

Template for comments and convener's observations

Date:2025-12-05

Document: CEEMS_P2_N012

Project: CEEMS/p 2

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 NL					I Understand that Models A and B are combined, and that Module C is outside the scope as it is related to registration and not type approval. But It would be a pity if we lose this information and option.	Move the content of Module C to an Annex and refer from to the annex with a sentence in line with our comment.	Agreed. Text of Model C from 1WD has been included as a new Annex A, with a reference to the Annex included in a new 1.1.4.
0002 US		1.1.1		ed	Capitalization of "Government administrations" and "Type Approval Control Systems" leads to confusion about the formality or specific subjects indicated by the terms. Furthermore, two alternate "shorthand" terms that are used subsequently for Type Approval Control systems creates unnecessary inconsistency. Natural meanings of "type approval control systems" and "type approval controls" could imply two distinct subjects when a reader encounters them elsewhere, especially given that no formal definition is provided for "Type Approval Control Systems"	"i. officials in government administration" ". . . policy makers are responsible for designing and developing type approval control systems." (hereinafter referred to as "type approval control systems or "type approval controls) Suggest to use "type approval control system" consistently throughout the document, rather than also providing the redundant alternative "type approval control," except for any instances where the latter is intended to have a distinct meaning.	Agreed.
0003 JP		1.1.1	iii	ed	After iii., add the following line of text. We consider that it's correct not to add a line break.	Change it to one sentence like this: iii legal metrology officials concerned with conformity assessment (including testing and type approval) of measuring instruments.	Agreed.
0004 US		1.1.2		ed		"Because of its general nature, this International Document has applicability across a broad range of fields, including several that facilitate trade, environmental protection, and healthcare."	Agreed, although proposed text has been modified slightly.
0005 US		1.1.2		ed	Revise: "This will assist industry by guaranteeing the quality of the products being sold" – This is language might be an overstatement.	"This information is provided to help industries ensure product quality, consumer safety, and fair commercial practices."	Agreed, although proposed text has been modified.
0006 US		1.1.3		ed	Revise: "This Document should be capable of being used for the type approval of all measuring instruments that are controlled for legal metrology purposes."	"This Document is intended for use in the type approval of all measuring instruments subject to legal metrological control."	Agreed.
0007 UK		1.2, 2.5, 2.8, 2.9, 4.1.1, 4.3.2, A.2, A.7		ed	"instrument", "measuring instrument", and "instrument type" are mentioned throughout the document.	For consistency, harmonise the terms where possible. A terminology for "measuring instrument" will provide clarity and be useful for translation purposes. Adopt the definition from the VIML 2022E,	Agreed.

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						<p>0.10 measuring instrument device used for making measurements, alone or in conjunction with one or more supplementary devices Note 1 A measuring instrument that can be used alone is a measuring system. Note 2 A measuring instrument may be an indicating measuring instrument or a material measure</p> <p>Or from the VIM 2012E,</p> <p>3.1 measuring instrument device used for making measurements, alone or in conjunction with one or more supplementary devices</p> <p>NOTE 1 A measuring instrument that can be used alone is a measuring system. NOTE 2 A measuring instrument may be an indicating measuring instrument or a material measure.</p>	
0008 US		1.2.3		ed, te	Revise: "It is only economically viable to test a small number of instruments in this way, most usually the "type" which will form the basis for approval.	"Only a small number of instruments can be tested to this degree while maintaining economic viability. A limited number are tested as exemplars of the "type" of instrument for which approval is being considered."	Agreed.
0009 JP		1.2.3	3 rd sentence	te	We consider that, like the verification in 1.2.2, type approval does not give assurance that the instruments will work satisfactorily over its working lifetime.	<p>Delete "This gives greater assurance that the instrument will work satisfactorily over its working lifetime."</p> <p>Also, delete "however," from the fourth sentence.</p> <p>Change the fourth sentence as follows:</p> <p>It has to be accompanied, by additional checks so that legal metrology authorities can be satisfied that all instruments of that type are satisfactory.</p>	Partially agreed.

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0010 US		1.2.4		te	A reader might want mention of more specific information regarding: "Moreover, the data gathered during both the initial and subsequent verification of a larger number of copies of a given type will, when systematically analysed, often yield information not available from type evaluation."	Perhaps it would be helpful to the reader to provide some summary examples of the kinds of data that verifications can provide that later result in changes to the type approval.	Noted. It would be useful to have some examples submitted.
0011 US		1.2.5		ed	Revise: "Second, the type evaluation and type approval stages may themselves identify matters which verification officers should look out for and will inform decisions on matters such as reverification periods."	"Second, matters identified during the type evaluation and type approval stages might provide verification officers with information that is helpful for subsequent evaluations of instruments of that type, e.g., appropriate reverification periods."	Agreed.
0012 US		1.2.6		ed	Revise: "1.2.6 A companion International OIML Document D 20, "Initial and Subsequent Verification" [2] is also available; it may prove to be useful when an appropriate balance between type evaluation and type approval and initial verification is being considered."	"1.2.6 A companion International OIML Document D 20 may be used in planning fit-for-purpose testing schemes that balance efforts for type evaluation, type approval, and initial verification processes."	Partially agreed.
0013 CA		02	2 Terms and definitions	ed	The numbering of subsections 2.x is mistaken. E.g. 2.3 and 2.6 are missing, and 2.4 and 2.5 are repeated twice. See also 2.14, 2.15, 2.20 etc...	Renumber subsections correctly.	Agreed.
0014 JP		2.4	Note	ed	Make it consistent with Note in 2.1.	- Revise the ISO/IEC 17000 edition in 2020. - Delete "following review." Change it as follows: Note: ISO/IEC 17000:2020 defines "attestation" as "issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated".	Agreed.
0015 JP		2.5	Note	te	In the second sentence, does "different class" mean different kind? If it refers to different accuracy class, shouldn't it be limited to "same or lower accuracy class of variants"?	Replace "different class" with "same or different accuracy class of variants."	Note deleted as use of the term "class" in this context is confusing.

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0016 US		2.7		te	<p>According to the definition, an evaluation is a judgment based on the outcome of testing.</p> <p>Are these outcomes of testing only, or are other outcomes also taken into account?</p> <p>Does a check (on the instrument) of an instrument's functionalities fall under evaluation?</p> <p>See also US1</p>	<p>Add clarification either in 2.21 or 2.7, where checks of an instrument's functionality (that may include small tests, whether or not according to a procedure) fall under.</p> <p>Note: These checks are performed on a test sample of the instrument.</p>	<p>Definition deleted as the term "type evaluation" is used throughout the document, and there is a dictionary definition of "evaluation".</p>
0017 CA		2.14	02.14 legal metrology authority	ge	<p>The definition includes "public" bodies only. However, I believe there are private bodies authorized by law on a national level. If that is the case, please consider the proposed change.</p>	<p>Consider replacing with "public (Government or local Government) or private body authorised by law on a national level to be responsible for legal metrological supervision as a whole or in part"</p>	<p>Agreed.</p>
0018 CA		2.16	02.16	ge	<p>Link the definition of "national issuing authority" back to 2.14 "legal metrology authority". Clearly state that these may or may not be the same... or state that they are the same, whichever is intended.</p>	<p>I am not sure which is the intended linkage, so I do not know what to suggest.</p>	<p>Not agreed. They are two separate terms.</p>
0019 UK		2.16, 2.23, A.2, A.3, etc			<p>"modules" is mentioned throughout the document.</p>	<p>A terminology for "module" will provide clarity and be useful for translation purposes.</p> <p>Adopt the definition from the VIML 2022E,</p> <p>4.04 module identifiable part of a measuring instrument or of a family of measuring instruments that performs a specific function or functions and that can be separately evaluated according to prescribed metrological and technical performance requirements as specified in the relevant Recommendation</p> <p>Example Typical modules of a weighing instrument are: weighing module, load cell, indicator, analog or digital data processing device, terminal, primary display</p>	<p>Agreed.</p>

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0020 US1		2.21		te	<p>According to the definition, testing is the determination of characteristics according to a procedure. This implies that there should always be a procedure.</p> <p>What about observations that are not done according to a procedure? Does a check (on the instrument) of an instrument's functionalities fall under testing?</p> <p>See also US2</p>	<p>Add clarification either in 2.21 or 2.7, where checks of an instrument's functionality (that may include small tests, whether or not according to a procedure) fall under. Note: These checks are performed on a test sample of the instrument.</p>	Definition taken from the VIML.
0021 CA		2.23		ge	<p>Definition of "Module" is not clear</p> <p>MC Contributor: FS</p>	Describe what a module constitutes in terms of a measuring device, e.g. where it merits a standalone type approval.	Definition of "module" has been added – see 0019.
0022 UK		2.23, 2.5, 3.1.1, 3.1.2,		ed	"model", "definitive model", "model regulations", and "subject model" are mentioned throughout the document.	For consistency, a definition of the different "models" might be useful.	Partially agreed. Text added to 3.1.1 and 3.1.2 to clarify that it is a "model of an instrument".
0023 CA		3.1		ed	<p>The approving official (decision maker) will often not be the official(s)</p> <p>Reference is made to an approving official</p>	A definition for an approving official should be provided.	Partially agreed. Deleted "approving" and changed the text to "official making the type approval decision".
0024 CA		3.1.2		ed	<p>It conveys to the users of these instruments and to verification officials that the model or range conforms to legal requirements and is adequate for use in approved applications.</p> <p>The scope of this document presumably is about approval of type and does not necessarily include any approvals related to a device's suitability for use in specific or "approved" applications.</p>	<p>Suggest the following: It conveys to the users of these instruments and to verification officials that the model or range conforms to legal requirements and is adequate for use in approved applications.</p>	Agreed.
0025 US		3.1.3		ed	Revise: "3.1.3 Because many variables, conditions, and limitations bear on the manner of type evaluation, it becomes necessary to choose between available alternatives and to plan type evaluations to accommodate the particular cases at hand."	"Many variables, conditions, and limitations bear on type evaluation. These factors should dictate the planning and selection of suitable testing methods for each particular case."	Partially agreed. Proposed wording has been adapted.

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0026 CA		3.2		ge	There is a gap between verification only and type approval category of devices. There are devices that are not approved, but still need regular calibration, monitoring, sealing, etc. To perform accurately. This should be clarified.	Define whether periodic calibration, sealing and monitoring would be classified as "requires type approval" or not, e.g. for electronic thermometers.	Not agreed. The current text makes it clear that instruments that do not require type approval will still undergo verification.
0027 US		3.3		ed	Revise: "It ensures that obligations under the World Trade Organisation's Technical Barriers to Trade Agreement are complied with.	"It ensures compliance with the obligations set forth in the World Trade Organisation's Technical Barriers to Trade Agreement."	Agreed.
0028 US		3.4		ed	Revise: "In the case of other countries where there may be limited resources, they will need to consider making partial or full use of evidence of third-party conformity assessment"	"Countries with more limited resources should consider making full or partial use of findings provided through third-party conformity assessments."	Agreed.
0029 CA		3.4.1	03.4.1	ge	<p>"Some countries have the capability to carry out the complete type evaluation and approval process, at least for some instruments, using their own facilities and staff. In the case of other countries where there may be limited resources, they will need to consider making partial or full use of evidence of third-party conformity assessment".</p> <p>It is worth mentioning explicitly that witness testing at other facilities is also an option. Right now, with the addition of "using their own facilities and staff", witness testing is not explicit and therefore less likely to be considered. Previously, before the added text in 1CD, witness testing would have been implicit at least. Now it is not even an option at all. By making that option considered, it provides a middle ground to being able to test things themselves or relying on others.</p>	<p>Proposed addition to final sentence in >>> <<<:</p> <p>"In the case of other countries where there may be limited resources, they will need to consider making partial or full use of evidence of third-party conformity assessment >>>or make use of witness testing performed by the country's staff at a third party facility<<<."</p>	Agreed.
0030 US		3.4.2		ed	"The three options can be summarised as follows"	"The three options for assessing compliance with instrument type requirements are summarized as follows:"	Agreed.
0031 CA		3.4.3	03.4.3	ge	<p>See comment on 3.4.1</p> <p>Because of the addition of "using their own facilities and staff, this no longer includes witness testing. Update this paragraph to also explicitly mention witness testing in addition to what is there.</p>	<p>Proposed addition in >>> <<<:</p> <p>"...and the partial or full use of evidence of third-party conformity assessment >>>or witness testing<<< is applied to other categories of instruments.</p>	Agreed.

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0032 CA		3.5.3			Instruments of a specific manufacturer which differ in measuring range and/or in scale intervals of measured ... This clause can be edited for clarity	Suggest the following: Instruments of a specific manufacturer which <u>otherwise are identical in design, materials, and major components, but only</u> differ in measuring range and/or in scale intervals of measured ...	Agreed.
0033 CA		3.5.4			It is not clear from the information presented as to who has the ultimate authority to determine if changes warrant a new type.	Suggest to add a statement to the following effect. It should be the responsibility of the evaluating body to assess differences either via a test or analysis to confirm that the devices can be maintained as similar types.	Partially agreed. National issuing authority added to introductory text in 3.5.
0034 US		3.5.4		ed	Revise: "An example is load platforms of weighing instruments and connectors at the input of electronic instruments."	"They also apply when different components are used as transducers between the measured quantity and the sensors of otherwise identical instruments, e.g., load platforms of weighing instruments and connectors at the input of electronic instruments."	Agreed.
0035 US		4.1.1.2		te	Unclear what is meant by "the expected timescales (service standards)" Is this inspection intervals? Service lifetime of the instrument?		Clarifications added.
0036 US		4.1.1.2		ed	"4.1.1.2 The requirements should also describe ..." It is easy to confuse the term "requirements" in this sentence with the technical requirement on the instrument.	"4.1.1.2 The <u>administrative</u> requirements should also describe ..."	Agreed.
0037 CA		4.1.3.2		ge	... drawn up... seems incorrect in the first sentence	Either ... draw up... or rephrase the sentence	Agreed. Changed to "draw up".
0038 US		4.1.5.1		ed	"4.1.5.1 The published documentation should describe ..." What is meant with "The published documentation"?	Explain 'published documentation' or use a different phrase	Agreed. Changed to "administrative arrangements".
0039 JP		4.2.4.2	2 nd sentence	ed	We propose that "national issuing authority" is appropriate than "approval authority."	Replace "approval authority" with "national issuing authority".	Agreed.
0040 JP		4.3.3.6	2 nd sentence	ge	Rather than using the vague phrase "in some cases," shouldn't the condition for obtaining the applicant's consent be clearly stated?	Replace "In some cases," with "Provided that the applicant's consent is obtained."	Agreed.

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0041 CA		4.4.2			Suggest to add additional criteria for establishing partial evaluations.	Suggest the following edit: A partial type evaluation is typically may be carried out when an already approved type has been modified such that after appropriate technical review and analysis of the modification, it is determined that only certain of its characteristics can be expected to have been affected by the modification, for example, when a new indicating device has been incorporated.	Agreed.
0042 CA		4.4.3		ed	Suggest to edit the last sentence for clarity.	Suggest the following updated wording: ... carried out to quickly establish either maintain confidence in the previous results or to establish determine which of the characteristics of a type may have been affected by its modification and require further review or testing .	Agreed.
0043 US		4.5		Ed, te	"4.5 Study of submitted documents: is awkward	"4.5 Sufficiency of submitted documents"	Partially agreed. Changed to "Examination of ...".
0044 US		4.6.4		ed	"The relevant OIML Recommendation will normally include test methods which prescribe test points." The clause does not mention if there is a possibility to deviate from the prescribed test points and under what conditions a deviation is justified.	Add an instruction about a possible deviation from the prescribed test points.	Partially agreed.
0045 US		4.7.3		ed	Revise: "It should identify the values of measured metrological characteristics and their uncertainties and instruments, devices and salient documents examined, personnel and laboratories that carried out the evaluation, provide a summary of tests carried out, and list any special procedures, standards, and equipment used in the process. It should contain important data, ambient conditions, and the time data where taken or it should identify the place where such data are stored. To the extent that findings are not based on measurement but on visual inspection, they should be as objective as possible in each instance."	"It should report the values of measured metrological characteristics and their uncertainties. It should identify the instruments, devices, and salient documents examined, as well as the personnel and laboratories that carried out the evaluation. A summary of tests carried out shall be provided along with any special procedures, standards, and equipment used in the process. It should contain important data regarding recorded ambient conditions and times, or it should identify the place where such data are stored. To the extent that findings are not based on measurement but on visual inspection, they should be as objective as possible."	Agreed, although proposed text adapted slightly.

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0046 US		4.8		ed	Revise: "On the basis that that the personnel carrying out the type evaluation process do not make the approval decisions, the report giving conclusions and recommendations should provide the basis for such a decision, for a definition of the type, and for the contents of a type approval certificate or rejection."	"[Because/given that/when/if] personnel carrying out the type evaluation process do not make approval decisions, the report should describe the basis for any conclusions or recommendations provided, the definition of the type, and the contents of the type approval certificate or rejection."	Agreed, although proposed text adapted slightly.
0047 US		4.8.2		te	The title is "Recommendation of the examiner(s)". However, the examination takes place before testing (according to definition 2.8). Since 4.8 is about the conclusion of the evaluation (after testing), the title should probably refer to the person performing the evaluation.	4.8.2. Recommendation of the evaluator(s)	Partially agreed.
0048 US		4.8.2		ed	The clause speaks about unqualified and qualified approvals. Is a qualified approval the same as a provisional approval as described in 4.10.2?	<ul style="list-style-type: none"> • approval; • provisional approval; • rejection; ... 	Agreed.
0049 CA		4.8.2	04.8.2 Recommend ation of the examiner(s)		The use of the terms "unqualified" and "qualified" is not clear in this context. Are the terms referring to the DUT, e.g. compliant vs non-compliant? In particular, the option "approval (unqualified)" requires clarification.	It is suggested to clarify the terms "unqualified" and "qualified" in this context, e.g. by elaborating, adding a note etc.	See response to 0048.
0050 US		4.8.3		ed	Revise: "Combinations of the above and, perhaps, of reference to certain components of the instrument that have been deposited can also be used to define the type."	"Combinations of the above, possibly also including references to certain components of the instrument that have been deposited, can also be used to define the type."	Agreed.

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0051 US		4.9.1		Ed, te	<p>"The type evaluation process that leads to the approval of a type, though generally carried out conscientiously, is based on a very small number of instruments and can generate only limited data."</p> <p>Unclear what is meant by "carried out conscientiously," or how this bears on the statement. Suggested edits for this paragraph are proposed.</p>	<p>"The type evaluation process that leads to the approval of a type is based on a very small number of instruments generates limited data. Therefore, even the best available judgment in granting type approval or setting the conditions of approval may result in decisions that later must be rescinded. For example, inaccurate judgements about the incidence of failure, the rate of deterioration of the copies of a type, or the verification intervals and procedures might not be recognized until more data is collected through subsequent examinations."</p>	Agreed.
0052 US		4.10		ed	Revise: "The approving official decides whether to issue a type approval certificate or a rejection notice and conveys the decision to the applicant as appropriate, together with other documents that may be relevant"	"The approving official decides whether to issue a type approval certificate or a rejection notice. That official then conveys the respective decision and any other relevant documents to the applicant."	Agreed, with adapted text.
0053 JP		4.10.2.2	1 st sentence	ed	We propose that "national issuing authority" is appropriate than "approval authority."	Replace "approval authority" with "national issuing authority".	Agreed.
0054 US		5.2.1	1 st bullet	ed	The list (and especially the word "official") is a bit confusing.	"identification of the application for type approval, applicant, manufacturer, and approving authority, and approving official, regulations complied with and jurisdiction(s) where approval is valid; specific instruments, components, and salient documents examined;"	Agreed.
0055 US		5.2.4.1	3 rd bullet	te	There should also be a reference to the clause in the OIML recommendation that has not been met.	<ul style="list-style-type: none"> characteristics and the values of their parameters found to be deficient as well as the corresponding acceptable values and the respective clause in the OIML recommendation; other conditions not fulfilled. 	Agreed.
0056 US		5.2.4.2		ed	Since D 19 makes a distinction between officials, the clause should mention which official is meant here.	5.2.4.2 When reasons for rejection are based on relatively small deficiencies or when deficiencies can be easily rectified, the notice may, at the option of the approval official, list changes in the type that would make it acceptable and, perhaps invite resubmission of the request after these changes have been made.	Agreed, with adapted text.
0057 CA		5.7		ge	Ownership is unclear in case of a "white label", where manufacturer is usually the applicant.	Define whether a "White Label" is allowed, i.e. where a manufacturer leaves the trademark blank on the type approval, so that the importers/distributors can be changed without needing to apply again?	Not agreed. A "white label" is not permitted.

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0058 UK		A.2, A.3		A.2, A.3	“legal metrological control” is mentioned in A.2 and A.3	<p>A terminology for “module” will provide clarity and be useful for translation purposes.</p> <p>Adopt the definition from the VIML 2022E,</p> <p>2.01 legal metrological control</p> <p>the whole of legal metrology activities</p> <p>Note Legal metrological control includes</p> <ul style="list-style-type: none"> • legal control of measuring instruments, • metrological supervision, • all the operations for the purpose of examining and demonstrating, e.g. to testify in a court of law, the condition of a measuring instrument and to determine its metrological properties, amongst others by reference to the relevant statutory requirements 	Agreed.
0059 DE					No comments, thank you for the drafting work		Noted.
0060 KR					No comments		Noted.

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