



**Agenda Item 10.2:**

**Recommendations from the  
OIML-CS Management Committee to the CIML**



## OIML Certification System (OIML-CS)

### Recommendations from the OIML-CS Management Committee to the CIML

## 1 Proposal regarding the use of ISO/IEC 17020

### 1.1 Background

OIML B 18:2018 *Framework for the OIML Certification System (OIML-CS)* specifies that OIML Issuing Authorities demonstrate their competence through the application of ISO/IEC 17065 *Conformity assessment — Requirements for bodies certifying products, processes and services*. At the first OIML-CS Management Committee meeting the possibility of OIML Issuing Authorities using alternative pathways to demonstrate their competence was discussed, with a view to potentially providing more flexible options, reducing barriers to participation, and encouraging more OIML Issuing Authorities.

Consequently, an ISO/IEC 17065 Working Group (“Working Group”) was established by the Management Committee to explore possible alternatives to ISO/IEC 17065 for OIML Issuing Authorities to use to demonstrate their competence.

ISO/IEC 17020 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection* was selected for specific analysis due to requests from Management Committee Members. It was recognised that similar reviews and analyses could be undertaken for other international, regional or national standards regarding the assessment of competency of OIML Issuing Authorities. However, the Working Group considered it timely and efficient to present the concepts and approach regarding the possible use of ISO/IEC 17020 to the Management Committee for consideration ahead of further work being undertaken in respect of other standards.

### 1.2 Functional approach (ISO/IEC 17xxx series)

The ISO Committee on Conformity Assessment (ISO/CASCO) has developed International Standards and Guides (sometimes referred to as the “CASCO toolbox”) to support conformity assessment. The basic concept under these standards is the *Functional Approach* as described in ISO/IEC 17000:2020, Annex A, which divides conformity assessment into three functions; (1) selection; (2) determination; and (3) review, decision and attestation.

Under this functional approach, ISO/IEC 17020 (Inspection) and ISO/IEC 17025 (Testing and Calibration) are classified as standards merely for the “determination” function. In contrast, ISO/IEC 17065, which is currently required under OIML B 18:2018 for the competency of OIML Issuing Authorities, covers all three functions.

In considering the possible use of ISO/IEC 17020 as an alternative to ISO/IEC 17065, the Working Group proposed that supplementary documentation relevant to the other two functions (“selection” and “review, decision and attestation”) is required in order to provide for equivalent outcomes to those of ISO/IEC 17065.

At present, the OIML-CS is classified as a “type 1a” certification scheme under ISO/IEC 17067 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*. This is due to the fact that the OIML-CS does not include surveillance activities as described in ISO/IEC 17067. However, any future enhancement of the classification of the OIML-CS under ISO/IEC 17067 to include surveillance activities (which would align the OIML-CS with other international certification schemes such as IECEx), would need to be supported by the development and implementation of conformity to type and surveillance activities such as:

- the ongoing conformity of production instruments to the certified type;
- quality management of the production process of measuring instruments; and
- the use, or misuse, of the OIML-CS logo and similar statements of conformity.

A key difference between the requirements of ISO/IEC 17020 and ISO/IEC 17065 concerns surveillance activities; notably ISO/IEC 17020 does not include such requirements. However, until such time as the OIML-CS incorporates surveillance activities, the requirements of ISO/IEC 17065 with respect to surveillance activities are not relevant to the assessment of competency of OIML Issuing Authorities under the OIML-CS.

### **1.3 Use of ISO/IEC 17020 and new OIML Document**

The Working Group conducted a detailed comparison of the requirements specified in both ISO/IEC 17065 and ISO/IEC 17020 to identify gaps and/or inconsistencies. It concluded that ISO/IEC 17020 provides similar levels of confidence in the competency and management of an OIML Issuing Authority. However, in order to support the use of ISO/IEC 17020 as an alternative means for OIML Issuing Authorities to demonstrate competence, the Working Group identified that additional requirements and guidance would be required to address any inconsistencies, and that these could be detailed in an OIML Document.

The main issues to be included in an OIML Document in order to provide guidance or interpretations are:

- the interpretation that the concept of the ‘inspection’ of a measuring instrument and the ‘type evaluation’ of a measuring instrument are equivalent for the purposes of the OIML-CS;
- in general, ISO/IEC 17020 provides for a generalised approach to the inspection/type evaluation process. As such, an OIML Document is required in order to provide detailed guidance and interpretations of the type evaluation process required under the OIML-CS;
- specifying that only ‘type A’ inspection bodies would satisfy the requirements of the OIML-CS;
- information regarding the control of certificates and marks of conformity;
- information regarding non-discriminatory conditions and procedures regarding applications for type evaluation;
- information regarding the public availability of type evaluation procedures and processes as well as issued OIML certificates;
- clarification of the need to safeguard impartiality when utilising the work of non-independent bodies as part of the type evaluation; and

- clarification of contractual terms for work undertaken as part of the inspection/type evaluation process.

The Working Group identified that the European Accreditation Publication (EA-2/17 M:2020) *EA Document on Accreditation for Notification Purposes* specifies in Annex A that ISO/IEC 17065 is the preferred standard for the accreditation of notified bodies performing type examination in the European Union (EU). However, to support the possible application of ISO/IEC 17020 under the OIML-CS, the Working Group also identified that Annex B of EA-2/17 M:2020 allows the use of ISO/IEC 17020 (with additional requirements) as an alternative means of assessing competency for the purpose of type examination in the EU.

The additional requirements identified in EA-2/17 M:2020 are:

- Clauses 6 and 7 of ISO/IEC 17025, and
- Clauses 4.1.2, 4.1.3, 7.5 and 7.6 of ISO/IEC 17065.

The Working Group considered that in the case of the OIML-CS, the requirements of ISO/IEC 17025 are already addressed as the OIML Issuing Authorities make use of test reports from approved Test Laboratories (which have to comply with ISO/IEC 17025). Consequently, the OIML Document should therefore just include the clauses from ISO/IEC 17065 mentioned above, and provide the necessary guidance and interpretations.

## **1.4 Working Group recommendations**

The Working Group developed a set of recommendations to allow OIML Issuing Authorities to use IEC/IEC 17020 (with additional requirements) as an alternative to ISO/IEC 17065 for demonstrating competence. The recommendations were:

### Recommendation 1

The Working Group recommended that the OIML-CS Management Committee adopt and implement the following proposal:

That the OIML-CS recognises and utilises the international standard ISO/IEC 17020 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*, and supplementary requirements (to be developed – see Recommendations 2 - 4 below), as an alternative means for OIML Issuing Authorities to demonstrate their competence.

### Recommendation 2

Subject to agreement with recommendation 1:

The Working Group recommended that the Management Committee (via the Maintenance Group) commence work to amend the relevant requirements of OIML B 18 and the OIML-CS Operational and Procedural Documents to allow for the use of ISO/IEC 17020 as an alternative means for OIML Issuing Authorities to demonstrate their competence.

### Recommendation 3

Subject to agreement with recommendation 1:

The Working Group recommended that the Management Committee establish a new Working Group to develop a new OIML Document to provide guidance and interpretations on the application of ISO/IEC 17020 to the assessment of competency of OIML Issuing Authorities within the OIML-CS. This new Working Group should also review the Joint IAF-OIML and ILAC-OIML Assessment Procedures to ensure they are aligned with this new OIML Document.

### Recommendation 4

Subject to agreement with recommendation 1:

The Working Group recommended that a new Annex be added to OIML B 18 to outline the position of the OIML-CS regarding the functional approach to conformity assessment established under the ISO/IEC 17xxx series of standards, i.e. “selection”, “determination”, and “review, decision and attestation”.

## **1.5 Management Committee approval**

At the Sixth Management Committee Meeting in March 2021 the Management Committee approved the four recommendations from the Working Group.

*Note:* In approving the four recommendations, the Management Committee specified that ISO/IEC 17065 is the preferred standard for OIML Issuing Authorities to use to demonstrate competence, and that this preference should be reflected in the amended OIML-CS publications and the new OIML Document.

## **2 Recommendations from the Management Committee to the CIML**

Based on the Management Committee approval of the four recommendations from the Working Group at its meeting in March 2021, the Management Committee recommends that the CIML approves the proposal to allow OIML Issuing Authorities to use ISO/IEC 17020 (with additional requirements) as an alternative to ISO/IEC 17065 for demonstrating competence. If the proposal is approved, the Management Committee will revise OIML B 18 *Framework for the OIML Certification System (OIML-CS)* and the relevant Operational and Procedural Documents in line with the Working Group recommendations detailed in 1.4 above.

Subject to the proposal being approved, the Management Committee also recommends that the CIML approves the establishment of a new Project Group, under the responsibility of the Management Committee, to develop a new OIML Document to provide guidance and interpretations regarding the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities in the OIML-CS.

*Note:* Members of OIML TC 3/SC 5 *Conformity assessment* who are not represented in the Management Committee will be invited to participate in the Project Group.

Further information on the project is provided in the project proposal in Annex A.

It is proposed that the use of ISO/IEC 17020 by OIML Issuing Authorities will be permitted from 1 January 2023. Consequently, the Management Committee decided to extend the transition period for

OIML Issuing Authorities to use self-declaration (with supporting evidence) to 31 December 2023 in order to provide time for the publications mentioned above to be developed and published, and for OIML Issuing Authorities to undergo a suitable accreditation or peer assessment (according to either ISO/IEC 17020 or ISO/IEC 17065).

**Draft Resolution no. 2021/...**

The Committee,

Noting the recommendations from the OIML Certification System (OIML-CS) Management Committee detailed in Addendum 10.2 to the Working Document for this meeting,


Approves the use of ISO/IEC 17020 (with additional requirements) by OIML Issuing Authorities as an alternative to ISO/IEC 17065 to demonstrate competence,

Requests the OIML-CS Management Committee to revise the relevant OIML-CS publications, including OIML B 18 *Framework for the OIML Certification System (OIML-CS)*, to implement the necessary changes to allow the use of ISO/IEC 17020 (with additional requirements) by OIML Issuing Authorities, and

Approves a new project under the responsibility of the OIML-CS Management Committee to develop a new OIML Document to provide guidance and interpretations regarding the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities in the OIML-CS, as detailed in the project proposal in Annex A of Addendum 10.2 to the Working Document for this meeting.

**Annex A: Project proposal – development of a new OIML Document**

**Proposal for a new project – New OIML Document D xx *Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities in the OIML Certification System***

	<b>Proposal for a new project</b>			
	<b>Within:</b>	OIML-CS Management Committee		
	<b>Date:</b>	13 July 2021		
<b>Proposer(s):</b>				
OIML-CS Management Committee	Country: N/A		Organisation: N/A	
<b>Proposed convener(s)*:</b>				
OIML-CS Management Committee	Country: N/A		Organisation: N/A	
<b>Type of proposed publication:</b>				
	<input checked="" type="checkbox"/> New	<input type="checkbox"/> Update	<input type="checkbox"/> Revision	
<input type="checkbox"/> Recommendation	<input checked="" type="checkbox"/> Document	<input type="checkbox"/> Basic	<input type="checkbox"/> Vocabulary	<input type="checkbox"/> Guide
<b>Title of proposed publication:</b>				
OIML D xx <i>Guide for the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities in the OIML Certification System</i>				
<b>Terms of reference of the project, including detailed time frame in accordance with the provisions specified in B 6-1, 6.2:</b>				
The OIML-CS Management Committee will manage the process. Members of TC 3/SC 5 <i>Conformity assessment</i> who are not represented in the OIML-CS Management Committee will be invited to participate. A Final Draft D xx will be submitted to the CIML for approval in 2022.				
<b>Why should the OIML develop this publication?</b>				
Detailed information on the proposal to develop this publication is provided in Addendum 10.2 to the working document for the 56th CIML Meeting.				
<b>Countries/Economies known to, or intending to apply this publication, if applicable:</b>				
Providing guidance and interpretations on the application of ISO/IEC 17020 to OIML Issuing Authorities under the OIML-CS will provide an alternative pathway for OIML Issuing Authorities to demonstrate their competence, with a view to potentially providing a more flexible option, reducing barriers to participation, and encouraging more OIML Issuing Authorities.				
<b>Relevant associated OIML publications:</b>				
OIML D 30:2020 and D 32:2018				
<b>List of appropriate liaisons and their work related to this proposed project (include supporting documentation as necessary and reference it here):</b>				
ILAC and ISO/CASCO				
* As the CIML Member(s) of the Country(ies) holding the convenership of this project, I/we recognise the importance of TC/SC/PG secretariat/convenership work and will make available the resources to ensure the work on the publication is completed in a timely and professional manner in accordance with the provisions in OIML B 6-1 and the detailed time frame as part of this proposal.				