5.3)

Note: Use additional pages as required.

State	Name of requirement	Requirements: reference document(s) and applicable clause(s)	Evaluation procedures: document(s) and applicable clause(s) if necessary

A.3 Means used for establishing mutual confidence in the competence of Testing Laboratories (4.6)

Note: Use additional pages as required.

State	Means of establishing mutual confidence		
	Accreditation	Peer assessment	Supplementary (if carried out, see 4.7)

A.4 The Participants and Associates indicated below hereby attest that they have achieved a voluntary mutual arrangement to accept and utilize Test Reports and Certificates issued by other Participants in their national type approval program for the category of instruments specified in A.1. This DoMC has been established in accordance with the requirements of OIML B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* dated .....

State	Identity and signature of Issuing Authority [designated (a) if reviews and transmits Test Reports and (b) if not] (4.4)	CIML Member or other governmental official (signature optional)	Date

A.5 BIML receipt

Date recorded at BIML: ..... (effective date)

Signature: ..... Director, BIML

ANNEX B

Basic means of establishing mutual confidence by accreditation or peer assessment

B.1 Introduction

B.1.1 The requirements used for accreditation or peer assessments of the competence of Testing Laboratories shall be consistent with the requirements of ISO/IEC 17025 (1999). Issuing Authorities shall carry out internal audits of their procedures consistent with the requirements of ISO/IEC Guide 65 (1996).

B.1.2 In this Annex, B.2 and B.3 are outlines with specific references to relevant clauses of ISO/IEC 17025 (1999) as indicated in parenthesis ( ) and with specific references to relevant clauses of ISO/IEC Guide 65 (1996) as indicated in brackets [ ]. Also indicated are specific references to relevant clauses in OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* (Edition 2003) as indicated by { }.

Note: Models that may be used for specific applications (interpretations) of the ISO/IEC 17025 and ISO/IEC Guide 65 are provided in OIML B 10-2 *Checklists for Issuing Authorities and Testing Laboratories carrying out OIML type evaluations* and may also be available in other relevant OIML Documents.

B.2 ISO/IEC 17025 as applicable to Testing Laboratories and OIML Issuing Authorities, when applicable

B.2.1 Scope (1), [1], {1}

The assessment of a Testing Laboratory is carried out either by a recognized accreditation body or by peer assessment.

B.2.2 Normative references (2)

OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* (Edition 2003)

OIML Recommendations (various, for specific measuring devices)

B.2.3 Terms and definitions (3), [3], {2}

B.2.4 Management requirements {3.3.1}

B.2.4.1 Organization and management (4.1)

The Principal Testing Laboratory shall have adequate test facilities and equipment; competent management, technical, and support personnel; and documented procedures for type evaluation of instruments and devices covered. It shall ensure the confidentiality of information and proprietary rights of customers and shall operate with impartiality and integrity.

B.2.4.2 Quality system (4.2)

The Testing Laboratory shall establish, implement, and maintain a documented quality system for type evaluations and shall observe good laboratory practice in carrying out tests. It shall regularly assess its performance in accordance to such requirements.

B.2.4.3 Document control (4.3)

The Testing Laboratory shall establish and maintain procedures to control all documents associated with type evaluations.

B.2.4.4 Request, tender, and contract review (4.4), {3.1, 3.2}

The Testing Laboratory shall adhere to the procedures

for the application for type evaluation established by the Issuing Authority and shall provide customers with the schedule of fees in advance.

B.2.4.5 Sub-contracting of tests (4.5), {3.3.4}

The Issuing Authority may authorize a Principal Laboratory to sub-contract some specified testing; however, the Issuing Authority shall ensure the competence of all laboratories utilized through either accreditation or peer assessment of compliance with ISO/IEC 17025. Customers for type evaluation shall be informed in advance of the intention of using a subcontractor for specified tests, and the subcontractor shall be identified accordingly in the Test Reports. The Principal Laboratory shall prepare the Test Report and, therefore, be responsible for all test results.

B.2.4.6 Purchasing services and supplies (4.6),

The Testing Laboratory shall have policies and procedures for the selection and purchasing of all services and supplies necessary for type evaluations.

B.2.4.7 Services to the client (4.7), {3.2}

The Testing Laboratory shall provide clarification of all requirements for customers and permit access to monitoring testing under appropriate safeguards.

B.2.4.8 Complaints (4.8), {6.2, 6.4}

The Testing Laboratory shall follow established procedures for resolving complaints, disputes, and appeals regarding type evaluations and Test Reports.

B.2.4.9 Control of nonconforming testing (4.9), {6.5}

The Testing Laboratory shall have procedures for taking action, informing affected parties, and recalling necessary documents when nonconforming testing is identified.

B.2.4.10 Corrective action (4.10), {6.1}

The Testing Laboratory shall have policies and procedures for taking action to correct and monitor administrative or technical actions that have resulted in giving nonconforming test results.

B.2.4.11 Preventive action (4.11), {6.1}

The Testing Laboratory shall initiate corrective actions for problems that might cause nonconforming testing as soon as such problems are identified.

B.2.4.12 Records (4.12), {3.3.1}

The Testing Laboratory shall establish and maintain procedures for identifying, filing, accessing, and disseminating type evaluation Test Reports.

B.2.4.13 Internal audits (4.13)

The Testing Laboratory shall conduct periodic internal audits by trained personnel, who are independent of the activity, to verify compliance with all procedures necessary to demonstrate competence in type evaluation testing.

B.2.4.14 Management reviews (4.14)

The management personnel of the Testing Laboratory shall conduct periodic reviews of the administrative and technical procedures to ensure their continuing suitability and effectiveness and to introduce any necessary improvements and efficiencies.

B.2.5 Technical requirements

B.2.5.1 General (5.1)

B.2.5.2 Personnel (5.2)

The management of the Testing Laboratory shall ensure that the staff involved in type evaluations is qualified and maintains competence through experience, education, training, and appropriate supervision.

B.2.5.3 Facilities and environmental conditions (5.3)

The Testing Laboratory shall have the necessary and appropriate facilities for power, lighting, temperature,

and humidity, and other controls necessary to carry out the required type evaluations.

B.2.5.4 Test methods including sampling (5.4), (5.7), {3.3.3}

The Testing Laboratory shall implement all test methods including sampling as specified in the relevant OIML Recommendation and any referenced supplementary documents.

B.2.5.5 Equipment (5.5)

The Testing Laboratory shall have all the identified necessary and appropriate equipment for type evaluation testing and shall have documented procedures for the appropriate operation, maintenance, repair, and calibration of the equipment.

B.2.5.6 Measurement traceability (5.6)

The Testing Laboratory shall acquire and maintain the reference and working physical standards necessary for calibrations and type evaluation testing. The documented calibrations of all physical standards shall be traceable to national standards.

B2.5.7 Handling and transportation of test items (5.8)

The Testing Laboratory shall have procedures for the transport, handling, protection, and storage of all samples of instrument types received and evaluated.

B.2.5.8 Assuring the quality of test results (5.9)

The Testing Laboratory should implement procedures for assuring the quality of test results such as maintaining the quality control of standards, participating in laboratory intercomparisons, and exchanging information and test data.

B.2.5.9 Reporting the results (5.10), {3.4.1}

The Testing Laboratory shall prepare the report of the type evaluation in accordance with the requirements of the Test Report Format in the relevant OIML Recommendation and for any additional requirements (listed in A.2, for example).

B.3 ISO/IEC Guide 65 as applicable to OIML Issuing Authorities

B.3.1 Scope [1], {1}

This subclause applies to an Issuing Authority that carries out a certification process for measuring instruments submitted for type evaluation.

B.3.2 Normative references [2]

OIML B 3 (ex P 1) *OIML Certificate System for Measuring Instruments* (Edition 2003)

OIML Recommendations (various, for specific measuring devices)

B.3.3 Terms and definitions [3], {2}

The relevant terms in ISO/IEC Guide 2, the VIM, and the VIML apply.

B.3.4 Certification body [4], {2.5}

The certification body is the "Issuing Authority" that reviews and transmits a Test Report under a DoMC.

B.3.4.1 General provisions [4.1], {3.1}

The policies and provisions of the body shall be nondiscriminatory and shall provide the same level of access to all customers. The procedures for evaluating instruments shall be as given in the relevant OIML Recommendation and any other documented additional requirements.

B.3.4.2 Organization [4.2]

An organizational chart with the description of the responsibilities and functions of all sub-units of the body shall be publicly available.

B.3.4.3 Operations [4.3], {1.1}

The body shall take all necessary steps to evaluate the conformity of measuring instruments to the metrological requirements of the relevant OIML Recom-

mendation and of any other additional requirements accepted by the Committee on Participation Review, against which the customer wants his instrument to be evaluated.

B.3.4.4 Subcontracting [4.4], {1.1, 3.3.1, 3.5.1}

A body may subcontract work related to the examination and testing of an instrument but shall not delegate its final decision, or judgment, to approve or not to approve an instrument based on the report of the type evaluation. It shall take full responsibility for such work and shall carry out the necessary assessments to ensure the competence of a subcontractor. A customer for type evaluation testing shall be informed of the details regarding any subcontractor involved.

The Issuing Authority may subcontract only that part of examination and testing for which detailed procedures exist.

B.3.4.5 Quality system [4.5]

The body shall operate a documented quality system.

B.3.4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification [4.6], {6.7 – 6.9}

The body shall specify and document the conditions and procedures for granting, maintaining, extending, suspending and withdrawing a certification.

B.3.4.7 Internal audits and management reviews [4.7]

The body shall conduct periodic internal audits and management reviews at defined intervals sufficiently short to ensure its continuing suitability and effectiveness and shall take any necessary corrective actions in a timely manner.

B.3.4.8 Documentation [4.8]

The body shall have available current information about the following: the authority to operate; certification rules and procedures; evaluation procedures; fees charged for evaluations and certifications and financial support received; the rights and duties of customers (manufacturers or suppliers); procedures for appealing decisions including the handling of complaints, appeals and disputes; and a directory of measuring instrument types that have been certified including their manufacturers or suppliers.

B.3.4.9 Records [4.9]

The body shall establish and maintain procedures for identifying, filing, accessing, and disseminating Test Reports and Certificates of Conformity issued. Records shall be kept for at least 10 years.

B.3.4.10 Confidentiality [4.10]

The body shall have means to safeguard confidentiality of the information obtained in the course of its certification activities.

B.3.5 Certification body personnel [5]

B.3.5.1 General [5.1]

The body shall have competent personnel for carrying out their assigned functions, including making the required legal metrology judgments.

B.3.5.2 Qualification criteria [5.2]

The body shall have defined criteria for assessing the competence of its own and contracted personnel involved in the type evaluation and certification process. All personnel involved shall follow defined rules, including those relating to the confidentiality and independence from commercial or other interests.

B.3.6 Changes in the Issuing Authority's certification requirements [6]

The body shall give public notice of any intended changes in its certification requirements and shall provide any views expressed by interested parties to those responsible for consideration before changes are implemented.

B.3.7 Appeals, complaints and disputes [7], {6.2}

The body shall have procedures for addressing appeals, complaints and disputes brought about by suppliers or other parties and shall document any subsequent actions and their effectiveness.

B.3.8 Application for certification [8] {3}

B.3.8.1 Information on the procedure [8.1]

The body shall provide customers up-to-date information regarding procedures and shall require the manufacturer of the measuring instruments to follow the body's rules in the applicable procedures.

B.3.8.2 Application [8.2], {3.1.1}

The body shall require an official application form to be completed by a duly authorized representative of the customer.

B.3.9 Preparation for evaluation [9], {3.2}

The body shall review the application prior to a type evaluation to ensure that the requirements are understood, that any differences in understanding are resolved, and that it has the capability of performing the requested evaluation.

B.3.10 Evaluation [10], {A.1}

The body shall identify the designated Testing Laboratories in which the specimen or specimens of the measuring instrument type is to be evaluated.

B.3.11 Report of the evaluation [11], {3.4}

The designated Testing Laboratory shall deliver to the body a report on the findings of the evaluation that is prepared in accordance with the format contained in the applicable OIML Recommendation and any other applicable documents, and the body shall in turn promptly inform the customer.

B.3.12 Decision on certification [12], {3.5.1}

The body shall make a decision, or judgment, to review and transmit a Test Report and, if requested, to issue an OIML Certificate of Conformity of a measuring instrument type based on a review of the Test Report regarding the information gathered during evaluation and testing and any other relevant information.

B.3.13 Surveillance (Supervision of Testing Laboratories; 8.2)

The body shall have documented procedures to enable surveillance of evaluations carried out, and it shall document the results of its surveillance activities.

B.3.14 Use of licenses, certificates and marks of conformity [14], {5}

The body shall control the ownership, use, and display of its certificates.

B.3.15 Complaints to manufacturers or suppliers [15]

The body shall require the manufacturer or supplier to keep a record of all complaints received with regard to the compliance of a certified instrument with requirements and to document and inform the body of any action taken with respect to such complaints.

ANNEX C

General format:

Questionnaire on "National Capabilities for Type Testing"

(To be completed by Applicants according to 4.4(a))

DECLARATION OF MUTUAL CONFIDENCE Reference:

OIML Recommendation: .....

Category of measuring instruments (including accuracy classes, measuring ranges, etc.):

.....

C.1 STATE .....

C.2 ISSUING AUTHORITY (Organization/Department) .....

.....

C.3 ADDRESS .....

.....

.....

.....

C.4 CONTACT (or RESPONSIBLE) PERSON .....

Tel.: ..... Fax: ..... E-mail: .....

C.5 Do you have national legislation (or national requirements) for this category of measuring instruments?

Yes ..... No .....

If "No", proceed to C.8.

C.6 Is your organization responsible for both type evaluation and type approval?

Yes ..... No .....

C.7 If the answer to C.6 is "No", please identify the organization/department responsible for type evaluation:

.....

.....

.....

C.8 Identify the Principal Testing Laboratory, including any necessary specialized laboratories, involved in type evaluation for this category of instruments in your country and indicate whether the laboratory is a specialized, subcontract laboratory.

.....

.....

.....

C.9 How many OIML Test Reports and/or Certificates have you issued based on this OIML Recommendation?

.....

.....

.....

.....

C.10 Are there differences between your national type evaluation requirements and the requirements in the relevant OIML Recommendation? Yes ..... No .....

If "Yes", please elaborate:

.....

.....

.....

C.11 Has your Testing Laboratory or Laboratories identified in C.7 been accredited to carry out the applicable type evaluations by an accreditation body? Yes ..... No .....

C.12 If the response to C.11 is "Yes", identify the accreditation body and the date assessed

.....

.....

.....

C.13 Please give a brief general description of the applicable testing facilities

.....

.....

.....

C.14 Describe any specialized testing facilities required by this Recommendation and utilized for testing the effects of influence factors (intensity, range, capacity, severity, etc.), for example:

a) Electromagnetic immunity

.....

.....

.....

b) Power mains interference

.....

.....

.....

c) Electrostatic discharge

.....

.....

.....

d) Temperature and humidity chambers

.....

.....

.....

C.15 Have your Testing Laboratory or Laboratories identified in C.7 participated in intercomparisons?

Yes ..... No .....

If "Yes", identify the instruments (or devices), Participants, and dates and attach the report on the intercomparisons, if available:

.....

.....

.....

C.16 How many persons are employed full time in each Testing Laboratory or Laboratories identified in C.7?
.....

a) Are the responsibilities of the staff documented? Yes ..... No .....

b) Do you provide specialized and periodic training in type testing for your staff? Yes ..... No .....

C.17 Briefly describe the organization (or provide an organizational chart) of the staff of the Laboratory or Laboratories:

.....

.....

.....

Responsible person: .....

Title: .....

Signature: .....

Date: .....

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