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

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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  - Nonconformity: Certificate holder pays evaluation fees and the certificate is withdrawn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

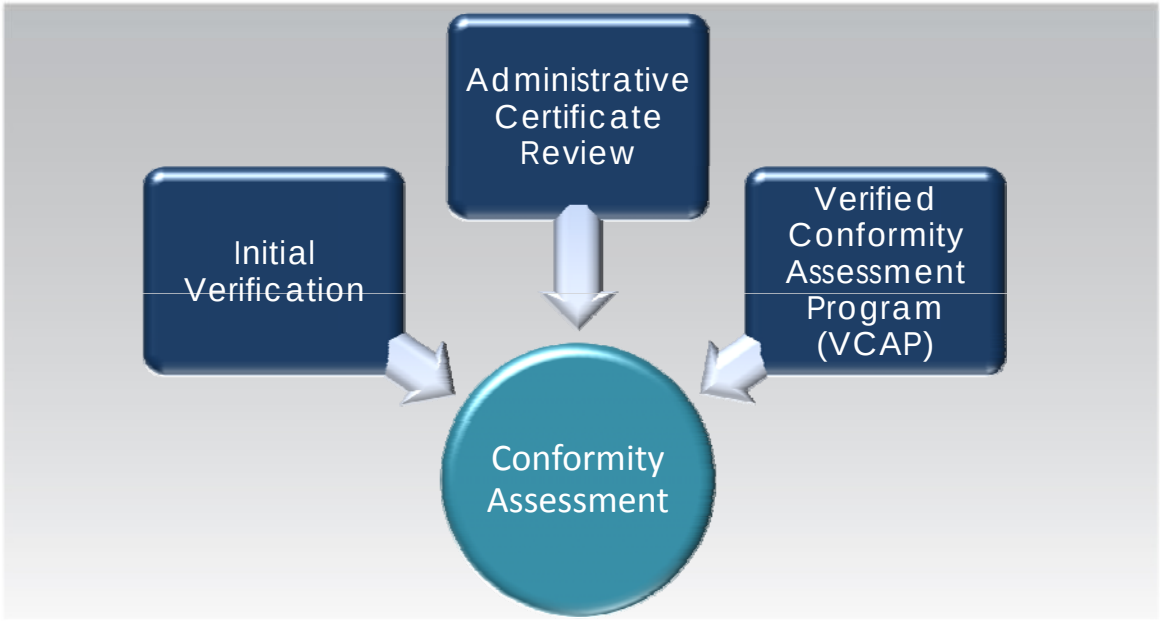
Conformity Assessment Defined

"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



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

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 <u>all</u> instruments

Administrative Certificate Review: Applies to <u>all</u> 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.

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.

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

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Thank You