



<b>Collated comments on Committee Draft:</b>			
<b>2CD OIML Dxx:201x: Conformity to type (CTT) – Pre-market conformity assessment of measuring instruments</b>			
CD date:  2014-11-13	Circulation date:  2014-11-13	Closing date:  <b>2015-02-13</b>	
Convener: <b>New Zealand and the BIML</b>	<b>TC 3/SC 6/P 1/N020</b> <b>2015-03-27</b>		

Country Code	Clause/paragraph/table	gen./edit./techn.	COMMENTS	PROPOSED CHANGE	OBSERVATIONS OF THE CONVENER on each comment submitted
AU	-	Gen.	<p>We do not think that the document is ready yet for a vote which is the reason for our no vote. We believe that the intent of the document should be to provide guidance to OIML member states regarding the establishment of a regional or national CTT system. In a similar way to the scope and intent of OMIL D 1, OIML D 5, OIML D 8, etc.</p> <p>As such, we would like to propose that the structure of the document be reviewed in order to focus on advice and guidance from a legal metrological perspective about the design and operation of a CTT system, including how it can link/interact with other regional/national CTT systems.</p> <p>Below, we would refer to some of our previous comments and added others for consideration.</p>		<b>Noted.</b>

Country Code	Clause/paragraph/table	gen./edit./techn.	COMMENTS	PROPOSED CHANGE	OBSERVATIONS OF THE CONVENER on each comment submitted
AU	Clause 3	Gen.	Clause 3 (Scope) should be moved to become Clause 1.	Clause 3 (Scope) should be moved to become Clause 1.	<b>OK.</b>
AU	Clauses 4 & 5	Gen.	Clauses 4 & 5 should either be deleted or moved to be informative annexes. Both clauses describe conformity systems which are not from a legal metrological perspective.	Clauses 4 & 5 should either be deleted or moved to be informative annexes.	<b>Clause 4 moved to (informative) annex 1. Clause 5 becomes a new informative annex.</b>
AU	Clauses 6 & 7	Gen.	We agree with Japan's previous comments and would strongly recommend that clauses 6 and 7 are expanded upon to provide greater details on how systems can be designed, what issues could arise, how National Authorities can address these and minimise associated risk. Specific instrument related examples may be useful.	We would strongly recommend that clauses 6 and 7 are expanded. It is recognised that this would require a significant amount of work. Consideration could be given to how to manage such a workload, e.g. project groups for specific topics or clauses.	<b>Unfortunately, despite having requested text proposals, the conveners have not received any such proposals from the project group members.</b>
AU	-	Gen.	As an international organisation, providing greater recognition and coordination between the metrological systems of member states should always be an overarching goal. It is suggested that an additional clause be included addressing how CTT systems could be potentially linked and recognised between regions and nations. While the development of such mechanisms might be beyond the scope of this document and working group, this document could seek to identify common aspects and themes required for any national CTT program which could be recognised internationally. Future work could then elaborate upon these principles with the possible development of a "CTT MAA" being a potential future goal.	It is suggested that an additional clause be included addressing how CTT systems could be potentially linked and recognised between regions and nations.	<b>From the discussions at the 46<sup>th</sup> CIML Meeting (Prague, 2011), when the CIML approved the current project (Resolution no. 22) it is clear that the scope of the project is to identify current best practices in conformity to type.</b>
AU	-	Gen.	It is recognised that the comments above (and supplied previously) would require a significant amount of work in redrafting the document. Consideration could be given to how to manage such a workload, e.g. project groups for specific topics or clauses.		<b>The conveners consider to submit to the CIML a proposal for a follow-up project</b>

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CECIP	Scope		The sense of this document is not clear enough. Is it thought as a collection/listing of actually existing conformity assessment procedures in the world just for information? What is the intention? The answers can help to identify chances and consequences.	Clarification	<b>The intention of the document is to provide considerations for and present current best practices in conformity to type in legal metrology.</b>
CECIP	6. Considerations for a CTT program		In this chapter there are several possibilities listed which refer to the European system like B+F and H1. We miss here B+D where the production of the manufacturer is under supervision. This combination has high importance in the EU. That has to be very clear for all readers.	Integrate information and example to B+D	<b>OK.</b>
CECIP	Figure 1		The information in the box “Type evaluation” starts with “OIML certificate”. That may lead readers to wrong interpretation. To go via an OIML certificate will be for a long time period be only one possibility to get national or regional type approval certificate. Although this is an OIML document all conformity assessment procedures concerning production set up in a country have to be independent from the way how the certificate was issued. Going via OIML certificate shall not give additional requirements to manufacturers. Fair competition requires the same level of quality for production of the instruments.	Make a footnote that OIML Certificate is an alternative only.	<b>Agree with the comment. Note added to table 1 and a footnote to par. 3.2</b>
CECIP	Note following Figure 1		It is written: “..... may lead to the withdrawal of the certificate.” It is not clear for us which kind of certificate is meant. Certification of production, OIML certificate or type approval certificate.	Add kind of certificate.	<b>Agree. “type approval” inserted.</b>
CECIP	Annexes		We miss an Annex for modules B+D.	Add an Annex for B+D	<b>OK.</b>
UK	Table of Contents, 2	gen.	The document would benefit from an ‘Introduction’ section (to replace what is probably the current section 2) and a ‘Definitions’ section. The 2CD contains a number of definitions which are located throughout the document and these should be collated for ease of reference. Sections 4 and 5 are effectively examples of conformity assessment systems which should probably be put into an Annex.	Insert sections titled “Introduction” and insert contents from section 2  Insert section on “Definitions” and collate all definitions and terms into the new “Definition” section	<b>OK.</b>  <b>All definitions are now in par. 2.1</b>

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UK	3 Scope	gen.	It seems odd that the "scope" paragraph is in section 3 and in any case it is not clear to whom the document is addressed. It is assumed that it is addressed to policy makers in Member States (should they add CTT requirements in to their national legislation) or Regional groupings of Member States (arguably it is the EU which has taken the lead in introducing CTT). But is it also a document addressed to TC/SCs who might want to introduced elements of CTT in their Recommendations?	"Scope" should be moved to beginning of the document and populated with more clear and explicit information.	OK.
UK	1	tech.	"Market Surveillance" seems to be used mainly to describe all activities not concerned with Type Approval, Verification and Production-Stage CTT. However, the UNECE definition quoted in the footnote to the first paragraph seems to go a lot wider than this - since it refers to "[all] activities carried out and measures taken by designated authorities to ensure products comply with... legislation" that seems to me to include Type Approval, Verification and Production-Stage CTT activities. Moreover, in the EU context, "Market Surveillance" more usually refers to the inspection of products after they have been placed on the market and is conducted primarily by inspections or test purchases in the distribution chain. My understanding is that in the legal metrology context we tend to use "Market Surveillance" to mean primarily those activities and thus to exclude Inspection of equipment "in use".	It would be help to clarify "Market Surveillance" if the three different usages of "Market Surveillance" are explicitly defined before using the one opted for in the paper.	<b>Definitions for surveillance and market surveillance have been included in par. 2.1.</b> <b>An informative annex explaining the different uses of "surveillance" has been added.</b>

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UK	2, 4,6,etc.	gen.	VIML, NAWID, MID, etc. should be referenced to the Biography in Annex 6.	We proposed numbering the biography and linking the publications mentioned in the document to the biography in Annex 6, e.g  ISO/CASCO [2],  [VIML] [6], etc.	<b>OK.</b>
UK	2,4, 5, etc.	gen.	Some of the acronyms are defined within the paragraphs, e.g., NCBs, IECEE, CAC, CAR, etc., whilst some are not defined any where in the document, e.g., UNECE, ISO, OIML, VIML, etc.	For consistency, we proposed defining all acronyms within the paragraphs and linking publications, where appropriate, to the Biography	<b>A list of acronyms and initialisms is now included.</b>
UK	2	gen.	The OIML Mutual Acceptance Arrangement for measuring instruments (MAA) is mentioned but there's no additional information on the OIML MAA publication.	Suggest referencing the OIML MAA in the Biography:  "OIML Publication B 10 Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (Edition 2011)"	<b>OK.</b>
UK	Section 2, 3rd para:	edit.	<i>At verification [VIM, 2.44], each individual instrument from the production is then subjected to limited testing, typically at ambient temperature only, to verify whether the instrument performs within maximum permissible errors. Verification includes an assessment of the compliance of the design of the instrument with the approved type, as described in the type approval certificate, before it is put into use for regulated purposes.</i>	Amend sentence as proposed.	<b>Agreed.</b>

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UK	Section 2, 5th para, 1st bullet	edit.	<i>New technologies make it difficult and often impossible to verify with non-destructive testing whether hardware components in production instruments have the same function or the same specifications as those in the samples that were tested for type approval.</i> [Presumably this can be determined is you are prepared to dismantle the instrument]	Amend sentence as proposed.	<b>Disagree. Whether testing is destructive or non-destructive is, in this case, irrelevant.</b>
UK	2	tech.	The current section 2 contains some statements regarding how "... the system of type approval and verification worked quite well ..." and how "developments [in technology] call the reliability of the existing systems into question". Although not perfect, the conformity assessment systems adopted under the EU Directives work very well and have evolved to adapt to new technologies, etc. It is also worth considering that these systems apply to a wide range of instrument/equipment/device types, including those which pose a significant danger (e.g. pressure vessels), and are seen to, generally, be effective. The statement made that the current conformity assessment systems that are in place "... no longer provides sufficient assurance that verified instruments comply with all applicable requirements." Is therefore questionable. The three bullet points relating to Australia, if retained, should be put into context or provided with an explanation.	Amend section 2 to clarify the statements.	<b>The text does not say that the current conformity assessment systems that are in place no longer provide sufficient assurance that verified instruments comply with all applicable requirements. The text refers only to the traditional form of type approval followed by initial verification as no longer adequate. The main purpose of the document is, in fact, to present current conformity assessment systems that are considered adequate.</b>

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UK	5 Placing of the IEC Material	tech.	It is unclear as to why this appears as Section 5, ie before Sections 6 and 7 which are the core of the document. It would make more sense to place any description of the IEC systems after Section 8 "Examples of existing systems in the field of legal metrology", eg a new Section 9 [renumbered appropriately] "Examples of existing systems outside the field of legal metrology". It would also look more balanced if the model for the treatment of NTEP/VCAP and NAWI/MID were followed - ie a brief description in the new Section 9 and the rest of the Detail put into a new Annex.	Create a new Section 9 and relocate any description of the IEC systems into this section.	<b>The description of the IEC systems has been moved to an informative annex.</b>
UK	6	tech.	In the second paragraph of section 6, reference to 'placing on the market' and 'putting into use' is missing. Three different control systems (A, B and C) are also outlined but there is uncertainty about the concepts and structures proposed. The 'Design' stage for each system is generally acceptable. However, the 'Production' stage is an area that requires improvement.	Clarify the three different control systems and add a paragraph on "putting into use"	<b>Disagree. "Putting into use" (or "installation") is not considered as a relevant element in the context of CTT. "Placing on the market" is used in the text describing the three systems, but the concept does not include any conformity assessment activities; it is a concept of legal relevance.</b>
UK	Section 6, 1st para:	edit.	<b>If Conformity to type is to be adopted to address the issues identified in Section 2, it should function as</b> an integral part of legal metrological control [VIML, 2.01] for measuring instruments for which national legislation requires type evaluation [VIML, 2.04] and type approval [VIML, 2.05] before such instruments may be placed on the market.	Amend sentence as proposed.	<b>Text modified (now 3.1, first paragraph)</b>

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UK	Section 6, 2nd para:	edit.	<i>Legal metrological control systems may exist in different forms, i.e. consist of different conformity assessment procedures. Accordingly, Conformity to type may appear as a separate conformity assessment procedure, or be part of another conformity assessment procedure (initial verification, surveillance). It will, however, always be applied in the production phase. This is illustrated by considering three different legal metrological control systems: A, B and C (see Figure 1).</i>	Amend sentence as proposed.	<b>Agreed. (3.1, 3<sup>rd</sup> para. modified)</b>
UK	6, 4 <sup>th</sup> para:	edit.	For system A, CTT appears to have been mentioned as a separate activity to initial verification (“For those requirements for which compliance cannot be assessed during initial verification, the assessment of the conformity of the instrument with the approved type (i.e. conformity to type) should ensure that the instrument complies with those requirements;”) Modules B + F are provided as an example of this system but if they are separate activities, as described in the text, then this is not B + F (i.e. it is effectively B + ‘something’ + F). There is also no reference made to B + D which is an equivalent procedure to B + F.	Clarify the assessment procedure activities.	<b>These are spelled out in the annexes.</b>
UK	6	tech.	For system B, conformity to type is specified as a standalone activity but no information is provided as to what activities should be undertaken. Initial verification is then performed based on the CTT mark that would have been applied but this will require some form of Mutual Acceptance Arrangement to be in place to allow/enable the verification body to accept the CTT mark. How would this work in practice and how does it add value?	Add additional information on how system B would work in practice.	<b>That is difficult because, as stated in the text, we are not aware of any such system in operation.</b>
UK	6	tech.	For system C, reference is made to Annex H1 of the MID. However, Annex H1 also covers the ‘initial’ verification of the product. As the diagram is currently drawn it does not align with Annex H1 as CTT is not separate from initial verification as it is shown.	Amend the diagram to align with Annex H1.	<b>Disagree. Module H1 is presented as a variation of system C.</b>

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UK	6	tech.	The section: “Elements to be considered for inclusion in a CTT procedure” (page 8) may address some of the questions/issues raised above and some of the items listed could be beneficial, e.g. repeating some of the type approval tests.	Merge the section : “Elements to be considered for inclusion in a CTT procedure into page 8 content.	<b>Not sure what the comment is, but the section “Elements to be considered ...” is now a numbered subsection of “Considerations for a CTT program”</b>
UK	7	gen.	What is “RAPEX”? “RAPEX” is not defined anywhere in the document	Suggest defining the “RAPEX” in the paragraph where it is mentioned or in the Biography.	<b>OK.</b>
UK	8.1	edit.	It would be useful to define “NIST Handbook 44” in the Biography	Suggest referencing the NIST Handbook 44 in the Biography:  <i>“NIST Handbook 44 - 2015 (Current Edition) Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices”</i>	<b>OK.</b>
UK	Section 8, final para:	edit.	Other variations of the systems considered here may exist. For instance: verifications may be performed either by metrological authorities, or, under certain conditions, by the manufacturer or authorized private certification bodies. Such variations, however, <b>do</b> not affect the role of conformity to type.	Amend sentence as proposed.	<b>Agreed.</b>
UK	8.2	gen.	NAWID and MID are referenced in a footnote, and also listed in the Biography. Thus defining them twice in separate locations.	For consistency, we proposed defining these publications in one location only, namely the Biography in Annex 6.	<b>OK.</b>
UK	8.2	gen.	What is the “Blue Guide”? The “Blue Guide” is not defined anywhere in the document.	Suggest defining the “Blue Guide” in the Biography.	<b>OK.</b>
UK	8.2	gen.	“notified body” is mentioned in several parts in 8.2 but only defined further down the document in Annex 2, footnote 8.	Suggest either cross-referencing “notified body” in 8.2 to footnote 8 in Annex 2 or moving the footnote up to 8.2.	<b>OK. Footnote added.</b>
UK	8, Annex 2, footnote 8, Annex 5 footnote 10	gen.	“NAWI-directive”, NAWI Directive” and “NAWID” is mentioned in several parts of the document.	For consistency we suggest harmonising the definitions, preferably” NAWID” in line with “MID”	<b>OK.</b>
UK	Annex 4, Annex 5 footnote 10	gen.	“normative documents” is mentioned in several parts in Annex 4 but only defined further down the document in Annex 5, footnote 10.	Suggest either cross-referencing “normative documents” in Annex 4 to footnote 10 in Annex 5, or moving the footnote up to Annex 4.	<b>OK. Footnote now in annex 3.</b>
UK	Annex 3, 4, etc	edit.	The symbol “(…)” needs to be clarified.	Please clarify the “(…)”	<b>OK.</b>

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CZ	Annex 2	gen	Information about module D which is quite important in this context is missing.	To include information about module D of European conformity assessment system to Annex 2 or to create a new annex for it.	<b>OK.</b>
FR	TITLE OF THE CD (French)	edit	The translation of the title in French is not correct	Conformité au type (CTT) – Evaluation de la conformité des instruments avant mise sur le marché  Description des activités de surveillance avant la mise sur le marché, centrées sur l'évaluation de la conformité des instruments de mesure afin d'assurer la conformité des instruments fabriqués (ou leur production) au type qui a été certifié.	<b>Thank you.</b> <b>[amend French title on cover page]</b>
FR	2	gen	The situation described at the end of the second paragraph was probably valid 30 or 20 years ago but nowadays manufacturers have better developments tools, better organization with quality assurance and the way conformity assessment procedures are performed is not anymore as described due to more constraint on certification bodies. The fact that the instrument is representative of the production is a must and in addition the documentation to be provided play an important role.	Remove the statement or explain that the situation has improved a lot.	<b>Paragraph added (Introduction, final para.)</b>
FR	4 middle of the last para	edit	Replace ...that are traditionally. by that were traditionally		<b>OK.</b>
FR	5 para 11		It would be interesting to indicate in case instruments are taken from the market by whom the choice of the instrument taken is done (the manufacturer ? the distributors, the certification body? An independent body ?)	Indicate by whom it is done	<b>This text is from IEC and has now been moved to an annex. From the context it is reasonable to assume that the certification body selects the instruments in the sample.</b>

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FR	5 para 13		More information would be useful	<p>First par a in b) indicate the extent of the QMS and the scope of the evaluation (does it include the fact that only instrument in conformity to type and fulfilling all the requirements are delivered by the factory? Does the evaluation team include a specialized assessor in the technical field?)</p> <p>d) indicate the rule applicable to the sampling (is it foreseen that it is done at the occasion of unexpected visits of the factory ? is it done on stock or on the market ?)</p> <p>second para a ) inspection of what ? and by whom (NVB?) follow up of what ? same question</p>	<b>This information is available in IECEE documents. A note with a reference to the IECEE web site is added.</b>
FR	Point 6 description of systems	tech	<p>We are afraid the reference to European procedure B+F in system A is misleading</p> <p>In module F there is no verification mark in the old meaning of the mark of an initial verification</p> <p>One of the very important part of the system in the European procedures is the documentation. It is as much important as the testing of a sample and it should be mentioned</p> <p>In Europe the most frequently used procedure is B+D so we strongly recommend that it is included in the considerations. CTT in module D is not as described in one of the cases mentioned., in module D there is also surveillance)</p> <p>B (Type examination) + D (Declaration of conformity to type based on quality assurance of the production process)</p>	<p>Clarify about European B+F</p> <p>Include the association B+D in the description of the systems.</p>	<p><b>The legal meaning of the CE-marking plus supplementary metrology markings may not be the same as for the traditional verification mark, but, for the purpose of this document, the distinction is not so important.</b></p> <p><b>B+D is added.</b></p>

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FR	Point 6		Elements to be considered Bullet 4 : demonstrate doesn't seem to correct wording Isn't it to "declare the conformity" Bullet 5 : not clear what is meant : sealed by whom and with what identification ? with what kind of guarantee ? is also electronic sealing foreseen ? It seem to refer to a case A where an instrument is sent from a factory to the place of use ?		<b>Bullet 4: Changed to "declare".</b>  <b>Bullet 5: That should be left open, it could be either.</b>
FR	Point 7	tech	a) We agree but there is also a need for a guide on the documentation in the application file b) If a system is legal and responsibilities and duties well defined where is the problem ? We agree that sharing of information is a must		<b>Noted.</b>
JP	3. Scope	Gen.	We understand that the primary scope of this document is to provide informative references/examples for the member states which are developing a new CTT program. Based on this understanding, we support the 2CD to be approved and published as a new OIML Dxx.	No changes are proposed.	<b>Thank you.</b>
JP	4 (ISO / CASCO) and 5 (IEC)	Gen.	We still consider that the example of other organizations should not be included in the main text. However, we accept the explanation by the secretariat to our comments on 1CD in connection with the primary scope of this document.	No changes are proposed.	<b>Noted.</b>
JP	6 and Figure 1	Gen.	The three systems A, B and C are based on regional systems such as NTEP/VCAP and MID/NAWID. We acknowledge that these systems are useful examples which have been implemented widely in the respective regions. However, there is a significantly wide variety of legal metrological control systems in the OIML member states particularly in verification systems. There are other different systems besides these three in the member states.	We propose to add the following note:  <i>The present document may be implemented with consideration for metrological control systems of member states.</i>	<b>The stated scope of the document would cover this.</b>
JP	6. Figure 1	Edit.	The title of Figure 1 is missing. The term 'system' in the main text is referred as 'stage' in the figure. It is difficult to distinguish the colours used in the figure in	An informative figure title should be added. The same term 'system' should be used in the figure and text. Use of a hatching or screen tone is recommended in replacement of the	<b>Figure title added.</b>  <b>Printing in grey scale works fine.</b>

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			a hardcopy in B/W.	colours.	