

Result of online voting and comments

TC 3/SC 6: Conformity to type

p 1: Premarket surveillance activities

PG vote and comment on 3CD Conformity to Type (CTT) – Pre-market conformity assessment of measuring instruments

Voted Yes: 10

Voted No: 1

Abstained: 1

Country	Action	Comment
AUSTRALIA	Voted No on 2018-06-08	
CANADA	Voted Yes on 2018-06-11	
FRANCE	Voted Yes on 2018-06-11	
GERMANY	Voted Yes on 2018-06-12	
INDIA	Voted Yes on 2018-05-23	
IRAN	Voted Yes on 2018-06-11	
JAPAN	Voted Yes on 2018-06-11	
NETHERLANDS	Voted Abstain on 2018-06-11	
NEW ZEALAND	Voted Yes on 2018-05-03	
POLAND	Commented on 2018-06-09	
SOUTH AFRICA	Voted Yes on 2018-06-11	
UNITED KINGDOM	Voted Yes on 2018-06-06	
UNITED STATES	Voted Yes on 2018-06-07	

Template for comments and convener's observations

Date:2018-07-13

Document: TC3_SC6_P1_N027

Project: TC 3/SC 6/p 1

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 AU-1				Ge	Australia fully supports the development of this Document. The implementation and harmonisation of CTT across OIML members is of great importance. However, we do not believe that the 3 Systems (A, B & C) currently described in this CD reflect how current and future CTT programs operate in Australia. Consequently Australia would not be harmonised with this Document if it is approved without amendment; as such, we are forced to vote "No". If AU-3 (below) is accepted and a new 'System D' included in the Document, we would be able to change our vote to "Yes".		See response to 0017 (AU-03).
0002 IR				Ge	We found this document useful, additional advantage is presenting the different models of CTT programs.		Noted.
0003 NL			general	ge	Due to circumstances at the moment we restrict to the comment that many of the comments yet provided by the P-members we support and will require some additional work on the draft. Maybe a next CD will need to be produced.		Decision taken to adopt major change procedure (B 6-1:2017, 6.2.4.6). 4CD issued for PG vote and comment.
0004 PL			General	Gen	We don't have technical comments. We found this document useful, additional advantage is presenting the different models of CTT programs in US and EU.		Noted
0005 DE			General	gen.	We principally agree with the draft document, but strongly recommend to consult with WELMEC WG 5 in order to make sure that OIML Dxx, especially Annex 7, is in line with the European approach as defined in several documents, such as the "Blue Guide" (EU_OJC_2016_272), the Guide "Good practice for market surveillance" (2017) from the AdCo_Group, the European Regulation on "Accreditation and Market Surveillance" (EU_765_2008), the WELMEC Guides 5.2 (2015) on Market Surveillance (NAWI, MID) and 5.3 on "Guide on Risk Assessment"		Wording in Annex 7 has been updated to align with the referenced documents.

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0006 DE			General	gen.	We would support a definition of "Market Surveillance" in the VIML, preferably also in dialogue with WELMEC WG 5. We also suggest to consider a revision of OIML D9 in order to include definitions for terms such as pre-market surveillance, post-marked surveillance, initial verification, market supervision, etc.		Noted. Proposals to be forwarded to relevant TC/SCs.
0007 FR		1	Introduction	ge	In general this chapter gives a very poor image about legal metrology controls whereas in many countries or regions since more than 25 years all this has been considered and dealt with. The ideal image of the old inspector being able to detect non conformities on mechanical instrument is a naïve picture	Even if we are in favour of the document we strongly believe the chapter should be rephrased in order not to give such a poor idea about the value of legal metrology certification and controls nowadays	Agreed. This clause has been rephrased.
0008 FR		1.2		ge	The sentence "The instruments submitted for type evaluation should be representative of the final production of the type of instrument, but very often they are still prototypes, or, at best, well prepared samples." seems to open the door to the use of sample that are not representative of the type of instrument or the use of golden samples. This chapter undermines the value certification. The time where prototypes were provided by manufacturer is over since many years. The question of the golden samples has been considerde by some countries or regions since many many years.	Proposed sentence: "The instruments submitted for type evaluation shall be representative of the final production of the type of instrument".	Agreed. Sentence has been changed.
0009 JP		1.2	Introduction 2 nd sentence	Gen./Edit.	The condition of sample instruments for type evaluation depends on the manufacturer, and some samples are very close to the final products. So, the expression "very often they are still prototypes..." may not be appropriate. Also, difference between "prototype" and "well prepared sample" is not clear, and it is not sure if the latter is better than the former.	We recommend changing the expression as shown below. <i>The instruments submitted for type evaluation should be representative of the final production of the type of instrument. but very often they are still prototypes, or, at best, well prepared samples. In practice however, some of them may be prototypes or well-prepared samples.</i>	See response to 0008.

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0010 FR		1.3		ge	Concerning the sentence "Verification also includes an assessment of the compliance of the design of the instrument with the approved type, as described in the type approval certificate", we believe that the compliance of the design of the instrument with the approved type is not only based on the type described in the certificate but also and mainly with the type described in the technical documentation.	Proposed sentence:"Verification also includes an assessment of the compliance of the design of the instrument with the approved type, as described in the type approval certificate and the technical documentation"	Agreed. The proposed wording has been adopted.
0011 FR		1.4			This is already dealt with in some mebers or regions this shouls be reflected in the document		Agreed. Wording has been amended.
0012 FR		1.5			A change of the software without breaking the seals or without traceability may be accepted only for non metrological parts To let people believe it is current is not OK It would mean that all manufaturers and certification bodies have not done their job properly		Agreed. Wording has been amended.
0013 JP		1.10	Introduction	Edit./Tech.	The problem of the three examples is a fact that the instrument <u>did not conform</u> to the approved type. A load cell without temperature compensation do not make a legal problem by itself. We therefore propose rephrasing of the 1 st sentence for better understanding.	We propose rephrasing the sentence as follows. <i>The problem as defined here has been illustrated by the following issues identified in an OIML Member State, where final products did not conform to the approved type:</i>	Agreed. Wording has been amended.
0014 AU-2		3.1.10		te	The definition should clarify whether it refers to an individual instrument or an approved type of instrument. We understand it should be with reference to an individual instrument.	Amend as "the first making available of an individual measuring instrument or pre-package on the market" Or add a clarifying Note to the definition such as: "In the context of this Document, this definition applies to individual instruments rather than an approved type of a measuring instrument." Or similar.	Agreed. A Note has been added.

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0015 JP		3.1.4	Definitions (note), 5 and Annex 7	Gen./edit.	Countries outside EU are generally not familiar with the term "market surveillance". The note of 3.1.4 mentions that (1) 'conformity assessment procedure of CTT' should not be confused with (2) 'market surveillance' which is typically applied in EU. The difference between (1) and (2) is however still not clear even after referring Annex 7. In addition, the item e) of Clause 5 mentions that market surveillance plays a complementary role to evaluate a CTT program. We request rephrasing the note to explain the difference more clearly.	Assuming we understand correctly, we propose the following revisions of Note to express the difference clearly (shown with underline and strike-through). <i>Note: The concept of CTT as considered in this document refers to a systematic procedure as a part of the pre-market conformity assessment procedure applicable to measuring instruments, which is often performed by issuing authorities or manufacturers. It should not be confused with 'market surveillance' after the products are placed on the market, which is often performed ad-hoc by public authorities based on risk assessment and market intelligence, e.g. user complaints. 'Market surveillance' is further discussed in Annex 7.</i>	Partially agreed. The Note has been amended to align with the modified wording in Annex 7.
0016 JP		3.1.X	(new)	Edit.	The term "CTT Program" is used frequently in this draft document, but it is not defined or explained.	Add a new clause defining "CTT program" as shown below for example. <i>3.1.X conformity to type (CTT) program Entity of a national or regional framework for implementing the concept of CTT.</i>	Agreed. A definition has been added at 3.1.5.
0017 AU-3		4		Ge	Traditionally, verification has included an assessment of compliance with the approved type. This is discussed in the introduction. This document maintains the expectation that CTT is part of, or must be performed prior to, verification. Each of the three described systems for CTT (A, B and C) involve CTT being performed prior to verification. In my view, the principles, of verification and CTT are very distinct. The aim of verification is to determine whether the individual instrument is operating accurately (within specified limits of error). The aim of CTT is to determine whether the instrument conforms to the approved type (i.e. influences and disturbances).	Add a new CTT System D. This would separate CTT and verification. This system could be illustrated in Figure 1 by placing initial verification and CTT in parallel in the production phase. The system could be described as follows: 4.2.5 System D 4.2.5.1 System D includes - Type evaluation and type approval, as in System A; - CTT as a separate conformity assessment procedure. The system may include the use of a conformity mark indicating participation in a CTT program. - Verification as a separate conformity assessment procedure. Here verification provides no evidence or assessment of CTT. - Conformity assessment procedures after placing on the market, as in Systems A, B and C.	Agreed. "System D" has been added.

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					It is suggested to amend clause 4 to recognise that CTT may be conducted independently of verification. This would provide greater flexibility for legal metrology bodies to develop CTT programs. This would primarily apply when CTT is performed by testing a sample of production instruments, as is the case in Australia.	4.2.5.2 This system allows for verification and CTT to be undertaken as independent activities. This system may be implemented with or without the use of a CTT conformity mark on instruments. Where there is no mark, conformity may be established through certificates or sharing of test results. Example: WSA 16 – 2013 Water Services Association of Australia (WSAA): <i>Water Meter Pattern Compliance and Data Sharing Code of Practice</i>	
0018 JP		4.1.1	Considerations for a CTT program	Edit.	“Verification” should be identified as “initial verification” for clarification.	Add “initial” before “verification” as shown below. <i>In order to address type approval followed by initial verification before</i>	Agreed.
0019 FR		4.1.2		te	The installation phase can for some measuring instrument categories be critical as the quality of the installation can impact the metrological performances. Therefore some countries regulate this installation.	Proposed sentence: “Legal metrological control systems may be considered as consisting of a sequence of conformity assessment procedures covering the various phases of the life cycle of measuring instruments: the design phase, the production phase, the installation phase, the distribution phase and the in-service phase”.	Partially agreed. Installation has been included after distribution.
0020 JP		4.1.2	Considerations for a CTT program	Gen./edit.	Timing of CTT should also be indicated in the life cycle of instruments for clarification (also see our comment to 3.1.4.).	We propose revising the last sentence as shown below (underlined). <i>It is during <u>the production phase when CTT takes place, and distribution phase when market surveillance typically takes place.</u></i>	Agreed.
0021 US		4.2	04.2.1; Figure 1; Annex 7	Ge	The US recognizes that this document is devoted to pre-market conformity to type (CTT) processes. Nevertheless, we recommend inserting some language that highlights the importance and effectiveness of market (field) surveillance and evaluation, as referenced in <i>Annex 7: The relationship with ‘market surveillance’</i> . This part of metrological control is also depicted in Figure 1 and would benefit by having some text to explain these processes.	Insert a new section (4.2.2):	Agreed.

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						Following installation of the measuring instrument and a period of service in the field, the legal metrological control systems may include post-market activities such as market surveillance (Annex 7), inspections, and re-verification (as shown in Figure 1). These post-market activities provide assurances that measuring instruments and systems are operating as intended; they also have the potential to provide significant information concerning the long-term performance of the instruments and the prevalence of non-conforming instruments to manufacturers, CTT bodies, regulators, and customers.	
0022 AU-4		4.2	Figure 1	Ed	The document defines the term 'subsequent verification' and uses this term in 4.2.2.1 when describing system A. However, Figure 1 uses the undefined term 're-verification'. It is recognised that both terms are commonly used in OIML publication and by legal metrology authorities, but it is suggested to use a consistent term in this document.	In Figure 1 replace the term 'Re-verification' with "subsequent verification."	Agreed.
0023 IR		4.2	Figure 1	ed	the term 'subsequent verification' has been used in 4.2.2.1 while term 're-verification' has been used in system A shown in Figure 1.	It should be better to use "Subsequent verification" or "re- verification" (please replace "Subsequent verification" with "re- verification" or vice versa)	See response to 0022.
0024 FR		4.2.1		te	In C the possibility that the surveillance of the production is done by a body different than the one responsible for the approval is not mentioned In NAWID and MID the possibility exists	Change the text not to restrict a possibility given in MID and NAWID	Agreed.
0025 JP		4.2.2.2 1st dot point	Considerations for a CTT program	Gen./edit.	Regarding System A, initial verification is considered in many countries to include assessment of conformity to type (CTT) for each of the produced instruments. It means that CTT is implemented implicitly in such countries.	Add the sentence to the 1 st dot point as shown below (underlined). ● <i>traditional type evaluation, type approval and verification procedures for measuring instruments used for trade: weighing instruments, petrol pumps, etc. <u>Where, the verification is considered to ensure conformity to type (CTT).</u></i>	Agreed.

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0026 US		4.2.2.3	System A	Ed	The sentence reads, "A variation of System A is the case where the manufacturer has a certified quality system covering the production phase and is authorized to apply a verification mark. In this case, CTT is part of the certified quality system." It is unclear from this if the quality system is a substitute for the CTT body. Who provides the authority for the manufacturer to apply the verification mark – the quality system or the CTT?		Clarification has been provided on who provides the authority.
0027 JP		4.2.3 System B	Considerations for a CTT program	Gen.	System B proposes a separate procedure for CTT. The procedure for initial verification is expected to be close to that of CTT, however. System B might impose additional cost for the manufacturers or authorities responsible for CTT.	No changes are requested because some mitigation strategies are already proposed in Clause 5.	Noted.
0028 JP		4.2.4 System C	Considerations for a CTT program	Gen.	System C requires the national issuing authority for type evaluation conduct CTT. Some authorities do not have sufficient resources to conduct assessment for CTT for all items of instruments, however.	No changes are requested because some mitigation strategies are already proposed in Clause 5.	Noted.
0029 US		4.2.4.3	System C	Ed	Same as above.		See response to 0026.
0030 AU-5		5	-	Ge	Time-to-market is one of the major issues for manufacturers which makes it important for regulators looking to implement regulatory changes with minimal burden. This document should include considerations to address the issue of time-to-market.	Add a new item under clause 5: f) Impact of CTT on time to market and the supply of production instruments. Like other regulatory controls, CTT could increase the time delay for manufacturers to bring new products to market or the time it takes to supply production instruments. → Where CTT involves type evaluation tests, consider a risk-based approach when determine sample sizes and relevant influence and disturbance tests. Also consider implementing corresponding changes to related regulatory controls. For instance, regulatory bodies may consider changes to type approval requirements such as accepting manufacturers' test results provided manufacturers participate in a CTT program.	Agreed.

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0031 US		5	e	Ge	Could there be a more explicit emphasis of the feedback mechanisms of market surveillance processes to CTT programs? This paragraph suggests that such processes exist, but the way it is included suggests that it is not a significant activity in metrological control.	Include suggestion above under 4.2.1 – insertion of a paragraph 4.2.2.	See response to 0021.
0032 US		5	Issues identified and possible mitigation strategies. Following e)	Te	Related to the issue on feedback mechanisms from market surveillance processes to CTT programs, there are cases where even though CTT programs are in place, final installation is not carried out in a way that ensures the correct operation of the measurement equipment. Could there be explicit language included that suggests a linkage between installation processes and CTT programs?	Insert an additional case in this section: f) Market surveillance uncovers performance flaws associated with field installation and calibration. → CTT program encourages an industry code of practice whereby the manufacturer ensures technicians, engineers, or installers are properly trained to install and calibrate devices to perform to legal requirements.	Agreed. Added as a new item g).
0033 FR		6.2.2		te	The MID and NAWID provide the affixing of not only the CE but the CE with a supplementary metrology marking (M)	after ...the CE marking please add “and the supplementary metrology marking (M)”	Agreed.
0034 JP		6	Examples of existing CTT programs	Gen.	The three systems A, B and C in 4.2 are based on regional systems such as NTEP/VCAP and MID/NAWID introduced in Clause 6. We acknowledge that these systems are useful examples. However, there is a significantly wide variety of legal metrological control systems in the OIML member states particularly in verification systems.	We propose adding the following note mentioning such a practical situation: <i>Note: The present document should be implemented in consideration of practical metrological control systems in the member states.</i> This note may be added to one of the clauses 4.1.3, 4.3.1 or 6.3 (as a new clause).	Not agreed as the Scope explains that the document provides “considerations” and “illustrative examples”.

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0035 US		Annex 4 - 21.1.3.3.1		Ed; Te	The system in the US has changed so that the original text must be amended. The list of available certification bodies has been expanded to provide more options for instrument manufacturers.	New text: The selected Certification Body is to be accredited by ANSI-ASQ National Accreditation Board (ANAB) or by a Signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition. The ANSI, ANAB and ILAC are accreditation bodies for management systems. ANAB and ILAC accredit certification bodies (CBs) for ISO 9001 quality management systems (QMS), ISO 17025 laboratory testing facilities and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements.	Agreed.
0036 US		Annex 4 - 21.1.3.3		Ed	Capitalize "Responsibilities" in section title	Certification Body's Responsibilities	Agreed.
0037 DE		Annex 7		gen.	We wouldn't quite agree that Market Surveillance represents a "non-systematic approach". As Market Surveillance should be performed on the basis of a risk analysis we think it is a systematic approach. Of course, there is always some random elements when obtaining a sample, however, for us, the whole approach follows a certain systematic procedure.		Agreed. The wording in Annex 7 has been amended.
0038 JP		Annex 7	Last sentence of Definition	Edit.	The second item of the two elements of definition of "market surveillance" is difficult to understand.	If we understand correctly, we recommend rephrasing the second sentence as shown below. <i>2. It will not apply to activities carried out to ensure that a compliant measuring instrument has been properly adjusted and is being used correctly while in service. although where they are carried out by persons who can also identify a non-compliant product and initiate further market surveillance checks they may be regarded as part of a market surveillance system. However, when the activities are carried out by persons who identifies a non-compliant product and initiates corrective actions, the activities may be regarded as a part of market surveillance system.</i>	Agreed.

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