

PROCEDURAL
DOCUMENT

OIML-CS
PD-04

Edition 2

**Assessment and approval of Test
Laboratories**

OIML-CS PD-04 Edition 2



ORGANISATION INTERNATIONALE
DE METROLOGIE LEGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Foreword

This publication has been prepared by the Maintenance Group of the OIML Certification System (OIML-CS) Management Committee (MC).

The MC approved this Edition 2 of OIML-CS PD-04 by electronic ballot on 30 November 2018. This edition takes effect immediately upon publication.

This publication is directly related to the *Framework for the OIML Certification System (OIML-CS)* (OIML B 18 [1]) which contains the framework for the operation of the OIML-CS.

The text of this publication is based on the following documents:

Edition	Document	Report on Voting/Acceptance
PD-03 Edition 1	PD-03 Edition 1	Published: July 2017
PD-03 Edition 2 (Draft)	BIML_SC8_P1_SG3_N004	Draft for MG comments - 20180226
PD-03 Edition 2 (Draft)	BIML_SC8_P1_SG3_N016	Draft for MG comments - 20180608
PD-03 Edition 2 (Draft)	OIML-CS_SC1_P1_N076 OIML-CS_SC1_P1_N077	Draft for MG comments - 20180928

1 Introduction

1.1 The OIML Certification System (OIML-CS) has been established

- a) to promote the global harmonization, uniform interpretation and implementation of legal metrological requirements for measuring instruments and/or modules,
- b) to avoid unnecessary re-testing when obtaining national type evaluations and approvals, and to support the recognition of measuring instruments and/or modules under legal metrological control, while achieving and maintaining confidence in the results in support of facilitating the global trade of individual instruments, and
- c) to establish rules and procedures for fostering mutual confidence among participating OIML Member States and Corresponding Members in the results of type evaluations that indicate conformity of measuring instruments and/or modules, under legal metrological control, to metrological and technical requirements established in the applicable OIML Recommendation(s).

1.2 OIML B 18 *Framework for the OIML Certification System (OIML-CS)* [1] establishes the rules for a framework for the OIML-CS. OIML B 18 [1] is supplemented by a range of Operational Documents and Procedural Documents which are developed, maintained and approved by the OIML-CS Management Committee.

2 Scope

This document is one of a series of Operational Documents and Procedural Documents that define the rules for the operation of the OIML-CS.

This publication contains the requirements and the associated procedures for including a Test Laboratory in the OIML-CS, including the processes relating to the assessment of a Test Laboratory, the Review Committee (RC) review and Management Committee (MC) approval. This publication should be used in conjunction with the associated procedures for OIML Issuing Authorities as detailed in PD-03 [2].

These procedures apply to the following Test Laboratories:

- a) An internal Test Laboratory of an OIML Issuing Authority;
- b) A third-party Test Laboratory; and
- c) A Manufacturer Test Laboratory (MTL).

These procedures relate to the framework for the OIML-CS as given in OIML B 18 [1], the Operational Rules as given in OD-01 [3] and OD-02 [4], and the Procedures as given in PD-01 [5], PD-02 [6], PD-03 [2], PD-05 [7], PD-06 [8], PD-07 [9] and PD-08 [10].

3 Terminology and abbreviations

The terminology and abbreviations defined in clause 3 of OIML B 18 [1] apply.

4 General

4.1 A certification body in an OIML Member State may apply to be an OIML Issuing Authority. Any application to be an OIML Issuing Authority (see PD-03 [2]) shall be accompanied by a corresponding application to include one or more Test Laboratories as detailed in this document. An existing OIML Issuing Authority may also apply to add a Test Laboratory using the procedures detailed in this document.

4.2 The MC is responsible for the approval or rejection of OIML Issuing Authorities (see PD-03 [2]) and their associated Test Laboratories, including extensions to scope, under Scheme A and Scheme B. The Review Committee (RC) is used to provide a recommendation to the MC on the approval or rejection of applications for OIML Issuing Authorities (see PD-03 [2]) and their Test Laboratories including extensions to scope.

5 Application for a Test Laboratory under Scheme A

5.1 Application and accompanying information

An application to include a Test Laboratory under Scheme A shall be sent by an OIML Issuing Authority to the Executive Secretary. The application may be made in conjunction with the application for an OIML Issuing Authority (see PD-03 [2]). Applications shall be made using the *Test Laboratory Application Form* (hereafter referred to as the “Application Form”) which can be found on the OIML-CS website and shall be accompanied by the following information:

- a) information about the assessment of competency (either peer assessment or accreditation as detailed in 5.2);
- b) designation and contact details of the Testing Laboratory and whether it is an internal Test Laboratory, a third-party Test Laboratory or an MTL;
- c) a list of the tests and examinations of the relevant OIML Recommendation it performs;
- d) information about its type testing capabilities;
- e) in the case of an MTL: the procedures between the OIML Issuing Authority and the MTL to manage the controlled supervision*;

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- f) in the case of accreditation, the certificate of accreditation and the scope of accreditation of the Test Laboratory and the most recent accreditation assessment report which includes the relevant scope of the OIML-CS Declaration and enough information that an assessment of the legal metrology aspects of the accreditation can be determined, if accreditation applies;
 - g) in the case of peer assessment, a copy of the peer assessment report covering the relevant scope of the Test Laboratory;
 - h) the most recent internal audit of the Test Laboratory (whether it is accredited or not) conducted on the basis of ISO/IEC 17025 [11] [14] and OIML D 30 [12] for the relevant scope;
 - i) the results of intercomparisons conducted in the relevant field, if any;
 - j) a copy of the most recent OIML test report issued for each of the considered categories.

*If the Test Laboratory is an MTL then the OIML Issuing Authority must provide documentary evidence that the requirements in clause 7 are fulfilled.

5.2 Assessment requirements for Test Laboratories

5.2.1 General

All Testing Laboratories under Scheme A shall be assessed either by accreditation or peer assessment using requirements that comply with ISO/IEC 17025 [11] [14] and OIML D 30 [12] for the scope of the measuring instrument category(ies). In either case, the assessment process must comply with the requirements detailed below.

5.2.2 Accreditation

Where accreditation is chosen, the Accreditation Body that carries out the assessment of a Test Laboratory under the OIML-CS shall participate in a mutual recognition arrangement among Accrediting Bodies (regional or international), for instance the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement).

The assessment team shall include a Legal Metrology Expert, approved by the MC, for each category of measuring instrument in the intended scope of the new Test Laboratory in the most recent accreditation assessment. It is possible to use Legal Metrology Experts that have not yet been approved by the MC on the condition that the requirements of PD-02, 8.3 [6] are followed. The accreditation body shall ensure that the Legal Metrology Expert(s) is impartial and independent and is not directly associated with the OIML Issuing Authority and Test Laboratory.

Further information can be found in the Joint ILAC-OIML Assessment Procedure [13].

Note: ISO and ILAC have issued a joint communiqué to re-confirm that a transition period, until 30 November 2020, will be provided for accredited laboratories to transition to the 2017 version of ISO/IEC 17025. Both the 2005 [14] and 2017 [11] versions of ISO/IEC 17025 will remain valid during the transition period (see http://ilac.org/latest_ilac_news/joint-iso-and-ilac-170252017-transition-communicue-published/). However, each OIML Issuing Authority should confirm the transition process that applies within their jurisdiction with the relevant accreditation body.

5.2.3 Peer assessment

5.2.3.1 Where peer assessment is chosen, the peer assessment shall be carried out by a team of experts that will include a Management System Expert (team leader), approved by the MC, knowledgeable in assessing quality management systems of Test Laboratories on the basis of ISO/IEC 17025 [11] [14], and one Legal Metrology Expert, approved by the MC, per category of measuring instrument.

The assessment team shall include all the necessary competencies required to complete the assessment of the Test Laboratory. The assessment team may comprise any number of people (as agreed to between the applicant and the team leader/Lead Assessor), however it shall contain a team leader, Experts with suitable assessment experience and Experts with suitable legal metrology knowledge.

5.2.3.2 The OIML Issuing Authority is responsible for arranging the peer assessment of the Test Laboratory. The OIML Issuing Authority shall make the necessary arrangements for an assessment team to be formed from the list of approved experts and will inform the Executive Secretary. It is possible to use experts that have not yet been approved by the MC on the condition that the requirements of PD-02, 8.3 [6] are followed. The team leader and Legal Metrology Expert(s) shall be impartial and independent and shall not be directly associated with the OIML Issuing Authority and Test Laboratory. The team leader and Legal Metrology Expert(s) shall declare their impartiality and independence prior to the assessment. The OIML Issuing Authority or the Test Laboratory is responsible for bearing the cost of the assessment team. The Executive Secretary shall forward the Application Form and all relevant information to the members of the assessment team to enable them to commence their assessment. The assessment team shall review the Application Form and the submitted documentation. If necessary the team leader may request additional information from the OIML Issuing Authority. The initial planning is carried out for the number of days and the number of assessors on site. The date for the assessment is agreed between the Test Laboratory, OIML Issuing Authority and the assessment team.

5.2.3.3 The assessment visit shall be undertaken in accordance with ISO/IEC 17025 [11] [14] and OIML D 30 [12]. The findings will be discussed with the Test Laboratory and OIML Issuing Authority at the end of the assessment. The assessment team will complete a *Test Laboratory Peer Assessment*

Report form. A copy will be given to the Test Laboratory and OIML Issuing Authority and a copy will be sent by the team leader to the Executive Secretary.

5.2.3.4 Any issues or non-compliances identified during the assessment process must be resolved by the Test Laboratory to the satisfaction of the assessment team. In some cases it may be necessary for a follow-up visit by one or more members of the assessment team. The final reports are sent by the team leader for submission to the Executive Secretary. Where non-conformities identified during the site visit require rectification or corrective action by the Test Laboratory, the team leader shall review the corrective actions and determine whether the item(s) raised have been sufficiently addressed in order to close the issue. Where non-compliances, identified during the site visit, remain unresolved more than 12 months beyond the site visit, the Executive Secretary shall manage the difficulties in consultation with the team leader.

5.3 Approval process

5.3.1 The Executive Secretary will review the Application Form and the supporting documentation and will complete the *Executive Secretary Review* section of the Application Form. The Executive Secretary may request further information to be supplied by the OIML Issuing Authority and/or the Test Laboratory.

5.3.2 Documentation review and approval

5.3.2.1 Once the Executive Secretary has reviewed the documentation, including the relevant accreditation or peer assessment report, and is satisfied that all information is present the Executive Secretary will distribute the Application Form and all of the supporting documentation to the RC for review. Where the RC review raises questions and/or dissatisfaction the Executive Secretary will refer the matter to the OIML Issuing Authority/Test Laboratory, or to the team leader in the case of questions/concerns being raised regarding the Peer Assessment Report, to seek additional information. Any additional information supplied will be circulated to the RC members.

5.3.2.2 When the members of the RC have completed their review of the Application Form and supporting documentation the RC will provide a recommendation to the MC on the approval or rejection of the Test Laboratory. The recommendation is recorded in the *Review Committee Recommendation* section of the Application Form and is sent to the Executive Secretary. In the event that the RC makes a recommendation to approve the Test Laboratory the Executive Secretary shall forward the Application Form (including, where relevant, the corresponding application from the Issuing Authority (see PD-03 [2]) to the MC for approval. In the event that the RC does not make a recommendation to approve

the Test Laboratory the Executive Secretary shall notify the OIML Issuing Authority and the Test Laboratory of the decision and the reason(s) for rejection.

5.3.2.3 Where the RC has made a positive recommendation, the MC shall vote on the approval of the Test Laboratory. If the MC rejects the application then the MC shall specify the reason(s) for the rejection. The Executive Secretary shall notify the OIML Issuing Authority and the Test Laboratory of the rejection and the associated reasons and further action will be discussed at the next MC meeting or by correspondence. If the application is approved the Executive Secretary shall notify the OIML Issuing Authority of the approval.

5.3.2.4 When the OIML-CS Declaration has been updated to include the Test Laboratory the Executive Secretary will also update the list of Test Laboratories on the OIML-CS website.

6 Application for a Test Laboratory under Scheme B

6.1 Application and accompanying information

An application to include a Test Laboratory in the OIML-CS shall be sent by an OIML Issuing Authority to the Executive Secretary. The application may be made in conjunction with the application for an OIML Issuing Authority (see PD-03 [2]). Applications shall be made using the *Test Laboratory Application Form* (hereafter referred to as the “Application Form”) which can be found on the OIML-CS website and shall be accompanied by the following information:

- a) information about the assessment of competency (on the basis of “self-declaration”);
- b) designation and contact details of the Test Laboratory and whether it is an internal Test Laboratory, a third-party Test Laboratory or a Manufacturer Test Laboratory (MTL);
- c) a definition of the capability of the Test Laboratory in terms of the tests and examinations of the relevant OIML Recommendation(s) and of additional national requirements included in the OIML-CS Declaration, if applicable, it performs;
- d) information about its type testing capabilities, e.g. flow range, temperature range, etc.;
- e) evidence to support the “self-declaration”, e.g. internal assessment reports on the basis of ISO/IEC 17025 [11] [14] and OIML D 30 [12] for the relevant scope.

6.2 Application review and approval

6.2.1 Once the Executive Secretary has reviewed the documentation, including the relevant “self-declaration”, and is satisfied that all information is present the Executive Secretary will complete the

Executive Secretary Review section of the Application Form. The Executive Secretary may request further information to be supplied by the OIML Issuing Authority and/or the Test Laboratory.

6.2.2 The procedure in 5.3.2 shall be followed.

7 Additional requirements for MTLs

7.1 In order to address potential conflicts of interest the MTL shall operate under the controlled supervision of at least one OIML Issuing Authority that is identified in the OIML-CS Declaration. In the case where two or more OIML Issuing Authorities want to make use of the same MTL, this must be clearly stated in the OIML-CS Declaration and the OIML Issuing Authority responsible for the supervision of the MTL must also be identified. The controlled supervision includes at least the following safeguards:

- a) the OIML Issuing Authority has clear and documented instructions (quality system procedures) for the MTL concerning the test program and the equipment under test (EUT);
- b) the OIML Issuing Authority 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 OIML Issuing Authority is informed when the MTL starts and finishes the agreed tests;
- d) the OIML Issuing Authority 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 OIML Issuing Authority;
- e) after finishing the tests, the OIML Issuing Authority 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 OIML Issuing Authority considers necessary; for these re-tests the OIML Issuing Authority may – with the applicant's consent - use another OIML Issuing Authority's registered laboratory;
- f) an MTL shall not subcontract testing.

7.2 The OIML Issuing Authority shall exercise a controlled supervision as defined in 7.1. 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 MTL and the OIML Issuing Authority, and their effectiveness is subject to regular surveillance audits as part of the accreditation assessment or peer assessment.

7.3 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 competencies 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.

7.4 The suitability and effectiveness of the procedures described above are evaluated as part of the ISO/IEC 17025 [11] [14] accreditation or included in the scope of the peer assessment of the corresponding OIML Issuing Authority.

7.5 Several OIML Issuing Authorities may designate the same MTL¹. In this case, upon agreement among the OIML Issuing Authorities, one of them may be identified in the OIML-CS Declaration as the principal OIML Issuing Authority that is responsible for the procedures and information required according to 7.1 through 7.4. Nevertheless, the remaining OIML Issuing Authorities in the OIML-CS Declaration still retain responsibility for confirming that the procedures and information required according to 7.1 through 7.4 are satisfied prior to utilizing the MTL.

8 Extension (or reduction) of scope of a Test Laboratory

An OIML Issuing Authority may apply to extend, or to reduce, the scope of one or more of its existing Test Laboratories, by completing the “*Test Laboratory Extension to Scope*” form which can be found on the OIML-CS website. The OIML Issuing Authority shall submit the form to the Executive Secretary who will process the request in accordance with the relevant and appropriate procedures detailed above.

¹ Example: In the Declarations of both IA1 and IA2 the MTL of manufacturer X is listed as an (additional) test laboratory.. IA1 is identified as the principal IA that is responsible for the supervision and control of the MTL according to subclause 4.1 of PD-03. If manufacturer X applies for type evaluation of a new instrument to IA1, then IA1 is responsible for ensuring that the entire process follows the procedures and requirements laid down in 7.3. If manufacturer X applies for type evaluation of another new instrument to IA2, then IA2 must also ensure that the entire process follows the procedures and requirements laid down in 7.3, the difference being that IA2 may make use of the previous information that IA1 has already provided (e.g. information about results of intercomparisons, or other information according to subclause 6.1 of PD-03).

9 References

- [1] OIML B 18:2018 *Framework for the OIML Certification System (OIML-CS)*
- [2] PD-03 *OIML-CS Procedural Document PD-03: Application and approval of OIML Issuing Authorities, Utilizers and Associates*
- [3] OD-01 *OIML-CS Operational Document OD-01: Management Committee*
- [4] OD-02 *OIML-CS Operational Document OD-02: Test Laboratories Forum*
- [5] PD-01 *OIML-CS Procedural Document PD-01: Appeals, Resolution of Complaints and Disputes*
- [6] PD-02 *OIML-CS Procedural Document PD-02: Procedures to approve Legal Metrology experts and QMS experts*
- [7] PD-05 *OIML-CS Procedural Document PD-05: Processing an application for an OIML Type Evaluation Report and OIML Certificate*
- [8] PD-06 *OIML-CS Procedural Document PD-06: Use of OIML Type Evaluation Reports and OIML Certificates*
- [9] PD-07 *OIML-CS Procedural Document PD-07: Transition Arrangements under the OIML-CS*
- [10] PD-08 *OIML-CS Procedural Document PD-08: Signing the OIML-CS Declaration*
- [11] ISO/IEC 17025:2017 *General requirements for competence of testing and calibration laboratories*
- [12] OIML D 30:2008 *Guide for the application of ISO/IEC 17025 to assessment of Testing Laboratories involved in legal metrology testing*
- [13] Joint ILAC-OIML Assessment Procedure in the field of legal metrology (February 2018)
- [14] ISO/IEC 17025:2005 *General requirements for competence of testing and calibration laboratories*