



BIML 12 No. 108/WK-cp

2012.02.03

To: CIML Members and OIML Corresponding Members

Subject: Membership of the new OIML technical subcommittee on *Conformity to Type*
(TC 3/SC 6)

Dear colleagues,

In Resolution No. 22 of the 46th CIML Meeting (Prague, 2011) the CIML approved the establishment of a new subcommittee of TC 3, *Conformity to type*, and assigned responsibility for it jointly to New Zealand and the Bureau.

In the same Resolution, the CIML approved, as a work item for the new subcommittee, the development of a guidance document on “the scope for pre-market surveillance activities focused on the conformity assessment of measuring instruments to give assurance that manufactured (or production) instruments meet their approved type”. For this work item, a Project Group needs to be established.

You are hereby invited to indicate, using the attached form:

- Whether you wish to be registered as a P-member or as an O-member of the new TC 3/SC 6. Note that only OIML Member States can be registered as P-members of the subcommittee (please refer to OIML B 6-1:2011, clause 5.6).
- For countries that wish to be registered as a P-member of the new subcommittee: the name and contact details of your country's representative.
- Whether you wish to be registered as a P-member or as an O-member of the Project Group. Note that only P-members of the new subcommittee may be P-members of the Project Group (please refer to OIML B 6-1:2011, clause 5.7).

The deadline for your reply is 3 May 2012.

For your information, I have attached an article from the January 2012 OIML Bulletin (see pages 26–27) giving a brief overview of the events that led to the establishment of the new subcommittee.

Best regards,

Willem KOOL
BIML Assistant Director



OIML TC 3/SC 6 *Conformity to type*
Co-secretariats: New Zealand and the BIML

Response Form

(to be returned by 3 May 2012 to Willem.Kool@oiml.org)

A. For OIML Member States:

For the new TC 3/SC 6, I wish to be registered as (please check as appropriate):

P-member

my country's representative will be:

myself

Dr./Mr./Ms.

E-mail:

O-member

For the Project Group 1 of TC 3/SC 6, I wish to be registered as:

P-member

O-member

B. For OIML Corresponding Members:

For the new TC 3/SC 6, I wish to be registered as O-member:

Yes

No

For the Project Group 1 of TC 3/SC 6, I wish to be registered as O-member:

Yes

No

The OIML Member / Corresponding Member contact:

for (country):

Name:

Date:

CONFORMITY TO TYPE

A new OIML Technical Subcommittee on CTT

WILLEM KOOL, BIML Assistant Director

Generally, measuring instruments under legal control are subjected to conformity assessment before they may be legally used. Traditionally, such conformity assessment is in two stages: type approval and verification.

At **type approval**, one or more instruments are subjected to a wide range of tests (temperature, electromagnetic compatibility, etc.) that often require specialized and expensive test facilities and can only be meaningfully performed in a laboratory. The instruments submitted for type approval testing 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.

At **verification**, 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.

When this system of conformity assessment was developed, measuring instruments under legal control were relatively simple compared to modern electronic instruments. They were mainly mechanical, while the first electrical and electronic instruments had components that were more easily recognizable and software could not be changed without breaking a physical sealing. Moreover, manufacturers operated primarily in a national market and the national (or local) legal metrology inspectors were familiar with the manufacturers and their production processes. Under these circumstances, the system of type approval and verification worked quite well to ensure that instruments under legal control complied with applicable technical and metrological requirements.

Some developments that took place over the last decades have put the reliability of this system of conformity assessment in legal metrology into question, for instance:

- New technologies make it difficult and often impossible to verify 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.
- Software can be easily modified, often without having to break any physical sealing.
- As a result of globalization, instruments may be type approved in one country, produced in another country, and verified and used in yet another country.

Nowadays, it is very difficult for the verification officer to ascertain that the instrument he is verifying is actually in conformance with the design as described in the type approval certificate, or in compliance with all applicable technical and metrological legal requirements.

The problem may be formulated in the following way: “Traditional conformity assessment in legal metrology (i.e. type approval followed by verification) no longer provides sufficient assurance that verified instruments comply with all applicable requirements”.

This issue has been discussed within the OIML for several years in a more or less informal way: in conjunction with a number of CIML Meetings, an ad-hoc group of CIML Members would discuss the issue. These exchanges were useful to learn about the problem and about the steps that individual countries were taking to tackle it. However, the discussions in the ad-hoc group did not yield any tangible result. Finally, in 2010, the CIML Member for Australia, Dr. Grahame Harvey, submitted a proposal to establish a new OIML technical committee that should be allocated the task of developing a certification system under which measuring instruments would be certified to be in conformity with their approved type.

This proposal was discussed by the CIML at its 45th Meeting in Orlando in 2010, but no consensus was reached. There was disagreement over whether or not the OIML should develop such a certification system at all, and whether such a project should be allocated to an existing technical (sub-)committee or to a new (sub-)committee. The CIML decided¹ to postpone making any decision and instructed the BIML to organize a seminar on Conformity To Type (CTT) with the objective of further studying the issue and drafting proposals for further OIML activities in this field.

¹ See Resolutions 15 and 19 of the 45th CIML Meeting (Orlando, USA, 2010) available on the OIML web site at: http://www.oiml.org/download/docs/ciml/45_ciml_resolutions_english.pdf

An electronic working group, chaired by the CIML Member for New Zealand, Mr. Stephen O'Brien, and facilitated by the BIML, was established to prepare the program for the seminar.

The seminar², with some 50 participants, was held on 29 and 30 June 2010 in Utrecht, the Netherlands. The program for the first day included presentations about standards on conformity assessment in general (ISO/CASCO "toolkit"), conformity assessment systems in the IEC (for electro-technical products), existing CTT systems and initiatives in the USA, Europe and Australia and the perspectives of developing and utilizing economies. On the second day, two panel discussions were held: to identify critical issues for the OIML, and to discuss elements for a possible OIML CTT project.

The conclusions of the Utrecht seminar may be summarized as follows:

- The issue of CTT is of strategic importance for the OIML.
- The support of instrument manufacturers is critical for the success of any CTT activity.
- The CIML should formally assign responsibility for CTT to a (new or existing) OIML technical (sub-) committee.
- The OIML should develop a publication (OIML Document) with "best practices" for CTT.

It was also concluded that a follow-up seminar should further discuss two specific issues relating to the CTT issue:

- information included in the type approval certificate, and
- how a certification system could be used in a regulatory environment.

A follow-up seminar had already been scheduled to allow CIML Members to further discuss the CTT issue

² For full information about the Utrecht CTT seminar, see: http://www.oiml.org/seminars/2011_CTT/

and to draft a resolution for the CIML. This seminar (CTT-II)³ took place on 10 October 2011, immediately preceding the 46th CIML Meeting in Prague.

The CTT-II seminar showed that there was consensus among CIML Members that the OIML should develop a guidance document on Conformity to Type, as had been recommended in the conclusions of the Utrecht seminar. But the issue of in what way such a new work project should be allocated was not resolved until the CIML Meeting following the CTT-II seminar took a resolution⁴ which:

- approved the establishment of a new subcommittee (TC 3/SC 6 "Conformity to type"), which shall undertake as a project the development of a guidance document on the *"scope for pre-market surveillance activities focused on the conformity assessment of measuring instruments to give assurance that manufactured (or production) instruments meet their approved type"*,
- assigned the responsibility for the Secretariat of the new subcommittee jointly to New Zealand and the BIML,
- invited the new subcommittee to take into account:
 - the information provided at the seminars held in June and October 2011, and
 - the current programs in the USA and the EU and any best practices identified elsewhere.

The co-secretariats of the new TC 3/SC 6 will start their activities in early 2012. First, CIML Members will be invited to become P- or O-members of TC 3/SC 6 and asked whether they wish to be registered as a P-member for the project. At the same time, OIML Corresponding Members and Liaison Organizations will also be invited to collaborate as observers. ■

³ Information about the CTT-II seminar is available on the OIML web site at: http://www.oiml.org/seminars/2011_CTT-II/

⁴ Resolution 22 of the 46th CIML Meeting (Prague, 2010), see: http://www.oiml.org/download/docs/ciml/46_ciml_resolutions_english.pdf