



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

OUTCOME

List of files:

CTT 2011-I / 00	(This document)
CTT 2011-I / 01	List of Participants
CTT 2011-I / 02	Conformity Assessment and the CASCO Toolbox
CTT 2011-I / 03	Background to Conformity to Type (CTT) in OIML
CTT 2011-I / 04	IEC Conformity Assessment Systems -- A comparison
CTT 2011-I / 05	OIML Conformity to Type -- A Perspective from US Manufacturers
CTT 2011-I / 06	Perspectives of manufacturing industry
CTT 2011-I / 07	Information about EU system
CTT 2011-I / 08	NTEP Conformity Assessment Program
CTT 2011-I / 09	Conformity to Type Testing and the Australian Urban Water Industry
CTT 2011-I / 10	Perspectives of an OIML Type Approval Utilising Economy: New Zealand
CTT 2011-I / 11	Mechanisms in place in various countries
CTT 2011-I / 12	NTEP/VCAP (USA) Documentation
CTT 2011-I / 13	Report of the CTT Seminar (29+30 June 2011, Utrecht, the Netherlands)



OIML Seminar on Conformity to Type (CTT)

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List of Participants

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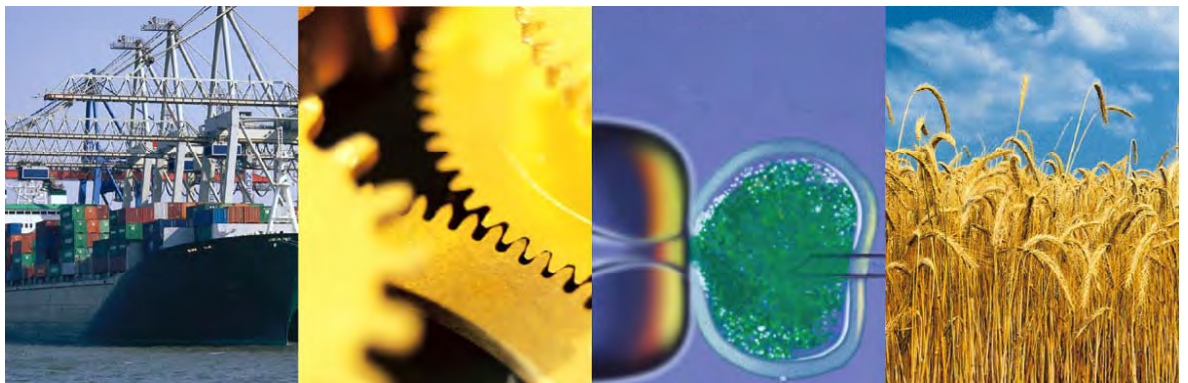
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Conformity Assessment and the CASCO Toolbox



Sean Mac Curtain

CASCO Secretary

OIML Seminar on Conformity to Type (CTT)

29 – 30 June 2011 Netherlands

Standards for a better world



ISO's Mission

ISO develops **high quality voluntary** International Standards which **facilitate** international exchange of goods and services, **support** sustainable and equitable economic growth, **promote** innovation and **protect** health, safety and the environment



Standards – they simply help economies thrive!

- Are an important link in **global supply chains**
- Underpin international trade - **access** to markets
- **Reduce technical barriers** to trade - support Multilateral trade
- Help **renew confidence** and promote economic recovery



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... for consumers

- safer, healthier, more environmentally sound products and services
- products with improved quality and reliability
- compatibility within and between products
- greater consistency in the delivery of services
- improved choice and access to goods and services
- lower costs
- better product or service information



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The World Standards Cooperation (WSC)

The leading international standardization organizations



- Multi-discipline and cross-sector



- For electrotechnology



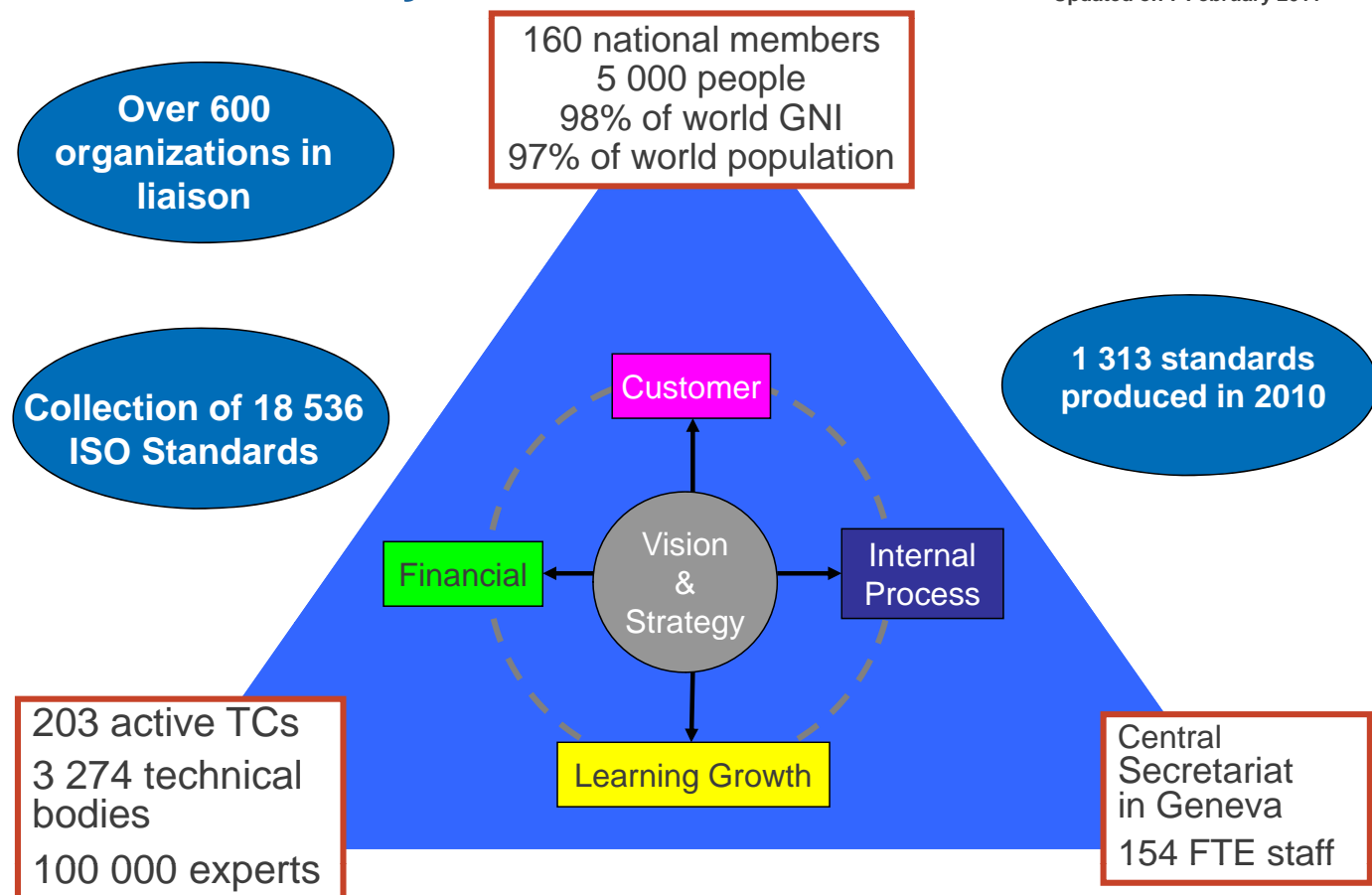
- For telecommunications

Collaborate to meet the challenges of converging technologies

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ISO – A Global System

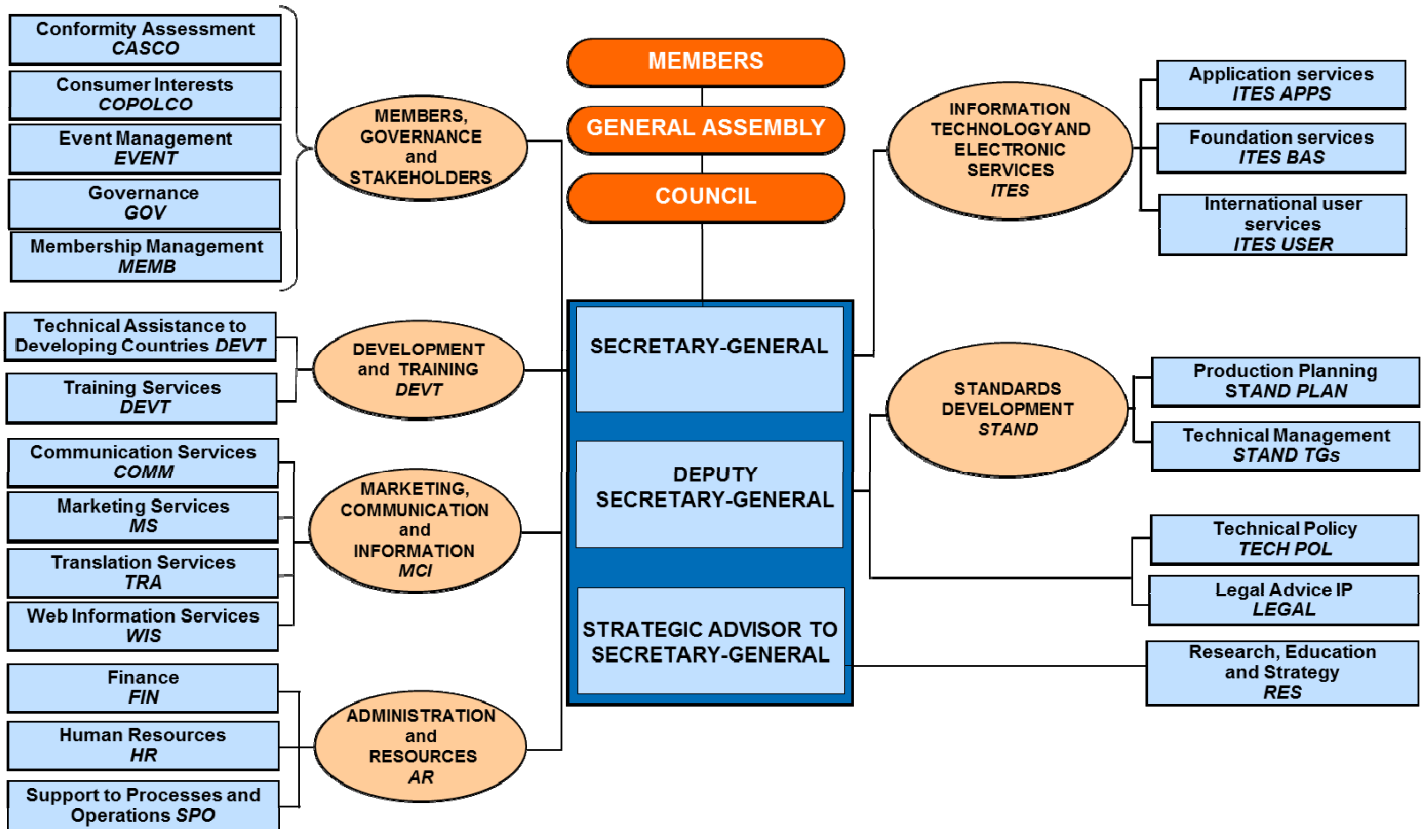
Updated on 7 February 2011



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Central Secretariat Organization Chart



ID 1769805 – March 2011

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Double layer of consensus for ISO standards

- At the level of **delegates/experts** who participate in technical committees, sub-committees, working groups, i.e. industry specialists, technologists, users, consumers, etc.
- Then, at the level of **countries** through their national standards bodies (NSBs), involving all stakeholders in national mirror committees

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CTT 2011-I/02

5/19

ISO - Responding to market needs

Over 40 new technical bodies established since 2005

- Information and societal security
- Response to climate change
- Energy efficiency and renewable resources
- Sustainable building design and operation
- Water services
- Nanotechnologies
- Intelligent transport systems
- Food safety management
- Health informatics
- Social responsibility
- Tourism and related services
- Fisheries and aquaculture
- Carbon footprint
- Services
- Biotechnology
- Finance



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What is conformity assessment

What is Conformity Assessment?

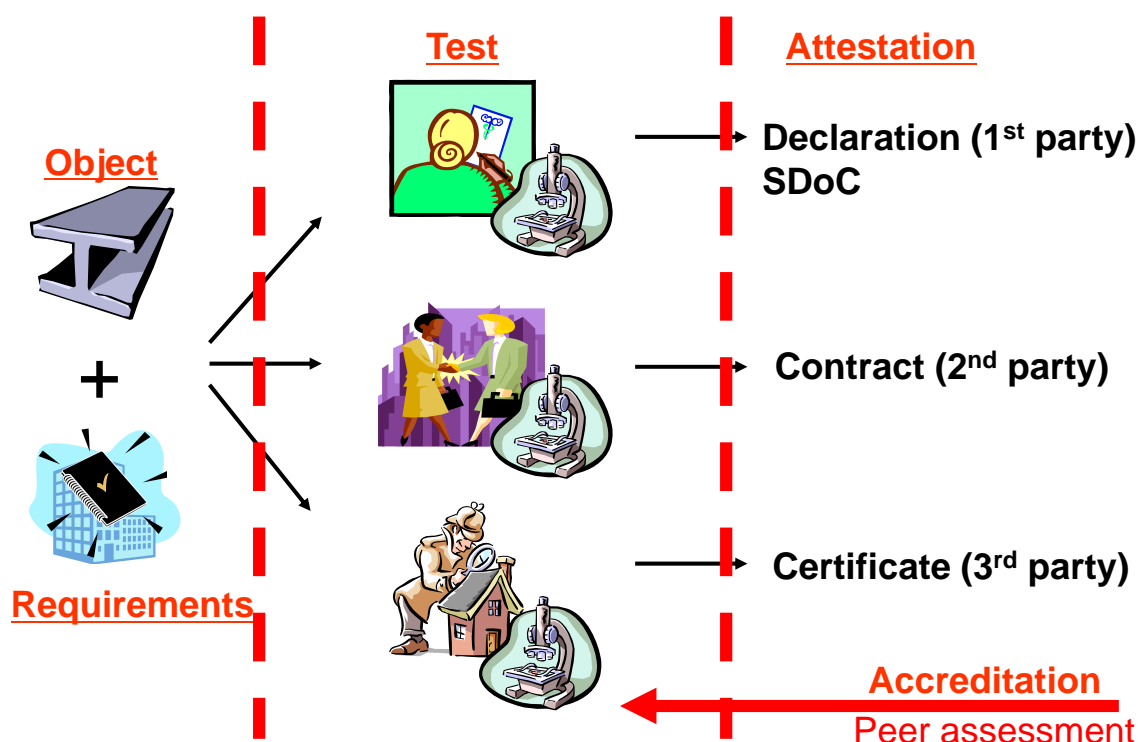
Conformity Assessment:

The demonstration that **specified requirements** relating to a product, process, system, person or body **are fulfilled**.

[Clause 2.1,

ISO/IEC 17000:2004(E): *Conformity assessment — Vocabulary and general principles*]

The Conformity Assessment processes



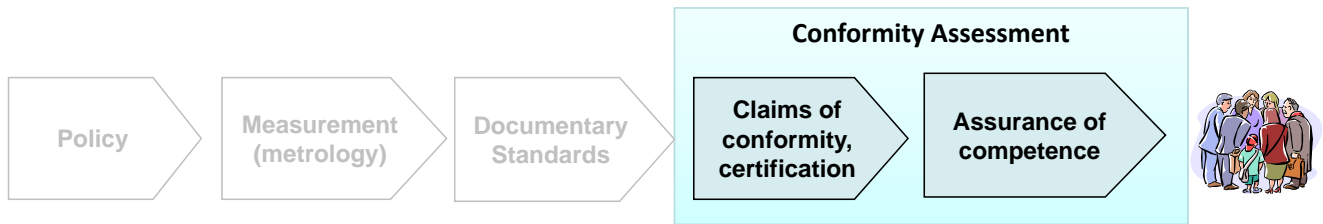
TWO CASCO PRINCIPLES

- The ISO Directives identifies two major principles applied in the development of Conformity Assessment documents:
 - **Principle of neutrality**
 - This policy states that all documents containing requirements for products, processes, services and persons shall be written such that conformity can be assessed by a manufacturer or supplier (1st party), a user or purchaser (2nd party), or an independent body (3rd party).
 - **Sector Policy**
 - This policy states that ISO/CASCO does not encourage the unnecessary poliferation of sector documents however where there is a geniune need by a sector for such a document CASCO will assist in its development. An example is the Food industry and motor industry.

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The CASCO Toolbox

International standards and guides on conformity assessment are jointly published by ISO and IEC, and are developed by ISO/CASCO

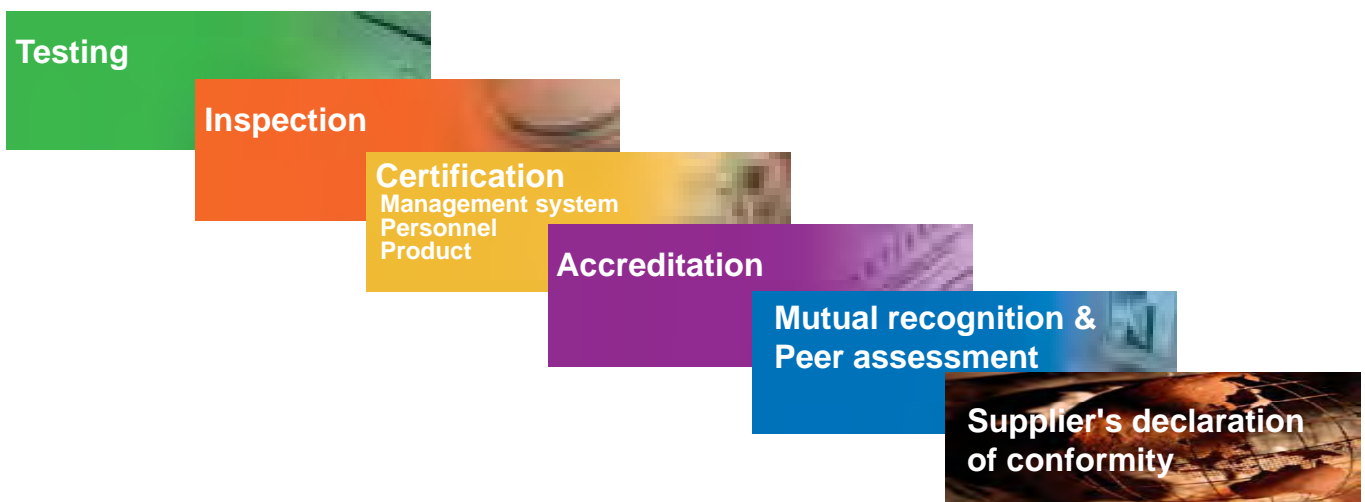


The ISO/CASCO toolbox refers to 26 International Standards and Guides produced by the *ISO Policy Committee on Conformity Assessment* (ISO/CASCO) covering:

- Principles and terminology
- Common elements
- Code of conformity assessment practice
- Writing specified requirements
- Testing
- Inspection
- Suppliers declarations of conformity
- Certification
 - Product
 - Management systems
 - Persons
- Accreditation
- Peer assessment
- Mutual recognition

1
7

The ISO/CASCO toolbox provides specific standards and guides on each conformity assessment activity



The decision to use one type of conformity assessment, depends on the customer's requirements, the level of risk associated with the product/service and regulatory requirements

Mechanisms for performing CA - Testing

- Definition from ISO/IEC 17000 (4.2) – Testing
 - Determination of one or more characteristics of an object of conformity assessment, according to a procedure.
 - NOTE “Testing” typically applies to materials, products or processes.
- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO 15189:2007, *Medical laboratories - Particular requirements for quality and competence*
- ISO/IEC 17043:2010, *Conformity assessment -- General requirements for proficiency testing*



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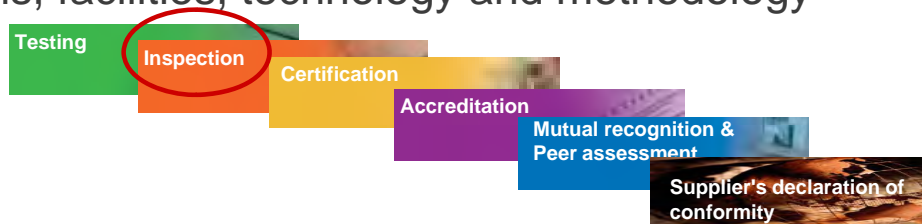
Mechanisms for performing CA - Testing

- Common form of conformity assessment
- Provides the **basis for other types of conformity assessment** like inspection and product certification
- Product is tested against a **specified set of criteria**
- Used to make **decisions on the performance of the product**
- Depending on specific requirements from customers and the risk associated with the product, the **testing laboratory may choose to be accredited**

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Mechanisms for performing CA - Inspection

- Definition - Inspection
 - Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the **basis of professional judgement**, with general requirements
 - NOTE Inspection of a process may include inspection of persons, facilities, technology and methodology



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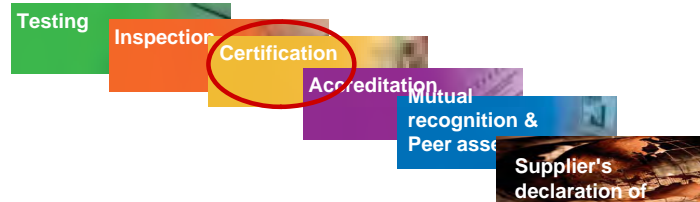
Mechanisms for performing CA - Inspection

- Inspection bodies
- Examine
 - a huge range of products, **materials, installations, plants, processes, work procedures and services**, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation
- Overall aim
 - to **reduce risk** to the buyer, owner, user or consumer of the item being inspected
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

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Mechanisms for performing CA - Certification

- Definition from ISO/IEC 17000 (5.5)
 - Third party attestation related to products, processes, systems or persons”
 - NOTE 1 Certification of a management system is sometimes also called registration
 - NOTE 2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable
- Definition of Attestation from ISO/IEC 17000 (5.2)
 - Issue of a statement based on a decision following review that fulfillment of specified requirements have been demonstrated



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Mechanisms for performing CA - Accreditation

- Definition in ISO/IEC 17000 (5.6)
 - Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks



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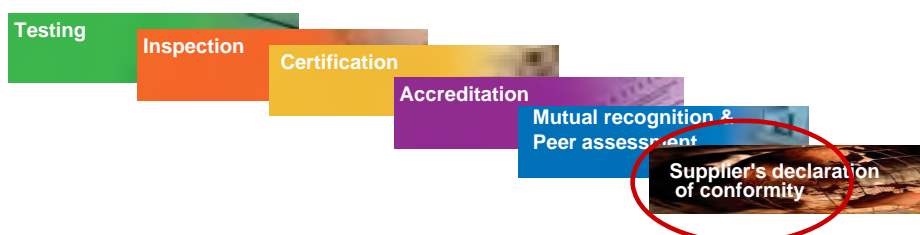
Mechanisms for performing CA - Accreditation

- Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks
- Accreditation of testing laboratories, product certification and inspection bodies is independent verification that they are competent to perform the activities for which they are accredited
- ISO/IEC 17011, *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*

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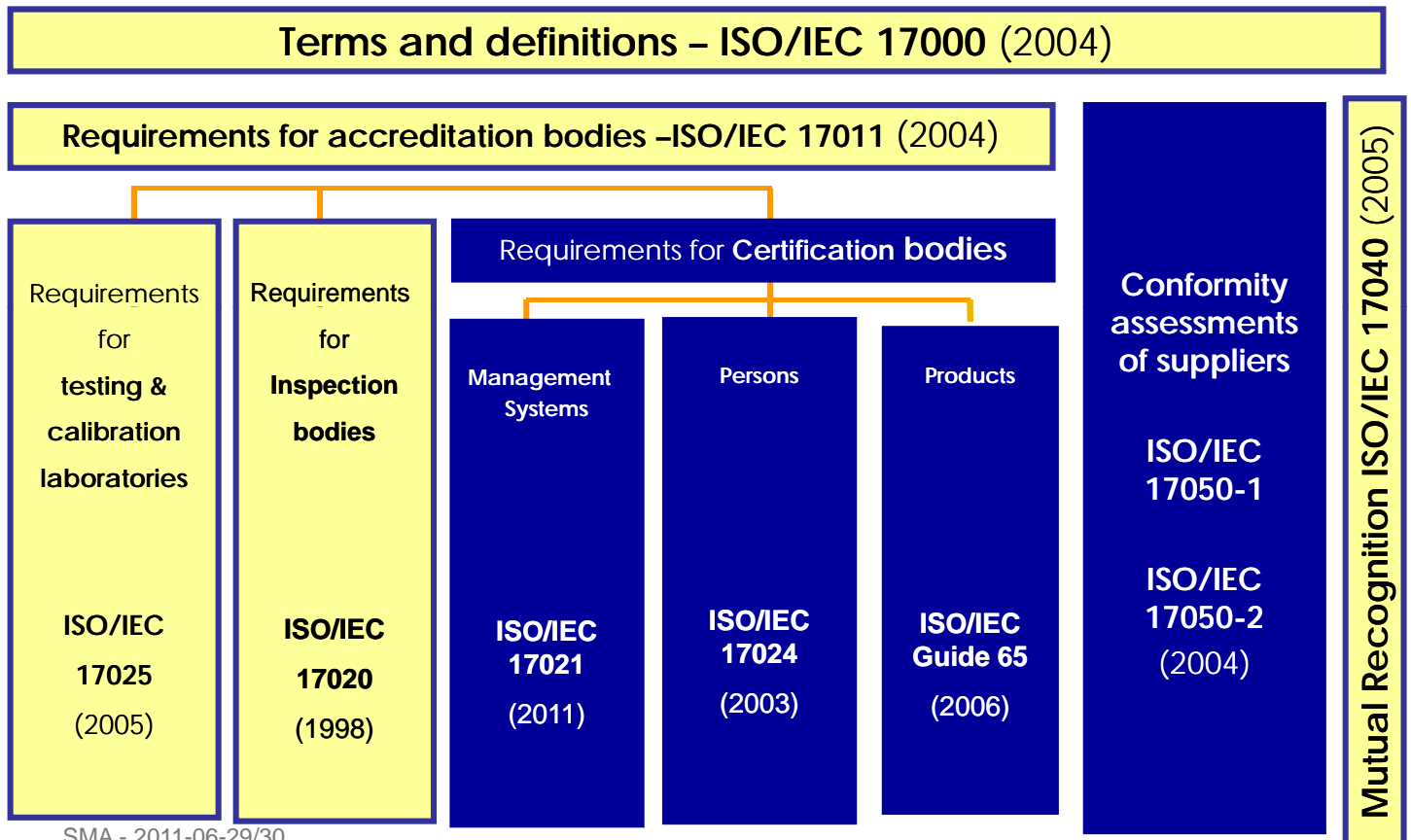
Mechanisms for performing CA - Supplier's Declaration of conformity (SDoC)

- Most widely used claim of conformity in the market
- ISO/IEC 17050-1:2004, *Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements*
- ISO/IEC 17050-2:2004, *Conformity assessment -- Supplier's declaration of conformity -- Part 2: Supporting documentation*



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The “CASCO Toolbox” relationships...



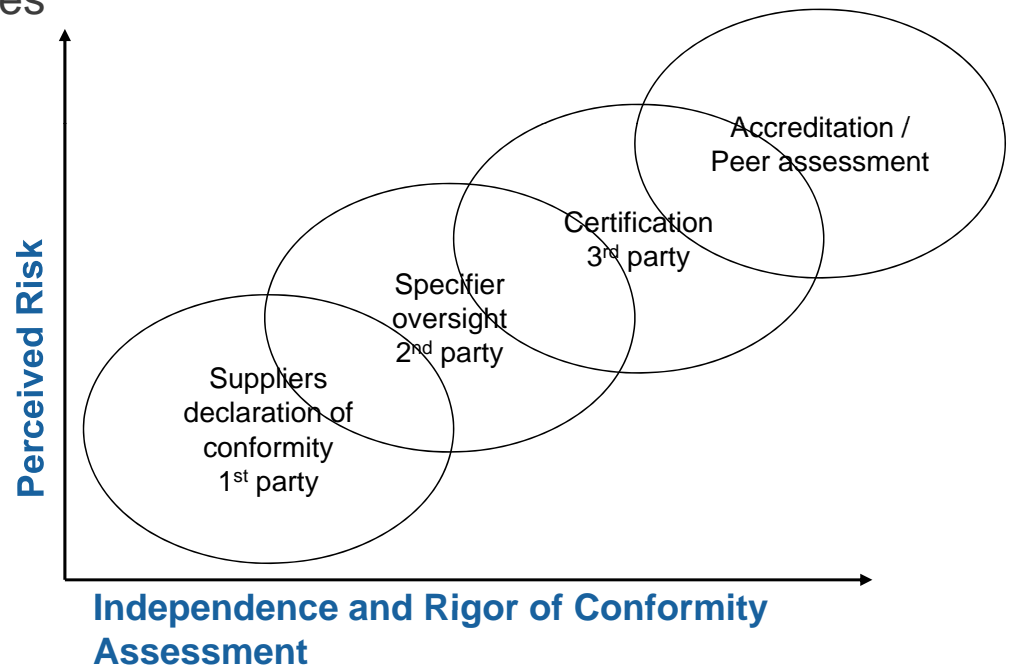
CASCO Standards in Progress

- ISO/IEC **17021:2011** (CASCO WG 21), Conformity assessment — Requirements for **3rd party certification auditing of management systems** (Published 01 February 2011)
- ISO/IEC **17065** (CASCO WG 29), Conformity assessment — Requirements for certification bodies **certifying products, processes and services** (DIS – Expected publication 2012)
- ISO/IEC **17024** (CASCO WG 30), Conformity assessment — General requirements for bodies operating **certification of persons** (DIS- Expected publication 2012)
- ISO/IEC **17020** (CASCO WG 31), Conformity assessment — General criteria for the operation of various types of **bodies performing inspection** (DIS- Expected publication 2012)
- ISO/IEC **17067** (CASCO WG 32), Conformity assessment – Fundamentals of **product certification** (Product scheme development) (WD 2)
- ISO/IEC TS **17022** (CASCO WG 33), Conformity assessment – Third party management system **audit reports** (PDTS Expected publication 2012)

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Application of conformity assessment activities is sometimes expressed in relation to managing risk

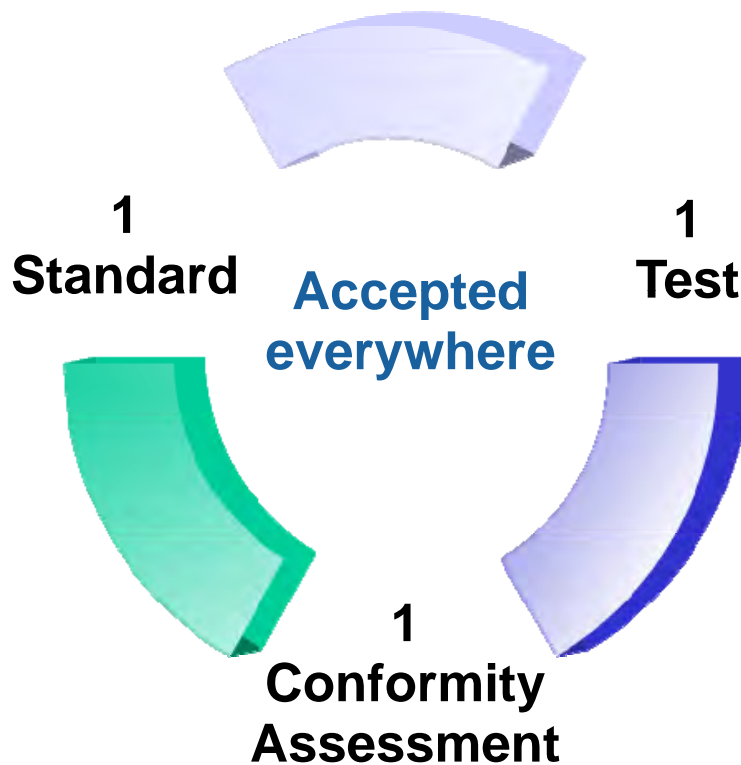
- Confidence in safety, health, environment, fair commerce
- Regulations based on risk
- Choice of activities
 - Testing
 - Inspection
 - SDOC
 - Certification
 - Accreditation



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CASCO Structure and operation

The 1-1-1 dream of Conformity Assessment



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ISO/CASCO structure

- **112 ISO members** are represented in CASCO (70 participating members and 42 observers).
- 18 international organizations are **liaison members** of CASCO: BIPM, CECOC, CAC, EFAC, EOQ, Eurolab, IAF, IFAN, IFIA, IIOC, ILAC, INLAC, IPC, IQNet, ITU-T, OIML, UILI, UNFCCC and IEC.
- Both policy and technical work
- Continual improvement cycle



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CASCO Interpretation Process

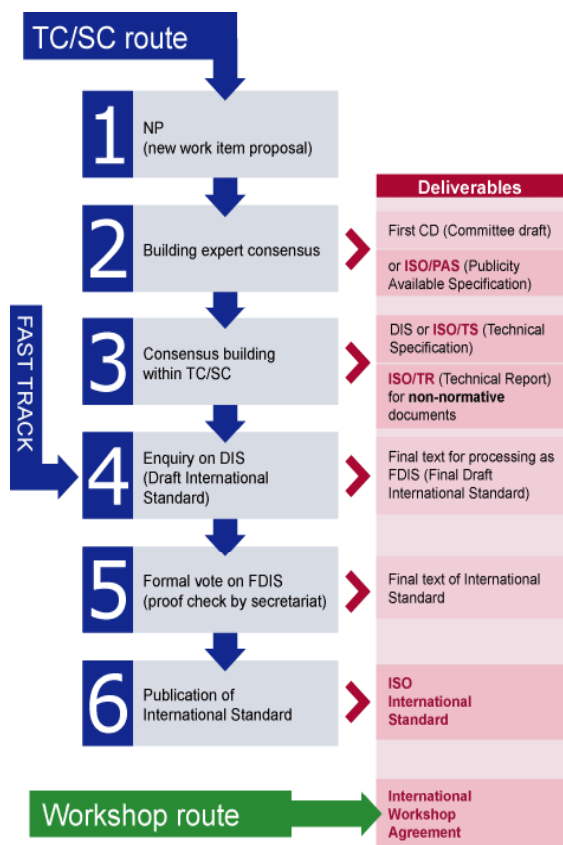
- Provides a uniform consistent approach to interpretation and maintenance of existing standards and guides
- Responses are available on ISO website
- Accepted as the official interpretation structure
- Ten interpretations done to date
 - ISO/IEC Guide 65
 - ISO/IEC 17021
 - ISO/IEC 17011

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Developing CASCO Standards

Conformity Assessment Standards

- Standards generation



- **ISO Standard**
 - A normative document, developed according to consensus procedures, which has been approved by the ISO membership and P-members of the responsible committee in accordance with Part 1 of the ISO/IEC Directives as a draft International Standard and/or as a final draft International Standard and which has been published by the ISO Central Secretariat
- **ISO/PAS Publicly available specification**
 - A normative document representing the consensus within a working group.
- **ISO/TS Technical specification**
 - A normative document representing the technical consensus within an ISO committee
- **ISO/TR Technical report**
 - An informative document containing information of a different kind from that normally published in a normative document.
- **International Workshop Agreement (IWA)**
 - An IWA is an ISO document produced through workshop meeting(s) and not through the technical committee process.
- **ISO Guide**
 - Guides provide guidance to technical committees for the preparation of standards, often on broad fields or topics

CASCO Working Groups

- ISO/CASCO P Members nominate to the WG.
- **A-Liaison** members nominate to WG. **D-Liaison** can be established between an organization and a WG.
- They are nominated as experts and required to input as **experts**. **WG group members act as independent experts not as national delegates**.
- The WG develops a Working draft document (**WD**). It evolves into a Committee Draft (**CD**) document.
- The CD goes to member bodies who distribute to **NMC** (NMC) for CASCO.
- At this stage no longer the experts but the national consensus comments.
- Responsible for the development of the document (Standard/Guide) (DIS and FDIS and publication).



Topical issues in CASCO

- 1) **Market Suveillance** – Information booklet to be developed on regulatory Good Practice aimed to assist developing economies
- 2) **Interpretation Panel** – Completion of 8 requests for interpretation – process is functioning well
- 3) **CASCO Newsletter** developed and 3rd edition released
- 4) **IAF-ISO Action plan** on monitoring the effectiveness of Accredited Management System Certification – progress is on schedule.
- 5) **Web conferencing** being used relatively extensively for workshops and WG meetings. Facilitates participation from developing economies
- 6) Composition of the **CPC structure** –more efficient
- 7) **Communication** strategy
- 8) **Open day** 5th October

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The End at last!

**Thank you
and
any questions**

- http://www.iso.org/iso/resources/conformity_assessment.htm
- [ISO video](#)
- maccurtain@iso.org
- chalet@iso.org
- bleeker@iso.org



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

1

Background to Conformity to Type (CTT) in OIML

Dr. Grahame Harvey
First Vice President
CIML

2

Overview

- Metrological Control Systems
- Initial drivers for OIML CTT activity
- 2004 proposal for linking to MAA
- Presidential Council WG on CTT
- More recent activity on CTT
- Critical issues identified
- Options for OIML involvement
- Summary

3

Metrological Control Systems

A national (OIML) standard

Pattern (type) approval (C of T)

Conformity to type (CTT)

Verification test procedures

Initial verification

Subsequent verification

4

Initial Drivers for OIML Activity

- Advent of electronic instruments means that initial verification is no longer able to detect non-conformances with the specifications for the pattern.
- Accidental discoveries in Australia
 - load cells lack of temperature compensation
 - NAWI instruments with different power supplies
 - EMC components missing
- Voluntary CTT system in Australia
- Issues with evidential breath analysers
- Analysis of pattern approval applications

5

Initial Proposal for Linking to MAA

- 2004 CIML discussion on MAA fees
 - Discussion of MAA fees with a component for issuing authorities and a fee on each certificate.
 - Noting the savings for industry in approval fees, it was proposed to incorporate a mandatory loading on MAA certificates to fund a CTT system
- CIML rejected this proposal because it did not want to compromise the acceptance of the MAA.

6

Presidential Council WG on CTT

- Presidential Council established a WG on CTT in 2005.
- Meetings were held annually until 2008
- At CIML 2010, CIML considered a proposal to create a new technical committee on CTT. However, CIML resolved instead to hold this seminar.

7

Outcomes of WG on CTT

- Meeting 1 in 2005: There was strong support for developing a CTT proposal, involving:
 - International coordination,
 - Sharing of information on non-conformities through an “alarm” database,
 - It was noted that the latter could raise confidentiality and legal issues.
- Meeting 2 in 2006:
 - The meeting considered in detail a discussion paper that the secretariat had prepared for the meeting.
 - It was resolved to carry out surveys of industry and regulators.

8

Outcomes of WG on CTT (2)

- Meeting 3 in 2007:
 - The two surveys conducted by BIML were considered.
 - The survey of regulators revealed that few member states had a competent system to detect non-conformities. Most relied on initial verification that can detect blatant non-conformities but is mostly ineffective for CTT.
 - About a third of respondents to the industry survey were opposed to the introduction of an OIML conformity to type program. The remainder either supported such a program or had no opinion.
- A presentation by a representative of CECIP was strongly supportive of a conformity to type program. The representative noted that some major European manufacturers were considering the introduction of their own voluntary program.

9

Outcomes of WG on CTT (3)

- Meeting 4 in 2008:
 - The meeting considered an issues paper prepared by the secretariat.
 - The representative from CECIP informed the WG that European manufacturers were supportive and open to the idea of a CTT program.
 - The representative from the USA informed the WG of a “Proof of Production vs. Type” program that had recently been established by the Scale Manufacturer’s Association in America. This program incorporates initial verification, an administrative (certificate) review and conformity testing.
 - In addition, some representatives informed the WG that several manufacturers have approached them requesting a higher level OIML type approval (OIML ++) incorporating CTT.

10

More Recent Activity on CTT

- At CIML 2009, a Round Table on Metrological Control was held in which some papers were presented on CTT.
- Also in 2009, the BIML prepared a discussion paper on Conformity Assessment of Measuring Instruments (BIML 09 N° 402/JFM) that also raised the application of CA to prepackages.
- At CIML 2010, CIML considered a proposal to create a new technical committee on CTT. However, CIML resolved instead to hold this seminar.

11

Outline of the CTT System Considered by WG

- Recognition of manufacturers' quality systems based on certification by an IAF signatory. Note that some national authorities already require auditing of the manufacturers quality system (similar to Annex D of MID).
- A light level of auditing of production possibly in cooperation with Regional Bodies. Further auditing would be carried out if a significant non-conformity were detected.

12

Critical Issues Identified

- Funding of CTT testing. Although not a large amount of funding is required because:
 - Only a few instruments sampled from any region
 - Only a subset of approval tests carried out
 - (some ideas on funding will be presented later in the seminar)
- Confidentiality and legal issues. The storage and transmission of information that impacts negatively on a company is a very significant issue and BIML would need to take legal advice.

13

Options for OIML Involvement

- No involvement.
- Establish a TC to prepare a guidance document for member economies with no further involvement
- Establish a TC to develop an MAA type system with BIML coordination and transmission of testing data
- As for the last dot point but including conformance of prepackages.

14

Summary

- With technological development, there is a clear need for a conformity to type (CTT) system.
- Industry has in general been supportive.
- To make further progress, the OIML WG and seminar activities need to be replaced by formal technical committee work.
- There are legal, confidentiality and funding issues to be addressed.

15



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

IEC Conformity Assessment Systems A comparison

**OIML Seminar on Conformity to Type
29th to 30th of June, 2011 in Utrecht/NL**



Dr Uwe Klausmeyer
Immediate Passed Chairman IECEx

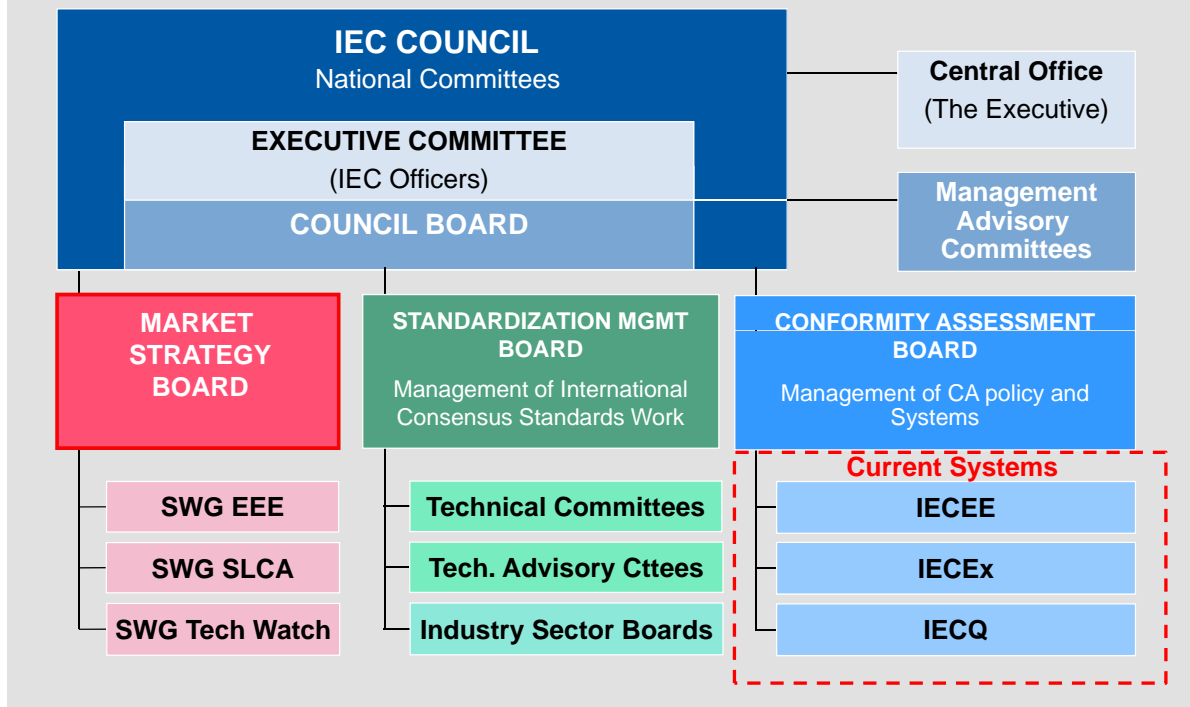
- The International Electrotechnical Commission with 60 full members
- Founded in 1906 to promote international co-operation on all questions of standardization and related matters in the field of electrotechnology, including Conformity Assessment.



- The IEC and ISO are twins as international SDOs, located in the same building (Rue de Varembe 3, Geneva, CH)
- IEC full member 60 countries plus 21 associated (ISO: member 108 plus 54 associated)
- Close collaboration:
 - via ISO/IEC Directives and Guides as the procedural rules to be followed for the development and maintenance of international standards
 - on international scenes like WTO, especially for the TBT agreements
 - development of CASCO standards

- **Impartiality, stakeholder principle**
- **Parliamentary process within rectification of standardization documents (comments, voting)**
- **Integration of regulatory requirements, close contact to regulators and early involvement in the standardization process – see EU New Approach**
- **Goal: One standard – accepted everywhere and by each stakeholder**

- **Strict separation between standardization and conformity assessment**
- **Main CASCO standards for certification:**
 - ISO/IEC Guide 65 (replaced soon by ISO/IEC 17065) and ISO/IEC Guide 67
- **Other CASCO standards:**
 - ISO/IEC 17025 Laboratories
 - ISO/IEC 17021 Management systems
 - ISO/IEC 17024 Competence of Persons
- **IAF/ILAC accreditation accepted by national regulators as a goal, replacing national accreditation systems**
- **CA schemes should only driven by market demand or regulators, NOT by commercial interest of CA bodies**



Principles of IEC systems for conformity assessment (CA)

- Peer assessment of CBs and TLs, usually based on IAF/ILAC accreditation as an add on, conducted with technical assessors, applying CASCO standards plus technical guidance documents (Technical Panel with ILAC/IAF based on a MoU)
- Detailed rules and procedures laid down in SOPs (operational documents – ODs)
- Using test report templates related to the IEC standard requirements
- Conducting proficiency testing programs
- Using a single online certification tool, operated by IEC in the Central Office Geneva for total transparency of the CB activities worldwide



Main benefits of the IEC CA systems

- International independent testing and certification as a basis for global confidence of the stakeholders, esp. consumers and regulators
- Test results recorded in a structured template as a basis for the “Fast track” national certification (time to market in international trade)
- Potential of the IEC CA systems for direct certificate acceptance by national regulations (IECEX in AU and NZ)



Size of the systems

	IECEE	IECEX	IECQ
Member bodies	53	30	17
Certification bodies	71	40	21
Test laboratories	341	43	21



Use of the IECEE Schemes



Use of the Schemes to their fullest extent will promote the exchange of information necessary in assisting **Manufacturers** around the world to obtain certification or direct acceptance in the global markets

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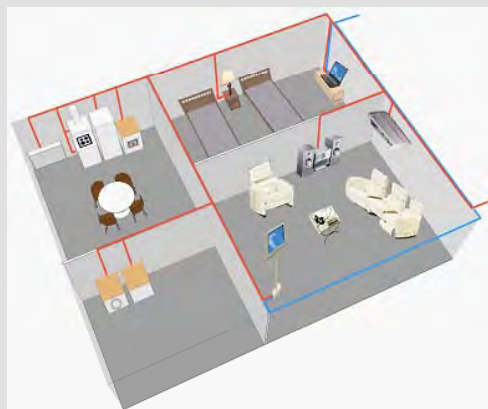
The scope of the CB Scheme

Electrical accessories
(TC 23)

Luminaires
(TC 34)

Electric cables
(TC 20)

Lamps and related
equipment (TC 34)



Safety, Performance, Sourcing
IECEE

Information Technology
(TC 108)

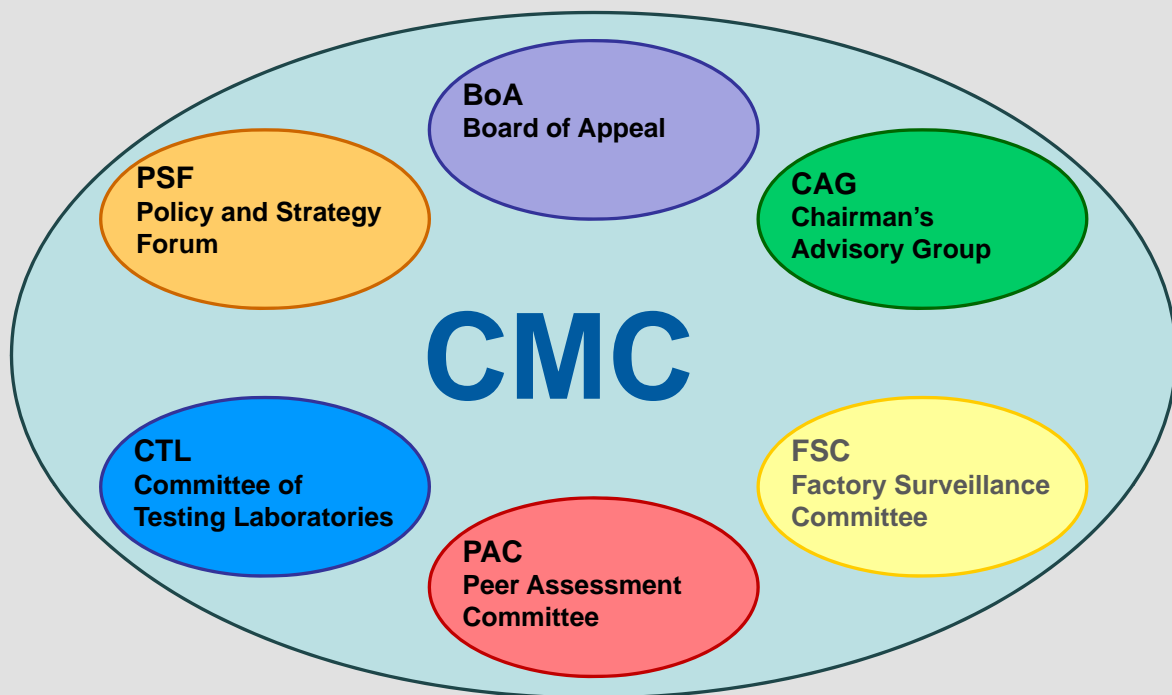
Multimedia
(TC 100)

Fibre optics
(TC 86)

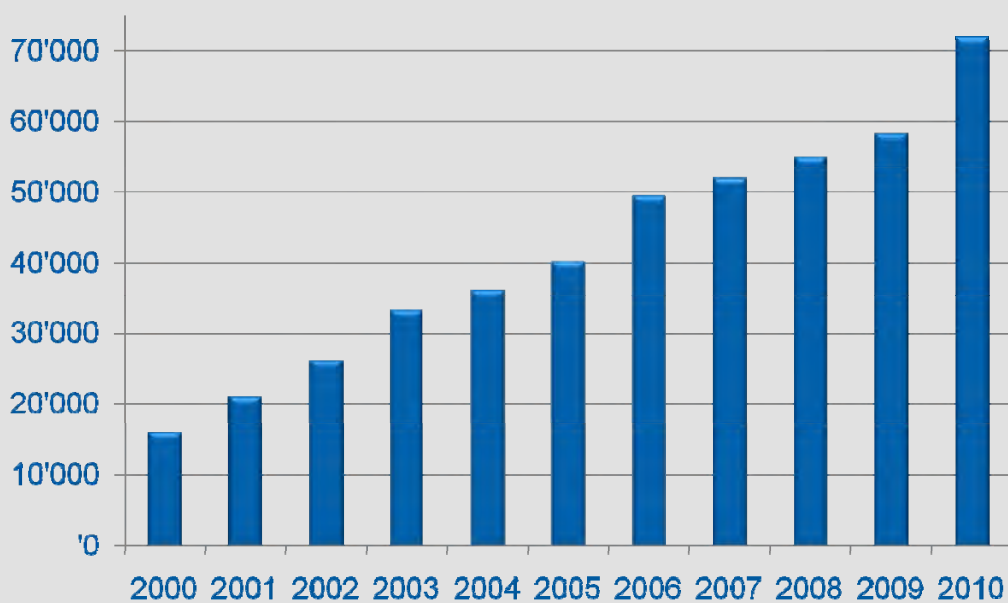
Cables, wires,
waveguides (TC 46)

Household appliances
(TCs 59 & 61)

12/49
12/49



13/49



14/49



What is IECEx?

The single International IEC System with Schemes covering Certification to Standards that relate to Equipment and Services in areas relating to Explosive Atmospheres, to provide an Internationally accepted means of *demonstrating claimed compliance with International Standards*

IECEx is a “**Conformity Assessment Tool**” providing confidence that **Products, Services and Personnel** covered by an IECEx Certificate meet specified requirements, (International Standards)

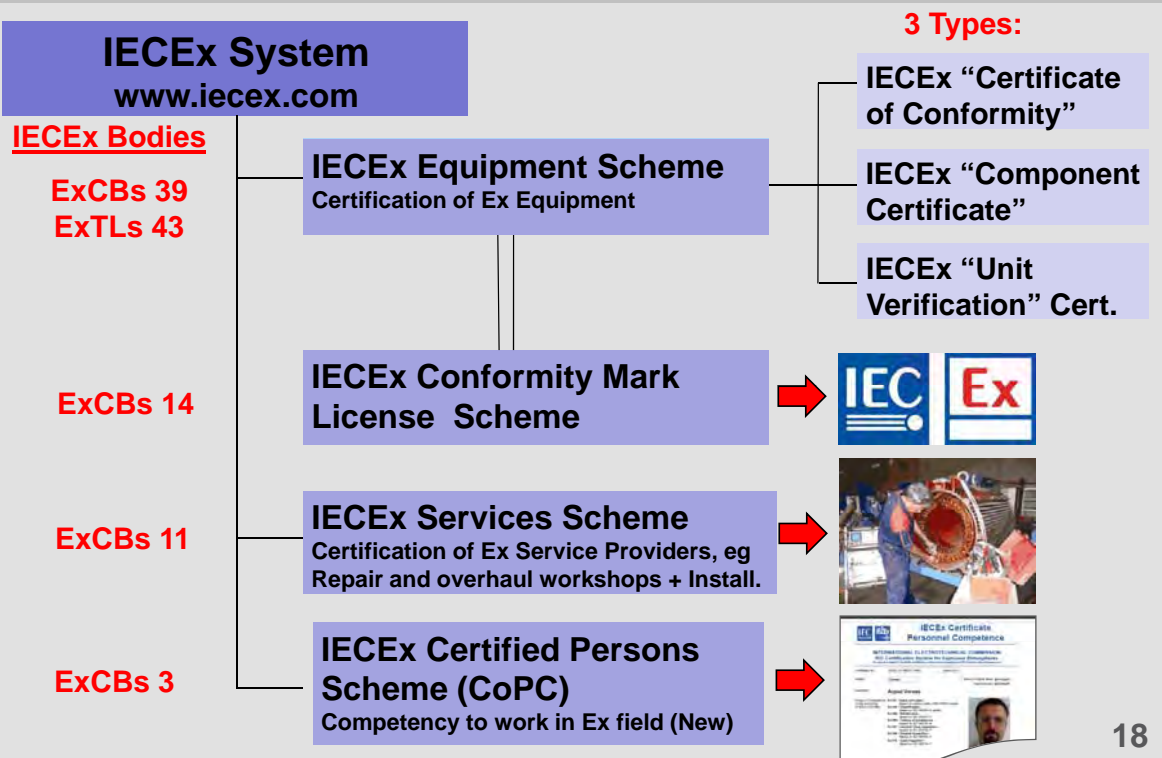
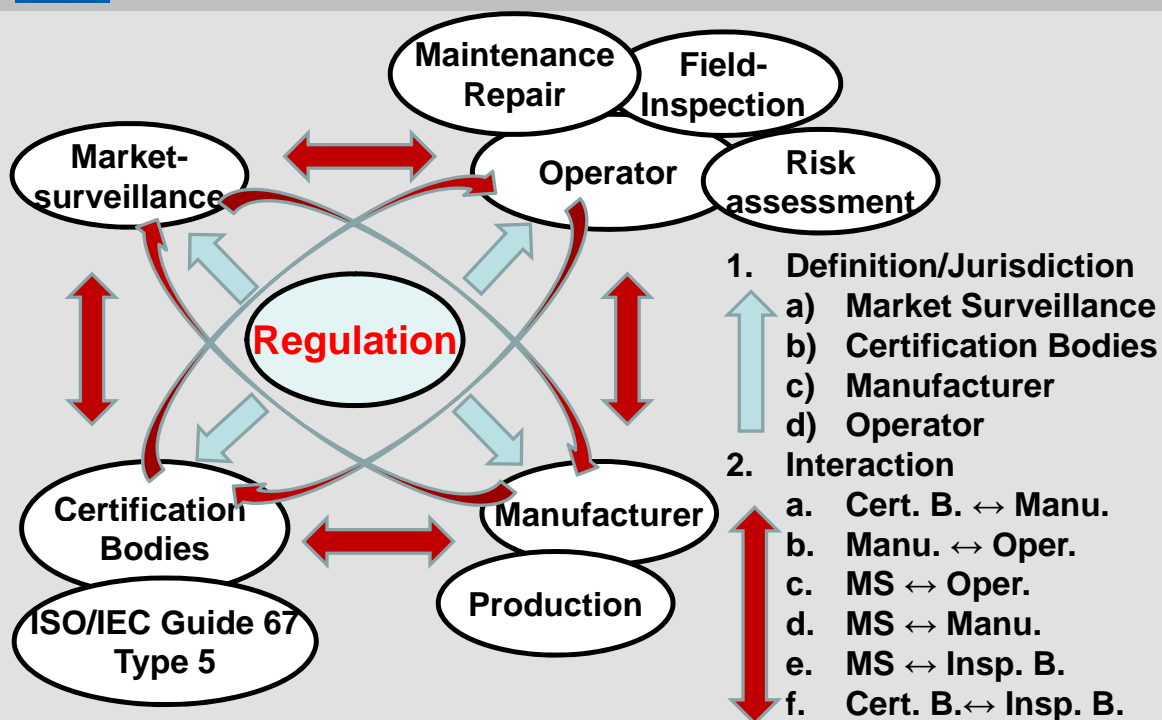
“IECEx is the International Standard way of doing Ex Certification”



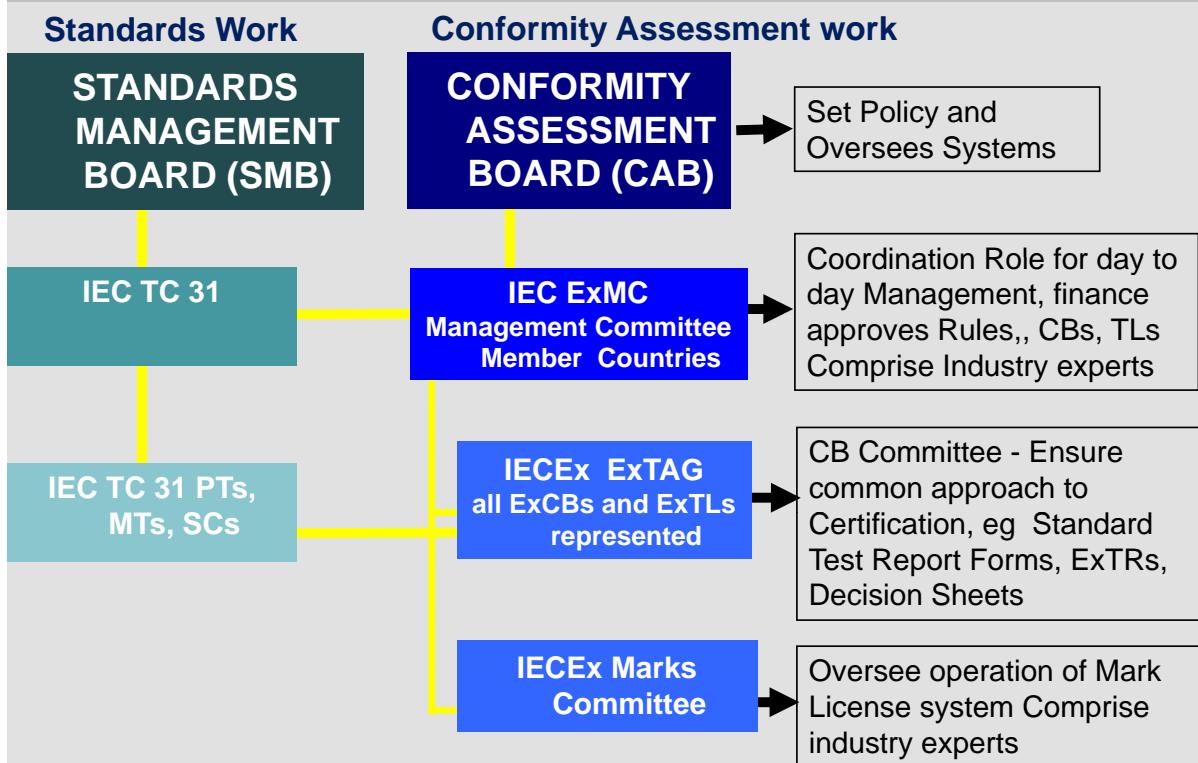
Examples of Equipment Covered by IECEx

- Transducers, Sensors etc
- Switchgear
- Control Stations
- Motors
- Luminaries and Lighting
- Underground vehicles
- Radios + Communication
- Junction boxes
- Control Modules
- Control Systems
- Instrumentation
- Analyser houses
- Ventilation Rooms
- Components
 - Terminals
 - Adaptors / Reducers
 - Cable terminations
 - Glands
- Many others





IECEx Management and Governance Structure as at Jan 2011



IECEx Certificates + Licenses Issued

Ex Equipment, Components + Systems

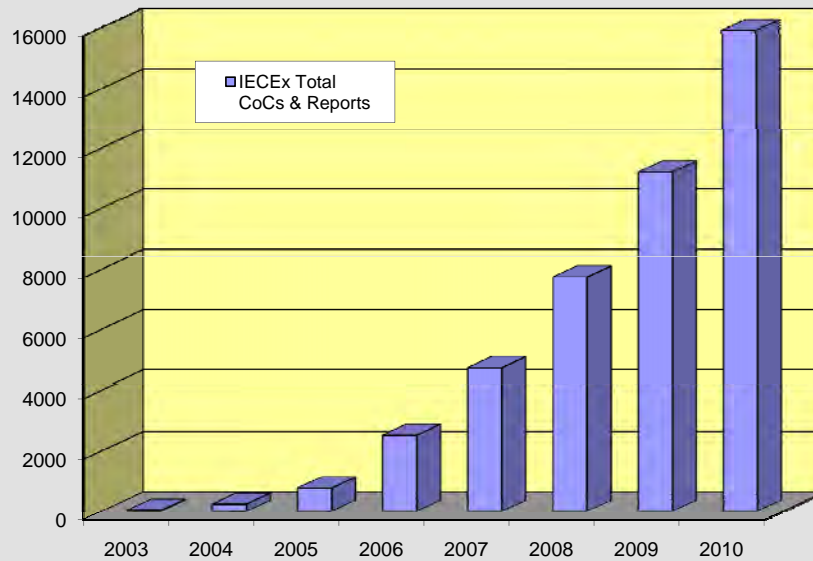
Ex Equipment Unit Verification

Ex Equipment Mark License

Ex Services, eg Repair to IEC 60079-19

Ex Competent Person

+ Installation coming



**New United Nations
Publication via UNECE
endorsing IEC TC 31
Standards + IECEX as
“world’s best practice”.**



Full Text

http://www.unece.org/press/pr2011/11trade_p03e.htm

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

**A Common Regulatory Framework
for Equipment Used in Environments
with an Explosive Atmosphere**



What is IECQ

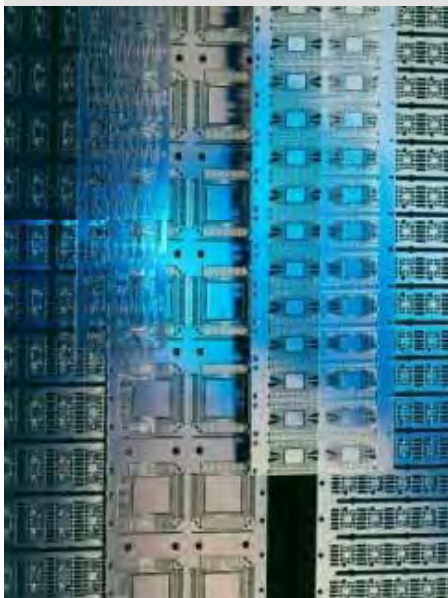
IECQ is the IEC International Conformity Assessment Scheme providing a single International Assessment and Certification System covering electronic components, related materials, sub assemblies and processes.

IECQ therefore provides a single International Conformity Assessment tool to support the "**Business to Business Supply Chain Management System**".



IECQ System

IECQ System www.iecq.org



Process Approvals
Eg Electrostatic Discharge Management
ESD etc

Component Approvals
Qualification, Capability (Production of
Components +Assemblies)

IECQ HSPM QC 080000
Hazardous Process Management

ECMP
Electronic Component Management Plan
(Avionics + Others, railways, medical)

**ITL (Test Laboratories Operating in
IECQ)**

- **IECQ ECMP provides assessment by independent IECQ qualified Certification Bodies that eliminates the need for multiple assessments by different customers of component suppliers, eg Boeing/Airbus and other airframe manufacturers and sub-contractor**



- Provides aerospace industry the ability to utilise Commercial – off - the shelf (COTS) components, in a confident manner, resulting in cost savings against military spec components
- Provide assurance that processes exist for managing non availability of replacement parts and components
- International “On-Line” IECQ Certificate for quick checking by industry + Regulators



Differences between the systems

- IECEE and IECQ are not so strongly submitted to national regulations like IECEx
- IECEE and IECQ are not structured for the lifecycle approach like IECEx
- IECEE is collaborating with several IEC/TCs, IECEx only with IEC/TC 31
- IECQ serves electronic industry only
- IECEx will get mechanical products under their scope by standards made by IEC/SC 31M
- IECEx accepts tests made at manufacturer's location only by (remote) witnessing of an ExTL



Acceptance of test results not made in an Ex Test Laboratory

- Accreditation bodies worldwide do not tolerate “easy living” in the Ex product certification
- IECEE has developed a sophisticated procedure (TMP, WMP, SMP – OD 2027 to 2030), but this procedure has been declined by regulators
- IECEx is using the OD 024 which allows testing at other locations than the ExTL with “remote witnessing”
 - initial assessment of the test facilities in partial accordance to ISO/IEC 17025
 - full control of each individual test sample by the ExTL (identification, treatment)
 - tests done “remote” under full control of the ExTL via web camera, recorded and archived
 - ongoing surveillance of the location



INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

Thank You





OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

OIML Conformity to Type

A Perspective from US Manufacturers

Presented by the Scale Manufacturers Association

OIML Conformity to Type Seminar
29 – 30 November 2010
Utrecht, The Netherlands

2

Scale Manufacturers Association

- A non-profit organization founded in 1945.
- 10 member companies
- Represents manufacturing, sales and service of all accuracy classes of scales, balances and load cells.
- A forum for participation and a relied on voice in the regulatory process.



29 June 2011

3

OIML Conformity To Type

Scale Manufacturers Association Objective

“This cooperative endeavor of voluntary members is dedicated to the best interests of the scale industry as a whole; to the owners and users of scales, who are entitled to the best practical weighing equipment which can be produced; and to the public, which is so dependent upon accurate and dependable weights.”

29 June 2011

4

OIML Conformity To Type

Setting the Tone of the Presentation

- An effective regulatory system creates an environment in which transactions favor neither the buyer nor the seller.
- The fairness of a regulatory system is vital to all parties concerned.
- Significant changes to a regulatory system impact manufacturers more than any other party or group.

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5

OIML Conformity To Type

Presentation Introduction

- **Why does the legal metrology community feel that a CTT program is necessary?**
- **What experience led the legal metrology community to feel that a CTT program is necessary?**
- **What has been learned from other similar programs?**
- **What challenges will an OIML Recommendation create on a national level?**
- **How many CTT programs will device manufacturers, be subject to?**
- **Will components of a CTT program duplicate requirements in other Recommendations?**

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6

OIML Conformity To Type

US Verified Conformity Assessment Program (VCAP)

- Why?

In a controlled evaluation 6 of 8 instruments failed compliance testing.

- What tests would confirm compliance?

- Tests that cannot be conducted in the field!
- Tests influence factors (environmental) effects such as temperature, voltage, etc.

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OIML Conformity To Type

US Conformity Assessment Program (VCAP)

- Predictable but disturbing results showed the need for improved compliance levels.
- Needed to confirm compliance with influence factor requirements that cannot be verified in the field.
- Need to maintain the value of the NTEP Certificate of Conformance.
- VCAP was created to address these needs.

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8

OIML Conformity To Type

Before VCAP Was Created

- The Scale Manufacturers Association developed a Production Meets Type (PMT) program in 2002.
- Why?
 - Manufacturers wanted a voice in the development of this program;
 - Manufacturers bear the burden of proving compliance;
 - Regulators may fail to consider important factors in program development.
- PMT was a voluntary program that several SMA members implemented.
- PMT was in place for four years and offered to the legal metrology community for their use.

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9

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VCAP Program Similar to PMT

- The VCAP program is mandatory while the PMT was voluntary.
- VCAP was built on the PMT program and contains many of the same elements focusing on influence factor testing to practical sampling levels.
- Both program use third party auditors.
- Both programs verifies existence of quality management system and access to necessary test equipment

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10

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Concerns

- Are audits consistent between:
 - Different auditors?
 - Multiple facilities of single device?
 - Device manufacturers and Private Label certificate holders?
- Are VCAP audits reported in the same way?
 - Device compliance versus process capability
 - Specific device models versus a range of device parameters

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11

OIML Conformity To Type

How Many Different CTT Programs are Needed?

- An OIML Recommendation is used to create a country specific program.
- Countries are free to add country-specific requirements.
 - Could lead to multiple programs which will be difficult to all members of the weights and measures community.
- Reciprocity needed between CTT programs.
- Multiple CTT programs result in higher market entry costs to manufacturers.

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12

OIML Conformity To Type

Complexity of a Conformity Program (1/3)

Many companies own private label certificates.
This creates a unique situation.

Company "A" purchases a indicator from Company "B"



"Approved" Terminal from
Company "B"

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13

OIML Conformity To Type

Complexity of a Conformity Program (2/3)

Many companies own private label certificates.
This creates a unique situation.

Company "A" also purchases a platform from
Company "C"



"Approved" Platform from
Company "C"

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14

OIML Conformity To Type

Complexity of a Conformity Program (3/3)

Many companies own private label certificates.
This creates a unique situation.

Company “A” combines the two components into a complete instrument and has it “approved” in their company name.



**“Approved” Instrument
in the name of Company “A”**

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15

OIML Conformity To Type

Marketplace Sanctions and Legal Issues

- Can a recommendation developed by consensus properly address local marketplace sanctions and legal issues?
- Differences in national laws and regulations indicate that it would not be possible.
- This adds to the concerns of a proliferation of programs and again brings up the question of “How Many Different CTT Programs are Needed?”

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16

OIML Conformity To Type

Does a CTT Program Affect Existing Requirements?

- Is there overlap between existing requirements / regulations with those in a CTT program?
- How much additional cost and work will be required for implementation and management of a CTT program for regulators and for device manufacturers?
- Will compliance rates significantly improve after CTT implementation?
- Is CTT over regulation?

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17

OIML Conformity To Type

In Summary (1/2)

- **Did the VCAP accomplish it's goal of improved compliance?**
 - no clear answer because it is not fully implemented.
 - Only load cells are currently covered under VCAP. The next device type will probably be implemented in 2012 or 2013.
- **Potential proliferation of conformity programs is a concern to the weights and measures community.**

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18

OIML Conformity To Type

In Summary (2/2)

- **Complexity of an OIML Recommendation to address enforcement issues.**
 - We do not believe that a Recommendation can accomplish this!
- **Have we reached the point of over regulation?**
 - As the SMA we believe that too many CTT programs will become overly burdensome.

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19

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Thank You!

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20

OIML Conformity To Type



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands



OIML Seminar on Conformity to Type (CTT)

Perspectives of manufacturing industry



Content:

- About CECIP
- Role and responsibilities of manufacturers in the European market under legal control
- Questions to a voluntary quality management system for production (QMS) under supervision of OIML

About CECIP:

Members are the 15 national associations of weighing industry from the following countries:

Austria	Poland
Czech Republic	Romania
France	Russia
Germany	Slovak Republic
Hungary	Spain
Ireland	Switzerland
Italy	United Kingdom
Netherlands	

About CECIP:

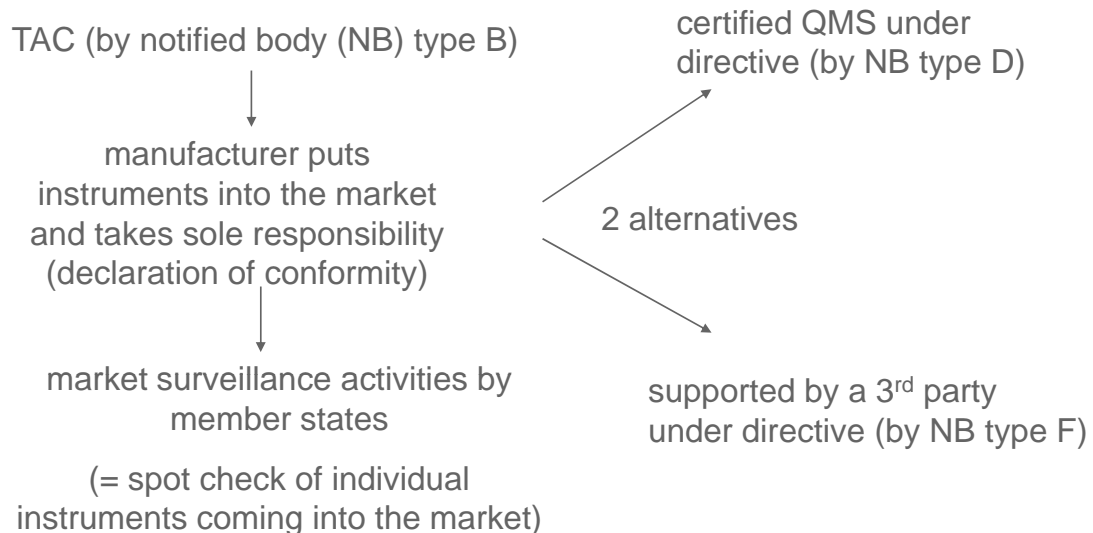
- 700 manufacturers
- turnover 3 billion Euro in 2008
- 50.000 employees
- + 4000 – 5000 micro companies (10.000 employees)
- global markets with more than 50 % of world wide trade volume

Role and responsibilities of manufacturers in the EU market under legal control

General overview:

- two-tier system : private and legal metrology
- harmonisation of regulations and cross approval of certificates and QMS certification between member states in EU resp. EEA via EU directives (one certificate is legal for all member states)
- legal metrology: 2 measuring instruments directives (NAWID and MID)
- legal metrology: same requirements for instruments' production inside or outside of Europe

Role and responsibilities of manufacturers in the EU market under legal control
procedure for putting instruments into the market:



Role and responsibilities of manufacturers in the EU market under legal control
procedure for putting instruments into the market:

“certification of QMS” means:

checking whether a manufacturer has set up suitable procedures for manufacturing, testing and tolerances to make sure that his instruments will be in conformity with the regulations.

“certification of QMS” does not mean:

Testing of individual instruments by the NB. That might be the case in very special cases only. Such may be done with spot checks by the market surveillance bodies.

Role and responsibilities of manufacturers in the EU market under legal control

Essential functions of the system:

- **law based system with legally defined consequences in case of non-compliance**
- legally based market surveillance to grant fair competition (certified QMS is an alternative but not mandatory)
- information exchange between market surveillance bodies of member states monitors non-compliances

Role and responsibilities of manufacturers in the EU market under legal control

Experience of manufacturers

- since 1993 with NAWIs under NAWI directive
- since 2006 with AWIs under MID

Added value for manufacturers having a certified QMS e.g.:

- time to market (instruments may be put into use immediately because no additional actions are necessary (e.g. no initial verification by a 3rd party/W&M))
- reduction of costs when testing in production only without repetition by a 3rd party/W&M

Voluntary QMS under supervision of OIML

General remarks:

CECIP supports quality and fair competition.
Therefore CECIP supports conformity to legal requirements in
general and on a high level!

To judge whether a voluntary OIML CTT would be an advantage
there are **many questions which have to be answered before.**

Questions to a voluntary QMS under supervision of OIML

1. A manufacturer wants to import instruments into EU. What is the
benefit of his certified OIML CTT QMS?

??? EU has established its own legal system

=> the manufacturer has to use a Notified Body of EU for certification
of his QMS instead/in addition in case he wants to put his
instruments into the market via certified QMS

2. A manufacturer wants to import instruments into the US using
NTEP CC. What is the benefit of his certified OIML CTT QMS?

??? NTEP has established its own system with VCAP

=> ???

Questions to a voluntary QMS under supervision of OIML

3. A manufacturer wants to import instruments into other countries of the world where a “legal” system is not yet in place. What is the benefit of his certified OIML CTT QMS?

??? Has to be identified.

4. A manufacturer wants to import instruments into EU, US and other countries of the world (item3).

Does he has to be certified by at least all 3 organisations in parallel ???????

Questions to a voluntary QMS under supervision of OIML

5. Other questions :

Does certification under the CTT mean

- checking procedures in production or
- checking of compliance of instruments coming out of production
- or something else?

What does compliance (e.g. demonstrated by a sticker) say when the requirements are not harmonised in the countries taking part? See OIML R76 for example. There are differences and specialities in several countries.

Questions to a voluntary QMS under supervision of OIML

5. Other questions :

What are the requirements to instruments which are type-approved in a country without using OIML certificate and OIML CTT? How are those instruments or QMS under supervision to grant fair competition?

OIML has no legal rights in countries. How can OIML achieve legal consequences to achieve fair competition in a country in case of non-compliances?

Questions to a voluntary QMS under supervision of OIML

5. Other questions :

- What could be the consequences at all when OIML detects non-compliance and a national TAC is already issued? OIML certificates and OIML CTT have no legal character in any country.
- How to detect non-compliance for instruments without OIML certificate at all?
- Are users willing to pay the costs for instruments produced under a voluntary CTT in case others can produce cheaper without that? Not joining the CTT and saving costs doesn't say that produced instruments are not in compliance.
- **Where is the benefit for a manufacturer to join the OIML CTT (return on investment for his additional costs)?**

Questions to a voluntary QMS under supervision of OIML

These questions and others have to be answered

because

**to make the idea successful is that all parties
involved in the system have to be convinced
and see a benefit for the future**

Thank you for attention





OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

OIML seminar on conformity to type June 2011

Information about EU system

Corinne Lagauterie

Ministry of Economy, Finance and Industry

Head of Bureau de la métrologie

French CIML member

French member of WELMEC Committee

Overview of the presentation

- Useful terms and principles
- Content of documentation
- Role of manufacturers and notified bodies
- Role of market surveillance authorities, cooperation, legal actions
- Present EU experiences



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Bureau de la métrologie



Basic principles of legal metrology

- For a list of regulated uses (transactions and others)
- Ensure that instruments in normal operation give correct and safe results
- By fixing metrological requirements that instruments have to fulfil all along their life cycle
- By setting up a system of controls from design to production and later in service with adapted level of testing and MPEs
- All the system is based on the principle that initial conformity to requirements and to type is ensured



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European and national regulation

Due to the fact that European directives are limited

- To only some categories (NAWI and 10 MID instruments)
- To the stage of putting on the market and putting into service,

the national legislation in the EU member states is a mixture of national and European requirements

Legal aspects such as penalties for non conforming instruments belongs to the national legislation



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Vocabulary used

MID : measuring instrument directive 2004/22

NAWI directive : Non automatic weighing instrument directive (90/384 now codified version 2009)

NB : notified bodies, bodies designated by the member states to perform certain activities defined in the directives

MI measuring instrument

WELMEC european cooperation in legal metrology



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Assessment according to MID

Conformity assessment procedure : 1 or 2 modules of control applicable to a category of MI

13 different modules (A, B, C, C1,D,D1,E, E1, F, F1, H, H1)

The possible choice is defined in the annexes specific to categories of instruments and they depend upon the complexity of the instrument

Main modules : B type examination, D Quality assurance of production, F verification of the product (also H1 design examination which covers also production phase)



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Link with OIML

Requirements for MI are written in a format of essential requirements (only some of them are precisely defined)

Principle of presumption of conformity by using harmonised standards or OIML normative documents but it is not possible to claim that conformity with OIML recommendation is mandatory



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Documentation

- Whatever are the modules used MID requires that the manufacturer establishes the technical documentation described in article 10 of MID
- This technical document is the basis for conformity evaluation : “it render the design, manufacture and operation of the MI intelligible and permit an assessment of its conformity with requirements of MID”



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Content of the documentation

The technical documentation shall be sufficiently detailed to ensure:

- the definition of the metrological characteristics,
- the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means,
- the integrity of the instrument.



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Content of the documentation

The technical documentation shall include insofar as relevant for assessment and identification of the type and/or

instrument:

- (a) a general description of the instrument;
- (b) conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc;
- (c) manufacturing procedures to ensure consistent production;



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Content of the documentation

- (d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;
- (e) descriptions and explanations necessary for the understanding of paragraphs (b), (c) and (d), including the operation of the instrument;
- (f) a list of the standards and/or normative documents referred to in Article 13, applied in full or in part;



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Content of the documentation

- (g) descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in Article 13 have not been applied;
- (h) results of design calculations, examinations, etc;
- (i) the appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with: the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances, the durability specifications for gas-, water-, heat-meters as well as for liquids other than water.



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Content of the documentation

- (j) the EC-type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.
4. The manufacturer shall specify where seals and markings have been applied.
 5. The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.



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Who has access to this documentation?

Where is it kept ?

The manufacturer establishes it (even if he uses a representative for certain tasks he cannot delegate the establishment of the documentation)

He provides it to the NB (s) he has chosen for the conformity assessment procedure (art 9 of MID)

He shall inform the NB that holds the technical documentation concerning the EC-type examination certificate of all modifications to the instrument that may affect the conformity of the instrument with the essential requirements or the conditions for validity of the certificate.



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Who has access to the documentation?

Where is it kept ?

The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions with the technical documentation for 10 years after the last measuring instrument has been manufactured (at the disposal of the national authorities).

The notified body shall hold the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the certificate (art 12 of MID covers professional secrecy except vis-à-vis the authority of the Member State which has designated it)



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Documentation - summary

- It is mandatory in all cases
- It is very detailed
- The description prevents that it is non representative of the future production and that the MI supplied for type evaluation is a “golden sample” or a “MI still under development”
- It has to be updated
- It is available for later checks by the NB
- When needed it is available for authorities



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Responsibilities of manufacturers

Whatever is the conformity assessment and module used by the manufacturer it is always mentioned in the definition of the module that the manufacturer is responsible for the conformity to the requirements

And for all instruments where certification of the type is required the responsibility covers the conformity to the type

Even when a manufacturer nominates a representative to perform some tasks, he cannot delegate his responsibility concerning conformity



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Paper declaration by the manufacturer and markings

Whatever is the conformity assessment used the manufacturer puts the CE marking and M on the instruments and issues a paper declaration of conformity

This declaration is kept by the manufacturer at the disposal of the national authorities for ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.



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Responsibilities of notified bodies

They have to fulfil the requirements that applies to them

Their tasks are described in the respective module annexes of MID

Their responsibility is limited to the task they have to performed (no general responsibility for the conformity of the instruments themselves)

The member state that have notified them shall ensure that they work correctly



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Module B

The manufacturer provides the documentation and in most cases a specimen representative

The NB studies the file and the specimen, in particular he has to examine the technical documentation to assure that the manufacturer has adequate means to ensure consistent production.

The NB delivers an EC type examination certificate valid 10 years (valid in all EU and even wider)

The manufacturer has to keep the NB informed of changes



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Module D

The manufacturer operates a quality system (QS)

The quality system shall ensure compliance of the instruments with the type as described in the EC-type examination certificate and the appropriate requirements of the Directive.

He asks a NB to assess this QS

When it is done the NB is also responsible of the surveyance of the QS (regular audits but also possibly unexpected visits)



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Module F

The manufacturer shall ensure conformity to the type and the requirements

The NB makes tests on individual instruments (visual inspection and tests)

And delivers a certificates of conformity in respect of the tests he has performed



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Sous-direction de la qualité, de la normalisation, de la métrologie et de la propriété industrielle
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Responsibility of member states

Transposition of the directives in the national regulation

Correct implementation (designation and surveillance of notified bodies, market surveillance)

Take appropriate actions so that instruments are brought back in conformity by the manufacturer or anyone who has put non conforming instrument on the market or in service



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Market surveillance

Several types of operation contribute to MS

- General information of all stakeholders
- Visits of manufacturers
- Examination of accompanying papers and simple tests
- Complete testing in laboratory

(See WELMEC guide 5.2)



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Market surveillance and synergy

- Exchange of information is foreseen in article 18 of MID (it covers type approval certificates, certificates of approval of QS and reports of notified bodies)
- In legal metrology instruments are also submitted to controls in service or after repair. At this occasion one may discover a non compliance which dates from the time the instrument was put on the market and in service, this will also contribute to market surveillance
- Information could also come from federations of manufacturers



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Experience

- WELMEC is supporting the harmonised correct implementation of MID
- WG 5 of WELMEC is a platform of cooperation and exchange of information (guidance documents available on welmec.org)
- Since 2008 a new EU regulation gives more duties to members states in market surveillance field. It also covers accreditation



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Conclusion

- Content of documentation
- Conformity assessment procedures
- Responsibility of notified bodies
- Responsibility of manufacturers
- Declaration of conformity
- Market surveillance and exchange of information
- Legal actions to bring instruments in conformity (possibility of removing it from the market)
- Legal obligation for the manufacturer to bring in conformity instruments
- Controls of instruments in service



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conclusion

The whole system contributes to ensure that the directive is correctly implemented and that only instruments in conformity with the requirements and with the type if applicable are put on the market

but all actors have to contribute continuously



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Thank you

Merci de votre attention
Questions ?

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OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands



National Conference on Weights and Measures
"That Equity May Prevail"

NTEP Conformity Assessment Program

DON ONWILER | EXECUTIVE DIRECTOR

June 29, 2011



Pre-1999 Approach to CTT

- NTEP receives challenge of certificate
- NTEP acquires samples of production instruments
- NTEP evaluates production instruments
 - Conformity: Challenger pays evaluation fees
 - Nonconformity: Certificate holder pays evaluation fees and the certificate is withdrawn



Pre-1999 Approach to CTT

- Puts challenger at financial risk
- Puts NTEP at financial risk
- Proven inadequate



1999: New Direction

- **1999:** Focus changed to production and quality control processes (front end)
- **2001:** Framework for Conformity Assessment was approved for NTEP Administrative Policy
- **2002:** Conformity Assessment Work Group created
- **2009:**
 - Administrative Policy Refined
 - Pilot program initiated for load cells



Conformity Assessment Defined

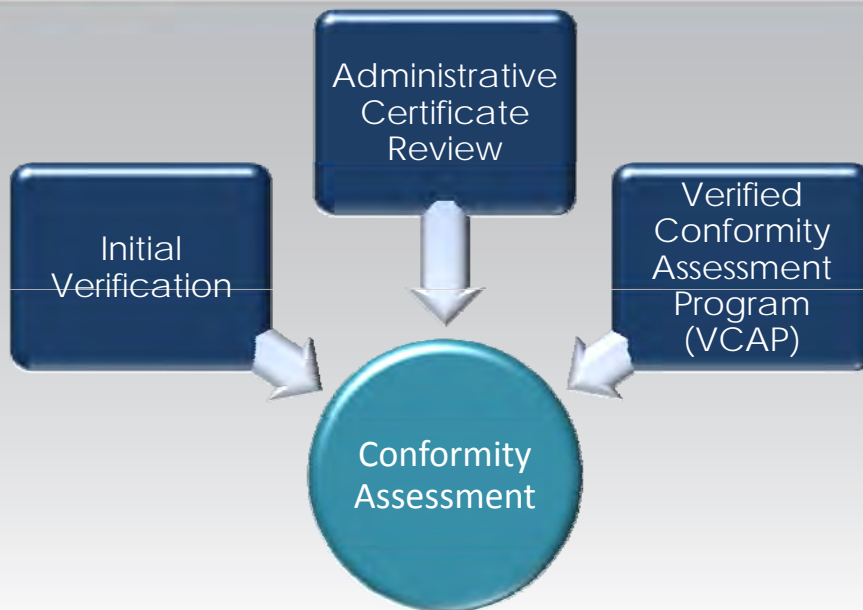
"A program to ensure the continued compliance of manufactured devices with the requirements defined in the Certificate of Conformance."

Participants in conformity assessment can include:

- Manufacturer or supplier
- Issuing Authority
- Dealer
- Service Personnel
- End User
- Regulatory Official, etc.



Elements of NTEP Conformity Assessment Program



NTEP Conformity Assessment Program

7



Initial Verification

- The 1st official inspection and test of a commercial weighing or measuring instrument by a weights and measures official
- Online reporting system in place for use by weights and measures officials
 - Report good and bad results
 - Voluntary participation
- Does not verify conformance to influence factors

NTEP Conformity Assessment Program

8



Administrative Certificate Review

- Certificate accurately reflect current metrological characteristics of the instrument
- Type remains in compliance with latest standards (NIST Handbook 44) including those adopted after the certificate was issued
- Periodic updates to certificates to provide information consistent with current NTEP practices

Input comes from all sources regarding production devices in comparison to Certificates of Conformance



Verified Conformity Assessment Program (VCAP)

A conformity assessment process must verify compliance with influence factor requirements, so...

- Manufacturer shall have VCAP program in place
- Manufacturer shall provide NTEP with a certification body audit report clearly stating compliance with VCAP

Described as *"verifying those things manufacturers should already be doing"*



VCAP Scope: Influence Factors

- Weighing instruments and elements subject to influence factor testing during type evaluation
 - Load Cells
 - Indicating Elements
 - Weighing/Load Receiving Elements with load cells that do not have their own NTEP certification
 - Complete scales
 - Automatic Weighing Systems
 - Belt-Conveyor Scales
 - Automatic Bulk Weighing Systems



Applying the Elements of Conformity Assessment

Initial Verification: Applies to all instruments

Administrative Certificate Review: Applies to all instruments

VCAP: Only applies to weighing instruments subject to:

- NIST Handbook 44 influence factor requirements
- Influence factor testing during type evaluation



VCAP: General Certificate Holder's Responsibilities

1. Quality Management System governing design and manufacture
2. Production and testing equipment and facilities
3. Identify Metrologically Significant Components



VCAP: General Certificate Holder's Responsibilities

4. Possess statistical process control
5. Sampling plan and acceptance criteria
6. Operator's manuals and calibration procedures
7. System to handle nonconforming instruments



Sample Sizes

Units per Year	Minimum Number (total of samples production) per Year
2 – 50	2
51 – 500	3
501 – 35,000	5
35,001+	8



VCAP: General Certificate Holder's Responsibilities

8. Controls over suppliers
9. Corrective Action System for noncompliant materials
10. Engineering Change System



VCAP: General Certificate Holder's Responsibilities

11. Document and Data Control System

12. Production Control System

13. System to identify and trace metrologically significant components

14. Training System with documentation of training



Verified Conformity Assessment

- Internal Self-Assessment Plan
- Subsequent audits on a 3-year interval

May be extended up to 5 years based on objective evidence



Certification Body's Responsibility

The selected Certification Body is to be accredited by ANSI-ASQ National Accreditation Board (ANAB). The ANSI-ASQ National Accreditation Board is the U.S. accreditation body for management systems. ANAB accredits certification bodies (CBs) for ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements, or equivalent.



Certification Body's Responsibility

Accreditation to Standard Industry Classification (SIC) codes (3596/3821) or equivalent.

Sequence Number: 847

2007 NAICS, U.S. Code: 333997

2007 NAICS U.S. Title: Scale and Bench Manufacturing



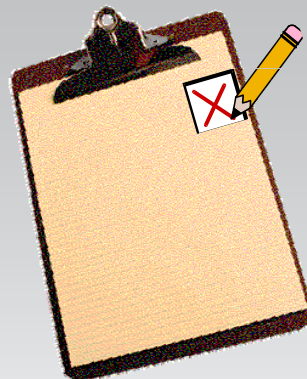
Certification Body's Responsibility

- International auditors available
- Notify NCWM when a major breakdown is found in certificate holder's VCAP program
- Submit "Systems Audit Checklist" with clear statement of compliance



Systems Audit Checklists

- Manufacturer Checklist
- Private Label Checklist





Private Label Checklist

1. Provide proof that the private label certificate is traceable to an active "parent" certificate
2. Provide records showing the supplier has a current VCAP audit meeting requirements
3. Provide purchase and sales records for the auditor verifying that no other supplier is being used for the certified instrument
4. Assist auditor to confirm the suppliers sales records agree



Private Label Checklist (continued)

5. Have a plan in place to report nonconforming instruments to the supplier and to address nonconforming instruments in inventory
6. Have an internal audit plan for verifying nonconformance action
7. Keep internal audit records for review at auditor's discretion
8. ISO auditor must provide a clear statement of compliance to NCWM



Consequences

- Failure to comply with any element of the Conformity Assessment Program results in an Inactive Certificate of Conformance
- Instruments produced before that date are traceable to an active certificate



Progress Report

VCAP deadline for load cell manufacturers: **May 2011**

- 22 Certificates were made inactive on May 31, 2011 for failure to submit a VCAP audit report
 - Most of those are still in process for VCAP compliance
 - Can reactivate within 12 months without new evaluation
 - If more than 12 months, a new evaluation is required
- 310 Certificates remain in Active status



Is VCAP Effective?

2009:

- Some load cell manufacturers were already doing the things required in VCAP
- Some were doing nothing to verify conformity or production load cells

June 2011:

- All load cell manufacturers with active NTEP Certificates of Conformance have verified conformity assessment programs for influence factors.

PRESENTATION TITLE

27



Next Steps:

- NTEP Committee Recommendation for next instrument type:

Weighing/Load-Receiving Elements under 2000 lb using load cells that are not traceable to NTEP certificates.

- Timeline: To be determined
- Open Hearings will be held at the 96th NCWM Annual Meeting on July 18 and 19, 2011.

NTEP Conformity Assessment Program

28



Assimilation of NTEP VCAP and OIML CTT?

- Find disagreements and address them together
- Harmonization lends credibility and strength to both organizations/programs
- One audit: less cost, less burden, full effect



National Conference on Weights and Measures
"That Equity May Prevail"

Thank You



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands



Australian Government
National Measurement Institute

Conformity to Type Testing and the Australian Urban Water Industry – Recent Developments and Experiences –

**29 June 2011
Utrecht, The Netherlands**

**Alex Winchester
National Measurement Institute, Australia**

measurement.gov.au

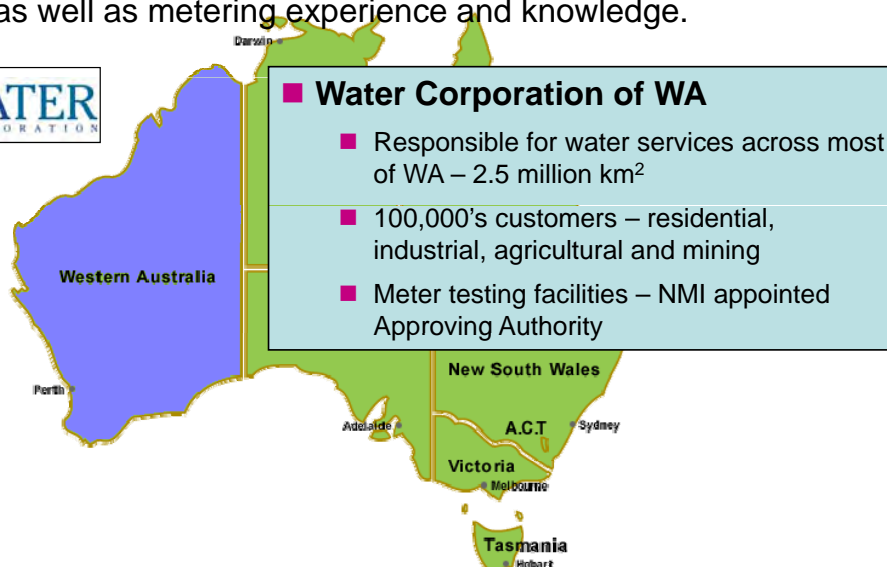


Outline

- Background
 - The Australian Urban Water Industry
 - The Role of National Measurement Institute
- Recent Developments
 - National Framework for Urban Water Metering
 - Water Metering Codes of Practice
- Compliance Testing Code of Practice
 - Development
 - Issues
- Experience and Lessons
 - User Funded Conformity Testing
 - Applications for Other Sectors
- Questions

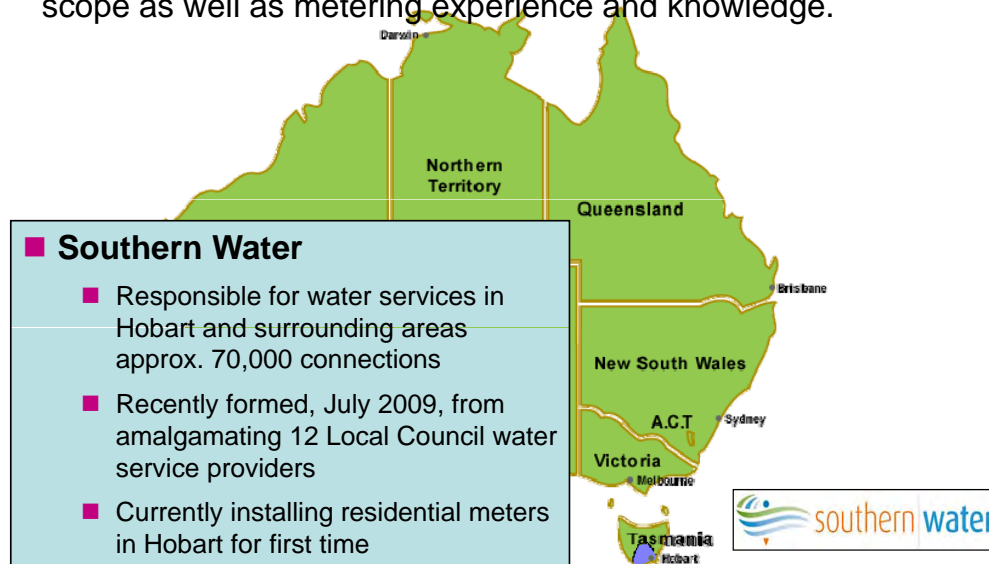
Background – Australian Urban Water Industry

- What does it look like?
- Australian water service providers vary extensively in size, scope as well as metering experience and knowledge.



Background – Australian Urban Water Industry

- What does it look like?
- Australian water service providers vary extensively in size, scope as well as metering experience and knowledge.



Background – Australian Urban Water Industry

- What does it look like?
- Water Services Association of Australia

- Peak industry association with 30 members and 29 associate members (water service providers).
- Members provide water and waste water services to approximately 16 million Australians and many industrial and commercial enterprises.
- Produces industry Codes of Practice and facilitates communication across industry.
- Focus on all aspects of the urban water industry, including water metering.



Background – The Role of NMI

**National
Measurement
Act
1960 (Cth)**

- Under the Act, the National Measurement Institute (NMI) has responsibility for the type (pattern) approval and initial verification of utility meters (inc. water meters) in Australia.

**National
Measurement
Regulations
1999 (Cth)**

- The Regulations currently provide an exemption for larger sizes of water meters – to be removed in future – however residential water meters must comply with the Act.











The Regulations also give NMI authority to examine approved measuring instruments to ensure that they conform to the approved pattern.

Recent Developments – A National Framework

- Includes metering workshops, technical consultation, Smart Water Meter Specification
- In 2010 the National Framework for Urban Water Metering was published
- Joint NMI and WSAWA document intended to provide nationally consistent principles and approaches to the metering of cold and heated, drinking and non-drinking water
- In addition to outlining current regulatory requirements, the framework specifies best practice principles and recommendations related to the metering of water



Recent Developments – Codes of Practice

- A supporting series of Codes of Practice containing technical requirements that underpin the guiding principles established in the Framework are being developed:
 - Sub Metering Code of Practice (CoP)  Finalised, pub. July 2011
 - Meter Compliance Testing CoP  Under development, pub. late 2012
 - Meter Selection CoP  Development to commence late 2011
 - Meter Installation CoP  ...
 - Meter Exchange CoP  ...
 - Fire Service Metering CoP  ...
 - Stand Pipe and Hydrant Metering CoP  ...
 - Trade Waste Metering CoP  ...

Compliance Testing Code of Practice - Development

- Work began in early 2011
- Progress...
 - First meeting 8-9 March 2011 – Sydney Water
 - Initial drafting of documentation underway
 - Industry-wide survey circulated – awaiting response
- Scope includes In-service Compliance Testing...
 - Testing meters after years of in-field service
 - Test Methodology – AS 3565.4
- ...and **Conformity to Type Testing**
 - Type testing new production-run meters
 - Test methodology – NMI/OIML R 49
 - NMI currently has a regulatory role ensuring Conformity to Type

Compliance Testing Code of Practice - Development

■ Technical Working Group membership includes:

- Sydney Water - Working Group Leader
- ACTew AGL – Australian Capital Territory
- Barwon Water – Geelong, Victoria
- Hunter Water – Newcastle, New South Wales
- Queensland Urban Utilities – Brisbane, Queensland
- SA Water – South Australia
- South East Water – Melbourne, Victoria
- Southern Water – Hobart, Tasmania
- Water Corporation of Western Australia – Western Australia
- Yarra Valley Water – Melbourne, Victoria ... plus WSAA and NMI

The need for conformity/compliance testing is accepted and well understood by many water service providers

Compliance Testing Code of Practice - Issues

■ Issues:

1. Funding the costs of Conformity to Type Testing

In principle agreement from working group that WSAA members will fund the costs of meter testing, both in-service compliance and conformity to type.

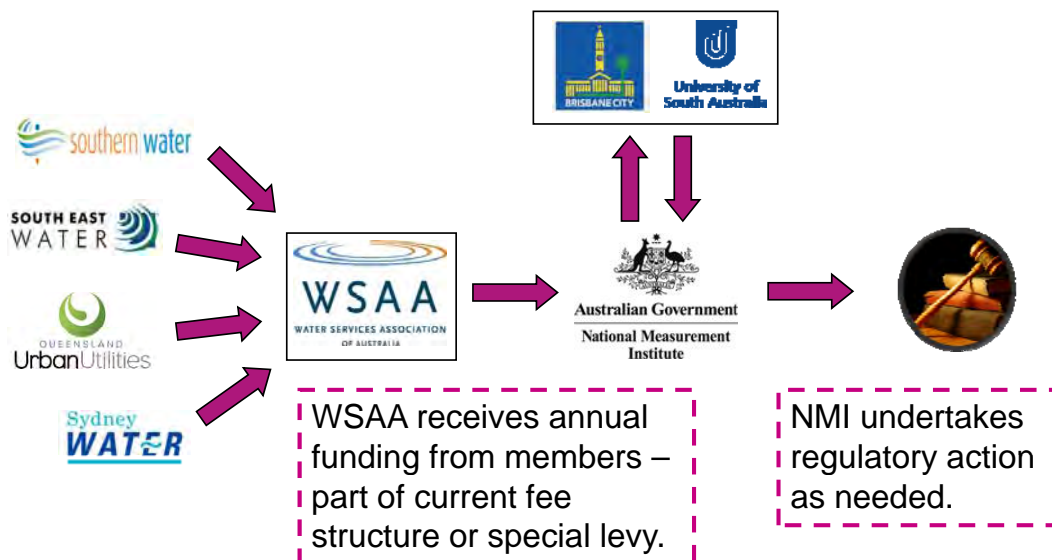
- For those water service providers that currently undertake some testing (almost exclusively in-service compliance), there are available cost savings due to increased batch/lot sizes across a nationally coordinated approach.
- For those water service providers that currently do not undertake compliance or conformity testing, there are obvious benefits and costs would be less than individual approaches.

Compliance Testing Code of Practice - Issues

■ Issues:

1. Funding models

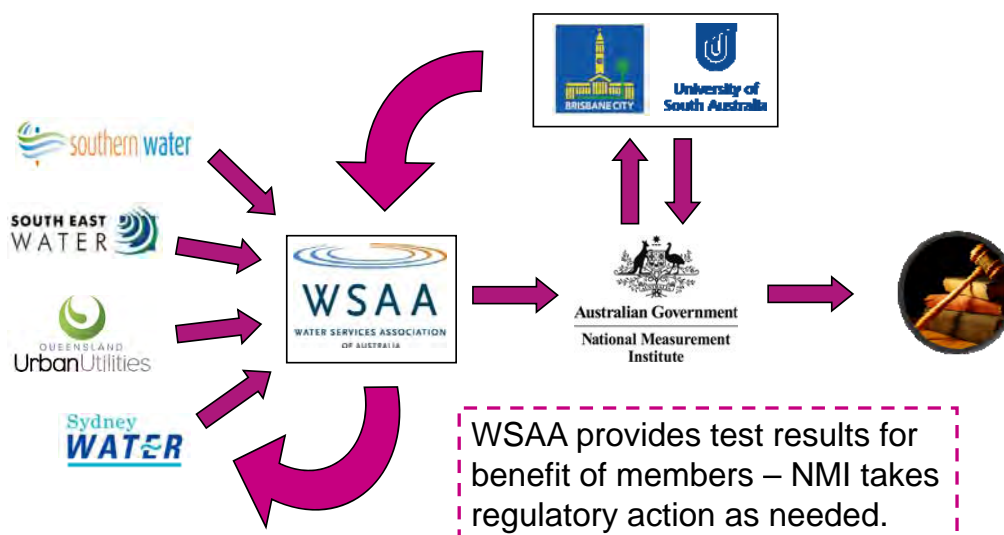
NMI receives WSAA funding and commissions testing at approved & accredited laboratories.



Compliance Testing Code of Practice - Issues

■ Issues:

1. Funding models continued...



Compliance Testing Code of Practice - Issues

- More issues...
 - 2. Actual costs of testing
 - 3. Test infrastructure capacity
 - 4. Statistical sampling
 - 5. Program coordination
 - 6. Responses to non-conformities
 - 7. Ownership and sharing of results
 - 8. Liability and privacy
- Most of these issues are highly interrelated, with solutions to one area creating problems in others and vice-versa



Lessons – User Funded Conformity Testing

- *Manufacturers* do not want to pay for Conformity Testing.
- *Consumers* are unable / do not want to pay for Conformity Testing.
- *National Authorities* can not afford to pay for Conformity Testing.

Generalisation

...BUT...

- *Users* of measuring instruments want to ensure the instruments they use every day are accurate, and many large Users have the capacity and inclination to pay for Conformity Testing.

“The water meter is the industry’s cash register”

- Users of measuring instruments could provide funding, under a range of models, for conformity to type testing, such as:
 - Utility Companies – water, gas and electricity meters
 - Grocery Stores – weighing instruments
 - Etc...

Lessons – Applications for Other Sectors

- Proactive engagement with user industries is vital.
- A coordinated approach is ideal – for example, contact through industry associations and groups.
- Obvious limitations depending upon the measuring instrument and industry in question.

There is no one-size-fits-all approach, however developing partnerships with industries and sectors that use measuring instruments can produce innovative funding models for Conformity to Type Testing.

Thank you!

Questions?

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Email: alexander.winchester@measurement.gov.au



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands



Perspectives of an OIML Type Approval Utilising Economy: New Zealand

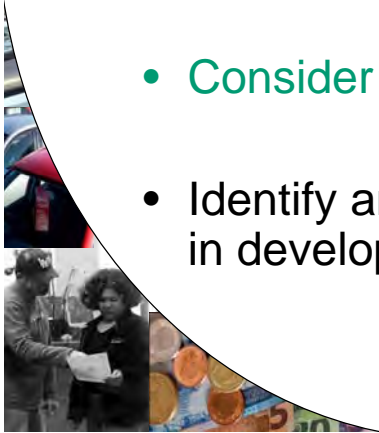
OIML Seminar on Conformity to Type (CTT) Utrecht, the Netherlands, 29-30 June 2011

Presented by:
Stephen O'Brien
Manager - Measurement and Product Safety Service
Ministry of Consumer Affairs
New Zealand



Presentation Outline

- Measurement and Product Safety Service's Role - focus legal metrology
- Give an overview - size and scope of New Zealand Type Approval regime
- Consider the need for a CTT programme
- Identify and discuss aspects to be considered in developing a CTT Programme



Measurement and Product Safety Service

- Operational unit in the Ministry of Consumer Affairs
- Responsible for administration and enforcement of:
 - Trade Measurement**
 - Product Safety**
 - Fuel Quality**
- Inspectors - national focus, regionally based
- laboratories - ISO 17025 Accredited (mass, volume and length metrology) – currently not R76 Type Approval



Measurement and Product Safety Service

- **Legal Metrology activities:**
 - Legislation
 - Provision of physical standards
 - National type approval
 - Accrediting private sector verifiers
 - Surveillance and enforcement
 - International Linkages
- Utilizing Participant OIML MAA's: R49, R76 and R60
- **Perspectives** of: Regulator, LM Authority, economy outside Europe, reliant on international OIML Approval Testing

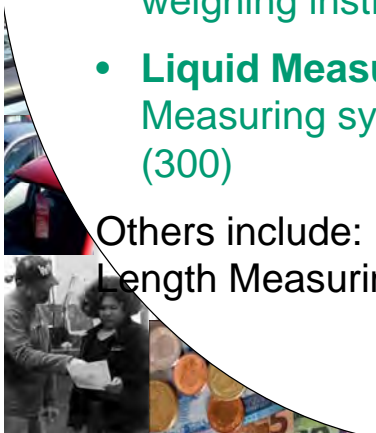
SIZE - NZ National Type Approval Regime

Nationally NZ has approximately **2000 instrument types** approved.

The largest categories are:

- **Weighing Instruments** - Including: automatic, semi-automatic, beltweighers, price computing and counting weighing instruments: 69% (1400)
- **Liquid Measuring Instruments** - Including: DFM, Measuring systems for fuels, milk and other liquids: 15% (300)

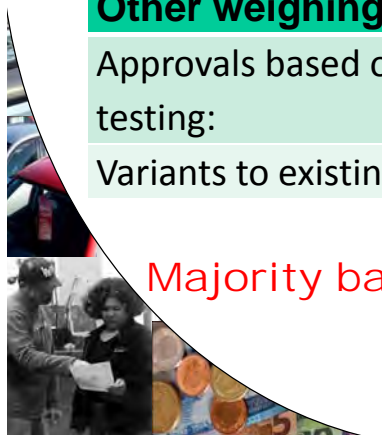
Others include: Volume Measures, Indicating Devices, Length Measuring Instruments and Measures of Length



SCOPE - NZ National Type Approval Regime

Total National Approvals issued: 194
(since January 2008)

In-situ Approvals	
Firewood or similar volume measures:	16
Other weighing/measuring instruments:	27
Approvals based on overseas OIML Type Approval and testing:	70
Variants to existing approvals:	76



Majority based on overseas Approval Testing



Where NZ OIML Type Approval Testing completed

NMI Australia	60%
NMi Certin B.V., The Netherlands	20%
NMO (Formally NWML), UK	10%
PTB, Germany	3%
CMI, Czech Metrological Institute	2%
NMIJ / AIST, Japan	2%
General Administration of Quality Supervision, Inspection and Quarantine of P.R. China:	2%
Swedish National Testing and Research Institute AB(S.P.)	1%
The Danish Accreditation and Metrology Fund (DANAK)	1%

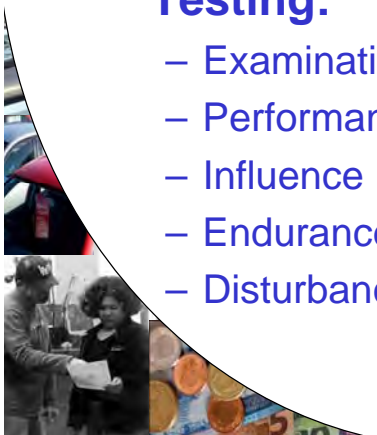
Relevance to CTT

- New Zealand - Relatively Small: Economy 4.5 Million people, 21st Gross Domestic Product (GDP) and 23rd Net National Income (NNI) per capita - OECD
- Over 2000 Type Approvals. Majority with reliance on overseas OIML Type Approval and test data
- Reduction of strong national **type approval testing capability**; increased complexity of **global supply chain**; and need for confidence that **production instruments** meet type - all support development CTT Programme
- Not alone in this regard: Total **113 OIML Member States** and **28 OIML Issuing Authorities** (Non-Automatic Weighing Instruments)
- Weighing and liquid measuring instruments critical

CTT – Missing Link between Pre and Post Market Testing

Pre-Market

- OIML and National Type Approval
- **Laboratory Testing:**
 - Examination
 - Performance
 - Influence
 - Endurance
 - Disturbance

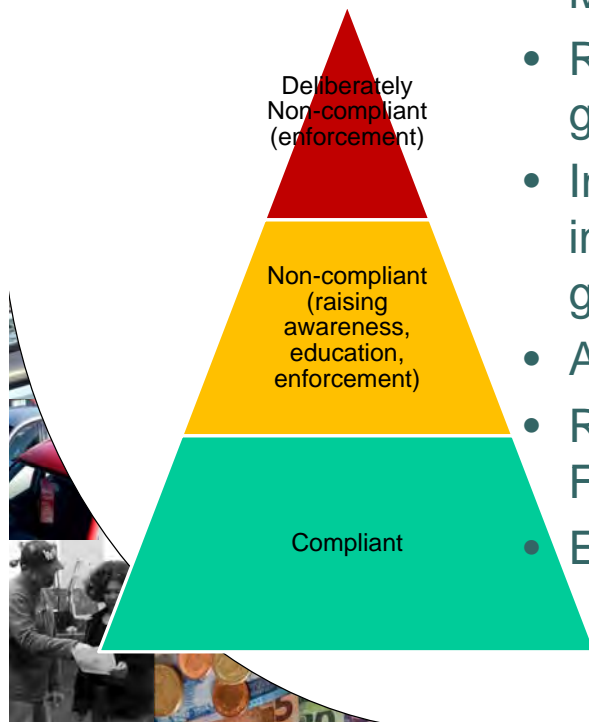


Post-Market

- Verification
- Surveillance and inspection activities
- Inspection of outputs – packages
- **Field Testing:**
 - Performance



Regulatory Model – Applied to CTT



- Majority compliant
- Regulator focus on middle group
- Incentivise compliance by introducing possibility of getting caught
- Activity raises awareness
- Reduced risk of Market Failure for Compliant group
- E.g. Lead in toys

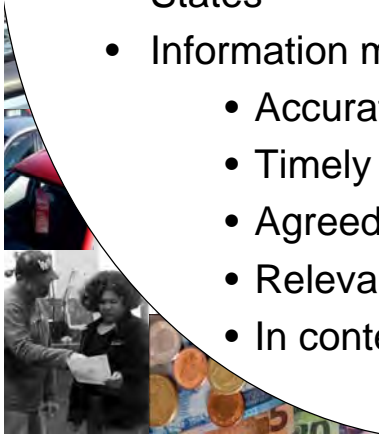


Risk Management Approach Needed

- Comprehensive risk management framework needed for CTT activities
- Framework needs to **identify**, **analyse** and **evaluate** risks to ensure limited CTT resources are effectively used:
 - 54 categories of instrument - range of medical, commercial, environmental and safety consequences for inaccuracy
 - Large number of OIML Type Approvals
 - Variety consequences affect individuals, marketplace or society
- CTT Programme - reference to ISO 31000:2009 *Risk Management Principles and Guidelines*

Exchange of Information

- Rapid exchange of information a key element of CTT Programme
- Example: EU RAPEX System - rapid alert system for all dangerous consumer products. Allows for the rapid exchange of information between Member States
- Information must be:
 - Accurate / Trustworthy
 - Timely
 - Agreed format
 - Relevant
 - In context



Developing Economies

- OIML needs to **consider** the views and perspectives of developing economies in an CTT Programme
- Real potential for developing economies to become a '**dumping ground**' for instruments that do not consistently meet their approved type
- **Lack of awareness** of the importance of type approved measurements by legal metrology officials, by custom authorities, by the responsible Ministries
- Need to know '**what and how**' to check for CTT, preferable at the border or importer
- General lack of knowledge of measuring instruments: **software** in particular and possibilities of manipulation
- Comprehensive, yet easy to check, system needed
- Eberhard Seiler – OIML Facilitator for developing country matters

APLMF - Regional Approach to CTT

- **Members: 22** Full : AUSTRALIA, CAMBODIA, CANADA, PEOPLE'S REPUBLIC OF CHINA, HONG KONG, INDONESIA, JAPAN, DPR OF KOREA, REPUBLIC OF KOREA, MALAYSIA, MONGOLIA, NEW ZEALAND, PHILIPPINES, PAPUA NEW GUINEA, RUSSIAN FEDERATION, SINGAPORE, CHINESE TAIPEI, THAILAND, USA and VIETNAM. Corresponding Member: LAO PDR
- OIML Issuing Authorities and Members with type approval capability
- Large regional economic and population base
- Provide training and development opportunities for members
- Role implementing OIML CTT Programme



Conclusions

- A robust CTT Programme critical to maintaining confidence in the OIML Type Approval System (MAA and Basic)
- Internationally regulators need assurance that production instruments entering their markets are consistent with the approved type over the entire time period that the instrument is produced
- Such a system needs:
 - Risk Management Approach
 - Involve a system for the exchange of information
 - Consider the needs of developing economies
 - Utilise Regional Capability - APLMF

- Thank you for your attention
- Any questions or comments?





OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

**Mechanisms in place in various countries to ensure that
measuring instruments comply with the approved type**

(texts provided by the countries)

Mechanisms in place in various countries to ensure that measuring instruments comply with the approved type

(texts provided by the countries)

Japan

In Japan, there is a "Verification System" by an official body such as a national or prefectural authority in which the verification mark is fixed when a product passes the examination of structure and instrumental error. In addition, another verification system called "Designated Manufacturer System" went into effect when Measurement Law was revised in 1993. In this system, the Minister of Ministry of Economy, Trade and Industry (METI) designates a manufacturer that has a certain level of quality control. The designated manufacturer is allowed to perform the initial inspection of their products and to fix an inspection (verification) mark that indicates conformity to the metrological requirements.

This system aims to exempt the manufacturer with a certain level of quality control from initial verification by the national/prefectural authority. The manufacturer is designated through a rigorous and comprehensive examination of quality control system. The requirements imposed on the manufacturer in the examination are specified based on the Measurement Law. These requirements are actually compatible with those specified by the ISO 9000. In addition, periodical annual examinations are conducted in order to continuously monitor the competence of the designated manufacturer.

The manufacturers in Japan maintain conformity of their products to the requirement under the Measurement Law through such a severe quality control system. Therefore, quality and conformity to type for all specified measuring instruments produced in Japan are secured enough by "Verification System" and "Designated Manufacturer System."

Specified measuring instruments produced in foreign countries also need to be verified. In addition, the Measurement Law in Japan allows oversea manufacturers to be designated and to fix the "verification mark." At present, twenty-six (26) factories in six (6) countries have been authorized by the government (METI) as the designated manufacturers.

Therefore, we have a strong concern that establishment of a new system of conformity to type may lead to imposing an additional cost and duties on national/ prefectural metrological authorities and the manufacturers.

Kenya

Kenya has in place a mechanism for this programme. It starts from type approval . It is by law established that all weighing and measuring equipment intended for trade use in the country must be of the approved type or if not yet approved they must undergo type approval before being put to trade use.

All type approvals are done at the Weights and Measures Departmental headquarters. Conformity to type tests (otherwise known as initial verification) are undertaken by the regional offices around the country. These tests are undertaken on the basis of open directives from the Headquarters which include the database and essential tests for each equipment. Therefore all equipment intended for approval are submitted to the office of Director, at the Weights and Measures Headquarters. Equipment of the type approved models are submitted at any regional office for purposes of undertaking conformity to type tests.

In this respect, the responsible organization has in place surveillance programs to ensure compliance in this area. The regional offices personnel frequently carry out inspection visits to industries and trade premises to ensure compliance.

The Netherlands

In the Netherlands, legal metrology is restricted to those areas of use of measuring instruments where it is expected that there is a substantial risk that the free market mechanism provides insufficient protection against unfair transactions and trade..

The concept of this framework is:

1. To only implement those areas of use for which regulation by legislation is considered absolutely necessary,
2. Keep the costs of administrative burden low,
3. Harmonize the existing regimes as much as possible,
4. Regulate on a high level of abstraction,
5. Strict separation of tasks between bodies designated for certification (NB's) and market surveillance bodies.

Where possible and/or desirable and where a sufficient level of competence and degree of organization is available, self-regulation under strict conditions is accepted and promoted.

This conceptual framework has been implemented in the Dutch law on Metrology which contains separate chapters comprising:

- ▲ Those transactions employing measurements for which legal requirements apply,
- ▲ Conformity assessment,
- ▲ The placing on the market and use of measurement devices and sanctions in case of offence,
- ▲ Surveillance and inspection.

Concerning conformity assessment the applicable European directives have been implemented. For certain instruments covered by MID, but of which their use is outside the measurement areas covered by NL legislation the enforcement still is applicable in case those measuring instruments are marked to state compliance with the MID requirements.

Further additional national regulation is in place for those types of instruments not covered by European directives but included in the scope of the legally regulated areas of use.

The national law also covers the requirements of enforcement with respect to the EU regulation for market surveillance.

The certification of measuring instruments on basis of performance of conformity assessment is executed by nominated private organizations, which have been notified to EU and other member states.

Surveillance is performed by a nominated authority. Execution of the surveillance task of which is 100 % covered by the government resources based on a multi-annual contract. The surveillance activity comprises in principle a random unannounced inspection on metrological aspects but taking into account a risk analysis on the kind of measuring instrument. The inspections include tests on compliance to the applicable accuracy requirements. In general all measuring instruments will pass in review in an about 4-year period. The contractor (government) requires annual reports on instruments inspected and detected abnormalities. Databases cover all individual measurement devices in use under legal metrology control.

Subsequent verification on a regular basis is in general not applied in NL. Only for taximeters this system of verification is implemented and for the other measurement instruments within legal control a subsequent verification is mandatory only after a repair whereby the seal has been broken. Organizations certified by a notified conformity assessment body are allowed to perform such verifications.

Concerning utility metering the legal metrological control is performed on a statistical basis and executed by the utility metering branch organization. The previous mentioned nominated surveillance body evaluates the statistical approach and reports to the Ministry on this approach and the results of the execution of this metrological control. Where necessary batches of instruments may be rejected on basis of these reports and are exchanged.

Since the certification of measuring instruments within the framework of legal metrological control is performed by nominated private organizations the approval and evaluation reports need to become available to the surveillance body in order to verify the metrological requirements. Hence this information is stored in a protected database maintained by the surveillance body on behalf of the government.

Poland

In Poland our law regulation controls measuring instruments which are used in following areas: in protection of health, life and environment; in protection of safety and law and order; in protection of consumers' rights; in collecting fees, taxes and non-tax budget dues as well as in establishing discounts, penalties, remuneration and compensations, and in charging and establishing dues and services alike; in customs control; in trade.

Forms of legal metrological control in Poland are:

- ⤴ Type Approval - carried out by GUM only;
- ⤴ Initial Verification - carried out by Regional Verification Offices, Local Verification Offices or authorized third-party companies (certain kinds of measuring instruments only);
- ⤴ Subsequent Verification - carried out by Regional Verification Offices, Local Verification Offices or authorized third-party companies (certain kinds of measuring instruments only).

In general legal metrological control in Poland consists of three steps: type approval, initial verification and subsequent verification. Measuring instruments subject to all three steps are listed in annex 1.

Mechanism used in Poland to ensure that measuring instruments comply with the approved type is the initial verification required before placing the instrument on the market.

According to the Law on measures (art. 8m) during initial verification there are following checks:

- ⤴ verification of compliance with approved type (construction, materials, metrological characteristics),
- ⤴ verification of markings and symbols,
- ⤴ verification of compliance with technical documentation if apply.
- ⤴ After certain of time period defined in legal regulations subsequent verification is being conducted.

During subsequent verification there are following checks:

- ⤴ verification if markings are present, verification if the instrument is not broken,
- ⤴ verification of metrological characteristics (MPE etc.).

Subsequent verification has its period of validity defined in law for every category of instrument. Subsequent verification can be every year like for some measuring instruments for liquids, every two or three years like for weighing instruments, every five or even ten years like for heat or gas meters. As a result of subsequent verification in case of positive result of inspection (for example testing whether measuring errors are within MPE prescribed in technical regulations) inspector leaves mark (sticker) or paper document (certificate) showing that instrument was positively verified.

Result of verification allows to use the instrument for next period.

Metrological surveillance plays also an important role as a mechanism used to ensure that measuring instrument complies with the approved type.

On the territory of Poland we have Metrological Surveillance inspectors that check some percent of measuring instruments in:

- ⤴ shops and other places where products are sold for customers and price is given as a result of measurement,

- ▲ filling stations,
- ▲ taxis,
- ▲ drugstores/pharmacies,
- ▲ other areas under legal metrological control.

Every year Bureau of Metrological Surveillance publishes the report showing how many instruments were checked, the percentage of good instruments, how many tickets were given, how many shops, pharmacies and other points were controlled.

Apart from this there is also market surveillance inspection, in Poland it is not metrological authority, but they can control points of sale, shops and producers, and they also check if measuring instruments have a proof of verification. If necessary, market surveillance inspection contacts metrological surveillance.

Comparing legal metrological control in Poland to the legal metrological control systems presented in OIML D16 "Principles of assurance of metrological control" we can evaluate the Polish system to be at the market stage highly restrictive with an element of balanced system (initial verification in some cases can be performed by authorized manufacturer).

Annex 1

Measuring instrument subject to type approval, initial verification and subsequent verification

1. Fixed storage tanks;
2. Instruments for measuring the speed of vehicles in traffic (radar, laser, control speedometers);
3. Weighbridges for weighing road vehicles in motion;
4. Road measuring tankers;
5. Tyre pressure gauges for motor vehicles;
6. instrument for measuring the standard mass per storage volume of grain: standard 20 L, usable 20 L, 1 L i ¼ L.

Measuring instrument subject to type approval and initial verification

1. Metal barrels;
2. Glass hydrometers - alcoholmeters and alcohol hydrometers.

Serbia

Currently in the Republic of Serbia there is no specific (national) program or system that addresses the issue of conformity to type. To be precise, in our country two mechanisms are deployed, i.e. type approval and verification of measuring instruments used for purposes under legal control. Verification of an individual measuring instrument is mainly performed if the type of the measuring instrument has been examined and a type approval certificate issued.

Verification of individual measuring instruments together with the supervision of measuring instruments brought about detection of non-conforming measuring instruments. This resulted in withdrawal of issued type approval certificate, about which it was reported in the relevant OIML enquiry some years ago.

In order to ensure that measuring instruments comply with the approved type some ways of analysis of production of measuring instruments or examination of quality system applied in such a production has been considered with intention to prevent non-conforming measuring instruments to be produced.

As Republic of Serbia is the country in transition that signed SAA with the European Union we are in process of harmonizing our legislation in field of metrology with the EU legislation. Consequently we are committed and we are making great efforts to adopt the mechanisms that are in place in EU to ensure that measuring instruments comply with the approved type or that addresses the issue of conformity to type.

United Kingdom

Conformity to Type (CTT) is established in the UK through the implementation of the two EC metrology Directives; the Non-automatic Weighing Instruments Directive (2009/23/EC) and the Measuring Instruments Directive (2004/22/EC).

The two EC Directives provide a number of commonly used conformity assessment procedures to ensure that measuring instruments comply with the approved type and the Directive. Other conformity assessment procedures are also available in the MID that establish conformity with the requirements of the Directive without the requirement to first conduct a type approval (these are not described below).

NAWI

There are two conformity assessment procedures in the NAWI Directive relating to CTT; EC verification and EC declaration of type conformity (guarantee of production control).

EC verification is the procedure whereby the manufacturer ensures and declares that the instruments, which are checked (tested and examined) by a Notified Body, are in conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of the Directive. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments.

EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer, who has adequately implemented a quality system, declares that the instruments concerned are in conformity with the type as described in the EC type-approval certificate and that they satisfy the requirements of the Directive. A Notified Body shall examine and evaluate the quality system to determine whether it ensures conformity of the instruments with the type as described in the EC type-approval certificate and with the requirements of the Directive. All the elements, requirements and provisions adopted by

the manufacturer shall be documented in a systematic and orderly manner in the form of written rules, procedures and instructions (covering the manufacturing process, quality control and assurance techniques, examinations and tests, etc.).

MID

The conformity assessment procedures in the MID relating to CTT are:

- ⤴ Annex D – Declaration of Conformity to Type based on Quality Assurance of the Production Process
- ⤴ Annex E – Declaration of Conformity to Type based on Quality Assurance of Final Product Inspection and Testing
- ⤴ Annex F – Declaration of Conformity to Type based on Product Verification

Annex B is the applicable conformity assessment procedure for EC type-examination, so the conformity assessment procedures are usually denoted as B + D, B + E and B + F.

In terms of the procedures, Annex D is broadly equivalent to the EC declaration of type conformity (guarantee of production quality) and Annex F is broadly equivalent to the EC verification as described above for NAWIs. Annex E also utilises the concept of an approved quality system, except for Annex E the quality system relates to final product inspection and testing (instead of the production process) and is typically only used for (electro-)mechanical or 'simple' measuring instruments, e.g. capacity serving measures.



OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

NTEP/VCAP (USA) Documentation



S. Conformity Assessment Process

Type approval (certification) is one of the main elements in the metrological control system for weighing and measuring devices used in commercial measurements. The NTEP Certificate of Conformance, issued by NCWM, is a tool used by weights and measures officials in the inspection and approval of those devices. NTEP looks at one or more devices in a family, during the evaluation process. This typically occurs in the early stages of product development or production, yet it is expected that a commercial device will have a useful production life of several years. It is inevitable that changes will occur in production methods or components, that new features will be added to improve the product to respond to user needs and that the technical and performance standards will change as *NIST Handbook 44* evolves in its annual cycle. Some of these changes will result in the manufacturer requesting a re-evaluation. The content and format of a Certificate of Conformance will also evolve over time.

It is vital that the Certificate of Conformance accurately reflects the device design and its features. It is also vital that the device be manufactured in conformance with the applicable requirements, while the Certificate of Conformance is in active status. In addition to the type evaluation, described in Section E through G of this document, the steps below outline the measures NTEP will use to keep the Certificate of Conformance accurate and to ensure conformance.

S.1. Main Elements

a. Initial Verification

Initial Verification is the first official inspection and test of a commercial weighing and measuring device by a weights and measures official. It is another element in the metrological control system. These tests offer an invaluable means to check production devices and many, but not all, of their features against the current requirements of *NIST Handbook 44* and to verify the information provided in the NTEP Certificate of Conformance is both accurate and correct. The information gathered by the states during Initial Verification will be used to provide feedback to NTEP. NTEP will use this information to assist in the process of verifying that production devices remain in compliance and that the information on the NTEP Certificate of Conformance remains accurate.

b. Administrative Review of a NTEP Certificate of Conformance

The Administrative Review of all NTEP Certificates of Conformance will be periodically conducted by NTEP. This review will help to ensure that:

1. The NTEP Certificate of Conformance accurately reflects current Metrological Characteristics of the device as well as Standard Features and Options.
2. The type remains in compliance with all current *NIST Handbook 44* requirements, including those requirements amended after the issue date of the Certificate. NTEP will consider information provided by the Certificate holder in the application and information provided by the States based on Initial Verifications.
3. The NTEP Certificate of Conformance is updated periodically to provide information consistent with current practices of NTEP.

NOTE: During the phase in period, NTEP will use special procedures to establish the review date for Certificates issued prior to the implementation of this Conformity Assessment policy. After this phase in period, the Administrative Review of current active NTEP Certificate will be an ongoing process relying on feedback received from the Initial Verification and VCAP.

The certificate holder will be notified and shall apply to NTEP for review on or before the Review Date in a format designated by NTEP.

c. NTEP Verified Conformity Assessment Program Procedures**Introduction**

Many NTEP Certified devices must meet *NIST Handbook 44* requirements for influence factors. It is not possible to verify these requirements during the Initial Verification in the field. Therefore, manufacturers of metrological devices (instruments) and/or components (modules) which are subject to influence factors, as defined in *NIST Handbook 44*, must have a Verified Conformity Assessment Program (VCAP) in place to ensure that these metrological devices and/or components are produced to perform at a level consistent with that of the device and/or component previously certified.

The Verified Conformity Assessment Program audit will be at one or more sites as required to verify compliance.

For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturer's quality system and on-site random testing and/or review of a production device(s) (instrument(s)) by the Registrar to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of *NIST Handbook 44*.

Devices that Must Meet this Requirement are Limited to the List Below:

1. Load Cell (T.N.8.)
2. Indicating Elements (T.N.8.)
3. Weighing/Load Receiving Elements with non-NTEP Load Cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. Automatic Weighing Systems (T.7.)
6. Belt-Conveyor Scales (T.3)
7. Automatic Bulk Weighing Systems (T.7.)

Requirements:**1. The NTEP CC Holder's Control Facility Responsibilities:**

- 1.1. A documented Quality Management System governing the design and manufacturer of the device.
 - 1.1.1. The NTEP CC holder shall prepare documentation of its various quality activities and practices required by this document and by NCWM's Verified Conformity Assessment Program policy and procedures; and shall demonstrate the effective implementation of those activities and practices. This should include (and/or reference) the manufacturer's quality manual, written procedures and work instructions, flowcharts, diagrams, drawings, etc., as appropriate.
 - 1.1.2. The NTEP CC holder shall have appropriate testing facilities and equipment necessary to verify Influence Factor compliance. *See also 1.14.*
 - 1.1.3. The NTEP CC holder shall utilize testing facilities and equipment to ensure that certified devices meet the influence factors appropriate for the device type as designated in *NIST Handbook 44*.
 - 1.1.4. The NTEP CC holder shall ensure that test equipment used either to: 1) directly perform influence factor testing or 2) calibrate other equipment that may be used to directly perform influence factor testing; is controlled.
 - 1.1.4.1. Such control shall include calibration using nationally traceable standards, and shall extend to equipment calibrated internally, and/or to equipment calibrated by an external service provider.
 - 1.1.5. The NTEP CC holder shall ensure that all applicable equipment shall have appropriate operating procedures and shall be accurate and repeatable to a degree sufficient to ensure credible influence factor testing and results.

- 1.1.6. The NTEP CC holder shall ensure that results of calibration activity shall be recorded and shall be made available to the VCAP auditor.

Identify the applicable Metrologically Significant Components (MSCs) of the device.

- 1.1.7. The NTEP CC holder shall ensure that there are processes in place for identification of those components, materials, parts, or assemblies that affect the device's response to the influence factors appropriate to the device type (MSC's).
- 1.1.8. A metrologically significant component is a part, assembly, material, design or procedure that has a direct influence on the performance or operation of a device or component thereof as identified by the device manufacturer.
- 1.1.9. Metrological integrity is maintained by verification that the applicable characteristics of those components identified as metrologically significant are unchanged from those used in the device certified. Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified.
- 1.1.10. The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list shall not be considered exhaustive and is included as examples.
 - 1.1.10.1. **Load Cell, Analog** – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design
 - 1.1.10.2. **Load Cell, Digital** – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type
 - 1.1.10.3. **Weighing/Load-Receiving Element, Electronic** – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell
 - 1.1.10.4. **Indicating Element, Electronic** – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components
- 1.2. Appropriate statistical methods are implemented to ensure that the process is in control as defined by the NTEP CC holder's Quality Management System.
- 1.3. An appropriate sampling plan, and acceptance criteria is in place and operating.
 - 1.3.1. The NTEP CC holder shall establish a random sampling plan appropriate for the production quantity of the device that is traceable to a nationally recognized quality standard, i.e., Acceptable Quality Level AQL or equivalent, or meet the minimum requirements as defined in Section 4 of this document.
 - 1.3.2. Devices shall be selected and tested in accordance to *NCWM Publication 14* as designated by the established sampling plan.
 - 1.3.3. Results of the testing, along with values of pertinent control parameters (e.g., time, temperature, humidity, etc.), shall be recorded and shall clearly identify whether the test passed or failed.
 - 1.3.4. Records shall be made available to the VCAP auditor of test results since the last VCAP audit.
- 1.4. Required operator's manuals and calibration procedures or other controlled documentation for all appropriate devices and components (either manufactured or purchased).

- 1.5. A Nonconforming Material system to control non/conforming/non-compliant devices and components (either manufactured or purchased).
 - 1.5.1. The NTEP CC holder shall control devices that do not meet specified requirements (i.e., nonconforming) to prevent their unintended use.
 - 1.5.2. This control shall include (as a minimum): identification, recording, segregation or isolation (as practicable), review, disposition approval, and notification to appropriate personnel at the manufacturing site(s).
 - 1.5.3. Review of non-conforming VCAP devices, and disposition approval, shall be performed by authorized and qualified personnel.
 - 1.5.4. Records shall be made available to the VCAP auditor.
- 1.6. Adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components.
 - 1.6.1. Control over subcontractors and sub-tier suppliers shall be defined in the NTEP CC holder's Quality Management System.
 - 1.6.2. Records of such control shall be made available to the VCAP auditor.
- 1.7. Appropriate Corrective Action system to deal with nonconforming/non-compliant devices.
 - 1.7.1. The NTEP CC holder shall identify, implement and record corrective actions needed to remedy the cause(s) of nonconformities and problems as a result of influence factor testing, and to prevent their recurrence.
 - 1.7.2. Corrective actions shall include objective evidence that the action was taken and effective.
 - 1.7.3. Corrective actions shall be reviewed and approved by authorized, qualified personnel.
 - 1.7.4. Results of corrective actions shall be retained and be readily available and easily retrievable by testing facility personnel. Records shall be made available to the VCAP auditor.
- 1.8. An Engineering Change system to control engineering/design changes affecting any MSCs.
 - 1.8.1. An engineering change system to control engineering/design changes affecting any MSCs including appropriate methods to ensure changes are released to production.
 - 1.8.2. Records shall be made available to the VCAP auditor of engineering changes since the last VCAP audit.
- 1.9. A Document and Data Control (including software and firmware) system to control changes affecting any MSCs or components of the VCAP program. Such controls shall include (at a minimum):
 - 1.9.1. review and approval for accuracy, completeness and adequacy prior to release,
 - 1.9.2. identification and availability of current/appropriate version levels,
 - 1.9.3. obsolete/superseded version are prevented from unintended uses (unless otherwise approved),
 - 1.9.4. records of document changes shall be maintained and made available to the VCAP auditor.
- 1.10. A production control system to control changes affecting any MSCs.
 - 1.10.1. The NTEP CC holder's Quality Management System shall identify the processes necessary to ensure that engineering changes are properly implemented throughout production.
- 1.11. An Identification and Traceability System (including serialization and lot/batch control as applicable) applied, as a minimum, to MSCs.

- 1.12. Documentation that personnel have been properly trained.
 - 1.12.1. The NTEP CC holder shall identify training needs, and provide training for personnel whose functions/activities affect the VCAP and particularly for those personnel performing influence factor testing.
 - 1.12.2. Training records shall ensure that personnel are qualified to perform their respective functions.
 - 1.12.3. Training shall be performed by authorized and qualified instructors (either internal to the manufacturer, or external by a service provider).
 - 1.12.4. Training needs and activity shall be recorded and shall be made available to the VCAP auditor.
- 1.13. If the NTEP CC holder contracts with an outside testing facility to conduct the influence factor testing, that facility will be subject to all pertinent VCAP requirements.
- 1.14. The NTEP CC holder shall plan and implement a program of internal self-assessment.
 - 1.14.1. The self-assessment shall be conducted at established intervals, not to exceed one year.
 - 1.14.2. The self-assessment shall evaluate the NTEP CC holder's own VCAP and their associated quality system procedures, practices, activities, and controls.
 - 1.14.3. The self-assessment shall demonstrate effective and compliant operation of the manufacturer's own VCAP.
 - 1.14.4. Results of the self-assessment shall be recorded.
 - 1.14.5. Records shall be made available to the VCAP auditor of self-assessments conducted since the last VCAP audit.
- 1.15. Subsequent audits will be held on-site to verify conformance to these standards. Subsequent audits will be conducted every three years until objective evidence is obtained to move to a maximum of every five years.
 - 1.15.1. Audits shall be scheduled as a stand-alone audit; not part of ISO, FM, UL, etc. The audit may be in conjunction with but not part of these audits.
 - 1.15.2. Audits shall be scheduled during testing to ensure that the VCAP auditor witness's devices that are being tested, data being recorded, actions being taken, etc.
 - 1.15.3. The NTEP CC holder has the right to appeal to NCWM if a VCAP certificate has been withdrawn due to the results of the on-site audit.
 - 1.15.4. The NTEP CC holder shall take corrective action within 90 days of non-conformances sited during the on-site audit. It shall be determined during the audit whether a follow up audit is needed or a review of objective evidence is necessary to close any non-conformances.

2. Certification Body's Responsibilities:

- 2.1. The selected Certification Body is to be accredited by ANSI-ASQ National Accreditation Board (ANAB). The ANSI-ASQ National Accreditation Board is the U.S. accreditation body for management systems. ANAB accredits certification bodies (CBs) for ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements, or equivalent.
- 2.2. With accreditation to Standard Industry Classification (SIC) codes (3596/3821) or equivalent.

<u>Sequence Number</u>	<u>2007 NAICS, U.S. Code</u>	<u>2007 NAICS U.S. Title</u>	
847	333997	Scale and Bench	
Manufacturing			
- 2.3. The selected Certification Body shall have international auditors available.

- 2.4. The Certification Body is required to notify NCWM when a major breakdown of the NTEP CC holder's VCAP program is found.
- 2.5. The Certification Body shall submit a completed "Systems Audit Checklist" to NCWM. Submitted documents must contain a clear statement of compliance as a result of the VCAP audit.

NCWM Responsibilities:

- 3.1. For new certificate holders, ensure that VCAP certification has been completed, within a one year cycle of the first maintenance fee, but not to exceed 18 months (example: if NTEP certified in July 2011, VCAP certification would be required by November 2012).
- 3.2. As part of annual maintenance, NCWM shall ensure that VCAP audit reports are on file, current, and that all non-conformances have been addressed.
- 3.3. Ensure that an appeals process is in place and made available to Certificate holders.

3. Sample Sizes:

- 4.1. The following sample sizes are to be used based on annual production.

<u>Units per Year</u>	<u>Minimum Number (total of samples production) per Year</u>
2 – 50	2
51 – 500	3
501 – 35,000	5
35,001+	8

S.2. Consequences

If a Certificate holder fails to submit an application for the Administrative Review, when requested, by the review date specified, the NTEP Certificate of Conformance will become inactive.

If a Certificate holder of a device subject to influence factors fails to submit documentation, by the required date, indicating that it has and continues to maintain a VCAP for influence factors, the NTEP Certificate of Conformance will become inactive.

Verified Conformity Assessment Program

Frequently Asked Questions



1. *What is VCAP?*

The Verified Conformity Assessment Program, or VCAP, is a program proposed by the National Conference on Weights and Measures to ensure compliance of certain device types with environmental requirements. These device types are ones for which performance can be affected by changes in their physical environment. The intent of the VCAP is to provide a level of assurance that these devices perform at a level equal to or better than the device that was evaluated by NTEP.

2. *What devices fall under the VCAP?*

Any device listed on a NTEP Certificate of Conformance whose performance can be affected by changes in its operating environment. Generally, these include load cells, digital weight indicators, weighing and load-receiving elements using load cells that do not have a NTEP certificate, complete scales, automatic weighing systems, belt-conveyor scales, and automatic bulk weighing systems. The program will begin with load cells only.

3. *Why is NTEP initiating this program now?*

The National Conference on Weights and Measures (NCWM) and National Type Evaluation Program (NTEP) have been concerned about production meeting type, protecting the integrity of the NTEP Certificate of Conformance since the inception of NTEP. A workgroup was developed to assist NCWM with this effort, which has provided feedback and recommendations to the conference. The NCWM Board of Directors believes it has reached a point that the Verified Conformity Assessment Program can be launched. Load cells traceable to NTEP certificates have been selected for the initial effort.

4. *Who must comply with the VCAP?*

Any holder of an NTEP Certificate of Conformance for a device type listed above must comply with the program. Again the program will begin with load cells.

5. *What is the difference between SMA/PMT and NCWM/VCAP?*

The PMT and VCAP are administered by two different organizations. Although similar, PMT is a manufacturer program developed by manufacturers, where VCAP is a regulatory requirement developed by NCWM.

6. *Is it enough for a manufacturer to submit a PMT compliance certificate?*

No. The certification body report must state compliance with VCAP. The PMT and VCAP are similar but not identical.

7. *Must I have my quality system ISO certified to comply with VCAP?*

No, while the ISO 9000 series quality standards and VCAP share a number of common features, ISO certification is not required.

- 11) A document and data control system to document, record, and distribute to affected parties changes affecting metrologically significant components.
- 12) A production control system that manages changes that affect metrologically significant components.
- 13) A system that identifies and traces metrologically significant components.
- 14) A training system for personnel with documentation to verify that the appropriate training has taken place.

12. *How can I show compliance with VCAP?*

Compliance with the VCAP can be verified by submitting to a VCAP audit of your manufacturing / testing facility by a VCAP auditor. The auditor will verify that the previously mentioned quality and control elements exist are documented, and that the appropriate procedures are being followed. The auditor also verifies that the proper equipment needed to test and calibrate the devices you manufacture is present, sufficient for the task, and that they are being properly calibrated and operated. The audit will also include testing of a randomly selected device. For that reason, it is best to schedule the audit at a time when devices are available for testing.

13. *How does Publication 14 Administrative Policy, Section S.1. c., Part 3 NCWM Responsibilities apply to companies applying for NTEP certification? Do they have to meet VCAP prior to application?*

For clarification, a change to 3.1 was made so it now reads: For new certificate holders, ensure that VCAP certification has been completed, within a one year cycle of the first maintenance fee, but not to exceed 18 months (example: if NTEP certified in July 2011, VCAP certification would be required by November 2012). Section 3.2. has been deleted.

14. *Where do I find an auditor? Can any quality auditor perform the VCAP audit?*

To perform a VCAP audit, the auditor must meet certain requirements. First, the auditor must be part of a certification body that is accredited by ANSI-ASQ National Accreditation Board (ANAB). The certification body must have accreditation to Standard Industry Classification (SIC) codes 3596 and 3821 or Sequence Number 847 NAICS, US Code 333997, Scale and Balance Manufacturing defined in the 2007 North American Industry Classification System or equivalent accreditation. There are several certification bodies that have auditors qualified to perform VCAP audits. We cannot make any specific recommendations.

15. *Can NTEP help companies locate a registrar that will administer and audit to the VCAP program requirements?*

The NCWM Board has decided not to publish a list of certification bodies and/or auditors as it could appear the NCWM is recommending the companies or individuals.

16. *How does the scope, or the numbers listed on an Accreditation Certificate for a certification body line up with the requirements for a certification body in the VCAP policy?*

It has been reported that the SIC codes and NAICS codes used are outdated. Manufacturers are working to identify the correct codes. This issue should not be a show stopper because the VCAP document already has the words “or equivalent”, recognizing other documents.

auditor may choose to conduct an audit at one or more sites to verify compliance. It is important to recognize that Section 1.4 addresses the sampling plan and testing of the finished device covered by the NTEP certificate. The sampling plan applies to the device covered by the NTEP certificate, not the metrologically significant components.

23. *We hold a number of NTEP Certificates of Conformance. Do we have to submit to a VCAP audit for each certificate?*

No. For example, if your company manufactures five different families of load cells each with its own NTEP Certificate of Conformance you must only submit to one VCAP audit. Successful completion of the VCAP audit will apply to all five NTEP Certificates of Conformance. During the audit, the auditor will know what NTEP Certificates of Conformance you are being audited for and will take the necessary steps to ensure that all are covered. If, for example, you make load cells of different capacities, the auditor will ensure that you have testing equipment sufficient to apply the appropriate test loads to each model of load cell that you manufacture.

24. *Who is going to test NTEP devices in a competent manner that confirms NTEP conformity and compatibility? This question centers specifically on the manufacturing or laboratory test equipment itself.*

The basic concept of NTEP is that by accepting an NTEP Certificate of Conformance (CC), each NTEP CC holder agrees to continue to manufacture and sell devices that meet the current requirements of *NIST Handbook 44* and the requirements described in the NTEP CC. Devices must show, by their markings, that they have an NTEP CC, and what tolerance values, class etc. the device meets. The NTEP CC holder has submitted a device which is typical of the production devices that will be manufactured and sold subsequent to the issuance of the NTEP CC. The intent of VCAP is to ensure that the NTEP CC holder has an acceptable Quality Management System in place for the requirements that must meet Influence Factors. In the case of load cells this is mainly temperature effects on linearity, hysteresis, span, repeatability, zero (vmin or MDLO), and creep. This can also include effects of barometric pressure and in the case of digital load cells, effects of variation in power supply parameters.

The simple answer is that the audit, by the certification body, which is based on the parameters described in the VCAP procedures, will be the basis of evidence that the NTEP CC holder is capable of meeting those requirements. The VCAP procedure is loosely based on ISO 9001:2000. The procedure describes an audit of the quality management system, with an addition of objective evidence, in the form of audits on devices that indicate the capability of the NTEP CC to meet the influence factor requirements. The audits of devices are conducted by the NTEP CC holder. If the auditor is convinced that the VCAP requirements are being met then a certificate indicating compliance would be issued and submitted to NTEP for review.

25. *What test equipment accuracy do you need to test devices for NTEP compliance?*

NCWM Publication- 14, Weighing Devices, Load Cells describes the testing accuracy required in Section C. In part it states:

"The error in the test process for force transducer (load cell) evaluations may not exceed one-third of the tolerance applied at the force transducer (load cell) (0.7 times the tolerance for the weighing system). The important characteristics for the test process for force transducers (load cells) (and indicators) for compliance with the influence factors requirements is

- 29. Does the manufacturer have the option of declaring an entire printed circuit board as the metrologically significant component rather than identifying the few components in the printed circuit board assembly that control the metrological function and are sensitive to changes in the environment?**

It is up to the manufacturer to declare a component a MSC. That could be an individual component or the assembly in which the component is used.

- 30. VCAP requirements Sections 1.2 and 1.4 appear to be very similar. Is there a difference between the “verification” that is stated in 1.2.3 and the “sampling” that is described in 1.4.? Are they separate requirements?**

Yes, they are separate requirements. Section 1.2 addresses metrologically significant components (MSC) and requires a change to a component identified as a metrologically significant part of the device to be verified. Section 1.2.3 recognizes that verification can take place by testing the finished device. Section 1.4 addresses the sampling plan and testing of the finished device covered by the NTEP certificate. The sampling plan applies to the device covered by the NTEP certificate, which can be the load cell.

- 31. Can sampling and testing be of a single part number or model family or does it need to occur through the range of different certificates held by the company?**

The sample sizes are based on annual production per Certificate of Conformance (CC). If the CC lists several models or versions in a family (capacity, size, enclosure style, etc.), you could combine the yearly forecast for all to determine the total production quantity and then test a mix of the versions based on the minimum sample size. Section 1.4.1 also allows other national recognized quality standard sampling plans, that is Acceptable Quality Level (AQL). The idea behind the AQL information is based on performing sample inspections of a fixed lot size of a product or part. Again, in the case of VCAP, the lot size is the annual product number per CC. So each CC stands alone, then the annual production of the cells per each CC should be determined, then the sampling plan is declared. After determining the number to be tested, selection and testing must be conducted in accordance to NCWM Pub. 14.

For clarification, a change to 1.4.2. was made, so it now reads: Devices shall be selected and tested in accordance to NCWM Publication 14 as designated by the established sampling plan.

- 32. Should the term “Control Facility” be used in the Introduction, second paragraph of Pub 14 Administrative Policy, Section S.1. c. to provide clarification of sites to be audited?**

To ensure compliance with VCAP, the auditor may need to audit more than one site (for example: testing, control, manufacturing) if they are at different locations. For clarification, the following changes to the sentence under the first paragraph of S.1.c. and the definition were made during the NCWM Annual Meeting in July, 2009: The Verified Conformity Assessment Program audit will be at one or more sites as required to verify compliance.

Control Facility: The control facility is the facility that is in control of the product before it goes into the marketplace, which could be one or more sites.

VCAP Systems Audit Checklist

For Private Label Certificate Holders



Many NTEP Certified devices must meet *NIST Handbook 44* requirements for influence factors. It is not possible to verify these requirements during the initial verification in the field. Therefore, manufacturers of metrological devices/instruments and/or components/modules which are subject to influence factors, as defined in *NIST Handbook 44*, must have a Verified Conformity Assessment Program (VCAP) in place to ensure that these metrological devices/instruments and/or components/modules are produced to perform at a level consistent with that of the device and/or component previously certified.

The VCAP audit will be at one or more sites as required to verify compliance. For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturer's quality system and on-site random testing and/or review of a production device(s)/instrument(s) by the register to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of *NIST Handbook 44*. **Private label certificate holders are not required to submit devices for testing, on-site or elsewhere.** The private label certificate holder is required to verify that the parent certificate holder has complied with VCAP requirements, has a current VCAP audit certificate, the VCAP certification is traceable back to the parent NTEP certificate and the parent NTEP certificate is active.

The selected Certification Body shall be accredited to the ISO 9001: 2000 standard (or later) for providing audits and certifications of management systems.

Devices That Must Meet This Requirement Are Limited To:

1. Load Cell (T.N.8.)
2. Indicating Element (T.N.8.)
3. Weighing/Load Receiving Elements with Non-NTEP Load Cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. Automatic Weighing Systems (T.7.)
6. Belt-Conveyor Scales (T.3.)
7. Automatic Bulk Weighing Systems (T.7.)

NOTES:

1) The NTEP CC holder has the right to appeal to the National Conference on Weights and Measures if a VCAP certificate has been withdrawn due to the results of the on-site audit. 2) The NTEP CC holder shall take corrective action within 90 days of non-conformances cited during the on-site audit. It shall be determined during the audit whether a follow up audit is needed or a review of objective evidence is necessary to close any non-conformances.

GENERAL INFORMATION			
Date of Audit:	Audit Type: <input type="checkbox"/> Internal (self-assessment) <input type="checkbox"/> Surveillance (certification body)		Name and Affiliation of Auditor:
AUDIT CHECKLIST Note: Include supporting evidence if required. If not, explain in the comments column.			
REQUIREMENT	YES	NO	COMMENTS
1. Is the private label certificate holder's NTEP certificate traceable back to a parent certificate holder and an active NTEP certificate?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Are records available to show the private label certificate holder has confirmed that the supplier has a current VCAP audit meeting applicable requirements	<input type="checkbox"/>	<input type="checkbox"/>	
3. Do the private label certificate holder's purchase and sales records verify that no other supplier is providing the product listed on the NTEP certificate?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Do the supplier's sales records agree with the private label certificate holder's purchasing records?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Does the private label certificate holder have a plan in place to report non-conformance to the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Does the private label certificate holder have a plan in place to address non-conforming devices already sold or in stock?	<input type="checkbox"/>	<input type="checkbox"/>	
7. Does the private label certificate holder have a plan in place to conduct internal audits to verify non-conformance action?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Do internal audit records exist?	<input type="checkbox"/>	<input type="checkbox"/>	
RESULTS			
Corrective Action Required? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Preventive Action Required? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Audit Findings:			

Submit VCAP Audit Reports to NCWM:

1135 M Street, Suite 110 / Lincoln, Nebraska 68508
P. 402.434.4880 F. 402.434.4878 E. info@ncwm.net W. www.ncwm.net

CTT 2011-I/12

Revised: July 2010

Page 1 of 1

12/20

VCAP Systems Audit Checklist For Manufacturers



Many NTEP Certified devices must meet *NIST Handbook 44* requirements for influence factors. It is not possible to verify these requirements during the initial verification in the field. Therefore, manufacturers of metrological devices/instruments and/or components/modules which are subject to influence factors, as defined in *NIST Handbook 44*, must have a Verified Conformity Assessment Program (VCAP) in place to ensure that these metrological devices/instruments and/or components/modules are produced to perform at a level consistent with that of the device and/or component previously certified.

The VCAP audit will be at one or more sites as required to verify compliance. For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturer's quality system and on-site random testing and/or review of a production device(s)/instrument(s) by the register to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of *NIST Handbook 44*.

Devices That Must Meet This Requirement Are Limited To:

1. Load Cell (T.N.8.)
2. Indicating Element (T.N.8.)
3. Weighing/Load Receiving Elements with Non-NTEP Load Cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. Automatic Weighing Systems (T.7.)
6. Belt-Conveyor Scales (T.3.)
7. Automatic Bulk Weighing Systems (T.7.)

NOTES:

1) The NTEP CC holder has the right to appeal to the National Conference on Weights and Measures if a VCAP certificate has been withdrawn due to the results of the on-site audit. 2) The NTEP CC holder shall take corrective action within 90 days of non-conformances cited during the on-site audit. It shall be determined during the audit whether a follow up audit is needed or a review of objective evidence is necessary to close any non-conformances.

GENERAL INFORMATION

Date of Audit:	Audit Type: <input type="checkbox"/> Internal (self-assessment) <input type="checkbox"/> Surveillance (certification body)	Name and Affiliation of Auditor:
----------------	-------------------------------------------------------------------------------------------------------------------------------	----------------------------------

AUDIT CHECKLIST Note: Include supporting evidence if required. If not, explain in the comments column.

REQUIREMENT	YES	NO	COMMENTS
1. Does your facility have a documented quality system?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is your quality system ISO9000 registered? If so, what is the registration level, date of certification and certificate number?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Are written procedures, work instructions, forms, drawings and/or visual aids in place supporting your quality system?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does your facility have the appropriate testing facilities and equipment to verify influence factor compliance for the device type as stated in <i>NIST Handbook 44</i> ?	<input type="checkbox"/>	<input type="checkbox"/>	Attach list of equipment.
5. Do test procedures exist that cover the testing of metrologically significant components and/or the instrument or module?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Are there test records available for review of these tests?	<input type="checkbox"/>	<input type="checkbox"/>	
7. Does your facility maintain control/calibration records on equipment used to test influence factor compliance on devices?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Are results of calibration activity available to the VCAP auditor for review?	<input type="checkbox"/>	<input type="checkbox"/>	
9. Does your facility maintain documented procedures on equipment sufficient to ensure credible influence factor testing and results?	<input type="checkbox"/>	<input type="checkbox"/>	
10. Are there processes in place for identification of Metrologically Significant Components (MSC's), materials, parts or assemblies that affect the device's response to the influence factors appropriate to the device type? Note: Manufacturer may choose to identify the completed instrument or module as the only metrologically significant component.	<input type="checkbox"/>	<input type="checkbox"/>	Attach list of metrologically significant components.
11. Are procedures in place to ensure that metrological integrity is maintained by verification and that the applicable characteristics of those components identified as	<input type="checkbox"/>	<input type="checkbox"/>	

Submit VCAP Audit Checklist To NCWM:

1135 M Street, Suite 110 / Lincoln, Nebraska 68508

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Revised: October 2009

Page 1 of 3

<p>metrologically significant or completed module or instrument are unchanged from those used in the device certified?</p> <p>Note: Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified. Manufacturer may choose to identify the completed module/instrument as the ONLY metrologically significant component.</p> <p>The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list <u>shall not</u> be considered exhaustive and is included as examples.</p> <ul style="list-style-type: none"> • Load Cell, Analog – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design • Load Cell, Digital – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type • Weighing/Load Receiving Element – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell • Indicating Element, Electronic – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components 													
12. Are there appropriate statistical methods implemented to ensure that the process is in control as defined by the NTEP CC holder's quality management system?	<input type="checkbox"/>	<input type="checkbox"/>											
13. Is there an appropriate sampling plan appropriate for the production quantity of the device that is traceable to a nationally recognized quality standard and acceptance criteria in place and operating?	<input type="checkbox"/>	<input type="checkbox"/>											
<p>14. Are devices selected and tested in accordance to NCWM Publication 14 as designated by the established sampling plan?</p> <p>The following sample sizes are to be used based on annual production.</p> <table border="1"> <thead> <tr> <th>Units Per Year (total of sample production)</th> <th>Minimum Number Per Year</th> </tr> </thead> <tbody> <tr> <td>2-50</td> <td>2</td> </tr> <tr> <td>51-500</td> <td>3</td> </tr> <tr> <td>501-35,000</td> <td>5</td> </tr> <tr> <td>35,001+</td> <td>8</td> </tr> </tbody> </table>	Units Per Year (total of sample production)	Minimum Number Per Year	2-50	2	51-500	3	501-35,000	5	35,001+	8	<input type="checkbox"/>	<input type="checkbox"/>	Attach appropriate sample plan for devices tested.
Units Per Year (total of sample production)	Minimum Number Per Year												
2-50	2												
51-500	3												
501-35,000	5												
35,001+	8												
15. Are results of the testing, along with values of pertinent control parameters (i.e., time, temperature, humidity, etc.) recorded and do they clearly identify whether the test passed or failed?	<input type="checkbox"/>	<input type="checkbox"/>											
16. Are records available to the VCAP auditor of test results?	<input type="checkbox"/>	<input type="checkbox"/>											
17. Is there a non-conforming material system in place to control non-conforming/non-compliant devices and components thereof (either manufactured or purchased)?	<input type="checkbox"/>	<input type="checkbox"/>											
18. Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?	<input type="checkbox"/>	<input type="checkbox"/>											

19. Are records of non-conformance available for review by the VCAP auditor?	<input type="checkbox"/>	<input type="checkbox"/>	
20. Are there documented quality system procedures that ensure adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components?	<input type="checkbox"/>	<input type="checkbox"/>	
21. Are there records of such control available to the VCAP auditor for review?	<input type="checkbox"/>	<input type="checkbox"/>	

22. Is there an appropriate corrective/preventive action system in place to deal with non-conforming/non-compliant devices?	<input type="checkbox"/>	<input type="checkbox"/>	
23. Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?	<input type="checkbox"/>	<input type="checkbox"/>	
24. Are corrective/preventative action records available and easily retrievable by testing facility personnel?	<input type="checkbox"/>	<input type="checkbox"/>	
25. Is there an engineering change system to control engineering/design changes affecting any MSC including appropriate methods to ensure changes are released to production?	<input type="checkbox"/>	<input type="checkbox"/>	
26. Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?	<input type="checkbox"/>	<input type="checkbox"/>	
27. Is there objective evidence of engineering evaluations of substitution of components that affect the instrument or module's response to environmental factors?	<input type="checkbox"/>	<input type="checkbox"/>	
28. Is there a document of data control (including software and firmware) system in place to control any MSC or components of the VCAP program?	<input type="checkbox"/>	<input type="checkbox"/>	
29. Is there review and approval for accuracy, completeness and adequacy of documents prior to release?	<input type="checkbox"/>	<input type="checkbox"/>	
30. Is there identification and availability of current/appropriate version levels of documents?	<input type="checkbox"/>	<input type="checkbox"/>	
31. Are obsolete/superseded versions prevented from unintended use?	<input type="checkbox"/>	<input type="checkbox"/>	
32. Are there processes in place to ensure the engineering changes are properly implemented throughout production?	<input type="checkbox"/>	<input type="checkbox"/>	
33. Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?	<input type="checkbox"/>	<input type="checkbox"/>	
34. Is there documentation available to show that personnel whose functions/activities affect the VCAP, have been properly trained?	<input type="checkbox"/>	<input type="checkbox"/>	
35. Do training records show that personnel are qualified to perform their respective functions?	<input type="checkbox"/>	<input type="checkbox"/>	
36. Are training records available to the VCAP auditor for review?	<input type="checkbox"/>	<input type="checkbox"/>	
37. Are internal audits of your quality system conducted on a regular basis?	<input type="checkbox"/>	<input type="checkbox"/>	
38. Are internal audit results of the quality system in place recorded and available for review by VCAP auditor?	<input type="checkbox"/>	<input type="checkbox"/>	
39. Are VCAP (self-assessment) internal audits conducted at least once a year as required per VCAP certification requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
40. Are records available of VCAP internal audits for the VCAP auditor to review?	<input type="checkbox"/>	<input type="checkbox"/>	
41. Was the VCAP audit scheduled during testing to ensure that VCAP auditor witnessed devices being tested, data being recorded, actions being taken, etc.?	<input type="checkbox"/>	<input type="checkbox"/>	
RESULTS			
Corrective Action Required? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Preventive Action Required? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Audit Findings:			

VCAP Checklist Supplemental Guide



This document is meant to compliment the VACP Audit Systems Checklist for Manufacturers by offering clarification or explanation of some items on the checklist. In addition, references to the requirements of the NTEP VCAP Procedures found in *NCWM Publication 14 Administrative Procedures, Section S.1.c* have been included.

When additional issues are brought to the attention of NTEP this document will be amended and expanded. Further questions should be referred to the NTEP Administrator and/or NCWM NTEP Committee chairperson.

1. Does your facility have a documented quality system?

A Quality Management System governs the design and manufacture of the device(s). This Quality Management System must be documented in your Quality Manual. (section 1.1 & 1.1.1)

2. Is your quality system ISO 9000 registered? If so, what is the registration level, date of certification and certificate number?

The ISO 9000 series quality standards and VCAP share a number of common features, however ISO certification is not required. Although there are some similarities, VCAP differs in its requirements. Therefore, ISO certification alone is not an acceptable substitute.

3. Are written procedures, work instructions, forms, drawings and/or visual aids in place supporting your quality system?

Do you possess the required operators' manual and calibration procedures for all appropriate production and testing equipment? Of course, you must not only possess these manuals, you must also ensure that your operators are familiar with them and follow the procedures contained within them. This would include a training system for personnel with documentation to verify that the appropriate training has taken place. (section 1.1.1 and 1.5)

4. Does your facility have the appropriate testing facilities and equipment to verify influence factor compliance for the device type as stated in NIST Handbook 44? Attach a list of equipment.

(sections 1.1.2, 1.1.3 and 1.14)

5. Do test procedures exist that cover the testing of metrologically significant components and/or the instrument or module?

Test procedures may be more than just the operator's manual for the equipment being used in the test. There may be preparation or other steps involved prior to using the test equipment that also need to be documented as part of the test procedure with training to cover the entire test procedure.

6. Are there test records available for review of these tests?

7. Does your facility maintain control/calibration records on equipment used to test influence factor compliance on devices?

Such control shall include calibration using nationally traceable standards, and shall extend to equipment calibrated internally, and/or to equipment calibrated by an external service provider. (section 1.1.4.1 & 1.1.6)

8. Are results of calibration activity available to the VCAP auditor for review?

(section 1.1.6)

9. Does your facility maintain documented procedures on equipment sufficient to ensure credible influence factor testing and results?

Do you have the required operators' manual and calibration procedures for all appropriate production and testing equipment? Of course, you must not only possess these manuals, you must also ensure that your operators are familiar with them and follow the procedures contained within them. (section 1.1.5)

10. Are there processes in place for identification of Metrologically Significant Components (MSC's), materials, parts or assemblies that affect the device's response to the influence factors appropriate to the device type? Note: Manufacturer may choose to identify the completed instrument or module as the only metrologically significant component. Attach a list of metrologically significant components.

You must identify those metrologically significant components (MSC) used in the device. These are the components, materials, processes, and software that have an effect on the performance of the device. It is up to you as a manufacturer to identify these items. To determine whether an item is metrologically significant or not you must ask whether a change in the characteristics of that item (such as temperature) will affect the performance of the device. If the answer is yes, then the item is metrologically significant. (sections 1.2.1 and 1.2.2)

11. Are procedures in place to ensure that metrological integrity is maintained by verification and that the applicable characteristics of those components identified as metrologically significant or completed module or instrument are unchanged from those used in the device certified?

(section 1.2.3)

Note: Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified. Manufacturer may choose to identify the completed module/instrument as the ONLY metrologically significant component.

The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list shall not be considered exhaustive and is included as examples.

- **Load Cell, Analog** – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design
- **Load Cell, Digital** – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type
- **Weighing/Load Receiving Element** – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell
- **Indicating Element, Electronic** – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components

(section 1.2.4.x)

12. Are there appropriate statistical methods implemented to ensure that the process is in control as defined by the NTEP CC holder's quality management system?

You must possess and use appropriate statistical tools or methods to ensure that the processes used to manufacture the device are in control. This is often referred to as statistical process control and is a means to determine whether your processes are consistent and repeatable. (section 1.3)

13. Is there an appropriate sampling plan appropriate for the production quantity of the device that is traceable to a nationally recognized quality standard and acceptance criteria in place and operating?

The sample sizes are based on annual production per Certificate of Conformance (CC). If the CC lists several models or versions in a family (capacity, size, enclosure style, etc.), you could combine the yearly forecast for all to determine the total production quantity and then test a mix of the versions based on the minimum sample size. Also allowed are other nationally recognized quality standard sampling plans that are Acceptable Quality Level (AQL). The idea behind the AQL information is based on performing sample inspections of a fixed lot size of a product or part. Again, in the case of VCAP, the lot size is the annual product number per CC. So each CC stands alone, then the annual production of the device per each CC should be determined, then the sampling plan is declared. (section 1.4.1)

14. Are devices selected and tested in accordance to NCWM Publication 14 as designated by the established sampling plan?

(section 1.4.2)

The following sample sizes are to be used based on annual production.

Units Per Year (total of sample production)	Minimum Number Per Year
2-50	2
51-500	3
501-35,000	5
35,001+	8

The above sampling plan is found in section 4.1 and may be used as an alternative to meet section 1.4.1.

15. Are results of the testing, along with values of pertinent control parameters (i.e., time, temperature, humidity, etc.) recorded and do they clearly identify whether the test passed or failed?

(section 1.4.3)

16. Are records of test results available to the VCAP auditor?

(section 1.4.4)

17. Is there a non-conforming material system in place to control non-conforming/non-compliant devices and components thereof (either manufactured or purchased)?

This system must deal with the identification, control, and disposition of these items. (sections 1.6, 1.6.1 and 1.6.2)

18. Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?

(section 1.6.3)

19. Are records of non-conformance available for review by the VCAP auditor?

(Section 1.6.4)

20. Are there documented quality system procedures that ensure adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components?

(section 1.7.1)

21. Are there records of such control available to the VCAP auditor for review?

(section 1.7.2)

22. Is there an appropriate corrective/preventive action system in place to deal with non-conforming/non-compliant devices?

Identify, implement and record corrective actions needed to remedy the cause(s) of nonconformities and problems as a result of influence factor testing, and to prevent their recurrence. (sections 1.8, 1.8.1 and 1.8.2)

23. **Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?**
(section 1.8.4)
24. **Are corrective/preventative action records available and easily retrievable by testing facility personnel?**
(section 1.8.4)
25. **Is there an engineering change system to control engineering/design changes affecting any MSC including appropriate methods to ensure changes are released to production?**
(section 1.9.1)
26. **Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?**
(section 1.9.2)
27. **Is there objective evidence of engineering evaluations of substitution of components that affect the instrument or module's response to environmental factors?**
28. **Is there a document of data control (including software and firmware) system in place to control any MSC or components of the VCAP program?**
(section 1.10)
29. **Is there review and approval for accuracy, completeness and adequacy of documents prior to release?**
(section 1.10.1)
30. **Is there identification and availability of current/appropriate version levels of documents?**
(section 1.10.2)
31. **Are obsolete/superseded versions prevented from unintended use?**
These documents are marked as "obsolete," "not official copy" or similar terminology, or simply removed from use/access entirely. (section 1.10.3)
32. **Are there processes in place to ensure the engineering changes are properly implemented throughout production?**
(section 1.11.1)
33. **Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?**
(section 1.12) How are MSCs marked or otherwise identified and how can they be tracked throughout supply/manufacturing/distribution system.
34. **Is there documentation available to show that personnel, whose functions/activities affect the VCAP, have been properly trained?**
(section 1.13.1)
35. **Do training records show that personnel are qualified to perform their respective functions?**
(section 1.13.2)
36. **Are training records available to the VCAP auditor for review?**
(section 1.13.4)
37. **Are internal audits of your quality system conducted on a regular basis?**
(section 1.15)
38. **Are internal audit results of the quality system in place recorded and available for review by VCAP auditor?**
(sections 1.15.4 and 1.15.5)

39. Are VCAP (self-assessment) internal audits conducted at least once a year as required per VCAP certification requirements?

This is an internal audit involving testing to VCAP requirements, where internal audits of the quality system under question 37 could be of the manufactures or distributor's own design and content. (sections 1.15.1, 1.15.2 and 1.15.3)

40. Are records available of VCAP internal audits for the VCAP auditor to review?

(section 1.15.5)

41. Was the VCAP audit scheduled during testing to ensure that VCAP auditor witnessed devices being tested, data being recorded, actions being taken, etc.?

The auditor is not expected to witness complete testing of a device/component. The auditor wants to witness the processes: Are testing and operating procedures followed? Do employees appear to be trained as records may indicate? If there is a failure on a test are follow-up procedures or processes followed? A failed test result does not mean a failed audit. (section 1.16.2)

Report on the OIML Utrecht Seminar on Conformity to Type

Stephen O'Brien¹

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

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.

¹ Mr. Stephen O'Brien is the CIML Member for New-Zealand. He was the convener of the ad-hoc working group established by the 45th CIML Meeting (Orlando, USA, 2010) to organise the program for the CTT Seminar.

- 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.
