

PROCEDURAL
DOCUMENT

OIML-CS
PD-03

Edition 4

**Application and approval of OIML
Issuing Authorities, Utilizers and
Associates**

OIML-CS PD-03 Edition 4



ORGANISATION INTERNATIONALE
DE METROLOGIE LEGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Contents

1 Introduction	5
2 Scope.....	5
3 Terminology and abbreviations	6
4 General.....	6
4.1 Application.....	6
4.2 Role of the Management Committee and the Review Committee	6
4.3 Requirements for OIML Issuing Authorities to demonstrate competence.....	6
5 Application to be an OIML Issuing Authority under Scheme A	7
5.1 Application and accompanying information	7
5.2 Assessment requirements for OIML Issuing Authorities.....	8
5.3 Approval process.....	11
6 Application to be an OIML Issuing Authority under Scheme B	13
6.1 Application and accompanying information	13
6.2 Approval Process.....	13
7 OIML Issuing Authority Appeals Procedures.....	13
8 Admission of Utilizers and Associates	14
8.1 Application	14
9 Process to suspend an OIML Issuing Authority.....	15
10 Extension or reduction of scope of an OIML Issuing Authority.....	15
11 Periodic review of participation	17
11.1 Scheme A	17
11.2 Scheme B.....	18
12 Withdrawal of an OIML Issuing Authority from the OIML-CS	18
13 Notification of changes.....	19
14 References	19
Annex A (Informative) - Summary of the tasks of an OIML Issuing Authority	20

Foreword

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

The Management Committee approved this Edition 4 of OIML-CS PD-03 by electronic ballot on 15 January 2024 and it was published on 16 January 2024. This edition takes effect immediately upon publication.

This publication is directly related to OIML B 18 *Framework for the OIML Certification System (OIML-CS)* [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	PD-03 Edition 2	Published: 20 December 2018
PD-03 Edition 3	PD-03 Edition 3	Approved and published: 20221114
PD-03 Edition 4 (Draft)	OIML-CS_SC3_P1_SG3_N074	Draft for MG comment: 20230921
PD-03 Edition 4 (Draft)	OIML-CS_SC1_P4_N123	Draft for MC approval: 20231213

1 Introduction

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

- a) to promote the global harmonisation, 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 adding an OIML Issuing Authority in the OIML-CS, including the processes relating to the assessment of the OIML Issuing Authority, the relationship with the assessment of associated Test Laboratories (as detailed in PD-04 [2]), the Review Committee review and Management Committee approval. It also contains the procedures relating to the extension or reduction of scope of an OIML Issuing Authority, suspension of an OIML Issuing Authority and the periodic review of participation.

This publication also contains the requirements and associated procedures for including Utilizers and Associates in the OIML-CS, including any additional national requirements.

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-04 [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 Application

A certification body in an OIML Member State may apply to be an OIML Issuing Authority. Any application to be an OIML Issuing Authority shall be accompanied by a corresponding application to include one or more Test Laboratories as detailed in PD-04 [2]. An existing OIML Issuing Authority may also apply to add a Test Laboratory using the procedures detailed in PD-04 [2].

4.2 Role of the Management Committee and the Review Committee

The Management Committee is responsible for the approval or rejection of OIML Issuing Authorities applications and their associated Test Laboratories (see PD-04 [2]), including extensions to scope, under Scheme A and Scheme B. The Review Committee provides advice, in the form of a recommendation, to the Management Committee regarding the approval or rejection of OIML Issuing Authority applications including extensions to scope.

4.3 Requirements for OIML Issuing Authorities to demonstrate competence

4.3.1 OIML Issuing Authorities shall demonstrate their competence through compliance with either ISO/IEC 17065 [11] or ISO/IEC 17020 [12] (with additional requirements – see 4.3.3).

Note: ISO/IEC 17065 [11] is the preferred standard for OIML Issuing Authorities to use to demonstrate their competence.

4.3.2 OIML publication D 32 [13] provides guidance and interpretations regarding the application of ISO/IEC 17065 [11].

4.3.3 When ISO/IEC 17020 [12] is used, the following additional requirements apply:

- a) the OIML Issuing Authority shall also comply with subclauses 4.1.2, 4.1.3, 4.4, 4.6, 5.2, 7.4, 7.5, 7.6, 7.11 and 7.13.6 of ISO/IEC 17065 [11];
- b) only a ‘type A’ inspection body can become an OIML Issuing Authority under the OIML-CS;
and

- c) the OIML Issuing Authority shall:
- i. maintain control of certificates and marks of conformity;
 - ii. implement non-discriminatory conditions and procedures regarding applications for type evaluation;
 - iii. ensure public availability of type evaluation procedures and processes as well as issued OIML certificates;
 - iv. safeguard impartiality when utilising the work of non-independent bodies as part of the type evaluation; and
 - v. implement contractual terms for work undertaken as part of the inspection/type evaluation process.

Note: See ISO/IEC 17020 [12] for information regarding type A inspection bodies.

4.3.4 OIML publication D 37 [14] provides guidance and interpretations regarding the application of ISO/IEC 17020 [12] and the additional requirements specified in 4.3.3.

5 Application to be an OIML Issuing Authority under Scheme A

5.1 Application and accompanying information

5.1.1 An application to be an OIML Issuing Authority in the OIML-CS under Scheme A shall be made using the *OIML Issuing Authority Application Form* (hereafter referred to as the “Application Form”) which can be found on the OIML-CS pages of the OIML website. The application form must be endorsed (signed) by the relevant International Committee of Legal Metrology (CML) Member and shall be supported by a corresponding application for one, or more, Test Laboratories (see PD-04 [2]). In applying to be an OIML Issuing Authority under Scheme A, this will commit the OIML Member State to designate at least one Utilizer¹ for the category(ies) of measuring instrument(s). Therefore, a corresponding application to be a Utilizer for the category(ies) of measuring instrument(s) will be required (see clause 8) for each organisation that will be a Utilizer in that country.

5.1.2 The application to be an OIML Issuing Authority shall be accompanied by the following information:

- a) information about the assessment of competency (accreditation and/or peer assessment as detailed in 5.2);
- b) designation and contact details of the OIML Issuing Authority applicant;

¹ The requirement to designate at least one Utilizer shall not apply when the OIML Member State does not regulate that particular category of measuring instrument in their country. A written explanation shall be provided to the Executive Secretary in this instance. This exception is not intended to unnecessarily limit participation and testing capability within the OIML-CS due to the regulatory structure of an economy.

- c) the scope of the OIML Issuing Authority applicant, including the category(ies) of measuring instrument and the relevant OIML Recommendation(s) and the Scheme(s);
- d) a list of all Test Laboratories indicating, for each one, which tests and examinations of the relevant OIML Recommendation(s) it performs (the assessment of Test Laboratories is detailed in Procedural Document PD-04 [2]);
- e) where relevant, the procedures between the OIML Issuing Authority applicant and any Manufacturer Test Laboratory to manage the controlled supervision according to PD-04, 7.1 [2];
- f) in the case of accreditation (see 5.2.2), the certificate(s) of accreditation of the OIML Issuing Authority applicant and the most recent accreditation assessment report(s) which includes the relevant scope 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 (see 5.2.3), a copy of the peer assessment report of the OIML Issuing Authority applicant;
- h) a copy of the most recent OIML type evaluation report issued for each of the considered categories in the event that the OIML Issuing Authority applicant is already an OIML Issuing Authority under Scheme B or they were previously an Issuing Authority or Issuing Participant under the OIML Basic or OIML MAA Certificate Systems respectively; and
- i) the most recent internal audit of the OIML Issuing Authority applicant (whether it is accredited or not) conducted on the basis of ISO/IEC 17065 [11] and OIML D 32 [12], or ISO/IEC 17020 and OIML D 37 [14], for the relevant scope.

5.2 Assessment requirements for OIML Issuing Authorities

5.2.1 General

All OIML Issuing Authorities under Scheme A shall be assessed by accreditation and/or peer assessment using requirements that comply with ISO/IEC 17065 [11] and OIML D 32 [13], or ISO/IEC 17020 [12] and OIML D 37 [14], for the scope of the measuring instrument category(ies). In either case, the assessment process must comply with the requirements detailed below. An accreditation assessment report and/or peer assessment report that will be used to support an application shall include the name(s) of the OIML expert(s) that participated in the respective assessment.

A combination of accreditation and peer assessment processes (and the associated accreditation assessment reports and peer assessment reports) may be used to support the demonstration of competency as part of an application to be an OIML Issuing Authority.

5.2.2 Accreditation

Where accreditation to ISO/IEC 17065 [11] is chosen, the Accreditation Body that carries out the assessment of an OIML Issuing Authority under the OIML-CS shall participate in a mutual recognition arrangement among Accreditation Bodies (regional or international), for instance the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA).

Where accreditation to ISO/IEC 17020 [12] is chosen, the Accreditation Body that carries out the assessment of an OIML Issuing Authority under the OIML-CS shall participate in a mutual recognition arrangement among Accreditation Bodies (regional or international), for instance the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA).

Irrespective of which standard is used, the assessment team shall comprise at least one Legal Metrology Expert approved by the Management Committee. It is possible to use Experts that have not yet been approved by the Management Committee on the condition that the requirements of PD-02, 8.3 [6] are followed.

The use of an Accreditation Body expert, in place of a Legal Metrology Expert, may be permitted by the Executive Secretary in accordance with the following conditions:

- a) The use of an Accreditation Body expert shall only be permitted for an accreditation assessment of an existing OIML Issuing Authority to support an application to extend its scope or to maintain an existing accreditation. Accreditation assessments intended to support applications for new OIML Issuing Authorities shall always include at least one Legal Metrology Expert.
- b) The OIML Issuing Authority shall make a written request to the Executive Secretary to use an Accreditation Body Expert in place of a Legal Metrology Expert prior to the assessment taking place. The request shall include a justification for the use of the Accreditation Body expert and information regarding the relevant competences and experience of the Accreditation Body expert.
- c) The Executive Secretary shall consult with the Management Committee Chairperson and Review Committee Chairperson prior to permitting the use of the Accreditation Body expert.
- d) The Review Committee shall be informed when an Accreditation Body expert has been used in place of a Legal Metrology Expert for an accreditation assessment. This should be documented in the accreditation assessment report and as part of the application process.
- e) A Legal Metrology Expert shall be used at the next available opportunity, e.g. at the next routine surveillance or re-assessment visit.

The accreditation body shall ensure that all members of the assessment team are impartial and independent and shall not be directly associated with the OIML Issuing Authority applicant.

The assessment team shall ensure that the guidance and interpretations detailed in OIML D 32 [12] or OIML D 37 [14], as appropriate, are addressed with evidence included in the accreditation assessment report.

Subject to the rules of the Accreditation Body and the discretion of the team leader, remote assessment techniques may be used to support and supplement on-site accreditation assessments. The use of such techniques shall not compromise the integrity or the findings of the accreditation assessment.

In the case of accreditation to ISO/IEC 17065 [11], further information can be found in the Joint IAF-OIML Assessment Procedure [15].

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 Management Committee, knowledgeable in assessing quality management systems on the basis of ISO/IEC 17065 [11] and at least one Legal Metrology Expert approved by the Management Committee.

The assessment team shall include all the necessary competencies required to complete the assessment of the OIML Issuing Authority applicant. The assessment team may comprise any number of people (as agreed to between the applicant and the team leader), 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 applicant 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 Management Committee 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 applicant. The team leader and Legal Metrology Expert(s) shall declare their impartiality and independence prior to the assessment. The OIML Issuing Authority applicant is responsible for bearing the cost of the assessment team. The Executive Secretary shall forward the Application Form and all relevant supporting documentation 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 applicant. 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 OIML Issuing Authority applicant and the assessment team.

5.2.3.3 The assessment visit shall be undertaken in accordance with ISO/IEC 17065 [11] and OIML D 32 [13], or ISO/IEC 17020 [12] and OIML D 37 [14], as appropriate. The findings will be discussed with the OIML Issuing Authority applicant at the end of the assessment. The assessment team will complete an *OIML Issuing Authority Peer Assessment Report* form which can be found on the OIML-CS pages of the OIML website. A copy will be given to the OIML Issuing Authority applicant 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 OIML Issuing Authority applicant 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 peer assessment 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 OIML Issuing Authority applicant, the team leader shall review the corrective actions and determine whether the item(s) raised has(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.

5.2.3.5 Subject to the discretion of the team leader, remote assessment techniques may be used to support and supplement on-site peer assessments. The use of such techniques shall not compromise the integrity or the findings of the peer assessment.

5.3 Approval process

5.3.1 The Executive Secretary will review the Application Form and the supporting documentation, including the relevant accreditation assessment report and/or peer assessment report and the documentation associated with the Test Laboratory(ies) (see PD-04 [2]), 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 applicant.

5.3.2 Documentation review and approval

5.3.2.1 Once the Executive Secretary has reviewed the documentation and is satisfied that all information is present, the Executive Secretary will distribute the Application Form and all of the supporting documentation to the Review Committee for review. Where the Review Committee review raises questions and/or dissatisfaction the Executive Secretary will refer the matter to the OIML Issuing Authority applicant, 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 Review Committee.

5.3.2.2 When the Review Committee has completed its review of the Application Form and supporting documentation the Review Committee will provide a recommendation to the Management Committee on the approval or rejection of the OIML Issuing Authority applicant. The recommendation is recorded in the *Review Committee* section of the Application Form and is sent to the Executive Secretary. In the event that the Review Committee makes a recommendation to approve the OIML Issuing Authority applicant the Executive Secretary shall forward the Application Form to the Management Committee for approval. In the event that the Review Committee does not make a recommendation to approve the OIML Issuing Authority applicant the Executive Secretary shall notify the OIML Issuing Authority applicant of the reasons for the recommendation.

5.3.2.3 Where the Review Committee makes a positive recommendation, the Management Committee shall vote on the approval of the OIML Issuing Authority applicant. If the Management Committee rejects the application then the Management Committee shall specify the reasons for the rejection. The Executive Secretary shall notify the OIML Issuing Authority applicant of the rejection and the associated reasons and further action will be discussed either at the next Management Committee meeting or by correspondence. If the application is approved the Executive Secretary shall notify the OIML Issuing Authority applicant of its approval.

5.3.2.4 When a new OIML Issuing Authority is approved by the Management Committee the OIML Issuing Authority shall sign a Declaration as detailed in PD-08 [10]. The Declaration will list the scope of the categories of measuring instruments and the Scheme(s) for which the OIML Issuing Authority and its Test Laboratory(ies) have been approved. By signing the Declaration the OIML Issuing Authority states that it will abide by the rules and procedures of the OIML-CS. The format of the *Declaration* can be found on the OIML-CS pages of the OIML website.

5.3.2.5 Under Scheme A, an OIML Member State having an OIML Issuing Authority shall designate at least one Utilizer² for those categories of instruments. The organisation(s) that intend to be a Utilizer shall apply according to the procedures detailed in clause 8.

5.3.2.6 When the Declaration has been signed the Executive Secretary will update the list of OIML Issuing Authorities on the OIML-CS pages of the OIML website.

² The requirement to designate at least one Utilizer shall not apply when the OIML Member State does not regulate that particular category of measuring instrument in their country. A written explanation shall be provided to the Executive Secretary in this instance.

6 Application to be an OIML Issuing Authority under Scheme B

6.1 Application and accompanying information

An application to be an OIML Issuing Authority in the OIML-CS under Scheme B shall be sent by the OIML Issuing Authority applicant to the CIML Member in their country. The CIML Member is responsible for submitting it to the Executive Secretary. Applications shall be made using the *OIML Issuing Authority Application Form* (hereafter referred to as the “Application Form”) which can be found on the OIML-CS pages of the OIML website. The application form must be endorsed (signed) by the CIML Member and shall be accompanied by the following information:

- a) information about the assessment of competency (on the basis of a self-declaration);
- b) designation and contact details of the OIML Issuing Authority applicant;
- c) a list of all Test Laboratories indicating, for each one, which tests and examinations of the relevant OIML Recommendation included in the scope, if applicable, it performs;
- d) evidence to support the self-declaration, e.g. internal assessment reports; and
- e) a copy of the most recent OIML type evaluation report issued for each of the considered categories in the event that the OIML Issuing Authority applicant is already an Issuing Authority under the OIML Basic System or an Issuing Participant under OIML MAA Certificate System, or a template showing the proposed format of the OIML type evaluation format where the OIML Issuing Authority applicant was not previously an Issuing Authority under the OIML Basic System or an Issuing Participant under OIML MAA Certificate System.

6.2 Approval Process

6.2.1 Once the Executive Secretary has reviewed the documentation, including the relevant self-declaration, and is satisfied that all of the documentation 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 applicant.

6.2.2 The procedure in 5.3.2 shall be followed, with the exception of 5.3.2.5.

7 OIML Issuing Authority Appeals Procedures

7.1 All OIML Issuing Authorities shall have documented procedures for accepting, considering and resolving appeals against decisions.

7.2 A CIML Member may act as a technical advisor and may request assistance from the BIML, the responsible OIML Technical Committee or Subcommittee, and/or the Management Committee in resolving technical issues associated with appeals and disputes of decisions of an OIML Issuing Authority in his or her country.

8 Admission of Utilizers and Associates

8.1 Application

8.1.1 Applications shall be made using the *Application to be a Utilizer* or *Application to be an Associate* form, as appropriate, which can be found on the OIML-CS pages of the OIML website. The application must be endorsed (signed) by the CIML Member or Corresponding Member Representative, as appropriate, and shall specify information about any additional tests and examinations required for national type approval that the Utilizer or Associate may require³. In addition, any conditions on the acceptance of OIML certificates and/or OIML type evaluation reports shall be specified, e.g. OIML certificates and/or OIML type evaluation certificates issued on the basis of test results of Manufacturer Test Laboratories will not be accepted.

Applications shall be submitted by the Utilizer or Associate applicant to the Executive Secretary.

8.1.2 Acceptance of evaluation reports, test reports and test data for additional national requirements is at the discretion of Utilizers and Associates. It is the responsibility of Utilizers and Associates to specify whether they will accept OIML certificates and/or type evaluation reports issued on the basis of a test report(s) from a Manufacturer Test Laboratory. This information shall be provided in the Declaration of the Utilizer or Associate.

8.1.3 The Executive Secretary shall review the application and will draft a Declaration based on the information provided.

Note: Acceptance of OIML certificates and OIML type evaluation/test reports under Scheme B is voluntary and may be detailed in the Declaration.

8.1.4 Once the Utilizer or Associate has signed their Declaration (see PD-08 [10]) the Executive Secretary will update the list of Utilizers or Associates on the OIML-CS pages of the OIML website.

³ In order to issue a national type approval certificate on the basis of an OIML certificate and/or OIML type evaluation report received from an OIML Issuing Authority, the National Issuing Authority may be required by national or regional laws and regulations to perform additional evaluations to those defined in the relevant OIML Recommendation.

9 Process to suspend an OIML Issuing Authority

9.1 Where it is alleged that an OIML Issuing Authority has failed over time to abide by the rules of the OIML-CS, and evidence is provided to the Executive Secretary to support the allegation, the Executive Secretary shall contact the OIML Issuing Authority concerned.

9.2 If the OIML Issuing Authority cannot provide evidence that they have complied with the rules of the OIML-CS, or if they cannot provide a solution to the reasons for the alleged non-compliance, the Executive Secretary shall produce a report to the Review Committee detailing the alleged non-compliance.

9.3 The Review Committee will review the report and if the Review Committee determines that the OIML Issuing Authority has not complied with the rules of the OIML-CS, it will request that the OIML Issuing Authority develop an action plan (including proposed timescales) to address the reasons for non-compliance.

9.4 If the OIML Issuing Authority fails to subsequently provide evidence that it has taken the appropriate action then the Review Committee may make a recommendation to the Management Committee regarding the possible suspension of the OIML Issuing Authority.

Note: Depending upon the nature of the non-compliance the Review Committee may recommend a partial suspension of the scope of an OIML Issuing Authority.

9.5 If the Management Committee votes to suspend the OIML Issuing Authority, or to partially suspend the scope of the OIML Issuing Authority, the Executive Secretary will notify the OIML Issuing Authority of the suspension and the actions that it must take to lift the suspension. Whilst it is suspended, the OIML Issuing Authority may only complete any ongoing applications under conditions defined by the Management Committee. These conditions should take into account the fact that tests and examinations may already have started. The OIML Issuing Authority shall not start any new applications whilst it is suspended.

9.6 The OIML Issuing Authority has the right to appeal the Management Committee decision to suspend it according to PD-01 [5].

10 Extension or reduction of scope of an OIML Issuing Authority

10.1 Existing OIML Issuing Authorities may apply to extend their scope for the following:

- a) extension of capabilities of an existing Test Laboratory;
- b) addition of a new Test Laboratory;

- c) addition of a new category of measuring instrument; or
- d) addition of a new edition of an OIML Recommendation (where a previous edition of the OIML Recommendation is in its scope).

10.2 Conversely, an existing OIML Issuing Authority can apply to reduce their scope for the following:

- a) reduction in the capabilities of an existing Test Laboratory;
- b) removal of a new Test Laboratory;
- c) removal of a category of measuring instrument; or
- d) removal of an edition of an OIML Recommendation.

10.3 Where the OIML Issuing Authority wishes to reduce its scope the OIML Issuing Authority shall inform the Executive Secretary. The Executive Secretary shall amend the scope of the OIML Issuing Authority accordingly in the Declaration. Approval of the Management Committee is not required in this situation, although the Executive Secretary will notify the Management Committee of the change.

10.4 Where the OIML Issuing Authority wishes to extend its scope it shall complete the Application Form, selecting the option for *Modification/extension to scope* in section 3.

10.5 Where the OIML Issuing Authority wishes to add a new Test Laboratory, or where the capabilities of an existing Test Laboratory are to be extended, the procedures detailed in PD-04 [2] shall be followed.

10.6 Where the OIML Issuing Authority wishes to add a new category of measuring instrument, evidence shall be provided in support of the application which details the competency of the OIML Issuing Authority and its associated Test Laboratory(ies) for the category of measuring instrument as appropriate. The relevant procedures detailed in clause 5 and/or clause 6 will be applied as appropriate.

10.7 Where the OIML Issuing Authority already has an edition of an OIML Recommendation in its scope, and it wishes to add a new edition of the OIML Recommendation to its scope following an *update* of the OIML Recommendation, it is sufficient for the OIML Issuing Authority to provide a gap analysis as evidence of its competence. An accreditation assessment and/or peer assessment, according to the new edition of the OIML Recommendation, is not required in this instance.

Note: This process for an extension of scope does not apply in the case where an OIML Recommendation has been *revised*. See OIML B 6-1 [16] for information regarding the review process for OIML publications.

11 Periodic review of participation

11.1 Scheme A

11.1.1 OIML Issuing Authorities and their associated Test Laboratories are required to undergo internal audits and re-assessments of competence according to the following maintenance process:

- a) a review by the Management Committee, once a year, of an internal summary report submitted to the Executive Secretary. The report shall highlight in particular, for the relevant scope of the OIML Issuing Authority and Test Laboratories:
 - i. Results of comparisons;
 - ii. Changes in personnel, structure and organisation;
 - iii. Results of management reviews;
 - iv. Results of internal audits;
 - v. Results of accreditation (surveillance) assessments, where applicable;
 - vi. Complaints received;
 - vii. Number of type evaluation reports issued;
 - viii. Number of test reports issued; and
 - ix. Number of certificates issued.

An *OIML Issuing Authority Report* template can be downloaded from the OIML-CS pages of the OIML website.

- b) a review by the Management Committee, every four years, of the accreditation assessment reports and/or peer assessment reports of the OIML Issuing Authorities and their Test Laboratories submitted to the Executive Secretary.

11.1.2 Where the evaluation of competence of an OIML Issuing Authority and their associated Test Laboratory(ies) has been based on peer assessment, the OIML Issuing Authority is responsible for organising peer assessments every four years under the conditions defined in 5.2.3 above for the OIML Issuing Authority activities and in PD-04, 6.2.3 [2] for the Test Laboratory(ies).

11.1.3 Where the evaluation of competence of an OIML Issuing Authority and their associated Test Laboratory(ies) has been based on accreditation, the OIML Issuing Authority is responsible for requesting the relevant accreditation body to include at least one Legal Metrology Expert approved by the Management Committee in the assessment team as soon as the scope of the Declaration is included in the assessment. A Legal Metrology Expert(s) approved by the Management Committee for the appropriate scope shall, at least once over the renewal cycle, participate in the accreditation assessment team with a maximum interval of five years.

11.1.4 The OIML Issuing Authority shall send all information, including accreditation certificates and assessment reports, peer assessment reports, etc., to the Executive Secretary as specified in 11.1.1. The Executive Secretary will review the documentation and may request further information to be supplied by the OIML Issuing Authority. Once the review of the documentation is satisfactorily completed by the Executive Secretary, the Executive Secretary distributes the documentation to the Review Committee.

11.1.5 The Review Committee will review the documentation and will make a recommendation to the Management Committee to approve or reject the continued participation of the OIML Issuing Authority. Based on the Review Committee recommendation the Management Committee will vote on the continued participation of the OIML Issuing Authority. If the Management Committee approves the continued participation the Executive Secretary will notify the OIML Issuing Authority.

11.1.6 If the Management Committee does not approve the continued participation of an OIML Issuing Authority the Executive Secretary will notify the OIML Issuing Authority, and may request additional information to address the reason for the rejection. The OIML Issuing Authority will have the opportunity to submit the information to the Executive Secretary who will notify the Management Committee. The Management Committee will then reconsider the continued participation of the OIML Issuing Authority.

11.2 Scheme B

OIML Issuing Authorities and their associated Test Laboratories are required to provide, on an annual basis, evidence to support the self-declaration, e.g. internal assessment reports, for a review by the Management Committee. An *OIML Issuing Authority Report* template can be downloaded from the OIML-CS pages of the OIML website.

12 Withdrawal of an OIML Issuing Authority from the OIML-CS

12.1 An OIML Issuing Authority may decide, for operational, business or commercial reasons, to withdraw as an OIML Issuing Authority from the OIML-CS, or to reduce their scope. In the event that an OIML Issuing Authority wishes to withdraw from the OIML-CS or to reduce their scope, the OIML Issuing Authority shall give notice to the Executive Secretary of its intention, but shall meet all current obligations to customers before actual withdrawal or reduction of scope.

12.2 If the OIML Issuing Authority is withdrawn from the OIML-CS at the proposal of the Management Committee, any ongoing applications shall be completed under the conditions defined by the Management Committee. These conditions should take into account the fact that tests and examinations may already have started.

12.3 In both cases, the Executive Secretary shall in turn notify the Utilizers and Associates who shall accept and utilise or recognise the OIML certificates and OIML type evaluation reports that were issued and registered prior to the withdrawal.

13 Notification of changes

An OIML Issuing Authority shall immediately inform the Executive Secretary of an essential organisational or technical change, such as a change to key staff or a change of location, which could impact on compliance with ISO/IEC 17065 [11] or ISO/IEC 17020 [12], as appropriate. The Executive Secretary shall consult with the Review Committee for a recommendation on the appropriate action to take, e.g. temporary suspension of scope.

14 References

- [1] OIML B 18:2022 *Framework for the OIML Certification System (OIML-CS)*
- [2] PD-04 *OIML-CS Procedural Document PD-04: Assessment of Test Laboratories*
- [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 17065:2012 *Conformity assessment – Requirements for bodies certifying products, processes and services*
- [12] ISO/IEC 17020:2012 *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*
- [13] OIML D 32:2018 *Guide for the application of ISO/IEC 17065 to assessment of certification bodies in legal metrology*
- [14] OIML D 37:2022 *Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities under the OIML Certification System*
- [15] Joint IAF-OIML Assessment Procedure in the field of legal metrology (January 2020)
- [16] OIML B 6-1:2019 *Directives for OIML technical work. Part 1: Structures and procedures for the development of OIML publications*
- [17] ISO/IEC 17025:2017 *General requirements for competence of testing and calibration laboratories*
- [18] OIML D 30: 2020 *Guide for the application of ISO/IEC 17025 to assessment of Testing Laboratories involved in legal metrology testing*

Annex A (Informative) - Summary of the tasks of an OIML Issuing Authority

A.1 This annex summarises the tasks of the OIML Issuing Authority in order to assist them in understanding their central role in implementing the OIML-CS.

A.2 The OIML Issuing Authority carries out the following tasks:

- a. designates the Test Laboratory(ies) that it wishes to use to carry out the necessary examinations and tests of the submitted type (of measuring instrument) and prepares the Test Report(s) of the results;
- b. ensures that the Test Laboratory(ies) is (are) competent according to requirements compatible with ISO/IEC 17025 [17] and OIML D 30 [18];
- c. ensures that the application and test procedures reflect the current OIML-CS requirements;
- d. specifies documented conditions under which tests are abbreviated or omitted;
- e. reviews the results of tests and examinations included in the Test Report(s);
- f. issues the OIML type evaluation report;
- g. for a successful evaluation, issues an OIML certificate for the type (of measuring instrument) to the applicant;
- h. for an unsuccessful evaluation, notifies the applicant in writing of the deficiencies in performance of the type (of measuring instrument);
- i. submits the OIML certificate to the BIML for registration;
- j. maintains active liaison with its CIML Member, whenever appropriate; and
- k. makes available documented procedures for accepting, considering, and resolving appeals against decisions.