



Report to the CIML

Taking into account test results from Manufacturers' Testing Laboratories (MTL) under controlled supervision by the Issuing Participants in DoMCs

1 Draft Resolution for the CIML Meeting 2011

This report summarizes the actions and proposals of TC3/SC5 in response to *Resolution 20* adopted at the 43rd CIML Meeting in October 2008:

"...For the time being, Issuing Participants shall not issue OIML MAA Certificates in the event that results of tests outside the scope of the DoMCs are taken into account (e.g. test results from manufacturers) in the Evaluation Reports. In this case an OIML Basic Certificate may still be issued as long as the MAA does not provide this possibility. The Committee supports the intention of TC 3/SC 5 to further discuss the acceptance of manufacturers' test results, with the aim of ultimately including them in the scope of the MAA if consensus can be reached on the conditions to be applicable to manufacturers ISO/IEC 17025 test laboratories."

This report has been developed on the basis of

- the experiences of voluntary peer assessments of the MTLs of two weighing instrument manufacturers in April 2009, that were performed in full accordance with the MAA rules, and
- the proposals made by CPR Members at the combined R 49/R 60/R 76 CPR meeting held in June 2009, and
- the proposals and comments received thereafter from CPR and TC3/SC5 members, and
- the proposals made at the TC 3/SC5 meeting held on 4 and 5 October 2010, and
- subsequent inputs from TC3/SC5 members until February 2011.

As a result, TC3/SC5 has agreed on the basic principles and conditions as explained in chapter 2 below, and proposes the following Resolution for CIML vote at the 46th CIML Meeting in October 2011:

Further to Resolution No 20 at the 43rd CIML Meeting, Issuing Participants may request the registration of Manufacturers' Testing Laboratories (MTLs) under a DoMC, provided that the conditions agreed by TC 3/SC 5 and laid down in a respective amendment to OIML B 10 are met. OIML MAA Type Evaluation Reports that contain test results from MTLs may be accepted by Participants on a voluntary basis.

The first part of the resolution will allow Issuing Participants in a DoMC to issue MAA Certificates based on test results from MTLs, while the second part will leave the option for still reluctant participants to accept respective Evaluation Reports on a voluntary basis. This compromise will

enable Participants in a DoMC to gain experiences with the new OIML MTL concept which is similar to MTL concepts used in other international certification schemes, such as the IEC CB scheme. It is expected that the second part of the resolution will be reconsidered after a certain time period when sufficient experience has been gained to take stock of the new MTL concept.

In case of a positive CIML vote, TC3/SC5 asks the CIML to also consider an online CIML ballot to approve the respective amendments to OIML B10 as proposed below in chapter 3.

Some few amendments to the OIML documents D30:2008 and D29:2008 have also been identified by TC3/SC5; these will, however, be considered within the ongoing projects p12 (Revision of OIML D 30) and a new project agreed at the 45th CIML meeting (Revision of OIML D29).

2 Basic principles and conditions applicable to MTLs and related Issuing Participants

2.1 Objective and procedure of the MTL concept

The aim of the new MTL concept is to enable an Issuing Participant to request registration of one or more specified MTLs in a DoMC in addition to its internal and/or subcontracting laboratories.

On request of an Issuing Participant the MTL(s) will run through the same assessment procedure as is foreseen for any (internal and/or subcontracting) Testing Laboratory under the MAA, i.e. the MTL has to demonstrate its competence and capability for performing tests under a certain DoMC either by accreditation or peer assessment. As for any other Testing Laboratory, the CPR will finally decide on the basis of the respective assessment reports. After a positive proposal of the CPR and the acceptance by the other Participants in the DoMC, the MTL will be included in the respective DoMC as a Testing Laboratory that can be used by the Issuing Participant that has requested the registration.

Requirements for MTLs are the same as for any other (internal and/or subcontracting) Testing Laboratory. The following safeguards are considered as interpretations of ISO/IEC 17025:2005, especially of Clauses No 4.1.4 and No 4.1.5, to ensure sufficient independence and impartiality, and to prevent potential conflicts of interest.

2.2 Controlled supervision by the Issuing Participant

The MTL shall be under controlled supervision of the related Issuing Participant. This includes certain safeguards as defined below in chapter 3.2. Similar MTL concepts are also used in other international certification schemes, such as the IEC CB scheme.

The Issuing Participant must have the ability to, and shall, exercise a controlled supervision as defined below in chapter 3.2 (see proposal for a new chapter 4.5.1 in B10).

The safeguards and actions to be taken in case of a failure of the equipment under test (EUT) 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 re-audits.

2.3 Independence and impartiality of the MTL

The MTL shall be a clearly defined part within the larger organization (company). The quality manual and other supporting documents shall define the specific responsibilities of the MTL and the interactions between the MTL and other organizational units of the company.

The quality manual and other supporting documents of the company shall also demonstrate that there are suitable provisions (as defined in chapter 3.2 below) that ensure that the MTL's personnel is free from any undue commercial, financial and other pressures which might influence their technical judgement.

2.4 Initial intercomparison

MTLs, as any OIML Testing Laboratory, shall participate regularly in bilateral, regional or other intercomparisons with at least one Testing Laboratory which is registered in the respective DoMC (periodicity to be defined).

Before an MTL can be included in a DoMC, it must have demonstrated its competence by at least one successful initial intercomparison with at least one Testing Laboratory listed in the DoMC (usually, but not necessarily, the internal and/or subcontracting laboratory of the Issuing Participant), where the intercomparison covered an appropriate range of the MTL's testing capabilities.

The test results of the intercomparison are considered in the first accreditation or peer assessment report to be presented and evaluated by the CPR.

3 Amendments to OIML B 10 (Reference: CD2 – November 2010)

In the following the proposed amendments to B10 are **marked red**.

3.1 B10 / chapter 3 (Abbreviations and terminology)

In accordance with OIML B3:xxxx, No 3.16, a definition of an MTL should be added as follows:

– 3.19 Manufacturer's Testing Laboratory (MTL)

A testing laboratory of a manufacturer 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 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.

3.2 B10 / chapter 4 (Conditions for establishment of a DoMC)

- 4.4 Issuing Participants shall request the registration of Testing Laboratories (internal and/or subcontracting) that will be responsible for issuing MAA Test Reports. In addition to its internal and/or subcontracting Testing Laboratory, an Issuing Participant may, under the provisions of 4.5, designate one or more MTLs, the test results of which are to be utilized. All those Testing Laboratories shall be assessed either by accreditation or peer assessment using requirements that comply with ISO/IEC 17025 [8] and OIML D30 [12] for the scope of the DoMC as defined in 4.3.
- 4.5 In addition to 4.1 through 4.4 the following applies for MTLs.
- 4.5.1 In order to prevent potential conflicts of interest the MTL is under controlled supervision of the related Issuing Participant. This includes at least the following safeguards:
 - There are clear and documented instructions for the MTL concerning the test program and the equipment under test (EUT);
 - There are clear and documented instructions for the MTL for the case that the EUT fails before the test program is finished;
 - The Issuing Participant is informed when the MTL starts and finishes the agreed tests;
 - 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;
 - After finishing the tests, the Issuing Participant may request the (identical) EUT (or a representative number of EUTs in case of family testing) to be submitted to its internal and/or subcontracting laboratory for re-tests (spotchecks) 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;
- 4.5.2 The Issuing Participant must have the ability to, and shall, exercise a controlled supervision as defined in 4.5.1. The safeguards and actions to be taken in case of a failure of the EUT 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 re-audits.
- 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 MTLs' personnel is free

from any undue commercial, financial and other pressures which might influence their technical judgement. In particular, the following is mandatory:

- The MTL is a clearly defined organizational unit (OU) within the company, or part of such an OU, where adequate procedures define the specific responsibilities of the MTL and the interactions between the MTL and other OUs of the company;
 - There is an organizational chart that shows the existence and organizational embedment of the MTL;
 - The MTL staff, including the head of the MTL, is identified and their competences and responsibilities are described;
 - The head of the MTL is free of any responsibilities which might influence its technical judgement, and he/she is responsible to a member of the top management in all technical conclusions.
- 4.5.4 The suitability and effectiveness of the above procedures are evaluated as part of the ISO/IEC 17025 accreditation or peer assessment (see OIML D30).
 - 4.5.5 Several Issuing Participants may designate the same MTL. In this case one of these shall be identified as the principal one being responsible for the procedures and information required according to 4.5.1 through 4.5.4.

3.3 B10 / chapter 5 (Application for participation in a DoMC)

- 5.2 For potential Issuing Participants only:

Information about its competence as defined in 4.2 of OIML B 3 [4];

A list of **all** testing laboratories (subcontracting, internal, **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;

Information about its type testing capabilities (including those of its designated subcontracting testing laboratories and **MTLs**, if any);

In case of an MTL: the procedures between the Issuing Participant and the MTL to manage the controlled supervision according to 4.5.1;

The certificates of accreditation ...

3.4 B10 / chapter 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;**
 - ...