

FINAL DRAFT
BASIC PUBLICATION

52nd CIML Meeting
Cartagena de Indias 2017

SUBMITTED
FOR CIML
APPROVAL

Revision of B 18:

Framework for the OIML Certification System (OIML-CS)

(Information)



ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Result of prMC voting

Revision of OIML B 18: Framework for the OIML-CS

prMC ballot at second prMC meeting
Shanghai, P. R. China
2017-06-13

prMC has 19 Members from OIML Member States

Votes cast: 14 (Yes: 14 – No: 0), 0 abstentions, Did not vote: 5¹

AUSTRALIA	Voted Yes
CHINA (P. R.)	Voted Yes
CZECH REPUBLIC	Voted Yes
FRANCE	Voted Yes
GERMANY	Voted Yes
INDIA	Voted Yes
JAPAN	Voted Yes
KOREA (R.)	-
NETHERLANDS	Voted Yes
NEW ZEALAND	Voted Yes
POLAND	-
RUSSIAN FEDERATION	-
SLOVAKIA	Voted Yes ²
SOUTH AFRICA	Voted Yes
SWITZERLAND	Voted Yes
TUNISIA	-
UNITED KINGDOM	Voted Yes
UNITED STATES	Voted Yes
VIET NAM	-

The collated comments on the following pages were received from prMC members on Working Draft 20170524 (which replaced WD 20170403). The observations were discussed and agreed at the second prMC meeting and an updated version, incorporating changes to address the agreed observations, was presented to the prMC for the ballot.

¹ Korea (R.), Poland, Russian Federation, Tunisia and Viet Nam were not present at the meeting

² Proxy given to the United Kingdom



prMC Comments on: Framework for the OIML-CS	Title: Draft Revision of OIML B18:2016 WD20170524 (replaces WD20170403)	
Document date: 20170524	Circulation date: 20170524	Closing date for comments: 05 June 2017
Convener: DE - Prof Roman Schwartz	Collated comments and agreed observations	

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
JP-1		gen	The present structure is not fully consistent. A cross-reference table between the B18 and ODs/PDs is shown in the last two pages below. Our concerns are highlighted in yellow in this table. Please be consistent in use of terminology and document format as an overall structure.	Consistency between B18 and the ODs/PDs should be taken into consideration.		Relevant comments have been adopted in the various documents.
JP-2		techn	In the prMC meeting in Berlin, we discussed about guides for application of ISO/IEC 17025 and ISO/IEC 17065. Did it conclude to install the guide documents specified to OIML-CS on ISO/IEC 17025 and ISO/IEC 17065 in the OIML-CS document system?	Create new PD to show guides for application of ISO/IEC 17025 and ISO/IEC 17065. Replace D29 and D30 in B18, ODs and PDs with this new PD.		This was discussed by the Presidential Council and they requested that OIML D 29 and D 30 remain in the existing TC/SC structure as they are developed in accordance with OIML B 6. Can revisit in the future if guidance specific to the OIML-CS is required.
US-1	1.2	edit	Begin with “The OIML-CS” and not “It”.	Begin with “The OIML-CS” and not “It”.	Low	Agreed
JP-3	1.3	techn	In clause 1.3 of B18, “However, the type evaluation conducted within the OIML-CS does not include any formal evaluation to establish that the type is representative of the intended production.” is stated. However, it is strongly recommended to clarify what type of product certification scheme among various schemes the OIML-CS is classified to.(See ISO/IEC 17067, Standard for “fundamentals of product certification and guidelines for product certification schemes”) This clarification is important for accreditation bodies to assess OIML Issuing Authorities because the extent of assessment depends on type of product certification scheme.	Insert “The OIML-CS is classified to Scheme type 1a defined in ISO/IEC 17067.” before the sentence “Such an evaluation....”		Agreed. “Note” will be added to section 1.3.

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
US-2	3.1	edit	Insert closed parenthesis after “[3]”.	Insert closed parenthesis after “[3]”.	Low	Agreed
US-3	3.16	techn	Should “controlled supervision” be defined in B 18?	Define/reference definition of “controlled supervision” (e.g., Clause 7 of PD-04)	Med	Agreed. Cross-reference will be added.
US-4	3.16 Note	techn	Is there anything written anywhere that if test data is obtained from an MTL, that must be clearly indicated on the OIML type evaluation report, and acceptance of that report is optional?	Include such a statement either in B 18, or at least in PD-04.	High	Agreed. Cross-reference will be added.
DE-1	3.22	edit	Bold type style after “OIML Certificate:”	Change to “normal” type style after the colon.		Agreed.
US-5	3.22	techn	Is “Type Examination Certificate” defined/used anywhere? Should it instead be “Type Evaluation Certificate”, for consistency with 3.40 (“Type evaluation”)?	Make use of “examination” and “evaluation” consistent throughout all of the documents.	Med	There was a conscious decision to move away from the term “Certificate of Conformity” as the OIML-CS is not a full Conformity Assessment System as there is no CTT. The term OIML Certificate is used, which is defined as a “Type Examination Certificate ...”.
PL-1	3.24		3.24 OIML Issuing Authority (IA): Certification Body from an OIML Member State issuing OIML Certificates and associated OIML type evaluation reports in accordance with Scheme A or Scheme B. <i>Note: An OIML Member State having an OIML Issuing Authority for a category of measuring instrument under Scheme A shall be a Utilizer (see 3.42) for that category of measuring instrument. The Utilizer may be a different organization to the OIML Issuing Authority.</i> Not agree with “note” and changes in p. 5.3. See above-mentioned comments.			Text in the <i>Note</i> has been modified to state that the OIML Member State will designate at least one Utilizer for each category of measuring instrument.
US-6	3.24 Note	edit	In the last sentence, replace “to” with “than”.	“The Utilizer may be a different organization than the OIML Issuing Authority.”	Low	Agreed

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
PL-2	5.3		<p>5.3 OIML Issuing Authorities that have been accepted for participation in the OIML-CS (see 11.5 f)) sign a Declaration indicating their scope for issuing OIML Certificates and OIML type evaluation reports under Scheme A and/or Scheme B. When an OIML Issuing Authority is accepted under Scheme A, the OIML Member State automatically becomes a Utilizer for the respective category(ies) of measuring instrument(s). The CIML Member signs the Declaration specifying the Utilizer(s) and indicating their acceptance of OIML Certificates and/or OIML type evaluation reports issued under Scheme A for the respective category(ies) of measuring instrument(s). They may specify additional national requirements or special requirements which deviate from those in the relevant OIML Recommendation(s)</p> <p>Not agree with “note” and changes in p. 5.3. See above-mentioned comments.</p>			Text has been modified to state that the OIML Member State will designate at least one Utilizer for each category of measuring instrument.

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
US-7	5.3	gen	<p>It is unclear why it is proposed that the Member State become a Utilizer, and not the OIML Issuing Authority. Was this discussed at the prMC meeting in Berlin? Similarly, why is it proposed that the CIML Member sign the Declaration, and not the OIML Issuing Authority? In the U.S. it will not be possible for the CIML Member to sign the Declaration on behalf of the OIML Issuing Authority. Further, the CIML Member cannot agree that the entire country (Member State) become a Utilizer, only the National Issuing Authority can become a Utilizer.</p> <p>Note that in 3.8, nothing is said about CIML Members signing a declaration.</p> <p>Note that in 3.42, the definition of Utilizer, there is no mention of the possibility of a Member State being a Utilizer, only a National Issuing Authority or National Responsible Body from an OIML Member State.</p> <p>Similarly, in 5.4, Utilizers sign the Declaration, not CIML Members.</p> <p>It seems unbalanced if CIML Members were to sign the Declaration in some cases, and National Issuing Authorities or National Responsible Bodies in other cases.</p>	<p>Modify the wording of 5.3 as follows:</p> <p>OIML Issuing Authorities that have been accepted for participation in the OIML-CS (see 11.5 f)) sign a Declaration indicating their scope for issuing OIML Certificates and OIML type evaluation reports under Scheme A and/or Scheme B. When an OIML Issuing Authority is accepted under Scheme A, the OIML Member State OIML Issuing Authority automatically becomes a Utilizer for the respective category(ies) of measuring instrument(s). The CIML Member OIML Issuing Authority signs the Declaration specifying the Utilizer(s) and indicating their acceptance of OIML Certificates and/or OIML type evaluation reports issued under Scheme A for the respective category(ies) of measuring instrument(s). They may specify additional national requirements or special requirements which deviate from those in the relevant OIML Recommendation(s).</p>	High	Text has been modified to state that the OIML Member State will designate at least one Utilizer for each category of measuring instrument. The Utilizer will sign the Declaration and not the CIML Member.
AU-1	7.10.1.1	gen	What timeline is provided for decisions regarding proposals for the transition of instrument categories between Schemes? And any other matters?	Please include timeframes for transition proposals and other MC work items.	Medium	Transition provisions to remain as specified.
CH-1	8.1	gen	In our view the OIML CS does not include the CIML or BIML (they are either supervisor or secretariat, not part of the system).	Delete bullet point a) and b) from list in 8.1	low	Agreed
DE-2	8.1	Edit/tech	According to figure 1 the structure of the OIML-CS comprises MC, RC; TLF and BoA, which are mentioned in c) – f). There are (only) links to CIML (a) and BIML (b). Figure 1 shows more than the structure of the OIML-CS.	Delete CIML and BIML from the list in sentence 1. Change the second sentence to “Figure 1 illustrates the structure of the OIML-CS within the structure of OIML.” Change the caption of figure 1 accordingly.		Agreed

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CH-2	9	gen	Chap 13 specifies that the CIML appoints the BoA (Chair and members). This duty is not reflected in chap 9	Add "appoints the Chairperson and the members of the BoA" in Chap 9	mid	Agreed
AU-2	11.4.2	gen	What is defined as a quorum? The current wording suggests that there is no quorum, rather a successful the vote requires 80% or 50% of all MC members, whether they are present (in person or by proxy) or not. This could result in difficulties in achieving outcomes in some meetings.	Perhaps a quorum could be defined as 80% of MC members.	Low	CIML have already approved these voting rules. Current requirements to be retained.
AU-3	11.4.2	gen	We disagree that 'other proposals' could be accepted with only 50% support. Support for such proposals should require at least 50% +1 of votes cast in favour. Ideally, the MC should strive to achieve a greater degree of consensus. One of the fundamental aims of a system such as the OIML-CS is to build trust and confidence between participating members. The voting rules should reflect this aim, thus requiring at least 60%-80% support for any and all matters.	Change the voting rules for 'other proposals' to at least a simple majority (50%+1). Ideally this should be changed to a much larger majority, such as two-thirds (as is the case in 11.4.3) or 80%.	Medium	CIML have already approved these voting rules. Current requirements to be retained.
AU-4	11.6.2	gen	The RC will be required to review documentation across the entire range of measuring instruments covered by OIML Recommendations. It is anticipated that the RC will have a substantial workload, particularly at the commencement of the OIML-CS. As such it may be necessary to establish multiple RCs for different instrument categories. The review of such documentation is likely to be a substantial task, in addition to the other work required of MC members. Would it be possible for an MC member to nominate an expert from their country/economy/organisation to the RC for a particular category of measuring instrument? That expert would act on behalf of the MC member.	Could it be clarified whether there will be only one RC or will there be an RC for each category or range of categories of measuring instrument (e.g. weighing instruments, flowmetering systems)? In either case, could it be clarified as to whether the MC member can nominate technical experts from the country/economy to represent the MC member on the RC(s) for different instrument categories?	High	There will only be one RC with a defined membership. It is intended that the membership be increased to ensure that there is a wide range of experience amongst the members to cover different measuring instrument categories. MC member can nominate experts from the country/economy.
AU-5	11.6.2	edit	The RC's primary function is to make recommendations to the MC regarding various technical matters. It is suggested that the wording of the clause reflect this primary function. The RC can also provide advice to the MC.	Suggest that the term "advise" be replaced with the term "recommend" in order to align with main function of the RC as described in OD-01. Eg. a) "...peer assessment reports, etc. and to make recommendations to the MC on the acceptance of potential OIML Issuing Authorities,"	Medium	Agreed

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
JP-4	11.7	gen	The descriptions on Working Groups are found only in OD - 01. But Working Groups should also be introduced briefly in the section 11.7 of B 18 which is the main document.	The Working Groups should be introduced in section 11.7 in OIML B18 as the main document.		Agreed
AU-6	13	gen	The BoA is to be independent of the MC. Can MC members serve on the BoA?	For consideration by the prMC.	High	MC members cannot serve on the BoA. Suitable wording added to PD-01.

Country Code/ Organization	Section	gen./ edit./ techn.	COMMENT	Proposed change	Priority	OBSERVATIONS OF THE CONVENER
AU-7	15.2	gen	<p>Australia supports the intention to transition instrument categories from Scheme B to Scheme A within a two year timeframe.</p> <p>However, the transition of an instrument category should be deliberate process, rather than an automatic process. An automatic process will either result in additional work for the MC in formally delaying a transition or, potentially, in the risk of an unintended transition of an instrument category.</p> <p>This risk may arise as a result of scheduling and the requisite timeframes involved in OIML decision making.</p> <p>As an example; for CIML to delay an automatic transition, a proposal needs to be submitted to CIML members 3 months ahead of the CIML meeting. Such a proposal would need to be approved by the MC, which would require at a minimum 1 month to consider and vote out of session (although this is not specified, see AU comment on 7.10.1.1 above). Such a proposal may require a WG to provide advice on the transition. At best, the necessary analysis to inform and prepare such a proposal would take at least 1-2 months.</p> <p>As such, for CIML to approve a proposal to delay a transition the MC would need to commence work on such a proposal no later than 6 months out from the automatic 2 year transition date. This assumes no delays and successful votes at both MC (out of session) and CIML (possibility out of session).</p> <p>If the MC is uncertain as to whether the necessary infrastructure (labs, experts, accreditations, RC processes) will be in place to support a Scheme A transition, then they may have to commence a process to delay the transition 6-12 months out from the CIML meeting. Will the MC be in agreement regarding the need for such a process given the potential uncertainty so far out from the automatic transition date? If an out-of-session CIML vote is required, is there any guarantee of a valid vote to support the delay?</p>	<p>Amend clause 15 such that it is the intention to transition an instrument category after 2 years.</p> <p>In order to transition an instrument category, the MC is required to submit a proposal to CIML for a vote.</p>	High	Current requirements to be retained.

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AU-7 (continued)	15.2	gen	<p>The best case scenario will be that the delay is not required, however this may only be realised at the time of the CIML vote, resulting in a significant amount of unnecessary work. Does the MC have the time and resources for this?</p> <p>Problems may also arise resulting from the accreditation schedule of ILAC signatories. If a Recommendation will transition in 2 years, and a laboratory is accredited every 4 years, some labs may need to wait up to 2 years before being able to participate in the OIML-CS Scheme A. Thus being at a disadvantage to their competitors.</p> <p>Why not make the decision to transition to Scheme A a deliberate one, allowing the MC time to be confident that all the necessary infrastructure is in place, and all participating labs appropriate time to become accredited for the new Recommendation, before proceeding with the proposal to CIML.</p>			
JP-5	17	edit	Please make corrections.	Present: [7] ISO/IEC 17025:2005... Correct: [8] ISO/IEC 17025:2005...		Agreed

14. Conduct of the Work	8. MC Interactions with the CIML 8.1 General 8.2 Content of the annual report 8.3 Proposals and Recommendations for CIML approval									
15. Operation of the OIML-CS	14. MC interactions with the TLF	6.5 Interface with OIML TCs/SCs			5. Application to be a new OIML IA under Scheme B 6. Application to be a new OIML IA under Scheme A 7. OIML IA Appeals Procedures 8. Admission of Utilizer and Associates 9. Declaring Additional National Requirements 10. Process to suspend an OIML IA 11. Extension or reduction of scope of an OIML IA 12. Periodic review of participation 13. Change of status 14. Withdrawal of an OIML IA from the OIML-CS 15. Notification of changes					
						5. Application for a new TL under Scheme B 6. Application for a new TL under Scheme A 7. Additional requirements for MTLs 8. Extension (or reduction) of scope of a TL				
							4. Processing an OIML Certificate under Scheme B 5. Processing an OIML Certificate under Scheme A 6. Registering an OIML Certificate: Schemes A and B 7. OIML Certificate issued on the Basis of Wrong Conclusions 8. Modification of an OIML Certificate: Schemes A and B			
								4. Use of an OIML Certificate and OIML Type Evaluation Report 5. Misuse of an OIML Certificate by its owner		
									4. Status, Acceptance and Revision of Existing OIML Basic and MAA Certificates 5. Existing OIML MAA Certificates 6. Existing OIML Basic Certificates 7. Transition from Scheme B to Scheme A 8. Transition of existing IA under the OIML Basic Certificate System to the OIML-CS 9. Transition of existing Issuing Participants under OIML MAA to OIML-CS	
										4. Record of Participation in the OIML-CS 5. Initiation and Maintenance of the Declaration 6. Acceptance of OIML Certificates and OIML Type Evaluation Reports
16. Finance										
17. References	15. References	7. References	10. References	11. References	16. References Annex A (Informative) - Summary of the tasks of an IA Annex B - Maintenance Process	9. References	9. Bibliography Annex A (Mandatory) - Format for an OIML Certificate Annex B (Mandatory) - Reference Number of an OIML Certificate Annex C (Informative) - Example of the OIML-CS Operation	9. References	10. References	7. References

The relationship with subordinate PDs is difficult to understand because the process of OIML-CS is not clearly stated in any document. Suggest adding a figure or flowchart in PD-03 to present an overview of the evaluation process.

Suggest to unify References.