



Bureau International de Métrologie Légale
Le Directeur

BIML 10 N° 464/JFM

14 June 2010

New work on Conformity to Type

Comments expressed by the Members of the Presidential Council

I COMMENTS FROM USA (SECRETARIAT OF TC 3/SC 5), 11 MAY 2010

Why an OIML Conformity-to-Type (CTT) System, if developed, should be developed within TC 3/SC 5

OIML TC 3/SC 5 (Conformity assessment) has responsibility for development and maintenance of the OIML document on the OIML Basic Certificate System (B3). Under the OIML Basic Certificate System, an instrument manufacturer submits their sample/prototype measuring instrument to an Issuing Authority in a country, which has the instrument tested according to the requirements in the appropriate OIML Recommendation by their own, or a subcontracted, testing laboratory. During the course of the testing, both the testing laboratory and the Issuing Authority typically work closely with the instrument manufacturer, which sometimes requires the sharing of proprietary information by the manufacturer. There are no accreditation requirements on either the Issuing Authority or the testing laboratory under the OIML Basic Certificate System, and there is no requirement on any country to accept the OIML Basic Certificates that are issued. Further, the Issuing Authority does not take any steps to determine whether the instruments produced by the manufacturer actually correspond (conform) to the type of instrument for which the OIML Basic Certificate was issued. While most product certification programs in other areas frequently do incorporate a production surveillance (CTT) component (e.g., see ISO/IEC 17065), when the Basic Certificate System was developed legal metrology Issuing Authorities were typically not doing this, and were instead relying on their field inspectors to loosely conduct CTT.

The OIML MAA Certificate System (B10), also under responsibility of TC 3/SC 5, extends the Basic Certificate System to the realm where test data obtained from testing laboratories under the control of Issuing Authorities is accepted by Issuing Authorities in other MAA participating countries on the basis of accreditation or peer-review audits of the testing laboratories. Since the MAA Certificate System already took a big step forward from the Basic Certificate System, it was decided (despite considerable pressure from a few CIML members) that incorporating a CTT component would be too big of an additional step to try until the MAA System achieved at least some initial success, which it now has.

Therefore, while the MAA Certificate System could benefit from another year or two of maturity before extending the System further, it is now worth considering the possibility of further extending the OIML Certificate System into an OIML Product Certification Program, in line with internationally accepted product certification practice, whereby the product certifying organization conducts both the type evaluation and conformity-to-type phases of the program. The reason for this is that the product certifying organization becomes intimately familiar with the manufacturer and their product during the type evaluation phase, and so it is most practical and efficient for the same organization to also inspect the production instruments (either each instrument, or on a statistical sampling basis). Further, as already mentioned, such arrangement minimizes the extent to which the manufacturer possibly needs

to share proprietary information. For OIML, the Issuing Authority would then naturally also serve as the product certifying organization.

Therefore, we view CTT as a natural extension of the OIML Certificate System and believe the most efficient use of resources would be for the Issuing Authorities to increase the scope of the work of type approval to production surveillance (conformity to type) at the manufacturer's request and expense.

If the work of developing an OIML Product Certification Program (CTT Program) was undertaken in another OIML TC or SC and went in a different direction than what has been outlined above, then OIML could find itself with disjointed programs, and at odds with the practice of the international conformity assessment community. If the development of an OIML CTT Program is treated as an extension of the OIML Certificate System, then the work clearly belongs in TC 3/SC 5.

Over the last several years, the TC 3/SC 5 Co-Secretariats have developed considerable familiarity and expertise in the intricacies of the OIML Certificate Systems and the B3 and B10 documents, and are in optimal position to extend the System to incorporate CTT.

Current Responsibilities for publications in TC3/SC5

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|---------------|---|
| D 29: | Guide for the application of ISO/IEC Guide 65 to assessment of measuring instrument certification bodies in legal metrology - Confirmed 2008-11-26 |
| D 30: | Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology - Confirmed 2008-12-01 - <i>Under revision</i> |
| B 3: | OIML Certificate System for Measuring Instruments (P1) - Confirmed 2003-01-01 - <i>Under revision</i> |
| B 3-Amend: | OIML Certificate System for Measuring Instruments - Amendment (2006) - Confirmed 2006-12-19 - <i>Under revision</i> |
| B 10-1: | Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (MAA) - Confirmed 2003-11-08 - <i>Under revision</i> |
| B 10-1-Amend: | Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (MAA) - Amendment (2006) - Confirmed 2006-12-19 - <i>Under revision</i> |
| B 10-2: | Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations |

II COMPLEMENTARY COMMENTS FROM USA, 18 MAY 2010

I would like to thank Jean-Francois for providing his clarifying remarks to you, and I would like to also add some clarifications of my own, which Jean-Francois and I discussed on Monday.

I will begin by clarifying that I believe that it is important that OIML carefully research and give full consideration to the preliminary question that Jean-Francois raises: should we develop a single OIML certification system covering both design and production or should we develop two complementary but separate OIML systems. I am completely open to eventually having either system in OIML.

However, since both systems are inextricably linked to type evaluation, and since responsibility for type evaluation resides in OIML in TC3/SC5, I cannot see any good reason for not pursuing this research of CTT options in TC3/SC5. On the other hand, I see several good reasons for pursuing CTT in TC3/SC5, as I have elaborated in my short paper sent to you by Willem on Monday (prior to my arrival at the BIML). I will summarize those reasons here by saying that it is presently the international norm (e.g., ISO/IEC Guide 65) that the certification body (Issuing Authority) maintain some responsibility for CTT since it already knows the product well, and since if, from the start, a fully separate CTT system is developed by a separate SC in OIML, there could be possible conflicts with the current OIML Certificate Systems (Basic and MAA).

I believe that starting the (research) work under the responsibility of TC3/SC5, perhaps in a TC3/SC5 Working Group, and then possibly splitting it off later if that makes sense, is far safer and preferable to starting with an already split effort and then possibly trying to merge two groups later.

III COMMENTS FROM PROF. ISSAEV, 28 MAY 2010

Looking through the exchanges by e-mails from the very beginning I have got the impression that Dr. Ehrlich is right.

From point of view there is no need to establish new Subcommittee. Having in mind the importance of CTT, which I supported all the time, I agree that it's possible to solve the problem by a corresponded new project. As I remember we discussed during the last PC Meeting the possibilities to rearrangement of TC/SC to the definite projects.

So, I'm in favor of Chuck' proposal.

IV COMMENTS FROM MR. CARSTENS, 31 MAY 2010

I am of the opinion that we should at all times look to simplifying the matter and look to the most cost effective means to address the issue. If the CTT is directly linked to the MAA as I understand it is I will support that it be in the same TC.

V COMMENTS FROM DR. HARVEY, 5 JUNE 2010

In previous discussions about my proposal for formal work on CTT, I have pointed out that there are two issues, a primary issue and a very secondary issue:

- Determining whether CIML wants to pursue work on CTT, an
- Determining where in the TC structure that work, if agreed to, should be done.

In March, when I proposed forming a new sub-committee TC3/SC6 to begin formal work on CTT, it was suggested to me that we should wait until the next Presidential Council meeting where we could decide where the work should be done. In my view, this was "putting the cart before the horse" and would unnecessarily delay CIML consideration of the primary issue. Accordingly I sought to avoid the

secondary issue by proposing the new work in TCxx where the location of this could be determined once CIML had agreed to undertake the new work.

However, it appears that the secondary issue of where the work should be undertaken will not go away and so I would like to make a few comments on this issue.

1. Firstly I think we have a naming issue (or identity crisis) with TC3/SC5. It is called “Conformity Assessment” but doesn’t deal with that at all. Its main activity is concerned with development acceptance arrangements to recognise the assessments of conformity made by other bodies. So we have B3 concerned with the OIML Certificate (a voluntary acceptance arrangement) that provides for the acceptance manufacturers’ test results and the MAA (a mandatory acceptance arrangement for signatories) that doesn’t provide for the acceptance of manufacturers’ test results.
2. The term “conformity assessment” is in fact more applicable to the activities of TC3/SC1 “Pattern Approval and Verification” and TC3/SC2 “Metrological Supervision”.
3. In fact the term conformity assessment applies to almost everything OIML does including prepackaging. Accordingly I don’t think it is a very strong argument to say that there are synergies between TC3/SC5 and CTT. There are probably stronger synergies between TC3/SC2 on “Metrological Supervision” and CTT.
4. Finally if, as I expect, CIML adopts a new TC structure where current projects become TCs then CTT will necessarily come under a separate TC and so the discussion of the secondary issue (of where the work is to be done) will become irrelevant.

In summary, I am strongly of the view that CIML should begin formal work on CTT. While the full scope of that work is yet to be determined, I envisage it embracing systems paid for by regulators, industry and users (In Australia we are moving towards the latter system for utility meters). It could be applicable to both measuring instruments and prepackages.

In principle I am relaxed about who holds the secretariat. Australia has volunteered but I am happy for another country to take that role. Having said that, I have two concerns about the work being done within the current TC3/SC5:

1. TC3/SC5 already has a large amount of work and this may detract from timely progress on CTT, and
2. More importantly, I think that if the work was undertaken within TC3/SC5 there would be a danger that it could become distorted into simply a means for acceptance of manufacturers’ test results under the MAA.

If the work were to be undertaken within a separate TC, I expect there to be strong liaison with other relevant TCs including TC3/SC5. There would be common members with TC3/SC5 and I certainly don’t see the development of a separate silo mentality.

Finally I would like to thank our Director for providing a very strategic and circumspect analysis of the issues relating to CTT. Australia’s view is that we should take small steps and make some progress rather than spend decades developing the ultimate system. I think that CTT is the most important issue that CIML has on its agenda and I urge you to support CIML initiation of this work.

VI COMMENTS FROM MR. VAN MULLEM, 7 JUNE 2010

From Netherlands side I would be in favour of bringing the system for conformity to type within OIML as much as possible in line with the present operational system in the EU.

Reading all arguments and considering the disadvantages as presented in the Note from Jean-Francois <BIML 10/419> our prevalence would be NOT to merge CTT with the existing OIML certification systems (Basic and MAA). The main reason for this point of view is the above mentioned argument concerning similarity of procedures with those of the EU.

Concerning knowledge and expertise, there could be an advantage in keeping the execution of both certifications systems and CTT in one hand, but a clear disadvantage in that case would be that the execution of the CTT on an approved type is likely to be performed by one and the same Issuing Authority; which would mean on all the instruments of that type produced and could imply acting all over the world. So the possible benefit of keeping competence in one hand will possibly not compensate for the economic drawback of lack of competition. Also this could result in risk on prejudice and weakening attention during verification.

From the presented correspondence I learned that there is no principal objection from US side for creating 2 complementary systems.

Further I have no objections to, and even some prevalence for allocation of the New Work within the existing SC 5 of TC 3. In this case the scope of this task should explicitly exclude merging the new system with the existing one's and include the task to make the systems complementary.

Splitting in 2 SC's would need a sharing of expertise of the members, which probably would result in 2 SC's having rather the same active members. If there would be some doubts concerning the workload for the secretariat and associated progression it could be decided to share tasks by introducing a co-secretariat.

VII COMMENTS FROM DR. SCHWARTZ, 7 JUNE 2010

1. Comments on the proposal of Australia for the establishment of a new technical committee (Ref.: BIML 10 No. 293/JFM/GH, dated 19 March 2010)

1.1 Proposed new subcommittee (SC)

Germany does not support a new SC at that time; if at all, a working group of TC3/SC5 should deal with this issue and start by collecting information about existing national and regional (e.g. EU) CTT programs and systems. Based on this, more detailed and well-founded ideas could be developed and decisions be taken towards a realistic approach for a future OIML CTT system that could provide added value to its possible users. Without sufficient, reliable knowledge about existing CTT systems, not only for measuring instruments but also under other certification schemes, such as IEC-Ex or IEC-CB, it will certainly not be possible to build up a successful new OIML CTT system.

In addition it is noted that at least in the EU, market surveillance and CTT are considered as different issues, performed by different Authorities, so that TC3/SC5 or a new working group of TC3/SC5 should clarify whether the focus of the discussion will be on CTT or market surveillance.

1.2 Justification

The very general statement „At the present time there is no formal program to ensure that ...“ is not true. At least for the EU and thus for Germany I can say that the majority of measuring instruments falls under European Directives that do not only cover type testing (so-called „module B“) but do cover also conformity of the production to an approved type, either by an appropriate quality management system of the manufacturer (so-called „module D“) that is acknowledged and supervised by an independent Notified Body (NB), or by product verification of each individual instrument (so-called „module F“ or in special cases „module G“) performed by a Notified Body that is normally different from the one responsible for type approval (module B).

From that it is clear that Germany (and certainly most of the EU member states) will not support a possible OIML CTT scheme that is not in line with existing EU Directives. A second, different CTT system in addition to the obligatory EU system would not be acceptable to both European Issuing Authorities (usually being Notified Bodies for type approval) and EU manufacturers.

1.3 Justification (contd.)

It sounds good to offer a new, voluntary OIML CTT system with a new, voluntary OIML conformity mark on a measuring instrument. But I suspect that what is voluntary at the beginning of the system will quickly be made mandatory by some National Legal Metrology Authorities so that products that are intended to enter the market of the respective OIML Member States shall bear the OIML CTT mark. All the more I emphasize that we will certainly not support an OIML system that instead of providing added value will put additional burden (effort and costs) on both Issuing Authorities and manufacturers.

2. Comments on the proposal of Australia for a new OIML Basic Publication (Ref.: BIML 10 No. 293/JFM/GH, dated 19 March 2010)

In line with what has been said under No 1.1 through 1.3 we find it premature to think about a new OIML Basic Publication. First of all, one should perform an investigation where detailed information about existing national and regional (e.g. EU) CTT systems is collected which could form a basis for the further development of well-founded ideas and a promising OIML strategy.

3. Comments on the extracts from the Directives for Technical Work (B6-1: 1993)

I'd like to point to No 2.7.4, last paragraph, where it is said that the proposal shall be sent simultaneously to other organizations with which OIML has established cooperative agreements. This must at all include CECIP, CECOD and probably other federations of manufacturers that have an OIML liaison status. I think it is absolutely essential that all stakeholders, including manufacturers, are on board, if OIML wants to avoid a miss with such an important issue as CTT is. Thus, I request, if not already done or foreseen, that at least CECIP and CECOD shall be involved in the process from the beginning.

4. Comments on the USA Position Paper (dated 11 May 2010)

4.1 We agree that an OIML CTT system, if developed, be developed by TC3/SC5 (see No 1.1 above), if not the structure of OIML technical committees will be completely reorganized according to the expected new OIML Technical Directives.

4.2 We do not, however, agree with several statements and proposals, e.g. in the first paragraph, last sentence. As I explained already above (No 1.2), at least in Europe, we have different Notified Bodies

(NB) with clearly distinguished roles as regards conformity assessment and product certification. OIML Issuing Authorities (e.g. PTB) are normally NBs for „module B“, i.e. type approval, whereas other NBs (normally verification authorities) are responsible for modules D (supervision of quality systems for production), and F or G (product verification). There are only a few exceptional cases where NBs are responsible for both module B and D, or module B and F.

In any case it is not true that we or other NBs (Issuing Authorities) „rely on our field inspectors to loosely conduct CTT“, at least not in Germany. There are different NBs with different roles and responsibilities in a functioning CTT system. That does not mean that there are no deviations or non-conformances, but these are tackled by the existing system and do not justify at all an additional CTT system.

4.3 We do also not agree with some statements in paragraphs 2 and 3. As was already discussed at the last CPR R60/R76 meeting in June 2009, we shouldn't mix the MAA issue with the issue of CTT. There is a link, of course, between these two issues, e.g. if a manufacturers test laboratory, that provides test results to an Issuing Authority, is also used to ensure CTT. But basically, the MAA - which itself still suffers from general acceptance - aims at the mutual recognition of test results in order to avoid unnecessary multiple testing for type approvals. This has nothing or very little to do with ensuring CTT for the series production.

We are especially opposing the idea that the OIML Issuing Authority should „then naturally also serve as the product certifying organization“. At least for PTB, but I am sure this holds for other European NBs as well, I can clearly say that this is and will not be our mission, because of the different, well-established roles we have as European NBs, as explained above. It is true that ISO/IEC Guide 65 is often interpreted in that way, but as far as I know this is not 100% clear and allows other interpretations.

Although we definitely do not share the view that „CTT is a natural extension of the OIML Certification System“, we still support the CTT discussion to happen in TC3/SC5 (see No 4.1), because we think that this SC is best prepared to do that.

5. Comments on the Note on the work proposal on CTT (Ref.: BIML 10 No 419/JFM, dated 12 May 2010)

We share most of the views of the BIML Director, especially the concerns expressed in questions 1 through 4 concerning the USA Position Paper (page 2/3).

We also agree that these questions are of strategic significance, and thus require to be carefully studied.

6. Summary of our comments

To summarize I can say that Germany:

- will not support an OIML CTT system that is not in line with existing EU Directives for measuring instruments, and that will probably put additional burden on both Issuing Authorities and manufacturers
- does not support the establishment of a new SC at that time,
- does not support the development of a new OIML Basic Publication at that time
- would participate in a new CTT working group if that were set up by TC3/SC5

- recommends the WG, if set up, to start by collecting information about existing / established national and regional (e.g. EU) CTT systems, including other certification schemes such as IEC-Ex and IEC-CB
- requests that OIML liaisons and other stakeholders such as CECIP and CECOD be given the opportunity to actively take part in the CTT discussion
- considers the MAA, the CTT, and market surveillance as issues that have to be investigated separately and thoroughly in a first step, before probably later it is thought about an all-embracing OIML certification system.

VIII COMMENTS FROM DR. MIKI, 13 JUNE 2010

Dear Jean-Francois,

Thank you for your mail. When I wrote to Willem on leaving from Paris about 10 days ago, I thought I would be able to send my comment soon. But I realized this issue has many effects in the OIML and each countries' legal metrology system, specifically on the problem that who has the responsibility about the conformity and how to ensure it.

At this point I can only say it would be too early to start the activity on the committee level.

I will make comment after consideration in the consultation of all CIML members.

Best regards,

Yukinobu