Development of an OIML Document on Pre-market Surveillance

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Paul DIXON
BIML Assistant Director
The OIML

- Intergovernmental treaty organization, established in 1955
- International standards setting organization under the terms of the WTO/TBT Agreement
- The mission of the OIML is to:

  “Enable economies to put in place effective legal metrology infrastructures that are mutually compatible and internationally recognized, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonize the level of consumer protection worldwide.”
OIML Structure

**OIML Conference**
- Representatives of Member State Governments
- Meets every 4 years

**International Committee of Legal Metrology (CIML)**
- One representative from each Member State
- Meets annually

**International Bureau of Legal Metrology (BIML)**
- Secretariat of the Organization
- Led by a Director appointed by the CIML
OIML Members

- 62 OIML Member States
- 64 OIML Corresponding Member Countries
OIML Liaisons (some examples)
Current OIML Priorities

• On-going technical activities
• Increase speed and efficiency of OIML technical work
• Meeting the needs of Countries and Economies with Emerging Metrology Systems (CEEMS)
• Operation of the OIML Certification System (OIML-CS)
• Cooperation with other organizations to promote metrology as an important part of a sound quality infrastructure (QI) of a modern economy
• Upcoming: Metrology for Digitization of the Economy and Society
OIML Publications

- The OIML issues several categories of publications:
  - International Recommendations, which are intended as **model regulations** for a number of categories of measuring instruments, and which OIML Member States are morally obliged to implement as far as possible
  - International Documents, which are informative and are intended for guidance purposes
  - Other publications - Vocabularies, Guides, Basic Publications and Expert Reports
  - All OIML publications are available for download, free of charge, from the OIML web site
OIML Document - Background

• Seminars on Conformity to Type (CTT) held in June and October 2011

• Key points identified, e.g.
  – CTT is important for the maintenance of on-going confidence in OIML Certificate Systems
  – CTT has a variety of interpretations across Member States
  – Agreed definitions for terms – need for differentiation between CTT and market surveillance
  – Avoid duplication of existing systems, e.g. EU, US VCAP
  – ISO CASCO ‘toolbox’
  – Funding models
  – How to deal with the “Golden Sample”
OIML Document - Background

• “Working Group” recommendations to CIML
• CIML approved the establishment of a new subcommittee (TC 3/SC 6) for CTT
• TC 3/SC 6 tasked with developing a guidance document:
  “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”
• Co-conveners: NZ and BIML
OIML Document - Structure

• Introduction
• Scope
• Terminology
• Considerations for a CTT program
  – Legal Metrological Control Systems
• Issues and possible mitigation strategies
• Examples of existing CTT in legal metrology
  – EU Directives (NAWI and MID) and US VACP
• Annexes
  – Annex 2: IEC Conformity Assessment systems
  – Annex 7: Link to Market Surveillance
OIML Document – Scope

• Conformity to Type (CTT) – **Pre-market** conformity assessment of measuring instruments

• Document provides considerations for countries and economies, or Regional Legal Metrology Organizations (RLMOs), that are planning to develop CTT programs in the field of legal metrology.

• Document provides illustrative examples of CTT programs currently in operation.
## Legal metrological control systems

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OIML Document – Link to Market Surveillance

• Significance of market surveillance terminology and concepts to the development of Document

• Annex 7 - relationship with ‘market surveillance’
  – Important that CTT is not confused with market surveillance
  – No definition of market surveillance in the VIML
  – Definitions in UNECE Glossary and OIML D 9
  – However, neither definition makes clear the relationship between market surveillance and legal metrological controls, e.g. verification and in-service inspection
  – Systematic controls versus ‘ad-hoc’ activities
• The OIML-CS is a system for issuing, registering and using OIML Certificates and their associated type evaluation reports for types of measuring instruments based on the requirements of OIML Recommendations

• Aims to facilitate, accelerate and harmonize work of national and regional bodies that are responsible for type evaluation and type approval of measuring instruments subject to legal metrological control

• Requires a type evaluation of sample(s) of measuring instruments which should be representative of the production

• Does not include any formal evaluation to establish that the type is representative of the production

OIML Document – Link to OIML-CS
Future Developments

• Development of 4CD to address comments received on 3CD, including an improved Annex 7
• Draft for CIML Preliminary Online Ballot by end 2018
• Approval of Final Draft in 2019
• Working Group established to explore the possible inclusion of CTT in the OIML-CS
• Development of a Market Surveillance definition for legal metrology (VIML) ...
Future Developments

• Such a definition will have two elements:
  – It will apply only to activities to identify and deal with non-compliance of regulated measuring instruments and prepackages after they have been placed on the market or put into service
  – 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

• Possible development of an OIML Document for Market Surveillance .... ??
Paul DIXON
BIML Assistant Director

paul.dixon@oiml.org
www.oiml.org