

Joint ILAC-OIML Assessment Procedure
in the field of legal metrology

February 2018

1. Preamble

The International Organization of Legal Metrology (OIML) was created by an intergovernmental treaty signed in 1955. Legal metrology is the activity by which a government sets up and enforces regulations related to measurement units, measurements and measuring instruments. Under the terms of the World Trade Organization's Technical Barriers to Trade Agreement, the OIML is an international standardizing body.

The role of the OIML is to develop mutual information and mutual confidence among its Members and to provide "model regulations" (called OIML Recommendations) that the Member States commit to using in their national legislation. On this basis, the OIML develops international systems for facilitating mutual acceptance in legal metrology amongst its Members.

The OIML Certification System (OIML-CS) is a system for issuing, registering and using OIML Certificates and their associated OIML type evaluation reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

It is a single Certification System comprising two Schemes: Scheme A and Scheme B. It is a voluntary system and OIML Member States and Corresponding Members are free to participate or not. Participating in the OIML-CS and signing the OIML-CS Declaration will commit, in principle, the signatories to abide by the rules of the OIML-CS. The *Framework for the OIML Certification System (OIML-CS)* [1] establishes these rules whereby signatories voluntarily accept and utilize OIML type evaluation reports, when associated with an OIML Certificate issued by an OIML Issuing Authority, for type approval or recognition in their national or regional metrological controls.

The OIML-CS came into operation on 1 January 2018, replacing two previous certificate systems; the OIML Basic Certificate System [2] and the OIML Mutual Acceptance Arrangement (MAA) [3].

The OIML-CS requires the OIML Issuing Authorities and their associated Test Laboratories to demonstrate compliance with ISO/IEC 17065 [4] and ISO/IEC 17025 [5] respectively. For participation in Scheme B, it is sufficient to demonstrate compliance on the basis of "self-declaration" with additional supporting evidence. However, for participation in Scheme A, compliance of the OIML Issuing Authorities and their associated Test Laboratories shall be demonstrated by peer evaluation on the basis of accreditation or peer assessment.

The compliance of the Test Laboratories under Scheme A can be demonstrated either by **accreditation** (by an ILAC Full Member signatory to the ILAC Mutual Recognition Arrangement (MRA) or to a regional arrangement recognized by ILAC, for the scope of "testing ISO/IEC 17025") or by **peer assessment** organized under the supervision of the OIML. In order to guarantee equivalency between these two processes in the framework of the OIML-CS, ILAC and the OIML signed in 2006 and revised in 2010 and 2014 a Memorandum of Understanding (MoU) [6], implemented by means of a joint ILAC/OIML work program.

Note: The compliance of OIML Issuing Authorities under Scheme A is addressed in a Joint OIML-IAF Assessment Procedure [7].

2. Authorship

This document was prepared by the ILAC-OIML liaison officers under the supervision of the ILAC Accreditation Committee (AIC).

3. Scope

The purpose of this document is to implement the provisions of the above MoU, related to the assessment of Test Laboratories in the framework of the OIML-CS. This document specifies in particular the requirements for the competence of the assessment team, and the reference documents which define the requirements to be assessed.

The provisions in this document are mandatory for participation in the OIML-CS under Scheme A in order to harmonize the accreditation assessments and the peer assessments.

4. Terms and definitions

For the purpose of this document, the terms and definitions given in the following publications and standards are used:

- OIML B 18 [1];
- OIML D 30 [8];
- ISO/IEC 17000 [9];
- ISO/IEC 17011 [10];
- ISO/IEC 17025 [5];
- OIML V 2-200 [11].

Definitions of terms frequently used in the present document are repeated below:

OIML Certification System (OIML-CS)

System for issuing, registering and using OIML Certificates and associated OIML type evaluation reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements in the relevant OIML Recommendations.

Note: See Annex A - Schematic overview of the OIML-CS.

OIML Issuing Authority

Certification Body from an OIML Member State issuing OIML Certificates and associated OIML type evaluation reports in accordance with Scheme A or Scheme B.

OIML-CS Declaration

Document that is signed by OIML Issuing Authorities, Utilizers and Associates accepting to abide by the rules of the OIML-CS. The scope of certification and/or acceptance of OIML type evaluation reports issued with an OIML Certificate under Scheme A or B are detailed in separate annexes which form part of the Declaration.

Management Committee (MC)

Committee established by the International Committee of Legal Metrology (CIML) to manage the OIML-CS.

Accreditation Body (AB)

For this document, an accreditation body shall be a signatory to the ILAC Mutual Recognition Arrangement (MRA) or to a regional arrangement recognized by ILAC for the scope of “testing ISO/IEC 17025”.

Team Leader (Lead Assessor)

A person who has overall responsibility for leading a peer assessment or an assessment by an AB.

Note: The term “Management System Expert” is used in the OIML-CS for a team leader participating in an OIML peer assessment.

Legal Metrology Expert

A person who provides specific technical and metrological expertise with respect to the scope of an accreditation or peer assessment; is a team member who provides advice but is not considered as an assessor unless he/she has the relevant assessor qualifications and training.

5. Guidelines for the use of accreditation under Scheme A of the OIML-CS

5.1. General

The accreditation body that carries out an assessment of a Test Laboratory under Scheme A shall be a signatory to the ILAC Mutual Recognition Arrangement (MRA) or to a regional arrangement recognized by ILAC for the scope of “testing ISO/IEC 17025”.

The accreditation body, when accrediting a Test Laboratory designated (or intended to be designated) by an OIML Issuing Authority (or potential OIML Issuing Authority), should pay particular attention to the following:

- the assessment team, including the selection of Legal Metrology Experts (see 5.2.) ;
- the scope of accreditation (see 5.3.) ;
- the requirements, including the use of the guide OIML D 30 [8] for the application of ISO/IEC 17025 [5] to the assessment of testing laboratories involved in legal metrology (see 5.4.) ;
- the assessment report, including the need for an English version (see 5.5.).

5.2. Assessment team

The accreditation body shall appoint an assessment team consisting of a team leader and a suitable number of Legal Metrology Experts to cover and adequately assess the requested scope of accreditation (see 5.3), before granting accreditation and at least once within an accreditation cycle.

If the Test Laboratory wishes to use accreditation to support their participation in the OIML-CS, the accreditation body shall select Legal Metrology Experts from the joint ILAC/IAF/OIML list established in compliance with the MoU (“Scope”, letter c), when the scope of an assessment covers that of the relevant OIML-CS Declaration. The Legal Metrology Experts shall be independent and impartial, and shall not be directly associated with the Test Laboratory being assessed or the OIML Issuing Authority or potential OIML Issuing Authority.

The procedure for a Legal Metrology Expert to be included in the list is detailed in Annex B.

The accreditation body should take into account any objection from the Test Laboratory regarding the composition of the assessment team. Particular consideration should be given to objections, e.g. from the relevant OIML Issuing Authority, that would prevent the Test Laboratory from using the accreditation as part of the Scheme A peer evaluation process.

5.3. Scope of accreditation

The Test Laboratory should be in a position to demonstrate that its accreditation covers the scope of the OIML-CS Declaration.

The accreditation body shall clearly specify which activity in the legal metrology field is included in the scope of accreditation, in particular through references to the relevant OIML Recommendation(s) and relevant regional/national regulations in the accreditation certificate (e.g. testing non-automatic weighing instruments on the basis of OIML R 76-1:2006 [12]) and to the OIML-CS Declaration.

5.4. Requirements

The assessment performed by the accreditation body is conducted on the basis of the requirements of ISO/IEC 17025 [5] in conjunction with guide OIML D 30 [8] and of the relevant OIML Recommendation(s) and regional/national regulations listed in the accreditation certificate.

OIML D 30 [8] provides guidelines for the application of ISO/IEC 17025 [5] requirements when assessing testing laboratories involved in the field of legal metrology.

5.5. Assessment report

Any assessment report to be used by the Management Committee in the Scheme A peer evaluation process shall be available in English in order for the (potential) OIML Issuing Authority to use the report as documentation to be submitted to the OIML-CS Management Committee.

Accreditation bodies should be willing to accept that the assessment reports may be submitted by the Test Laboratory to the OIML Issuing Authority to be used in the OIML-CS peer evaluation process.

6. OIML peer assessments

6.1. General

Where a Test Laboratory is not accredited or its accreditation does not cover the scope of the relevant OIML-CS Declaration, it may still be nominated for designation by an OIML Issuing Authority to carry out tests and examination of a measuring instrument or module submitted for type evaluation as part of the OIML-CS.

In this case, the Test Laboratory is subjected to a peer assessment organized under the supervision of the OIML.

6.2. Requirements

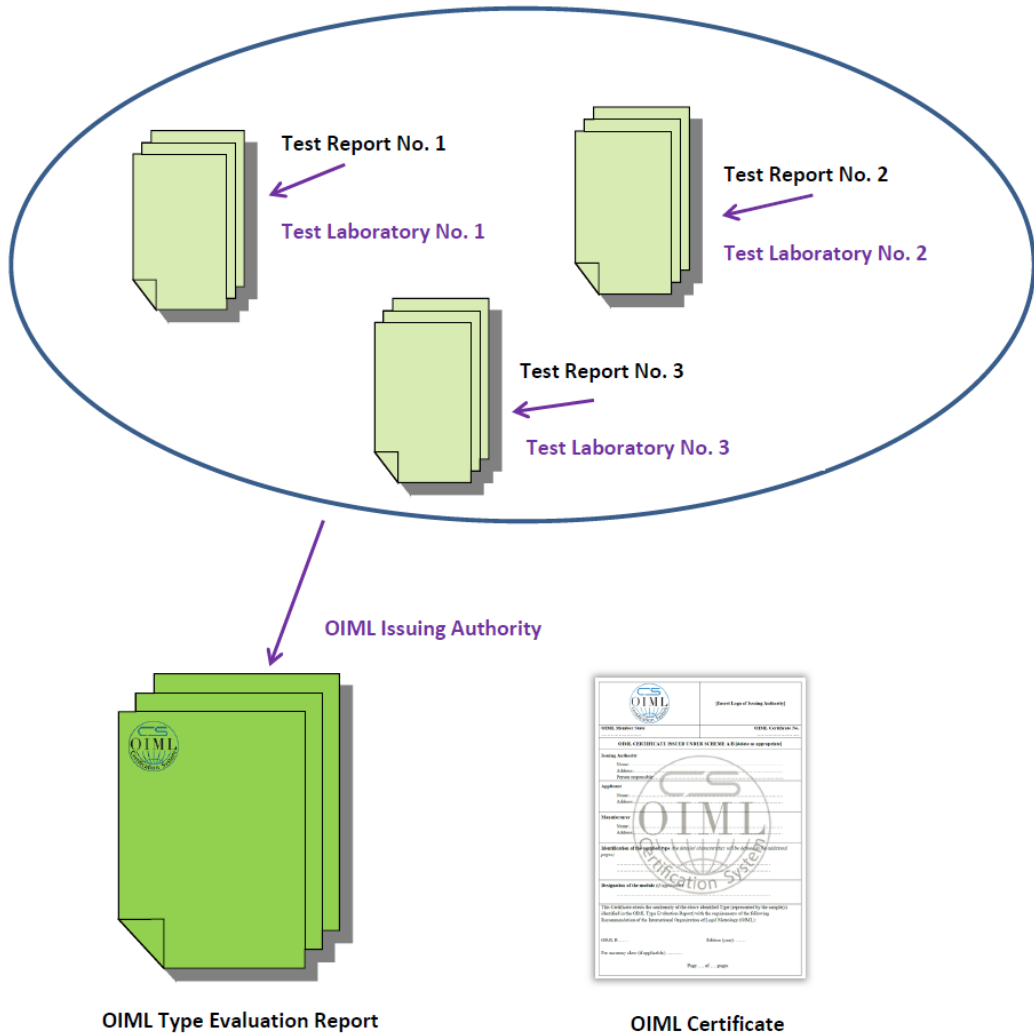
The peer assessment is conducted on the basis of the requirements of OIML-CS Procedural Document PD-04 [13], ISO/IEC 17025 [5], OIML D 30 [8] and the appropriate OIML Recommendation(s) and national requirements specified in the OIML-CS Declaration.

7. References

- [1] OIML B 18:2017 *Framework for the OIML Certification System (OIML-CS)*
- [2] OIML B 3:2011 *OIML Basic Certificate System for OIML type evaluation of Measuring Instruments*
- [3] OIML B 10:2011 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*
- [4] ISO/IEC 17065:2012 *Conformity assessment – Requirements for bodies certifying products, processes and services*
- [5] ISO/IEC 17025:2005 *Conformity assessment – General requirements for the competence of testing and calibration laboratories*
- [6] Memorandum of Understanding between ILAC, IAF and the OIML (current version signed in 2014)
- [7] Joint OIML-IAF Assessment Procedure in the field of legal metrology [to be developed]
- [8] OIML D 30:2008 *Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology*
- [9] ISO/IEC 17000:2004 *Conformity assessment - Vocabulary and general principles;*
- [10] ISO/IEC 17011:2004 *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies ;*
- [11] OIML V 2-200 Edition 2012 (E/F) *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM).*
- [12] OIML R 76-1:2006 *Non-automatic weighing instruments*
- [13] PD-04 *OIML-CS Procedural Document PD-04: Assessment of Test Laboratories*

ANNEX A

Schematic overview of the OIML-CS



ANNEX B (Informative)

Summary of the qualification criteria and procedures to include Management System Experts (team leaders) or Legal Metrology Experts on the joint ILAC/IAF/OIML list

The qualification criteria are detailed in OIML-CS Operational Document OD-01, 13.2, with the procedures to include **Management System Experts** (team leaders participating in OIML peer assessments) and Legal Metrology Experts detailed in OIML-CS Procedural Document PD-02. A summary of the qualification criteria and the procedures are provided below.

a) **Team Leaders** (participating in OIML peer assessments)

Criteria for the qualification of team leaders:

- The team leader shall be independent and shall not be an employee of a manufacturer of measuring instruments.
- Persons to be included in the list of team leaders to participate in OIML peer assessments of Test Laboratories shall be competent to assess management systems of Test Laboratories on the basis of ISO/IEC 17025.
- The person must be able to demonstrate that they are familiar with the requirements of the OIML-CS and OIML D 30. Participation in relevant training courses organized by the International Bureau of Legal Metrology (BIML) can be used to demonstrate fulfillment of this requirement.

Qualification process of team leaders nominated by an accreditation body:

- Persons to be included in the list of team leaders to participate in OIML peer assessments of Test Laboratories can be nominated by accreditation body signatories to the ILAC Mutual Recognition Arrangement (MRA) or to a Regional Arrangement recognized by ILAC for the scope of “Testing ISO/IEC 17025”.
- They shall be qualified as team leaders for the evaluation of testing laboratories according to ISO/IEC 17025 by the accreditation body which nominates them.
- The nomination is submitted to the Executive Secretary through ILAC.
- After inclusion in the list of team leaders, the Executive Secretary sends the information to ILAC/IAF.

Qualification process of team leaders that have not been nominated by an accreditation body:

- Any person that fulfils the criteria above, and wants to be included in the list of team leaders, may apply by filling in the “Application to be a Management System Expert (Team Leader)” form available from the OIML-CS website;
- The OIML-CS Executive Secretary, in turn, submits the application to the Management Committee (MC) for approval. The team leader will be approved in accordance with the voting rules specified in section 11.4 of OIML B 18;
- Once the team leader is approved by the MC, the Executive Secretary includes the information in the list of valid team leaders and sends it to ILAC/IAF for information;

b) Legal Metrology Experts

Criteria for the qualification of Legal Metrology Experts :

- The expert shall be independent and 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; and
- The expert shall demonstrate sufficient experience in assessing on the basis of ISO/IEC 17025 and OIML D 30. This experience may be demonstrated through participation in training organized by the BIML or equivalent training organized by accreditation bodies or by being a qualified assessor from an accreditation body and, if applicable, participation in additional training required by the MC.

Qualification process of Legal Metrology Experts :

- Any person that fulfils the criteria above, and wants to be included in the list of experts, may apply by filling in the “Application to be a Legal Metrology Expert” form available from the OIML-CS website;
- The OIML-CS Executive Secretary, in turn, submits the application to the Management Committee (MC) for approval. The expert will be approved in accordance with the voting rules specified in section 11.4 of OIML B 18;
- Once the expert is approved by the MC, the Executive Secretary includes the information in the list of valid experts and sends it to ILAC/IAF for information;
- These experts need to participate in harmonization actions organized by OIML.

Note 1: The list of Management System Experts (team leaders participating in OIML peer assessments) and of Legal Metrology Experts approved for each relevant category of measuring instruments is maintained by the BIML and is available on the OIML web site (<https://www.oiml.org/en/oiml-cs/>).

Note 2: The BIML may, with prior consent of the expert, provide to the accreditation body the expert’s CV and other relevant information.