



Agenda item 10.2

Recommendations from the OIML-CS Management Committee to the CIML

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Proposal regarding use of ISO/IEC 17020

- Background
- Functional approach (ISO/IEC 17xxx series)
- Use of ISO/IEC 17020 and new OIML Document
- Working Group recommendations
- Management Committee approval
- Recommendations



Background

- OIML B 18 currently specifies that OIML IAs demonstrate their competence through the application of ISO/IEC 17065
- MC discussed possibility of using alternative pathways to demonstrate competence - provide more flexible options, reduce barriers to participation, and encourage more OIML IAs
- Working Group established by the MC to explore possible alternatives
- ISO/IEC 17020 was selected for specific analysis due to requests from MC Members
- Working Group considered it timely and efficient to present the concepts and approach regarding use of ISO/IEC 17020



Functional approach (ISO/IEC 17xxx series)

- ISO/CASCO has developed International Standards and Guides to support conformity assessment
- Basic concept is the *Functional Approach* (ISO/IEC 17000:2020, Annex A), which divides conformity assessment into three functions:
 - “selection”
 - “determination”
 - “review, decision and attestation”



Functional approach (ISO/IEC 17xxx series)

- ISO/IEC 17020 (Inspection) and ISO/IEC 17025 (Testing and Calibration) are classified as standards for the “determination” function, whereas ISO/IEC 17065 covers all three functions
- In considering the use of ISO/IEC 17020, 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



ISO/IEC 17020 and new OIML Document

- 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
- Concluded that ISO/IEC 17020 provides similar levels of confidence in the competency and management of an OIML Issuing Authority
- To support the use of ISO/IEC 17020 as an alternative, additional requirements and guidance are required to address any inconsistencies
- These will be detailed in a new OIML Document (OIML D xx)



ISO/IEC 17020 and new OIML Document

- The main items to be included in the OIML Document are:
 - the concept that the ‘inspection’ of a measuring instrument and the ‘type evaluation’ of a measuring instrument are equivalent under the OIML-CS
 - Note:* The scope of 17020 covers type examination
 - ISO/IEC 17020 provides for a generalised approach to the inspection/type evaluation process so OIML D xx will 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



ISO/IEC 17020 and new OIML Document

- 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, and OIML certificates
- clarification of the need to safeguard impartiality when utilising the work of non-independent bodies as part of the type evaluation
- clarification of contractual terms for work undertaken as part of the inspection/type evaluation process



ISO/IEC 17020 and new OIML Document

- EA-2/17 M:2020, Annex A specifies that ISO/IEC 17065 is the preferred standard for the accreditation of notified bodies performing type examination in the European Union
- However, Annex B allows the use of ISO/IEC 17020 (with additional requirements) as an alternative
- 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
- In the case of the OIML-CS, requirements of ISO/IEC 17025 are already addressed as OIML IAs make use of test reports from approved Test Laboratories



Working Group recommendations

Recommendation 1

- The Working Group recommended that the OIML-CS MC 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.



Working Group recommendations

Recommendation 2

- Subject to agreement with recommendation 1:

The Working Group recommended that the MC (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.



Working Group recommendations

Recommendation 3

- Subject to agreement with recommendation 1:

The Working Group recommended that the MC establish a new Working Group to develop a new OIML Document (D xx) 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.



Working Group recommendations

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”.



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.



Recommendations to the CIML

- The MC 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 MC will revise OIML B 18 and the relevant Operational and Procedural Documents in line with the Working Group recommendations
- The MC also recommends that the CIML approves the establishment of a new Project Group, under the responsibility of the MC, to develop a new OIML Document (D xx) to provide guidance and interpretations regarding the application of ISO/IEC 17020 to the assessment of OIML Issuing Authorities



Recommendations to the CIML

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

- Further information is provided in the project proposal
- It is proposed that the use of ISO/IEC 17020 by OIML IAs will be permitted from 1 January 2023
- MC decided to extend the transition period for OIML IAs to use self-declaration (with supporting evidence) to 31 December 2023 - provide time for the publications to be developed and published, and for OIML IAs to undergo a suitable accreditation or peer assessment



Thank you

Any questions?

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