

Template for comments and convener's observations

Date:2018-01-15	Document: 1CD (TC3_SC5_P5_N006 / N007)	Project: TC 3/SC 5/p 5
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Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 NL-1				ed	Please apply OIML B 6-2 defined and worldwide harmonized ISO/IEC directives http://www.iec.ch/members_experts/refdocs/iec/is_oiecdir-2%7Bed7.0%7Den.pdf ISO/IEC uses and OIML B 6-2 requires the use of the terms “clause and sub clause” not “section” (see ISO/IEC directives part 2 subclause 6.1)	Change “section” to “clause” or “subclause” where applicable or only apply the reference number.	Agreed. Changes made throughout 2CD.
0002 JP				Ge	We have no comments to 1CD of OIML D xx: Guide for application of ISO/IEC 17065.	No changes are requested.	Noted.
0003 DK					No comments		Noted.
0004 UK		Preamble	Para 4	ge	The wording should fully reflect the statement referred to within ISO/IEC 17065. Add “applicable requirements of”	ISO/IEC 17065 calls for the implementation of the applicable requirements of ISO/IEC 17025.....	Agreed. Wording added.
0005 AU		Preamble		te	The document should cover both the type approval and type evaluation of measuring instruments. The definition of type approval should not include type evaluation as they are separate processes. (See AU comment on clause G.3-2). It is noted that type evaluation potentially includes activities (eg testing) which would be covered under ISO/IEC 17025.	Where the preamble refers to type approval, it should also refer to type evaluation.	Agreed. Wording amended.

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Informative in nature and harmonize and improve legal metrology, it cannot give specific requirements as stated: "This Document gives interpretation and specific requirements..."	"This Document gives interpretation and the application to legal metrology of the requirements of ISO/IEC 17065:2012..."	Agreed.
Of documents published by OIML, suggesting it as "Application of ISO/IEC 17065 to the assessment of measuring instrument certification bodies in legal metrology". As the manuscript classification is "Document", it might cause confusion.	Title = Application of ISO/IEC 17065 to the assessment of measuring instrument certification bodies in legal metrology"	Not agreed. Title consistent with OIML D 29 and OIML D 30.
For readability.	Issuing national type approval evaluation certificates or OIML Certificates are product certification activities. In these cases, certification is limited to compliance of types of instruments, families of types, and types of modules of instruments. <u>These product certification activities do not cover</u> the conformity of individual products, surveillance of production, <u>or</u> quality systems for production.	Agreed. Wording changed.
Tests could be carried out by first, second or third party for type evaluations. As per this guide, irrespective of where the test report is produced, the process of issuing certificate is still called third-party product certification. The level of scrutiny involved for test reports from first, second and third parties should be different.	The guide should specify requirements for bodies certifying products, based on the nature of the test reports submitted for certification. In other words, this guide should distinguish between the test reports produced by first party, second party and third party and specify requirements for each one of these.	Partially agreed. Reference to external and internal test laboratories added. Level of <i>scrutiny</i> for test reports should not be different, but supervised control of MTLs is referenced in Document.

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0010 BR		G.1		te	The "Scope" should contain the scope. It currently only contains definitions. For example D30 Scope Section: "This Document is applicable to all testing laboratories involved in legal metrology and in particular to those involved in type evaluation tests and examinations."	Similarly to D30, "This document is applicable to Bodies issuing national type approval or OIML - Certification Bodies, specifying the application to legal metrology of the ISO/IEC 17065:2012 requirements".	Not agreed. This section provides guidance and interpretation on the Scope clause in ISO/IEC 17065.
0011 NL-2		G.3		ed	Please apply OIML B 6-2 defined and worldwide harmonized ISO/IEC directives for Terms and Definitions lay-out (see ISO/IEC directives part 2 subclause 16.5.4 and 16.5.5)	For all the terms apply lower case terms; lowercase at start of definition and no dot at the end (while not a sentence)	Agreed. Formatting changed.
0012 AU		G.3-2		te	We disagree with the Note; "type approval" and "type evaluation" should be maintained as distinct and separate concepts as per the VIML. Type evaluation is the testing and examination of a measuring instrument and includes an evaluation of its compliance against a standard. Type approval is a decision, based on all available evidence of whether the measuring instrument is fit for purpose. If type approval is considered to be a third party certification activity (as per G.0-3), but is defined to include type evaluation, then by definition type evaluation, which includes type testing, is considered to be a third party activity. If a manufacturer performs type testing, which is defined as part of type evaluation, on their own	Delete the Note.	Agreed. Note deleted.

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					instrument, that testing should not be considered to be 'third-party' - regardless of the acceptance of those results by an Issuing Authority. Furthermore, it appears that the Note is unnecessary as latter parts of the document differentiate between type evaluation and type approval, e.g. G.6.2.1-1.		
0013 BR		G.3-3		ge	Explain "Client" as a definition. It is not necessary states "for legal metrology applications" as the document is already understood to be applicable to legal metrology.	Client: The applicant for national type evaluation approval or for OIML certification. Although the instrument may be manufactured by another company, the applicant has to assume responsibility for compliance.	Not agreed. "Applicant for national type approval or OIML Certification" is the definition of "client" for the purposes of this Document.
0014 FR		G.4.1.1-1		Ed	Guide IAF GD 5 doesn't exist anymore.	This reference should be deleted	Agreed. Note deleted.
0015 UK		G.4.1.1-1		ed	The reference to IAF GD5 is obsolete	Delete 'see also IAF GD5'	See 0014.
0016 UK		G.4.1.2.2-1		ge	It is the 'client' (see also G.3-3) & not a 'manufacturer' who needs to be informed of its responsibilities ...	Replace 'manufacturer' with client (& be consistent throughout document – e.g. G.4.6-1, G.4.6-3 ...)	Agreed. Wording changed.
0017 NL-3		G.4.2.6-1		gen.	This guidance is still unclear. The first sentence is a statement. The second sentence most probably is intended to refer to this statement, but it does not which allows for multi-interpretation. Maybe it was meant to start the sentence reading e.g: <i>"In this case.... may be interpreted as other."</i> .	Please amend to fit the intension and to prevent for misinterpretations	Agreed. Wording changed.

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0018 BR		G.4.6-1		te	Since a type approval is a decision of legal relevance, based on the evaluation report that the type of a measuring instrument complies with the relevant statutory requirements (definition), the issuing authority cannot issue an approval based on requirements that are not "legal", (in this case, as the regional and international requirements diverge). Consequently, it is not a national type approval. Then, the manufacturer shall be informed that the type evaluation (not type approval) will be conducted based on International Recommendation. In this case, an approval based on the international requirements might not mean the issuing of a national type approval, but only part of a set of tests that should be conducted, as there are additional national requirements.	When International Recommendations or standards are not strictly equivalent to national regulations, the certification body shall inform the manufacturer of the fact that national type evaluation will be performed according to the International Recommendation or standard, or to the national requirements, or both. The manufacturer shall be made aware of additional requirements that are necessary to national type approval.	Agreed.
0019 BR		G.4.6-1		ge	Who is responsible to make the manufacturer aware?	When International Recommendations or standards are not strictly equivalent to national regulations, the certification body shall inform the manufacturer the fact that national type evaluation will be performed according to the International Recommendation or standard, or to the national requirements, or both.	Agreed.
0020 NL-4		G.4.6-1		ed	line 3 concerns the action of evaluation and not the approval, while it is a "performance" and not the "decision"	revert "approval" to read "evaluation"	See 0005.

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0021 AU		G.4.6-4		te	<p>It is assumed that this requirement steams from OIML-CS PD-03, clause 9; relating to the need for an IA to inform the MC of additional testing requirements within the IA's jurisdiction.</p> <p>However, G.4.6-4 appears to go beyond just additional testing requirements. It could be interpreted that this clause requires the IA to advise the MC of all elements of the type evaluation and approval process administered by the jurisdiction. If this is the intent, clarification is required regarding what the MC considers to be acceptable in terms of this advice. Would a link to an existing public webpage be sufficient? Or would the MC require a detailed report?</p>	Clarification is required regarding what the MC would consider to be sufficient to satisfy this requirement.	Subclause deleted as the MC does not require this level of detail in the annual report.
0022 AU		G.5.1.1-1		ed	This clause appears to suggest that if the IA is a government body (i.e. public administration), its status as a government body is considered to be a threat to its impartiality. It is suggested that the opposite would be true.	Delete the parenthesis – (e.g. public administration).	Agreed. Wording deleted.
0023 FR		G.5.2.4		te	§ 5.2.4 of ISO 17065 cannot be « excluded » (as clearly mentioned in the introduction of ISO 17065) so a sentence should be added to explain the process in OIML concerning the elaboration of OIML recommendations with consultation of all parties involved during their drafting and voting process and the rules applicable to the certification system which are proposed under the management committee where all interested parties are involved		Subclause deleted.

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0024 UK		G.5.2.4-1		te	Impartiality is with respect to the Certification Bodies certification activities, for the purposes of product certification for legal metrology, a mechanism which includes all interested parties such as manufacturers, users and consumers appears to be very applicable contrary to the wording in the current Guidance	Delete G.5.2.4-1	See 0023.
0025 AU		G.5.2.4-1		ge	<p>The wording and intent of this clause is confusing. Does it mean:</p> <ul style="list-style-type: none"> a) That for the purposes of legal metrology it is not necessary to involve all interested parties; or b) That for the purposes of legal metrology it is not sufficient to involve all interested parties? <p>In the case of a) while direct representation may not be achievable (particularly from consumers in highly technical matters), the interests of all parties should be taken into account as part of the decision making process.</p> <p>In the case of b) it is unknown what more could be done in order to provide appropriate and balanced decision making.</p>	The intent and wording of the clause requires clarification.	See 0023.
0026 BR		G.6.1.1.2-1		te	What is relevant to one body might not be relevant to another, however, an applicable one refers to all relevant recommendation/recommendation for a specified product.	For the purposes of legal metrology, personnel shall have sufficient knowledge of the applicable national requirements and/or the OIML-CS and OIML Recommendations for a product, if part of an OIML Issuing Authority.	Agreed. Wording changed.
0027 UK		G.6.2.1-1		te	This extends the requirements of ISO/IEC 17065:2012 by requiring 'All the requirements of ISO/IEC 17025 shall be fulfilled by testing laboratories' & so seems out of place within a	Align wording with ISO/IEC 17065:2012 ('applicable requirements') or clarify from where this 'extended requirement originates & align Guidance accordingly	Agreed. Wording changed.

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					'Guidance' document		
0028 AU		G.6.2.1-1		ed	Is it possible to include a direct reference to OIML D 30 at this stage? Or will the Document number change as a result of the current revision?	If possible, please include direct reference to OIML D 30.	Agreed. Reference to OIML D 30 added.
0029 AT		G.6.2.2.1-1		Ge	The second sentence states: For the issuing of OIML Certificates under Scheme A of the OIML-CS, where accreditation is chosen, the scope of accreditation should cover the relevant OIML Recommendations. Question: Is the term „scope of accreditation” also meant for peer assessed bodies? ”		Agreed. Wording added to include peer assessment.
0030 NL-5		G.6.2.2.1-1		ed	Please apply OIML B 6-2	replace “must” and “should” by “shall”	Agreed. Wording changed.
0031 UK		G.6.2.2.1-1		te	It is possible that Certification Bodies may subcontract part of their activity to other conformity assessment bodies. Suggest changing the wording to be clear that subcontracted testing bodies must meet ISO/IEC 17025.	Subcontracted testing organisations must in particular comply with ISO/IEC 17025 and ...	Agreed. Wording added.
0032 UK		G.6.2.2.1-1		te	There are specific implications regarding the competence of CB personnel when assessing subcontracted bodies.either by assessing its subcontractors by reference to these standards (in which case the CB must demonstrate its competence to carry out such an assessment) or by asking ...	Agreed. Wording added.
0033 AU		G.6.2.2.2-1		ed	Could direct references please be provided? It is assumed this is to OIML-CS PD-04.	Please include reference to at least OIML-CS PD-04.	Partially agreed. “other applicable documents” deleted.
0034 AU		G.7.1.1-2		te	We disagree with the definition that type approval includes type evaluation – they are separate processes (as per the VIML) and should be	Please amend the sentence to read: “National type approval and issuing OIML	Subclause deleted.

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					maintained as such. See AU comment on clause G.3-2 above.	Certificates are supported by testing, examination and type evaluation of the measuring instrument under test.”	
0035 AU		G.7.1.1-4		te	We disagree with the definition that type approval includes type evaluation – they are separate processes (as per the VIML) and should be maintained as such. See AU comment on clause G.3-2 above.	Please amend the sentence to read: “Type evaluation includes evaluation of the design of a measuring instrument, in particular to assess the following aspects:...”	Agreed. Wording changed.
0036 BR		G.7.1.1-4		te	Include “marking” as a design evaluation.	National type approval and OIML certification include design evaluation, in particular for the following aspects: • suitability for use; • sealing; • marking; • checking facilities.	Agreed. Wording added.
0037 DE		G.7.1.3		te	A reference to OIML-CS PD-05 is missing	Replace “No OIML Guidance” by “For OIML Certificates the provisions of OIML-CS PD-05 should be applied	Agreed. Wording added.
0038 UK		G.7.4.1-1			The wording ‘National issuing authorities and OIML Issuing Authorities’ means ‘certification bodies’ according to G.1-1 & so it is unclear why ‘certification bodies’ is not the terminology used here.	Change ‘National issuing authorities and OIML Issuing Authorities’ to ‘Certification Bodies ...’	Agreed. Wording changed.

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0039 FR		G.7.4.4-1		te	In response to the answer made by the secretariat, please note that tests submitted by the manufacturer may not only be tests implemented in a MTL but can also be tests implemented in an OIML testing laboratory, before the type approval application is made to the issuing authority. It can especially be the case for module/part of measuring instrument.	Add : "In the case of recognition of a test report made before the type approval application, the issuing authority shall ensure that the tested instrument was identical to the instrument subject to approval."	Agreed. Wording added.
0040 DE		G.7.4.5		Te	A reference to OIML-CS PD-06 is missing	Add "National issuing authorities may perform the evaluation on the basis of a OIML Certificate and OIML Type Evaluation Report. Details are described in OIML-CS PD-05"	Agreed. Wording added.
0041 BR		G.7.9.1-1		te	It is worth noting an explanation of both situations, since this document aims to inform: 1 - Surveillance is not covered by OIML CS; 2 - In legal metrology, type approved instruments are subject to surveillance activities carried out by regional legal authorities. The main directives for surveillance are given in OIML D9.	1 - Surveillance is not covered by OIML CS; 2 - In legal metrology, type approved instruments are subject to surveillance activities carried out by regional legal authorities. The main directives for surveillance are given in OIML D9.	Agreed. Wording changed.
0042 AU		G.7.11.3-2		ge	What is the "regulatory designating authority"? Is this the national metrology authority within the jurisdiction from which the certificate was issued? Or is something else meant? Has consideration been given to necessary consultation processes with all national metrology authorities that are party to the OIML-CS? Is this done through the MC? As regulatory decisions may have been made	The term "regulatory designating authority" requires definition. Consideration should also be given to the obligations of the Issuing Authority in consulting with OIML-CS utilizers ahead of withdrawing Certificates.	Partially agreed. "Regulatory designating authority" specified in Preamble. Wording added to cover BML informing Utilizers.

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					within each jurisdiction on the basis of an OIML-CS certificate, if an OIML-CS certificate is to be withdrawn, those authorities will need to be consulted and provided with rationale for the withdrawal. As each of them will potentially need to make a series of highly complex regulatory decisions within their respective jurisdictions in order to deal with the withdrawn certificate.		
0043 AU		G.7.11.6-1		Ed		This sentence requires a full stop.	Agreed.
0044 AU		G.7.12.3-1		Ed		Sentence should begin with a capital "C"	Added wording "For national type approval".
0045 US		Multiple		ed	<p>All comments are format and proper usage of words related, at least in my opinion. No comments were provided on the technical wording/requirements of the document as they were found complete.</p> <p>Note; the comments in red are items that I feel are incorrect and should be corrected. The comments in black are reference only and support the correction of the comments in red.</p> <p>1. Pg 13 (very bottom of the page) directly under the section title is the sentence "<u>OIML Guidance to Section 3 (G.3-1 and G.3-3)</u>". Looking at the contents of this section I find</p>		Agreed. Document amended to address comments.

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					<p>reference to G.3-1, G.3-2, and G.3-3; I suggest that the word “and” in the sentence be changed to “thru”, “through” or reference all three-guidance point. The justification for the suggestion is that the use of the word “and” implies that there are on 2 guidance points (-1 and -2) while in fact there are three references to guidance points.</p> <p>2. Pg 15, I have the same comments as above but applied to the statement directly under “4.6 Publicly available information”. The guidance references are for G.4.6-1 through G.4.6-4.</p> <p>3. Pg 17, the statement directly under 5.1.3 refers to guidance statement G5.1.3-1 to G.5.1.3 -2. Inconsistent use. This shows that in the previous document the word “to” was used to indicate a range of guidance references. The word “to” could be used in my comments 1 and 2, above but not in its current location. I suggest this be changed to “and”.</p> <p>4. Pg 18, directly under 6.1.2.1, same comment regarding use of the word “and” when indicating a range of guidance statements.</p> <p>5. Pg 19, directly under 6.1.2.2 same reference to the use of the word “to”</p>		

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					<p>when there is no range.</p> <p>6. Pg 19, directly under 6.2.2.2 same reference to the use of the word “to” when there is no range.</p> <p>7. Pg 20, directly under 6.2.2.4 here the word “to” is used correctly to indicate a range.</p> <p>8. Pg 20, directly under 7.1.1 here the word “to” is used correctly to indicate a range.</p> <p>9. Pg 23, directly under 7.4.4, here the word “to” is used correctly to indicate a range.</p> <p>10. Pg 25, directly under 7.4.9 here the word “to” is used correctly to indicate a range.</p> <p>11. Pg 26, directly under 7.6.2 same reference to the use of the word “to” when there is no range.</p> <p>12. Pg 29, directly under 7.10.2, here the word “to” is used correctly to indicate a range.</p> <p>13. Pg 26. directly under 7.11.3 the statement “OIML Guidance to section 7.11.3 (G.7.11.3-1) should read OIML Guidance to section 7.11.3 (G.7.11.3-1 and G.7.11.3-2). Justification: there are two guidance statements in this section.</p> <p>14. Pg 30, directly under 7.12.3, here the word “to” is used correctly to indicate a range.</p>		

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					15. Pg 30, directly under 7.13.1 here the word “to” is used correctly to indicate a range. 16. Pg 32, directly under 8.2.4, here the word “to” is used correctly to indicate a range.		

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