



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.

29 June 2011

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?**

29 June 2011

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.

29 June 2011

7

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.

29 June 2011

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.

29 June 2011

9

OIML Conformity To Type

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

29 June 2011

10

OIML Conformity To Type

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

29 June 2011

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.

29 June 2011

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"

29 June 2011

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"

29 June 2011

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”**

29 June 2011

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?”

29 June 2011

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?

29 June 2011

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.**

29 June 2011

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.

29 June 2011

19

OIML Conformity To Type

Thank You!

Scale Manufacturers Association

Post Office Box 26972

Columbus, Ohio 43226-0972

Tel: +866 372 4627

Email info@scalemanufacturers.org

Darrell Flocken

Mettler Toledo

1150 Dearborn Drive

Worthington, Ohio 43085 USA

Tel: +614 438 4393

Email: darrell.flocken@mt.com

29 June 2011

20

OIML Conformity To Type