



## Report on the OIML Utrecht Seminar on Conformity to Type

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### Summary

On 29 and 30 June 2011 an OIML Seminar was held in Utrecht, the Netherlands, on Conformity to Type (CTT). The Seminar was organised by the International Bureau of Legal Metrology (BIML) in response to a request from the International Committee of Legal Metrology (CIML) made at its 45th Meeting.

The issues and concerns regarding the conformity to type of measuring instruments under legal control have been considered in a number of OIML fora for some time. This Seminar was seen as an opportunity to focus on CTT and identify a potential way forward for CIML consideration.

The Seminar was attended by 43 delegates representing a cross section of legal metrology regulators, issuing authorities and industry associations from the Asia-Pacific and European regions.

This report summarises the key points raised by speakers and during discussions at this Seminar. It also outlines the Seminar's informal recommendations on moving forward in the CTT area. These recommendations are intended to stimulate further discussion at the planned OIML CTT Seminar in Prague. They reflect consensus views but were not subject to formal vote and endorsement at the OIML Utrecht Seminar.

On the first day of the Seminar speakers presented the experiences and perspectives of international conformity assessment bodies, EU and US manufacturers and regulators from the US, EU, Australia and New Zealand. The second day took the form of a panel discussion. This discussion analysed the critical issues in relation to CTT and the perspectives of participants and identified agreed conclusions for the Seminar.

The presentations of all the Seminar speakers are available on the CTT web page: [http://www.oiml.org/seminars/2011\\_CTT](http://www.oiml.org/seminars/2011_CTT)

The key points identified in the presentations and subsequent discussions include:

- CTT is an area of work that has been discussed and considered within OIML fora for many years. From the global perspective complexities exist around: finding an appropriate funding model, exchanging information, global supply chains, responding to non-compliance and avoiding duplication of current EU and US CTT schemes. In spite of these complexities, conformity to type is seen as important for the maintenance of on-going confidence in OIML certification systems (the MAA and the Basic Certificate System) and needs to be the focus of a formal OIML Working Group.

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- Globally, regulators need assurance that production instruments entering their economies are consistent with the OIML certified type. This is an issue of particular importance to economies outside the jurisdiction of existing regional CTT systems and without strong national CTT compliance or testing programmes.
- Discussions at the Seminar highlighted that the term CTT has a variety of potential interpretations for individuals with regard to what it means, where it would be applied within the supply chain and who would be responsible for it. To enable CTT to be effectively discussed and progressed by the CIML a ‘working’ temporary definition of CTT needs to be established. This definition would differentiate CTT from post market inspection or surveillance of instruments and initial or subsequent verification. The informal consensus view of those present at the Seminar was that any OIML CTT activities should concentrate on pre-market assurance that “production meets type”.
- Mandatory national and regional CTT systems supported by legislative, administrative and enforcement frameworks are currently in place in some regions and economies (e.g. EU, USA Japan, etc.). If the OIML wants to improve CTT on a global level these existing systems need to be considered and taken into account.
- Understanding and application of the appropriate elements from the ISO/CASCO ‘toolbox’ of international standards and guides on conformity assessment is needed to ensure that any OIML work on conformity to type is consistent with international ‘best practice’. It is also important to obtain leverage from the knowledge and experience of ISO and the IEC in the conformity area.
- One suggested potential way forward was to form a joint OIML UNECE working group tasked with a mandate from the CIML to apply the ISO/CASCO toolbox to the OIML certificate systems and to improve CTT in the global marketplace. A similar approach was successfully applied in the IEC-Ex field and further examination may produce useful insights.
- The need for a ‘level playing field’ for instrument manufacturers, supported by a fair regulatory system was highlighted to ensure fair and equitable competition and to avoid market distortion from non-compliant instruments.
- Independent pre-market surveillance and instrument testing are important elements to be considered in any CTT programme to incentivise compliance by introducing the potential for detection of instruments that are non-compliant with their approved type. It does however need to be noted that OIML has no regulatory powers. Developing effective responses to non-compliance identified within the global marketplace would need careful consideration and may be outside the scope of legislative control in many jurisdictions. The OIML would need to seek legal advice if a CTT programme were to proceed.
- Instrument manufacturers have a number of questions regarding the potential benefits, compliance costs and practical operation of any OIML CTT activities that will need to be answered before they are able to support such a programme. CECIP, for example, is now in the position of needing more information about the details of any possible OIML CTT programme. The success of any CTT activity will rely on the support of instrument manufacturers so effective consultation and manufacturer involvement will be critical.



- Elements of the US National Type Evaluation Program (NTEP) Conformity Assessment Programme and its pilot application to load cells were described and discussed. This programme is aimed at ensuring the continued compliance of manufactured devices in the US with the requirements defined in their Certificate of Conformance. One of the key elements of this approach is the Verified Conformity Assessment Programme (VCAP). VCAP prescribes a number of requirements that US manufacturers must fulfil in order to maintain an active Certificate of Conformance.
- European Union legislation and directives in combination with a variety of national requirements form the current European system aimed at ensuring instruments conform to the applicable requirements and to their respective types. The Measuring Instruments Directive (MID) and fulfilment of the responsibilities prescribed in the applicable modular annexes (modules A-H) by notified bodies and manufacturers form the foundation of this system. Completion of the applicable modules in combination with the related documentation, manufacturer's declaration of conformity and market surveillance support CTT within Europe for the 11 categories of measuring instruments covered by the MID.
- Any potential OIML CTT activities need to recognise and complement the existing MID and legislative requirements within the EU and the developing US Verified Conformity Assessment Program (VCAP). Any OIML activity must add value and not duplicate current requirements or impose additional compliance costs without clear benefits.
- The need to avoid OIML duplication of existing EU and US CCT programmes must be balanced with the need for economies outside of Europe and the US to have access to or guidance on developing a CTT programme. Without some form of normative guidelines or co-ordination there is the potential for development of a proliferation of regional and national CTT programmes that may have contradictory or duplicate requirements creating technical barriers to trade.
- The OIML needs to consider the views and perspectives of developing economies. Without the support of a CTT programme developing economies have the real potential to become a 'dumping ground' for instruments that do not meet their type.
- The issue of 'dumping' measuring instruments is not just an issue that concerns developing economies. The issue is a potential problem for any economy that does not have an effective CTT programme.
- It was noted that consideration needs to be given to the role of Regional Legal Metrology Organizations such as APLMF, AFRIMETS and SADC MEL in future OIML CTT work.
- A variety of funding models need to be considered to fund CTT work. One possibility discussed was that of identifying the instrument users that would benefit from CTT and applying a 'user pays' funding model. Australian work with the Urban Water Industry is seen as a successful, small scale example of the operation of such a model.
- Fundamental to any work in the CTT area is to have agreed definitions for some of the terms used to describe the elements associated with CTT including market surveillance, the clear differentiation between CTT testing and in-service verification or re-verification, quality assurance, sampling, quality management programme, auditing and first, second and third party conformity assessment.



- A comprehensive risk management framework is needed to ensure the effectiveness of any CTT activities. Such a framework needs to be used to identify, analyse and evaluate risks to ensure limited global CTT resources are effectively targeted. Potentially, activity could be restricted to those areas where it is expected that a substantial risk would exist if the free market mechanism provides insufficient protection against unfair transactions or results in unsafe measurement outcomes (ISO 31000:2009 Risk Management Principles and Guidelines is a potential useful reference).

## Recommendations

NOTE: The following are intended to inform further discussion at the OIML Seminar in Prague. They reflect consensus views but were not subject to formal vote and endorsement at the OIML Utrecht Seminar.

Taking into consideration the strategic importance of Conformity to Type to global confidence in OIML certification (MAA and Basic Certificates), the complexity of issues surrounding this area of work and the need for normative guidelines, it is suggested that the CIML consider the following:

1. The CIML formally assigns responsibility for Conformity to Type to the work programme of an OIML Technical Committee. Due to the fact that Conformity to Type has overarching implications for all instrument categories and for both the MAA and Basic Certificate Systems, further CIML consideration needs to be given to where this work is assigned.
2. This Technical Committee is requested to develop a normative document or guidance document on Conformity to Type to reference current programmes in the US and the EU, identify 'best practice', and inform future global development work in this area. This document could:
  - compose a definition of CTT;
  - define terminology used in the CTT area;
  - identify potential roles and responsibilities of Issuing Authorities, Manufacturers, National Legal Metrology Authorities and Regulators in relation to CTT;
  - after consideration of compliance cost and effectiveness, identify and reference international 'best practice' and the appropriate elements from the ISO/CASCO 'toolbox' of international standards and guides on conformity assessment;
  - describe and identify key elements needed to be considered when setting up a CTT;
  - describe and reference existing MID and legislative requirements within the EU and the US Verified Conformity Assessment Program (VCAP);
  - provide information and technical advice for developing economies, economies outside of Europe and the US and Regional Legal Metrology bodies on CTT.

The support of instrument manufacturers will be critical to the success of any CTT activity. Their involvement and consultation in the development of this document is seen as important.



3. To utilise the planned one-day Seminar to be held in association with the 46th CIML Meeting in Prague to inform the CIML on CTT. In particular to look at the ISO/CASCO ‘toolbox’ of international standards and guides in this area and examine how they were successfully applied in the IEC-Ex field. This Seminar is considered important to continue to raise awareness and inform CIML Members and to build on the momentum from the Utrecht Seminar.

Prior to or during the CIML CTT Seminar it would be useful to develop a ‘working’ temporary definition of what is meant by a CTT programme to reduce the potential for miscommunication and facilitate discussion.

With a clearer knowledge of the elements of the ISO/CASCO ‘toolbox’ from this CIML Seminar, consideration should be given to a joint OIML / UNECE working group approach to CTT.

4. To improve the quality and expand the content of OIML Certificates and their related documentation to support CTT. It is suggested that in parallel with the development of a CTT normative guideline the content and quality of OIML Certificates and their related documentation could be reviewed and potentially improved to better identify the certified instrument and clearly prescribe the responsibilities of manufacturers. This could include the use of photographs or other identifiers.

## Conclusion

Conformity to Type is a strategically important work area for the OIML and the global legal metrology system. The Utrecht Seminar successfully highlighted and discussed a wide variety of issues and perspectives presented in this report for CIML Members to consider. The challenge as we move forward will be to ensure that the constructive dialogue that has been held to date is transformed into appropriate OIML activity.

The support of the BIML and NMI (the Netherlands) and the active participation of the presenters and the delegates that attended this Seminar is acknowledged and appreciated.

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