Template for comments and convener's observations

Date:2019-06-10	Document: OIML-CS_SC7_P1_N006	Project: OIML-CS/SC 7/p 1

Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
0001 AU		00.Exp Notes		ge	With regards to Note 2 the explanation should also cover TLs that are under application. That is, the interpretations and guidance provided in this document should be for the benefit of both TLs that are wishing to maintain or upgrade their accreditation as part of ongoing participation within the OIML-CS and any potential TLs looking to apply for approval.	Include an additional clause to the effect of: In addition, the guidance in this Document is applicable for any testing laboratory that may wish to apply for approval under the OIML-CS.	Agreed.
0002 AU		00.Exp Notes		ge	The expectation that there will be only one contract to cover all required testing for type approval may not be practically achievable in all cases. In particular for modular systems, it may not be uncommon for different modules to be tested in different TLs. On the other hand we generally agree that there should be one contract that covers the evaluation of an instrument. However in this case that contract is between the manufacturer and the IA, and as such relevant guidance and requirements should appear in OIML D 32, not in this Document. In practice separate contracts would be required for the testing. In these cases contracts should be between the manufacturer and the TL. The IAs should have a role in reviewing and endorsing any such contracts as part of quality control of the type approval process as a whole.	We suggest deleting the first paragraph. Or at least it should be clarified that it is only applicable in cases where the IA and TL are the same entity. The 2nd paragraph should be modified such that it is clarified that the manufacturer is the customer with respect to the contract. However the IA should review and endorse the contract for the testing to ensure that the testing is relevant and contributes effectively to the type evaluation.	Explanatory Note 4 deleted. Guidance moved or added to relevant clauses.
0003 CN		00.Explanatory note 4	1st paragraph	Te	Restrict the number of contracts to only one may be not impracticable. In many conditions, the manufacture need to pay to the test laboratory directly.	We propose to delete the 1st paragraph.	See 0002.
0004 DE		00.Explanatory Note 4	1st paragraph	Te	"Each application for type approval should lead to one contract only, covering all the tests and examinations to be performed. This contract shall be signed by the OIML Issuing Authority responsible for defining the tests and examinations to be performed." This note gives more organisational requirements than a guidance to ISO/IEC 17025. The number of contracts should not be regulated. In addition, it might be useful if the MTL or third party testing laboratory can send the invoice directly to the manufacturer and has a separate contract.	We propose to delete the 1st paragraph.	See 0002.

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0005 CN		00.Explanatory note 4	2nd paragraph	Te	This is the first time the word "custom" is used in this Document. The description of "custom" in this paragraph is inconsistent and not easy to implement. Since IA plays a special and important role during type evaluation process, we suggest defining who the customer is more precisely.	/	See 0002.
0006 DE		00.Explanatory Note 4	2nd paragraph	Te	"From the point of view of the Testing Laboratory, the "customer" should be the OIML Issuing Authority. However, in practice the manufacturer requesting the type approval is the "customer" of each Testing Laboratory involved in the type approval tests and examinations." We agree that it needs to be pointed out who is the customer of the testing laboratory. We would prefer to make it clear that officially, the customer of the testing laboratory is the OIML issuing authority and not the applicant of the type approval (cf. also G.8.6.2-1). This becomes important when a third party laboratory or an MTL performs the tests. In these cases it should be taken care that the OIML Issuing Authority is always involved in the communication to the customer.	Replace "the customer should be the OIML issuing authority" by "the customer is the OIML issuing authority" Delete the last sentence of the 2nd paragraph ("However, in practice the manufacturer requesting the type approval is the "customer" of each Testing Laboratory involved in the type approval tests and examinations").	See 0002.
0007 JP1		Explantory Notes Note 4	2nd paragraph	te	This document provides a guidance only for the Testing Laboratories and is not for the Issuing Authorities in OIML-CS. In this International Document, the customers for a Testing Laboratory are Issuing Authorities. The standpoint of this document should be different from that of D 32 based on ISO/IEC 17065. Furthermore, we propose separating "customer" to "direct customer" and "indirect customer". It is because a manufacturer receives a test report from the Testing Laboratory indirectly through the Issuing Authority, and the manufacturer may be considered as an indirect customer for the Testing Laboratory. On the other hand, the Issuing Authority is a direct customer of the Testing Laboratory. See also our comment, JP19.	Propose the following changes of the 2nd paragraph. *On the basis of the contract signed by the OIML Issuing Authority, each Testing Laboratory is responsible for reviewing the request regarding ~~considering~~ the tests and examinations it performs. From the point of view of the Testing Laboratory, the "direct customer" should be the OIML Issuing Authority. However, in practice the manufacturer requesting the type approval (applicant to the Issuing Authority) or Utilizers of OIML Certificates might be ~~is~~ the "indirect customer" of each Testing Laboratory involved in the type approval tests and examinations.*	See 0002.

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0008 CN		00.Preamble & Explanatory note 2		Te	In Preamble and Explanatory note 2, "**third-party (subcontracting) Testing Laboratories**" appears many times like,"…internal or **third-party (subcontracting) Testing Laboratories** of a national issuing authority…" What does it mean by using the word "Subcontracting" in the parenthesis follows "third-party"? Does it mean third-party Testing Laboratories is equal to subcontracting Testing Laboratories? We thing third-party is not equal to subcontracting in OIML and 17025. It is necessary to make a distinction between these two words.	/	"(subcontracting)" deleted.
0009 AU		2.2.1	G.2.2.1-1	ge	Validation is not the sole responsibility of CIML. Method validation includes ensuring the correct and consistent implementation of a documented test method in the individual laboratory. As such, we do not believe any guidance is required for this clause.	We suggest deleting this guidance.	Agreed. Note: the clause should be 7.2.2.1.
0010 BR		3		ed	Terms and definition - organization.	Organize the terms and definitions clause (3) alphabetically likewise B18 Document.	Agreed.
0011 DE		3	G.3-1	Te	ISO/IEC 17000 is under revision. We propose to refer to the new version (when finished before D30) or change it to a general reference without publication year.	Change "ISO/IEC 17000:2004" to "ISO/IEC 17000:20XX" or "ISO/IEC 17000"	The correct dated reference, and definitions, will be included in the published version of this Document.
0012 UK		3.1	G.3-1	ed	"…the definitions in ISO/IEC 17000:2004…" The ISO/IEC 17000 is under review and currently at Draft International Standard (DIS) stage and likely to be published as a new version by the time D30 is finalised. D30 should refer to the new version or to a general reference without year of publication.	Proposal is to change "ISO/IEC 17000:2004" to "ISO/IEC 17000:20XX".	See 0011.
0013 BR		4.1.5		te	An impartiality risk may compromise an OIML Certificate, which may also result in an impact throughout the OIML-CS participants. Insert a comment regarding impartiality.	For the purpose of the OIML CS, when a risk to impartiality is identified regarding any process that might have impacted the results of an OIML Certificate, OIML Issuing Authority shall be notified.	Agreed.
0014 DE		4.2.2	G.4.2.2-1	Te	G.4.2.2-1 says "Where the testing laboratory is required to release confidential information the OIML Issuing Authority shall be notified"	Delete G.4.2.2-1	Agreed.

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					According to ISO/IEC 17025 No. 4.2.1 the customer is informed about the information placed to the public domain. The customer of the testing laboratory is the issuing authority. We think the proposed guidance to 4.2.2 is not necessary. In addition, if the manufacturer was the customer of the testing laboratory, it might lead to a conflict with 4.2.1 if the OIML issuing authority is informed.		
0015 **CA**		4.2.2.1		GE	Seems to general. The issuing authority should only be notified if the released information relates to the technical aspects of the work. If the information is non-technical and between the testing lab and the client, there is no need to notify the issuing participant.		See 0014.
0016 **SI**		5.3	G.5.3-1	te	We understand that it is still necessary that the testing laboratory fulfils the requirement 5.3. The OIML Issuing Authority is not necessarily the same body as the testing laboratory.	Replace existing text with the following: No OIML Guidance. Note. Under the OIML-CS the range of testing activities will be documented in the Declaration of the OIML Issuing Authority.	Partially agreed. All text deleted.
0017 **DE**		5.4	G.5.4	Te	We do not think the guidance "In particular, this requirement applies when testing laboratory personnel use a manufacturer's test facility to perform type approval tests and/or examinations" is necessary. ISO/IEC 17025 says "This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility." The proposed guidance does not give any further information.	Delete G.5.4	See 0019.
0018 **CN**		5.4 6.3.5 6.4.2	G.5.4-1 G.6.3.5-1 G.6.4.2-1	Te	"In particular, this requirement applies when testing laboratory personnel use **a manufacturer's test facility** to perform type approval tests and/or examinations." In ISO/IEC 17025 it says, "This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a **customer's facility.**"	/	See 0019.

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					The word "**manufacturer's test facility"** are mentioned many times in this document. What is the difference between "**customer's facility**" and "**manufacturer's test facility**", why add the word "test" here? What is the initial intention of this guidance? This need to be clarified.		
0019 JP2		5.4	G.5.4-1 All	te	The present text is merely a guide for a part of Clause 5.4 of ISO/IEC 17025:2017. The current wording could be misunderstood as if the guidance applies to the entire Clause 5.4, and it may lead a misunderstanding of the scope this clause. Concretely, the requirement of Clause 5.4 applies to all laboratory activities. However, the present statement of G.5.4-1 could be misunderstood as if it limits the scope of the requirement only to the manufacturer's test facility. The wording of the guidance should be changed so that it only applies to the activities outside permanent facilities within the scope of Clause 5.4.	Replace the entire guidance with the statement below. *G.5.4-1 In OIML-CS, the expression "sites away from permanent facilities" in Clause 5.4 of ISO/IEC 17025:2017 includes a manufacturer's testing facility where type approval tests and/or examinations are conducted by the personnel of a Testing Laboratory.*	Partially agreed. The following wording to be used: 'Under the OIML-CS, the expression "customer's facility" includes a manufacturer's testing laboratory where the personnel of the testing laboratory conduct tests.'
0020 AU		6.2.2	G.6.2.2-1	ge	With regards to the last sentence, does this include national type approval work performed in accordance with OIML Requirements? Or is it intended to only cover OIML TC/SC/PG work?	If the former, we suggest modifying the last sentence as follows: "This includes work for the OIML performed at the national level and national type approval work performed in accordance with OIML Recommendations." If the latter, we suggest no change.	Wording of the second sentence has been improved to clarify the meaning. The wording has also been moved to 6.2.5 c) - see 0021.
0021 JP3		6.2.2	G.6.2.2-1	te	The guidance does not adequately match the requirement in Clause 6.2.2 of the ISO/IEC 17025:2017. This clause is provided for the documentation for the "competence of the personnel", not for the "training method". This guidance should be transferred to the appropriate clause in 1WD.	If this guidance for training method needs to be specified, it should be transferred to Clause 6.2.5 of 1WD as a guidance for 6.2.5 c) which is cited below. *Ref: ISO/IEC 17025:2017* *6.2.5 The laboratory shall have procedure(s) and retain records for:* *c) training of personnel;*	Agreed.

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0022 BR		6.2.3-1		te	According to the document scope, "This Document is applicable to all testing laboratories involved in legal metrology and in particular to those involved in type evaluation tests and examinations." Consequently, the applicable OIML-CS Procedural Documents awareness is only a requirement for those working for the purpose of the OIML-CS.	The personnel in charge of type evaluating testing shall be aware of the following: -relevant OIML Publications; -these guidelines; -applicable OIML-CS Procedural Documents (only for the purpose of OIML-CS).	Agreed.
0023 DE		6.2.6	G.6.2.6	Te	The guidance on 6.2.6 is too restrictive with regard to the format of the information ("A list shall be kept up to date…")	Replace "A list shall be kept up to date, indicating…" by "Documented information shall be available, indicating…"	Agreed.
0024 JP4		6.2.6	G.6.2.6-1	Te	The guidance does not adequately match the requirement in 6.2.6 of the ISO/IEC 17025:2017. This clause is provided for the "authorization of the personnel", and not for the "monitoring the competence". Since G.6.2.6-1 deals with "monitoring the competence", it should be transferred to the appropriate clause of 1WD.	Since G.6.2.6-1 states the requirement of the monitoring of the competence, this statement should be transferred to Clause 6.2.5 of 1WD as the guidance for the item e) in Clause 6.2.5 of the ISO/IEC 17025.	Agreed.
0025 JP5		6.2.6	G.6.2.6-2	Te	It is not clear whether G.6.2.6-2 distinguishes the difference in meaning between the words "qualify" and "authorize". Since "qualification" and "authorization" is clearly distinguished in the ISO/IEC 17025:2017, this guidance should also distinguish the two.	Assuming G.6.2.6-2 requires using the two words, substitute "qualified" to "qualified and authorized" so that this guidance still keeps the distinction among the two words. The word "qualified" is used twice in this guidance.	"qualified" replaced by "authorized".
0026 SI		6.2.6	G.6.2.6-2, 2nd ident	te	Taking into account G.7.8.3.1-2, reporting an opinion on the statement of compliance/ noncompliance of the results is not allowed in OIML test reports.	Delete 2nd ident.	Not agreed. The scope of the Document is wider than OIML test reports.
0027 BR		6.2.6-1		ge	Competence evaluation is described in 6.2.5. 6.2.6 regards authorizing personnel to specific tasks.	Move 6.2.6-1 to 6.2.5.	See 0024.
0028 SI		6.3.1	G.6.3.1-1	te	The guidance refers to equipment, not to facilities and environmental conditions.	Move the existing text under Section 6.4.5. Replace existing text with the following: No OIML Guidance.	Agreed.
0029 UK		6.3.1	G.6.3.1-1	ed	This guidance G.6.3.1-1 "Standards and test equipment" is listed under 6.3 "Facilities and environmental conditions", however, the correct location for "Standards and test equipment "should be 6.4 "Equipment"	Propose to move the sentence in G.6.3.1-1 to 6.4.	See 0028.
0030 BR		6.3.2		te	Environmental conditions in some cases are described in the OIML-Recommendations.	The laboratory shall consider the environmental requirements when specified in OIML R.	Agreed.

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0031 DE		6.3.5	G.6.3.5	Te	This guidance might easily be mixed up with the guidance to ISO/IEC 17025 No. 6.4.2. We propose to adapt the wording to make clear that the requirement of ISO/IEC 17025 No. 6.3.5 is related to the environmental conditions. In addition, we would add "other premises" than the manufacturer's to make the guidance more general.	Replace "This requirement applies when the testing laboratory uses the manufacturer's test facilities." by "This requirement applies when the testing laboratory performs tests at the manufacturer's or other premises"	Agreed. Wording improved.
0032 SI		6.3.5	G.6.3.5-1	te	This requirement applies also in other cases (e.g. in the case of tests performed outdoors), not only when the testing laboratory uses the manufacturer's test facilities.	Amend existing text with the following: This requirement <u>also</u> applies when the testing laboratory uses the manufacturer's test facilities.	See 0031.
0033 UK		6.3.5-1	G.6.3.5-1	ed	G.6.3.5-1 and G.6.4.2-1 have similar text and to avoid confusion it is useful to indicate that this guidance for 6.3.5 is related to "**Facilities and environmental conditions**", and not "**Equipment**".	Propose to change "This requirement applies when the testing laboratory uses the manufacturer's test facilities." with "This requirement applies when the testing laboratory performs tests at the manufacturer's facilities"	See 0031.
0034 SI		6.4.2	G.6.4.2-1	te	This requirement applies also in other cases (e.g. hired equipment), not only when the testing laboratory uses the manufacturer's test facilities.	Amend existing text with the following: This requirement <u>also</u> applies when the testing laboratory uses the manufacturer's test facilities.	Agreed.
0035 AUT		6.5.2	G.6.5.2-2	gen.	The purpose of this paragraph is unclear; please specify		Wording taken from D 30:20008, G.5.6.2.2.1-2. The Guidance is indicating that traceability may not be necessary, depending upon the nature of the test being performed, e.g. in the case of a stability test or the determination that the instrument has detected that a fault has occurred.
0036 CN		6.5.2	G.6.5.2-2		What does "fault determination" mean in this clause?	/	See 0035.
0037 JP6		6.5.2	G.6.5.2-1	te	Being an ILAC full member is an insufficient requirement for the accreditation body. The body should be an active signatory to ILAC MRA.	Substitute "full member of ILAC" with "a signatory to the ILAC Mutual Recognition Arrangement or to a regional arrangement recognized by ILAC" following the expression in 5.2 of PD-07 (Ed. 2).	Agreed.

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0038 CA		6.6.1		GE	Overly restrictive. While true for actual tests that may be outsourced, this is too much to expect that things such as calibration of thermometers (for measuring temperatures during tests) come from OIML approved labs. ISO 17025 accredited labs should be sufficient for these aspects, especially for internal testing labs of national authorities.		Not agreed. G.6.6.1-2 is restricted to externally provided *testing* services.
0039 SI		6.6.1	G.6.6.1-1	te	We understand that it is still necessary that the testing laboratory fulfils the requirement 6.6.1. The text in G.6.6.1-1 doesn't affect the laboratory's obligations.	Delete G.6.6.1-1	Agreed.
0040 AU		7.1.1	G.7.1.1-1	ge	Following AU comments on Explanatory Note 4, the use of the term "authorise" is perhaps too strong. It could be interpreted that the IA could or should become involved in all aspects of the testing contract (including price, timeframe, etc); and that the IA is a legal party to the contract.	We suggest rephrasing as follows or similar: "Where a contract between a TL and the manufacturer is necessary, the OIML IA should review and endorse the contract with respect to the proposed testing to ensure it is relevant and supports the type evaluation of the instrument. It is recommended that testing not commence until the IA has endorsed the proposed testing specified in the contract."	Agreed.
0041 JP7		7.1.3	G.7.1.3-1 (new)	te	Clause 7.1.3 of ISO/IEC 17025 is understood as a requirement for an agreement regarding the applied standard/decision rule between the Issuing Authority (direct customer) and the Testing Laboratory. For application to OIML-CS however, the standard/decision rule is provided by the applicable OIML Recommendation and it is already shared by the Testing Laboratory and the Issuing Authority. Therefore, the communication in advance about such rules between the Issuing Authority and the Testing Laboratory may not be necessary.	Propose adding the following new guidance. *G.7.1.3-1 In OIML-CS, the communication in advance between the Issuing Authority and the Testing Laboratory regarding applied standard/decision rule may not be necessary.*	Not agreed. The final sentence of 7.1.3 of ISO/IEC 17025:2017 already gives the option not to communicate.
0042 AU		7.1.5	G.7.1.5-1	ge	The use of the term used to describe the agreement from the IA with regards to the testing contract should be consistent throughout ("approval" here and "authorised" in G7.1.1-1).	We suggest changing "approval" to "endorsement" but only with respect to the proposed testing (See AU comment on G.7.1.1-1).	Agreed.
0043 DE		7.2.1.1	G.7.2.1.1	Te	This guidance has been transferred from the D30 guidance to ISO/IEC 17025 (2005) No. 5.4.1. ISO/IEC 17025 (2017) No. 7.2.1.1 does not contain all information given in ISO/IEC 17025 (2005) No. 5.4.1 and therefore this guidance seems to be misplaced here. This guidance refers to the handling of test samples and is already contained in G.7.4.1	Delete G.7.2.1.1 This guidance is given in G.7.4.1	Agreed.

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0044 DE		7.2.1.1	G.7.2.1.1	Te	See our comment on G.7.2.1.1 This guidance refers to sampling and is already contained in G.7.3.1	Delete G.7.2.1.1 This guidance is given in G.7.3.1	Agreed.
0045 AU		7.2.1.1	G.7.2.1.1-1	ge	This clause suggests that sampling is part of the type testing process performed by the TL. However G.7.3.1-1 states that sampling (in a ISO/IEC 17025 sense) is not part of type evaluation (and testing).	These clauses should be amended for consistency. We would tend to agree with the sentiment in G.7.3.1-1.	See 0043/0044.
0046 JP8		7.2.1.1	G.7.2.1.1-2	te	Since types of instrument to be tested are selected from a family of instruments by the Issuing Authority, not by the Testing Laboratory, G.7.2.1.1-2 is unnecessary or needs an amendment for clarification.	Delete this guidance or add a sentence "such a selection is done under the responsibility of the OIML Issuing Authority" as it is mentioned in G.7.3.1-1.	Agreed.
0047 SI		7.2.1.1	G.7.2.1.1-1	te	An issue of verifying that the sample(s) to be tested and/or examined are those validated by the OIML Issuing Authority is covered by Section 7.4.1 (cf. G.7.4.1-1)	Delete G.7.2.1.1-1	Agreed.
0048 SI		7.2.1.1	G.7.2.1.1-2	te	Selection of instruments to be tested amongst a family is not sampling as it is understand by ISO 17025. The testing laboratory is not involved in the selection of instruments to be tested and does not perform any sampling in a sense of ISO 17025.	Delete G.7.2.1.1-2	Agreed.
0049 SI		7.2.1.1	G.7.2.1.1-3	te	An issue of adjustments and modifications of the sample(s) authorized by the OIML Issuing Authority is covered by Section 7.4.1	Move the existing text under Section 7.4.1. Delete G.7.2.1.1-3.	Agreed.
0050 DE		7.2.1.1	G.7.2.1.1-4	Te	This guidance is quite general and does not help interpreting ISO/IEC 17025 No. 7.2.1.1. We suggest deleting it.	Delete G.7.2.1.1-4	Agreed.
0051 CA		7.2.2.1		GE	Overly restrictive for national bodies' own labs.		See 0009.
0052 AUT		7.2.2.1	G.7.2.2.1-1	gen.	The purpose of this paragraph is unclear; please specify		See 0009.
0053 SI		7.2.2.1	G.7.2.2.1-1	te	The text is not a guidance but a description of actual situation.	Replace existing text with the following: Not applicable. Note. Validation of methods is under the responsibility of higher authorities, e.g. the CIML for OIML Recommendations.	See 0009.

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0055 SI		7.3.1	G.7.3.1-1	te	Selection of instruments to be tested amongst a family is not sampling as it is understand by ISO 17025. The testing laboratory is not involved in the selection of instruments to be tested and does not perform any sampling in a sense of ISO 17025	Replace existing text with the following: Not applicable. Note: In general there is no sampling in the sense of ISO/IEC 17025 in the type evaluation process in legal metrology. Nevertheless, OIML Recommendations may require a selection of samples amongst a family of measuring instruments. Such a selection is done under the responsibility of the OIML Issuing Authority.	Not agreed. See 0055.
0056 SI		7.3.3		te	Since Sections 7.3.1 and 7.3.2 are not applicable then also 7.3.3 is not applicable.	Add guidance: G.7.3.3-1 Not applicable.	Agreed.
0057 CA		7.4.1		GE	This recommendation needs clarification.		No proposal for clarification provided.
0058 BR		7.4.4-1					No comment or proposed change provided.
0059 BR		7.5		ge	The guidance is given in 8.4.2.	Include: See 8.4.2	Not agreed. Guidance in 8.4.2 relates to retention period and has been deleted – see 0093.
0060 JP9		7.6.2	G.7.6.2-1 (new guidance)	te	Since internal calibrations of the test equipment may be conducted, there needs to be an OIML guidance here.	Add the following guidance. *G.7.6.2-1 If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the laboratory should refer to the applicable international standards (such as ISO and IEC) or other internationally established methods and practices.*	Agreed.
0061 AU		7.6.3	G.7.6.3-3	ge	We agree with the principle of this requirement. However since this is D 30, responsibility for compliance should be placed on the TL, not the IA. There should be a corresponding clause placed into OIML D 32, placing relevant responsibility on the IA to provide the guidance.	We suggest modifying the clause as follows: "If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the OIML TL is responsibility for requesting guidance from the IA."	See 0063.
0062 BR		7.6.3-3		te	The OIML-CS system aims to uniform interpretation and implementation of	Broader discussion among members.	See 0063.

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					legal metrological requirements for measuring instruments as well as to establish rules and procedures for fostering mutual confidence among participants. OIML should provide general guidance for OIML National Issuing Authorities on how to take measurement uncertainties into account, when not specified in OIML Recommendations. Individual guidance for OIML Issuing Authorities may diverge from one country to another. A broader discussion shall be taken into account.		
0063 JP10		7.6.3	G.7.6.3-3	te	In the current text, an Issuing Authority is responsible for providing a guidance regarding uncertainty. However, it is more appropriate to refer to the international standards or other internationally established methods and practices.	Substitute to the entire guidance with the following text. *G.7.6.3-3 If the relevant OIML Recommendation does not address how to take measurement uncertainty into account, the laboratory should refer to international standards (such as ISO and IEC) or other internationally established methods and practices.*	Agreed.
0064 JP11		7.7.2	G.7.7.2-1	ed	The present statement is not clear whether this guidance is compulsory or optional. Therefore, "shall" should be replaced with "may", and "if necessary" should be deleted.	Substitute the entire clause with the following sentence. *G.7.7.2-1 This <u>may</u> include participation in inter-laboratory comparisons organized by the BIML.*	Agreed.
0065 JP12		7.7.2	G.7.7.2-2 (new guidance)	te	To avoid an excessive requirement to the accreditation body regarding proficiency testing and/or inter-laboratory comparisons, a new guidance should be added.	Add the following new guidance. *G.7.7.2-2 If the following two conditions are fulfilled, they could be alternatives to the participation to proficiency tests or inter-laboratory comparisons:* *(1) There is sufficient evidence for the requirement of Clause 7.7.1 of ISO/IEC 17025:2017, and* *(2) The technical procedures and competence of the Testing Laboratory are confirmed by the Legal Metrology Expert according to the applicable OIML Recommendation.*	Not agreed. The Guidance G.7.7.2-1 specifies "may" – see 0064.
0066 UK		7.8.1	G.7.8.1.2-2	ed	In the last bulletin, the text "complementary type approval process" is not clear.	Propose changing to "compatible and interrelated type approval process"	Agreed.
0067 SI		7.8.1.2	G.7.8.1.2-2	te	It not clear what is "a complementary type approval process".	/	See 0067.

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0068 SI		7.8.2.1	G.7.8.2.1-3	te	Is it correctly written that test reports issued under the OIML-CS shall not bear the OIML-CS logo. Section 4.5.3 of OIML-CS PD-05 states: The OIML-CS logo shall be affixed on the OIML type evaluation report.	Replace existing text with the following: Test reports issued under the OIML-CS shall bear the OIML-CS logo.	Not agreed. See 0069.
0069 UK		7.8.2.1	G.7.8.2.1-3	ed	"Test reports issued under the OIML-CS shall not bear the OIML-CS logo" is not in line with 4.4.5 of OIML-CS PD-05: "The OIML test report shall … not bear any **OIML or OIML-CS logo**"	Propose to align by changing to "Test reports issued under the OIML-CS shall not bear any OIML or OIML-CS logo"	Agreed.
0070 JP13		7.8.3.1	G.7.8.3.1-1 2nd sentence	te	The second sentence cited below may cause a misunderstanding. *Statements of conformity related to the conformance of the instrument with the relevant OIML Recommendation are not allowed in OIML test reports.*	Consider rewording as follows. *Statements of conformity assessment of the type evaluation based on ISO/IEC 17065 and the relevant OIML Recommendation are not allowed in OIML test reports.*	Not agreed. "statements of conformity" is used in ISO/IEC 17025:2017.
0071 SI		7.8.3.1	G.7.8.3.1-1	te	OIML tests report templates foreseen that each completed test is marked as "passed"/"failed". Is this treated as "statement of conformity"?	Amend G.7.8.3.1 with a note, which will allow "passed"/"failed" partial decisions.	Not agreed. "Passed" / "Failed" should be removed from OIML test report templates.
0072 SI		7.8.3.2	G.7.8.3.1	te	Selection of instruments to be tested amongst a family is not sampling as it is understand by ISO 17025.	Replace existing text with the following: Not applicable.	Not agreed. See 0073.
0073 AU		7.8.3.2	G.7.8.3.2-1	ge	In practice, the IA may not physically provide the samples.	Suggest modifying as follows: "Under the OIML-CS the OIML IA is responsible for providing or endorsing the sample(s)."	Agreed.
0074 SI		7.8.5	G.7.8.5	te	Selection of instruments to be tested amongst a family is not sampling as it is understand by ISO 17025.	Replace existing text with the following: Not applicable.	Agreed.
0075 JP14		7.8.6.1	G.7.8.6.1-1	te	Clause 7.8.6.1 of ISO/IEC 17025 is understood as a requirement for documentation regarding the decision rule applied to the conformity assessment. In OIML-CS however, the documentation is unnecessary, and it may be replaced with a statement based on the applicable OIML Recommendation.	Replace the present text with the following guidance. *G.7.8.6.1-1 Reference to the applicable OIML Recommendation should be stated in the test report as the documentation for the conformity assessment.*	Not agreed. See 7.8.3.1.
0076 JP15		7.8.6.2	G.7.8.6.2-1	te	Clause 7.8.6.2 of ISO/IEC 17025 is understood as a requirement for providing a statement of conformity. In OIML-CS however, the Testing Laboratory may follow the procedure of the applicable OIML Recommendation.	Replace the present guidance with the following text. *G.7.8.6.2-1 The Testing Laboratories in OIML-CS should follow the procedure with a test report format specified in the applicable OIML Recommendation.*	Not agreed. See 7.8.3.1.

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0077 BR		7.9.2		te	For the purpose of OIML CS, complaints may come from different countries from where the test laboratories are.	For OIML CS purpose, consider that the laboratory shall be available for complaints from other countries.	Not agreed. The location of the complainant does not require specific OIML Guidance.
0078 CA		7.9.5		GE	See comments for 4.2.2.1 – too general. Needs a clause that notification is only necessary if it relates to anything related to the technical work. A complaint such as "you didn't respect your service standards" is not worth reporting to the issuing authority.		Agreed. Added "technical".
0079 DE		7.9.5	G.7.9.5	Ed	The guidance should be numbered G.7.9.5	Change number to "G.7.9.5"	Changed to G.7.9.5-1.
0080 DE		7.9.5	G.7.9.5	Te	The information gathered with the complaint might be considered confidential. To avoid a conflict with ISO/IEC 17025 No. 4.2.1, we propose to add a reference.	Add "The provisions of ISO/IEC 17025 No. 4.2.1 have to be observed".	Agreed.
0081 CA		7.9.7		GE	see 7.9.5		Agreed. Added "technical".
0082 DE		7.9.7	G.7.9.7	Ed	The guidance should be numbered G.7.9.7	Change number to "G.7.9.7"	Changed to G.7.9.7-1.
0083 DE		7.9.7	G.7.9.7	Te	The information gathered with the complaint might be considered confidential. To avoid a conflict with ISO/IEC 17025 No. 4.2.1, we propose to add a reference.	Add "The provisions of ISO/IEC 17025 No. 4.2.1 have to be observed".	Agreed.
0084 UK		7.9.7	G.7.9.7	ed	For consistency, G.7.9.7 should be numbered G.7.9.7-1	Proposal is to change G.7.9.7 to "G.7.9.7-1"	Agreed.
0085 DE		7.10.1	G.7.10.1	Ed	The guidance should be numbered G.7.10.1	Change number to "G.7.10.1"	Changed to G.7.10.1-1.
0086 JP16		8.1.3	G.8.1.3-2 (new guidance)	te	Requirement for an evidence to the conformity with ISO 9001 does not exists in OIML-CS which is necessary when Option B (8.1.3 of ISO/IEC 17025:2017) is selected.	Add the following guidance. *G.8.1.3-2 When the option B of the ISO/IEC 17025:2017 is selected, the Testing Laboratory should also submit evidences, such as a copy of the certification, as the evidence for fulfilment of the requirements of the ISO 9001 upon the review under OIML-CS. This evidence should also prove that the scope of ISO 9001 covers all activities of the Testing Laboratory.*	Not agreed. The OIML-CS requires compliance with all relevant parts of ISO/IEC 17025. Evidence of compliance with ISO 9001, e.g. ISO 9001 certiifcation, is not required under the OIML-CS.

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0087 DE		8.2.1	G.8.2.1	Te	The guidance refers to relevant documents which need to be controlled. Therefore, we propose to move the information to G.8.3.1 which deals with document control.	Delete G.8.2.1 (and amend G.8.3.1, see below)	Agreed.
0088 JP17		8.2.1	G.8.2.1-1	te	This guidance does not adequately match the Clause 8.2.1 of the ISO/IEC 17025:2017. This clause applies to the documentation for policies and objectives for implementing the ISO/IEC 17025. However, the contents of G.8.2.1-1 have no relations to the policies and objectives. Therefore, it is not appropriate to place this guidance here, and it should be transferred to the appropriate clause.	Move this guidance to Clause 8.2.4.	Partially agreed. See 0087.
0089 DE		8.2.4	G.8.2.4	Te	The requirements seem to be addressed to the OIML Issuing Authority. This might lead to confusion when applied to testing laboratories. Therefore we propose to delete the guidance.	Delete G.8.2.4	Partially agreed. The TL shall establish procedures associated with its participation in the OIML-CS. Wording amended.
0090 JP18		8.2.4	G.8.2.4-1	Te/ed	The meanings of "mutual acceptance" and "recognition agreement" are not clear.	We propose an amendment of the 1st sentence below assuming we understand correctly. *The Testing Laboratory does not have to assess, record and monitor by itself the participants in ~~a mutual acceptance or recognition agreement or arrangement~~ OIML-CS, but:*	Partially agreed. See 0089.
0091 SI		8.2.4	G.8.2.4-1	te	Not sure if G.8.2.4-1 applicable for the testing laboratory.	/	See 0089.
0092 DE		8.3.1	G.8.3.1	Te	The guidance to ISO/IEC 17025 No. 8.3.1 should be amended by further information taken from G.8.2.1 and adapted to the wording of G.8.2.1. The term "certification activity" from G.8.2.1 must be changed to "testing activity".	Replace "The testing laboratory shall maintain updated documentation on the legal and contractual requirements applicable to its activity of evaluation testing and examinations (e.g. OIML Recommendations). This applies in particular to the documentation on procedures mentioned in 8.2.4, which shall be appropriately updated and available" By "The testing laboratory shall maintain updated documentation on:	Agreed.

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						• the legal and contractual requirements applicable to its activity as a testing laboratory for an OIML Issuing Authority; • the requirements applicable to the measuring instruments by reference to which the testing and examination is carried out (e.g. OIML Recommendation R xxx, national regulation no. yyy); • any relevant general or technical standard pertaining to its testing activity. • the documentation on procedures mentioned in 8.2.4”	
0093 DE		8.4.2	G.8.4.2	Te	It is not the responsibility of the test laboratory to check whether OIML Certificates are still registered or not. If the availability of test results is questioned, it is the OIML Issuing Authority which is responsible for keeping test reports as long as the OIML certificate is registered.	Delete G.8.4.2	Agreed.
0094 AU		8.6.2	G.8.6.2-1	ge	This may create confusion as the manufacture is the traditional customer. However we agree the IA does have a special role to play in the process.	We suggest modifying as follows: “Under the OIML-CS, the OIML IA is considered to be a customer, in addition to the manufacturer, for the purposes of this clause.”	Partially agreed. Wording amended.
0095 JP19		8.6.2	G.8.6.2-1	Te/ed	Following our comment JP1, we request changes of the expression of this clause.	We propose replacing this guidance with the following text. *G.8.6.2-1 The “customer” in this clause covers both direct and indirect customers. In this International Document, the OIML Issuing Authority is the direct customer. When feedback from an indirect customer is received through their direct customer, the Testing Laboratory should also take it into account.*	See 0094.
0096 BR		8.7.1		te	Nonconformities that may affect an OIML Certificate shall be informed to the OIML Issuing Authority	The actions shall include informing the OIML Issuing Authority when the nonconformity affects the results of a test whose results were used to issue an OIML Certificate.	Agreed.
0097 DE		8.8.2	G.8.8.2	Te	The guidance reads “…the internal audit programme shall take into consideration the requirements of OIML-CS Procedural Document PD-03 and…” PD-03 deals with the approval of OIML Issuing Authorities, Utilizers and Associates.	Depending on the intention of the guidance: Delete “the requirements of OIML-CS Procedural Document PD-03 and” Or: add the specific requirement from PD-03 which is meant	Agreed. Text deleted.

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					If the guidance is only related to a certain interval that is needed, the second half of the sentence (…the requirement for the associated OIML Issuing Authority to report annually to the OIML-CS Management Committee") would be sufficient and the first half should be deleted. Or is there a particular requirement in PD-03 that has to be taken into account? Then we would prefer adding this requirement to the guidance.		
0098 DE		8.9.1	G.8.9.1	Te	ISO/IEC 17025 No. 8.9.1 deals with the intervals of the management review. Therefore, we believe a reference to the requirement for OIML Issuing Authorities to report annually is sufficient. The reference to PD-03 is too general and is no guidance.	Delete "the requirements of OIML-CS Procedural Document PD-03 and"	Agreed.
0099 DE		8.9.2	G.8.9.2	Te	We do not think this guidance is necessary. An assessment is regarded to be external when the external OIML issuing authority performed it. This seems to be self-evident, therefore we propose to delete this guidance.	Delete G.8.9.2	Agreed.
0100 UK		8.9.2	G.8.9.2-1	ed	Superfluous and possibly self-evident information. "… Audits performed on Testing Laboratories by the **external** OIML Issuing Authority are considered as **assessments by external bodies** and their results …"	Delete G.8.9.2-1	See 0099.
0101 DE		8.9.3	G.8.9.3	Te	This general requirement is very extensive, and we see a possible conflict with 4.2. We propose either deleting the guidance or at least limiting the reporting to issues relating to OIML work.	Replace "The outputs from management reviews related to management requirements and metrological and technical requirements shall be submitted to the OIML Issuing Authority" By "… shall be submitted to the OIML Issuing Authority as far as OIML activities are concerned"	Agreed.

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