



**TC3 / SC5 Votes on: B10 2CD
Non MTLs**

	P- Member	Vote	Comments
1	AUSTRALIA	Yes	Yes
2	AUSTRIA	Yes	No
3	BELGIUM		
4	BRAZIL		
5	BULGARIA	Yes	No
6	CANADA	Yes	Yes
7	CUBA		
8	CZECH REP.	Yes	No
9	DENMARK		
10	FINLAND	Yes	No
11	FRANCE	Yes	No
12	GERMANY	Yes	No
13	JAPAN	Yes	Yes
14	KOREA		
15	NETHERLANDS	Yes	Yes
16	NORWAY	Yes	No
17	P.R. CHINA	No	No
18	POLAND	Yes	No
19	ROMANIA	Yes	No
20	RUSSIAN FED.	No	No
21	SOUTH AFRICA	Yes	No
22	SPAIN	Yes	No
23	SWEDEN	Yes	Yes
24	SWITZERLAND	Yes	No
25	UNITED KINGDOM	Yes	Yes
26	UNITED STATES	Yes	No

Votes for Yes 19
73.1%



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Member	Clause	Comment	Secretariat Replies
AUSTRALIA	4	"Anyone" should be replaced by "Any CIML member or corresponding member . . "	The Secretariat's recollection is that the submission process is meant to be open to anyone, including industry (of course, the necessary conditions for establishing a DoMC must first be met). This issue can be readdressed during the next revision of B10.
AUSTRALIA	9.2	9.2.1	The Secretariat does not understand this comment.
CANADA	3.9	Section 3.9 should be modified as agreed to in document WD2010/3 (page 4/13) the definition of OIML Issuing Participant should not be linked to OIML Issuing Authority because that would imply that the OIML Issuing Participant must also issue OIML Basic Certificates. The new definition in B10 should read as proposed in WD2010/3: "Issuing Participant: a Participant (as defined in 3.9 above) that issues OIML MAA Type Evaluation Reports and MAA Certificates" - alternately, the definition of OIML Issuing Authority in OIML B3 could be changed to remove the second sentence and simply read: "OIML Issuing Authority: certifying body or person in an OIML Member State, designated by its CIML Member"	Agreed. Text has been changed to: participant (as defined in 3.8) that issues OIML MAA Type Evaluation Reports and MAA Certificates
CANADA	9.1	Section 9.1 applies only to OIML Issuing Participants who are also OIML Issuing Authorities and should be re-worded to state: "In the event that results taken outside (...) may still be issued by the Issuing Participant who is also an OIML Issuing Authority".	Not necessary, since by at least implication an OIML Issuing Participant has already been deemed capable by the CIML Member of being an OIML Issuing Authority for that category of instrument (see reply to 3.9).
CANADA	Anex B / Section 4	Because all Testing Laboratories (subcontracting and internal) used by an OIML Issuing Participant must be known, evaluated and listed in the DoMC, Annex B section 4 should be modified to remove "external testing facilities" and be replaced with: "The use of a modular approach for testing may lead to higher capabilities"	Disagree with the proposed change of wording because in this context the use of "modular approach" seems to be misleading. The following has been added for clarification: "...external testing facilities (e.g. by sub-contracting) may ..."



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CANADA	4.4	<p>Section 4.4 eventually should be modified to require that OIML Issuing Authorities comply with ISO/IEC Guide 17065.2 and that they show compliance through accreditation or peer review.</p> <p>Likewise, this section eventually should also be modified to state that Testing Laboratories are required to show compliance to ISO/IEC 17065.2 because section 6.2.2.4 of ISO/IEC guide 17065.2 states: <i>6.2.2.4 The certification body shall: b) ensure that the body that provides outsourced services, and the personnel that it uses, conform to requirements of the certification body and also to the applicable provisions of this International Standard and the certification scheme, including competence, impartiality and confidentiality.</i></p>	<p>Noted. Imposing such a requirement would be a departure of the current 'spirit' of B10, although this could change in the future, at least under certain circumstances such as the use of test data from manufacturers.</p>
JAPAN	General	<p>We deeply appreciate dedicated efforts by the secretariat of TC3/SC5 to revise B3 and B10. We particularly appreciate their positive and informative replies to our comments to B3-CD2 and B10-CD1.</p>	<p>Noted. The Secretariat thanks you for your kind remarks.</p>
JAPAN	6.2.1	<p>We consider "potential participants" shall be defined clearly. How CPR know the potential participants in advance? If it is not clear, the criterion (80%) to acceptance of new issuing participants does not make a sense because the number of potential participants is not certain.</p>	<p>6.2.1 applies to the situation where no DoMC for a category of instruments yet exists. However, the BIML representative will have already sent an inquiry to all CIML members asking about their interest in having one or more Issuing Authorities in their country be a Participant (Issuing or Utilizing), so that the BIML representative will know the number of potential Participants, and will convey that information to the provisional CPR members (that have previously been appointed by the CIML members when they originally express their interest in having their country taking part in the DoMC; see 6.1.6).</p>



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JAPAN	6.2.1	The criterion to acceptance (80%) is applied twice to the same number of potential participants. We recommend revising a sentence in 6.2.1 as shown below in accordance with the expression in 6.2.2. <i>"Responses from at least 80 % of the potential Participants shall be received. Each Issuing Participant is accepted provided that at least 80 % of the replies agree on its participation."</i>	While it would seem that 6.2.1 and 6.2.2 should have parallel requirements, for reasons that we do not recall these requirements were set to be different (6.2.1 being more strict). Since this issue was not raised during the most recent TC 3/SC 5 discussions, the Secretariat is reluctant to propose this change now. This matter could be readdressed by TC 3/SC 5 during the next revision of B10.
NETHERLANDS	1.1	Last bullet: Is it countries that owe test facilities? Advise to reword to for example "... where no test facilities are available"	The use of the term "own" in the last bullet is not meant to imply that the country itself owns the test facility. However, your suggestion has been incorporated for clarity.
NETHERLANDS	1.3	Suggest to split in 2 sentences deleting "since" (The last part of the present sentence is not the reason for the first part. The last part is the consequence.)	Accepted.
NETHERLANDS	1.4	Suggest amending: "Participating in a Declaration..." to: "Participating, by endorsing a Declaration.."	Disagree. A Participant does more than endorse.
NETHERLANDS	3.4	Verb missing. Suggest to amend: "declaration by Participants that..." to: "declaration by Participants stating that..."	Disagree. The declaration itself is an announcement or statement.
NETHERLANDS	3.9	Suggest amending: "...that has been accepted in a DoMC..." "...accepted to accede to a DoMC..."	Disagree. The term "accede" is not necessary and could possibly be misinterpreted.
NETHERLANDS	3.10	Suggest amending to: participant (as defined in 3.8) from an OIML Member State which does not issue any OIML MAA Type Evaluation Reports nor MAA Certificates, but which utilizes Certificates issued by Issuing Participants.	Agree that consistency is necessary. However, in both instances the term should be "that". Text has been modified accordingly. Disagree about changing "those" to "Certificates", since both test data and Certificates are applicable.
NETHERLANDS	3.11	Suggest amending to: participant (as defined in 3.8) from an OIML Corresponding Member willing to utilize OIML MAA Type Evaluation Reports issued by Issuing Participants. (or	Accepted.



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NETHERLANDS	3.17	Suggest amending to: “manufacturer and/or authorized representative submitting an ..”	Accepted
NETHERLANDS	4	“Anyone...” suggest amend to “Any (potential) participant or associate..”	The Secretariat's recollection is that the submission process is meant to be open to anyone, including industry (of course, the necessary conditions for establishing a DoMC must first be met). This issue can be readdressed during the next revision of B10.
NETHERLANDS	4.2	Suggest amending to: At least three Participants preferably from different regions, are required in order to establish a DoMC. At least two of them must be Issuing Participants (3.10).	Disagree. The explicit use of "shall" is meant to emphasize that this is a requirement.
NETHERLANDS	7.5	second bullet: “come from “ is undefined; therefore change: “The expert shall not come from a manufacturer of measuring instruments;” to: “The expert is no member of staff of a manufacturer of measuring instruments or has any interest in such organisation;” third bullet change to: “The expert shall demonstrate sufficient experience in assessing on the basis of IEC17025. This may be demonstrated by participation in trainings organized by the BIML or equivalent training organized by national accreditation bodies or by being a qualified assessor from a national accreditation body and, if applicable, participation in additional training required by the CPR;” fourth bullet suggest amend to: “The expert shall have good speech and writing skills in English language.....”	Partially accepted. Text has been revised.
NETHERLANDS	8.1	<i>“Each accepted Participant shall sign in duplicate a registration form drawn up according to the format defined in Annex C.”</i> would mean 2 times signing the same form. I assume this is not in line with what is intended in this clause	"sign in duplicate" does not mean to sign the same form twice, but rather to sign two identical forms. This way both the Participant and the BIML could maintain 'original' versions.



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NETHERLANDS	9.1	third line; suggest amend: "...they perform.." to: "they are able to perform the..."	Disagree. In order to sign the DoMC as an Issuing Participant, the capability to perform the tests that they specify they will perform must already exist and be agreed to by the CPR.
NETHERLANDS	9.3	suggest amend to: "This report, for the relevant scope of the DoMC , shall highlight in particular..."	Either way seems fine?
NETHERLANDS	10.4	Suggest amend: "...before withdrawing." to: "before actual withdrawal " or "before withdrawal is a fact "	Accepted. Text has been revised.
NETHERLANDS	13.3	This clause concerns a dispute and therefore could better be part of chapter 14. Moreover it is in a way linked to 14.4 For elucidation reasons suggest to modify to: "When the Participant , NAI or NRB has doubts on any part of the contents of a MAA Evaluation Report received (including the test data), a Participant shall consult the relevant Issuing Participant for clarification of the matter and take any further appropriate actions. In case the test data cannot be accepted, written justification for denial shall be sent to the relevant Issuing Participant and the manufacturer. The Issuing Participant may subsequently appeal this decision according to the procedure defined in 14."	Partially accepted. Text has been revised.
SWEDEN	5.2	This clause only applies to potential issuing authorities. What about the already existing issuing authorities? Are they already fulfilling the requirements in this clause? If not, they would need to be assessed again in this respect.	This clause applies to potential Issuing Participants, not to potential Issuing Authorities. What is specified in this clause is information that must be supplied to the BIML (and then to the CPR for its review) documenting the ability of the potential Issuing Participant to serve as an Issuing Participant. Typically a potential Issuing Participant is already an Issuing Authority for the relevant category of instrument, or at least must already be capable of serving as such an Issuing Authority.



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SWEDEN	6.1.1	<p><i>6.1.1 A CPR shall be set up for the purpose of:</i></p> <ul style="list-style-type: none"> • Reviewing • Deciding for which Testing Laboratory a peer assessment shall be conducted and in that case defining the scope of peer assessment or requesting an extension of the scope of accreditation, if appropriate. • Validating..... <p>The meaning of the second bullet above is not totally clear to us. We interpret the text as follows: If the CPR, when reviewing documentation, finds that the peer assessment or the accreditation, that is used as evidence of the Testing Laboratories competence, does not fully cover all relevant aspects, the CPR can require that the gaps should be filled. The CPR can require either that the peer assessment should be extended to cover what is missing or that the scope of accreditation should be extended.</p>	Your interpretation is correct.
UK	7.5	<p>The criteria need to be revised to permit people with 'experience of assessing type evaluation' to be accepted as the current requirement is too restrictive. At present, the criteria only permit people who are performing type evaluation to become an expert. However, technical experts from NABs, who have a number of years assessing/evaluating type evaluation tests, etc., may not be deemed to be competent under the current criteria whereas they are deemed competent by the NAB. All because someone performs type evaluation does not necessarily mean that they would make a good technical expert/assessor. This knowledge can only be demonstrated as part of an assessment team. 'Experience' could be defined as 'a minimum of x years participating in the assessment of type evaluation on behalf of a NAB'.</p>	Noted. What specific modifications are being proposed? The third bullet of 7.5 specifies "assessing"; is this not sufficient?