National Type Evaluation Program (NTEP) Committee
Interim Agenda

Judy Cardin, Chairman
Chief
Wisconsin, Weights and Measures

Reference
Key Number

500 INTRODUCTION

The NTEP Committee will address the following items at its 2009 Interim Meeting. Except when posted, all meetings are open to the membership. The members will be invited to dialogue with the NTEP Committee on issues on its agenda. The NTEP Committee is currently working on the following issues:

Table A
Index to Reference Key Items

Table B
Appendices

*Drafts of the sector summaries can be viewed at http://www.ncwm.net/ntep/index.cfm?fuseaction=meetings

Table C
Glossary of Acronyms*

BIML	Bureau of International Legal Metrology	IR	International Recommendation
CD	Committee Draft[1]	MAA	Mutual Acceptance Arrangement
CIML	International Committee of Legal Metrology	OIML	International Organization of Legal Metrology
CPR	Committee on Participation Review	R	Recommendation
DD	Draft Document[2]	SC	Subcommittee
DR	Draft Recommendation[2]	TC	Technical Committee
DV	Draft Vocabulary[2]	WD	Working Document[3]
DoMC	Declarations of Mutual Confidence		

[1] CD: a draft at the stage of development within a technical committee or subcommittee; in this document, successive drafts are numbered 1 CD, 2 CD, etc.

[2] DD, DR, DV: draft documents approved at the level of the technical committee or subcommittee concerned and sent to BIML for approval by CIML.

[3] WD: precedes the development of a CD; in this document, successive drafts are number 1 WD, 2 WD, etc.

* Explanation of acronyms provided by OIML.

Details of All Items
(In Order by Reference Key Number)

1. Mutual Recognition Arrangement (MRA)

Background: Both Measurement Canada and the NTEP labs continue striving to improve the data exchange under the Mutual Recognition Arrangement (MRA). During the 2008 NTEP labs meeting, an entire day was spent exchanging information regarding the current MRA for weighing devices. Several areas of improvement were identified including an initial review of new applications to establish an agreed-upon test plan for the evaluation. In addition, a training session was conducted to improve the consistency of data collected by the labs. Consistency in data collection will help to improve the ability of the various labs to exchange data. Measurement Canada has also supplied the U.S. NTEP labs with an updated version of an Excel spreadsheet program to standardize the test report forms for devices that fall under the MRA. This updated version of the spreadsheet checklist has been well received by the labs and is now in use for evaluations conducted by the labs.

Current Comment: We will continue to review progress and work on improvements during the NTEP lab meetings.

2. Mutual Acceptance Arrangement (MAA)

Background: Information regarding the OIML MAA can be found at www.oiml.org/maa. NCWM has signed the OIML MAA Declaration of Mutual Confidence (DoMC) for R 60 Load Cells as a utilizing participant.

The 2008 Annual Meeting of the CIML was held in October in Sydney, Australia. Four resolutions pertaining to the OIML MAA were adopted there. These resolutions were the outcome of a May 2008 meeting of the OIML TC 3/SC 5 on conformity assessment, which oversees the following OIML B documents that are classified as Basic Publications:

- OIML B 3 *OIML Certificate System for Measuring Instruments*, identified as project p7,

- OIML B 10-1 *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations*, identified as project p8, and

- OIML B 10-2 *Checklists for Issuing Authorities and Testing Laboratories carrying out OIML Type Evaluations*, identified as project p9.

The key resolution of most significance to the NCWM is that the ending date for OIML issuing authorities (including NTEP) to be able to issue what are now being referred to as OIML "Basic" Certificates (as distinguished from OIML "MAA" Certificates) for R 60 and R 76 has been extended indefinitely, which means that, in principle, NTEP can continue to issue such Basic Certificates (although it has not done so for many years). The reason for this extension is to provide time for those countries who utilize manufacturers' test data (under not-completely-supervised conditions) when issuing OIML Basic Certificates to convince other countries that this practice can be carried out successfully if proper safeguards are put in place. In the meantime, it was agreed that manufacturers' test data cannot be used as the basis of issuing an OIML MAA Certificate. The objective of this delay is to eventually allow manufacturers' test data to be used as part of the MAA system in a natural progression, rather than artificially and possibly prematurely ending the Basic Certificate System for any category of instrument. The CIML will monitor this situation.

The other resolutions dealt with when OIML Recommendations can become part of the OIML Certificate System, maintenance of earlier versions of revised recommendations, and revisions of OIML Basic Certificates.

Details of all four resolutions can be found in the Resolutions of the 43rd CIML Meeting on the OIML website. It is the intention of TC 3/SC 5 to begin revision of the B 3 and B 10 documents to incorporate these resolutions along with earlier, related CIML decisions.

3. NTEP Participating Laboratories and Evaluations Reports

Background: At the 2008 NCWM Annual Meeting, Stephen Patoray, NTEP Director, updated the Committee on NTEP laboratory and administrative activities since October 1, 2007.

The NTEP weighing and measuring laboratories held a joint meeting in April 2008 in Ottawa, Canada. The NTEP weighing laboratories also met in September 2008 before the meeting of the Weighing Sector in St. Louis, Missouri. The NTEP measuring laboratories met again in October 2008 prior to the Measuring Sector meeting in Atlanta, Georgia.

Current Comment: The NTEP Committee discussed contingency planning for continuity of NTEP operations. With the state of today's economy, what if NTEP lost a lab? How will NTEP maintain work-flow? Are there additional states interested in applying to become an NTEP field lab or an NTEP brick-and-mortar lab? The NTEP Committee will further discuss the issues during a long-range planning session and welcomes comments from the membership.

Jim Truex will update the Committee on any outstanding issues related to the NTEP participating labs.

Upcoming meetings: (locations are being evaluated)

NTEP Laboratory Meeting	Spring 2009	Ohio
Software Sector	May 2009	TBD
Grain Analyzer Sector	August 2009	Kansas City, Missouri
Weighing Sector	September 2009	TBD
Measuring Sector	October 2009	Same site as SWMA

4. NTETC Sector Reports

Background:

Grain Moisture Meter and NIR Protein Analyzer Sectors: The NTETC Grain Moisture Meter and NIR Protein Analyzer Sectors held a joint meeting in Kansas City, Missouri, August 20 and 21, 2008. A draft of the final summary will be provided to the Committee prior to the 2008 NCWM Interim Meeting for review and approval.

The next meeting of the Grain Moisture Meter and NIR Protein Analyzer Sectors is scheduled for August 2009 in Kansas City, Missouri. For questions on the current status of sector work or to propose items for a future meeting, please contact the sector technical advisors:

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Measuring Sector: The NTETC Measuring Sector met October 3 and 4, 2008, in Atlanta, Georgia. A draft of the final summary will also be provided to the NTEP Committee prior to the 2008 NCWM Interim Meeting for review and approval.

The next meeting of the Measuring Sector is scheduled for October 2009, in conjunction with the Southern Weights and Measures Association's Annual Meeting. For questions on the current status of sector work or to propose items for a future meeting, please contact the sector technical advisor:

Tina Butcher
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100 Bureau Drive, Stop 2600
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Software Sector: The NTETC Software Sector met May 20 and 21, 2008, in Columbus, Ohio. A final draft of the meeting summary will be provided to the Committee prior to the 2009 NCWM Interim Meeting for review and approval.

The next Software Sector meeting is scheduled for the spring of 2009, site to be determined. For questions on the current status of sector work or to propose items for a future meeting, please contact the NTEP Administrator:

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Weighing Sector: The NTETC Weighing Sector met September 23 - 25, 2008, in St. Louis, Missouri. A final draft of the meeting summary will be provided to the Committee prior to the 2008 NCWM Interim Meeting for review and approval.

The next Weighing Sector meeting is scheduled for September 2009, site to be determined. For questions on the current status of sector work or to propose items for a future meeting, please contact the sector technical advisor:

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NTETC Sector Summaries: The NTEP Committee will receive copies of the summaries prior to the NCWM Interim Meeting for its review and approval.

Current Comment: The Committee will hear an update on the activities of the NTETC Sectors at the 2009 NCWM Interim Meeting.

5. NTEP Participation in U.S. National Work Group (USNWG) on Harmonization of NIST Handbook 44, NCWM Publication 14 and OIML R 76 and R 60

Background: At its October 2006 meeting in Cape Town, South Africa, the 41st CIML approved DR 7: R 76-1 Non-automatic weighing instruments, Part 1: Metrological and technical requirements – Tests. The DoMC for R 76 was updated at the end of September 2008. Steve Cook, NIST WMD, will provide the current status of activities in these areas to the Committee during the 2009 NCWM Interim Meeting.

Current Comment: Steven Cook reported that the revision of R 76 "Non-automatic Weighing Instruments" is of major importance to U.S. interests because the Recommendation serves as the foundation for a majority of the laws and regulations governing weighing instruments around the world. The revision includes new language addressing metrological controls for type evaluations, conformity, initial and subsequent inspections, suitability of separable components and requirements for metrological software. The USNWG was consulted concerning proposals to harmonize Handbook 44 and R 76. As reported at the 2007 NCWM Interim Meeting, the DR of R 76-1 was approved by the CIML in October 2006. Most recently, the United States voted "yes" on the DR of R 76-2 "Test Report Format." The Secretariat (United States) to OIML R 60 – "Metrological regulation for load cells" plans to send an inquiry to OIML P-members about starting a revision of R 60. The questionnaire will ask for feedback on a broad scope of topics from the basic principles of R 60 (e.g., tolerances and accuracy classes) to exploring the addition of new requirements. For more information on these efforts, please contact Steve Cook at (301) 975-4003 or steven.cook@nist.gov.

6. Conformity Assessment Program

Background: The Conformity Assessment Program was established to ensure devices produced after the device has been type evaluated and certified by NTEP continue to meet the same requirements. This program has three major elements: (1) Certificate Review (administrative); (2) Initial Verification (inspection and performance testing); and (3) Verified Conformity Assessment (influence factors). This item is included on the Committee's agenda to provide an update on these elements.

Certificate Review: The question addresses how this would be accomplished given the limited resources of NCWM. It was suggested this item may need to continue on a "back burner" until resources can be clearly identified to proceed with the project in an efficient, thorough, and accurate manner.

During the 92nd NCWM, it was reported that this item continues on the "back burner" until funding can be identified for this project. The NTEP Committee considered the fact that continuing improvement is occurring on Certificates of Conformance and the improvements are making it easier for inspectors to verify. Therefore, for the time being, the NTEP Committee plans to discontinue reporting on this portion of Conformity Assessment in future NTEP reports.

Initial Verification (IV): Work group chair, Lou Straub, reported that Initial Verification checklists have been developed for small scales, vehicle scales, and retail motor fuel dispensers. Data has been received from several states on small-capacity price computing scales, and the pilot of Initial Verification for small-capacity scales has been completed. All data has been forwarded to NCWM staff for safekeeping.

The WG asked for direction from the NTEP Committee on how to proceed to the next step. Mr. Straub clarified that not all states or jurisdictions need to participate in submitting information to NCWM on Initial Verification. A subset of states would be sufficient. The NTEP Committee instructed the WG to proceed with development of additional checklists but there was a sense that the WG was reluctant until they know how states will react and use

the developed checklists. The NTEP Committee also noted the need to decide how to process the data generated from Initial Verification. The Committee acknowledges that VCAP is the priority and thinks IV is a very important element of conformity assessment but may need to rest until the states are ready to act.

Verified Conformity Assessment Program (VCAP): 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 work group was developed to assist the NCWM with this effort, which has provided feedback and recommendations to the conference. The NCWM Board of Directors thinks 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. All certificate holders of NTEP Certificates of Conformance for load cells have been notified. The following timeline for load cell certificate holders has been established and published.

NTEP VCAP Timeline – Load Cells				
Jul 2008 - Dec 2008	**Jan 2009 - Dec 2009**	**Jan 2010 - Mar 2010**	**Apr 2010 - Nov 2010**	**Nov 2010**
Refine VCAP procedures	LC manufacturers to put VCAP QM system in place	NTEP to evaluate incoming Certification Body audit reports	NTEP to contact manufacturers not meeting VCAP and encourage compliance before annual maintenance fee is due in Nov.	CCs declared inactive if CC holder fails to meet VCAP
Answer incoming questions	Conduct audit by Certified Body		Continue to evaluate incoming audit reports	
Refine/develop appeals process	Submit audit report to NCWM/NTEP			
Notify all CC holders of updated plan, Q&A, etc.				

Current Comment: The NTEP Committee has been asked to announce which device(s) will be next after load cells. The NTEP Committee wants some additional time to see what issues and concerns come to light with the load cell effort before making a decision.

See Appendix E – VCAP Frequently Asked Questions. This document is considered a living document subject to frequent updates as questions continue to be asked.

NCWM Publication 14, Section T., Appeal and Review Process is also under review to insure an adequate process for potential VCAP appeals.

Jim Truex will update the NTEP Committee and the NCWM Board regarding progress of Conformity Assessment issues.

7. NCWM Publication 14, NTEP Administrative Policy, Section S.1.c. (VCAP)

Source: Load Cell VCAP Work group

Background: During the VCAP discussions, the work group identified sections of the VCAP section of NCWM Publication 14 that needed to be addressed. Based upon decisions of the work group the following recommendation was forwarded to the NTEP Committee.

Recommendation to change NCWM Publication 14, NTEP Administrative Policy, Section S.1.c. as follows:

c. Verified Conformity Assessment Program (VCAP)

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 (instruments) and/or components (modules) are produced to perform at a level consistent with that of the device and/or component previously certified. ~~**A second or third party audit must verify the Conformity Assessment Program. The second or third party must be a Certified Registrar accredited for appropriate instruments.**~~

The Verified Conformity Assessment Program **audit** will be **a** site-specific **verification that** ~~**and**~~ will focus on ~~**any**~~ **the** site that controls the design~~**, manufacture, quality, or**~~ testing of the device.

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 ~~**Manufacturer shall have**~~ **NTEP CC holder's Control Facility Responsibilities:**

   1.1 A documented Quality Management System governing the design and manufacture 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 the 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 Note: 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.**

1.2. ~~**Identified**~~ **Identify** the applicable Metrologically Significant Components (MSC's) of the device.

1.2.1. **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).**

1.2.2. **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.**

1.2.3. **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.**

1.2.4. **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.**

1.2.4.1. **Load Cell, Analog – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design**

1.2.4.2. **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**

1.2.4.3. **Weighing/Load-Receiving Element, Electronic – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell**

1.2.4.4. **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**

1.3. Appropriate statistical methods implemented to ensure that the process is in control **as defined by the NTEP CC holder's Quality Management System**.

1.4. An appropriate sampling plan, and acceptance criteria is in place and operating.

1.4.1. **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. AQL or equivalent, or meet the minimum requirements as defined in Section 4, Sample Sizes.**

1.4.2. **Devices shall be tested in accordance to NCWM Publication 14 as designated by the established sampling plan.**

1.4.3. **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.**

1.4.4. **Records shall be made available to the VCAP auditor of test results since the last VCAP audit.**

1.5. Required operator's manuals and calibration procedures **or other controlled documentation** for all appropriate ~~**production and testing equipment**~~ **devices and components (either manufactured or purchased).**

1.6. A Nonconforming Material system to control nonconforming/non-compliant devices and components (either manufactured or purchased).

1.6.1. **The NTEP CC holder shall control devices that do not meet specified requirements (i.e. 'non-conforming') to prevent their unintended use.**

1.6.2. **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).**

1.6.3. **Review of non-conforming VCAP devices, and disposition approval, shall be performed by authorized and qualified personnel.**

1.6.4. **Records shall be made available to the VCAP auditor.**

1.7. Adequate control over subcontractors and sub-tier suppliers**, that supply metrologically significant components**.

1.7.1. **Control over subcontractors and sub-tier suppliers shall be defined in the NTEP CC holder's Quality Management System.**

1.7.2. **Records of such control shall be made available to the VCAP auditor.**

1.8. Appropriate Corrective Action system to deal with nonconforming/non-compliant devices.

1.8.1. **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.**

1.8.2. **Corrective actions shall include objective evidence that the action was taken and effective.**

1.8.3. **Corrective actions shall be reviewed and approved by authorized, qualified personnel.**

1.8.4. **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.**

1.9. An Engineering Change system to control engineering/design changes affecting any MSC's.

1.9.1. **An engineering change system to control engineering/design changes affecting any MSC's including appropriate methods to ensure changes are released to production.**

1.9.2. **Records shall be made available to the VCAP auditor of engineering changes since the last VCAP audit.**

1.10. A Document and Data Control (including software and firmware) system to control changes affecting any MSC's **or components of the VCAP program**. **Such controls shall include (at a minimum):**

1.10.1. **review and approval for accuracy, completeness and adequacy prior to release,**

1.10.2. **identification and availability of current/appropriate version levels,**

1.10.3. **obsolete/superseded versions are prevented from unintended uses (unless otherwise approved),**

1.10.4. **records of document change shall be maintained and made available to the VCAP auditor.**

1.11. A Production Control system to control changes affecting any MSC's.

1.11.1. The NTEP CC holder's Quality Management System shall identify the processes necessary to ensure that engineering changes are properly implemented throughout production.

1.12. An Identification and Traceability system (including serialization and lot/batch control as applicable) applied, as a minimum, to MSC's

1.13. Documentation that personnel have been properly trained.

1.13.1. 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.

1.13.2. Training records shall ensure that personnel are qualified to perform their respective functions.

1.13.3. Training shall be performed by authorized and qualified instructors (either internal to the manufacturer, or external by a service provider).

1.13.4. Training needs and activity shall be recorded and shall be made available to the VCAP auditor.

~~2.~~ **1.14.** If the ~~manufacturer~~ **NTEP CC holder** contracts with an outside ~~laboratory~~ **testing facility** to conduct the influence factor testing, that ~~laboratory~~ **facility** will be subject to all pertinent ~~Conformity Assessment Program~~ **VCAP** requirements.

1.15. The NTEP CC holder shall plan and implement a program of internal self-assessment.

1.15.1. The self-assessment shall be conducted at established intervals, not to exceed one year

1.15.2. The self-assessment shall evaluate the NTEP CC holder's own VCAP and their associated quality system procedures, practices, activities and controls.

1.15.3. The self-assessment shall demonstrate effective and compliant operation of the manufacturer's own VCAP.

1.15.4. Results of the self-assessment shall be recorded.

1.15.5. Records shall be made available to the VCAP auditor of self-assessments conducted since the last VCAP audit.

~~3.~~**1.16.** ~~A s~~**S**ubsequent audit**s** ~~report shall~~ **will** be ~~provided by the Registrar, at least every five years,~~ **held** on-site ~~visit to the manufacturing facility to review the statistical quality assurance and production records for all affected certified devices, and random testing or review of a production device in the manufacturing facility~~ **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.**

1.16.1. 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.

1.16.2. Audits shall be scheduled during testing to ensure that a VCAP auditor witnesses devices being tested, data being recorded, actions being taken, etc.

1.16.3. An audit report shall be provided by the Certification Body as defined in the VCAP Administrative Policy, Section S.1.c.

1.16.4. 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.

1.16.5. 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.

~~4. Information may be requested from a manufacturer in between the scheduled audits.~~

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

Sequence Number	2007 NAICS, U.S. Code	2007 North American Industry Classification System (NAICS) U.S. Title
847	333997	Scale and Balance Manufacturing

or equivalent.

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 an audit report to NCWM as defined in the VCAP Administrative Policy, Section S.1.c. This report must contain a clear statement of compliance as a result of the VCAP audit.

3. NCWM Responsibilities:

3.1. Ensure that VCAP certification has been met within a one year cycle of maintenance fee (example: if VCAP certified in July, certification required by November of the following year).

3.2. Verify that new customer/new certificate have process capability audit successfully completed prior to receiving certificate from NTEP.

3.3. As part of annual maintenance, NCWM shall ensure that VCAP audit reports are on file, current and that all non-conformances have been addressed.

3.4. Ensure that an appeals process is in place and made available to Certificate holders.

4. Sample Sizes:

4.1 The following sample sizes are to be used based on annual production (per cells covered by the NTEP CC).

Units per Year	Minimum Number (Total of samples Production) per Year
2 - 50	2
51 - 500	3
501 - 35,000	5
35,001+	8

Definition:
Control Facility: The control facility is the facility that is in control of the product before it goes into the marketplace.

8. NTEP Policy for Issuing Certificates of Conformance for Software

Source: NTETC Software Sector

Background: Excerpts of reports from the 1995 - 1998 Executive Committees were provided to NTETC Software Sector members at their April 2006 meeting. The chair asked the Sector to review the following NTEP policy decision adopted by the NCWM in 1998 relative to the issuance of a separate Certificate of Conformance (CC) for software.

During the 1998 NCWM, the following recommendation was adopted as NTEP policy:

- "Software, regardless of its form, shall not be subject to evaluation for the purpose of receiving a separate, software Certificate of Conformance from the National Type Evaluation Program."

- "Remove all of the software categories from the index of NCWM Publication 5, NTEP Index of Device Evaluations."

- "Reclassify all existing software CCs according to their applicable device categories."

The policy is still in effect today.

Also noteworthy is a statement in Section C of NCWM Publication 14, Administrative Policy. It states:

> In general, type evaluations will be conducted on all equipment that affect the measurement process or the validity of the transaction (e.g., electronic cash registers interfaced with scales and service station consoles interfaced with retail fuel dispensers); and all equipment to the point of the first indicated or recorded representation of the final quantity on which the transaction will be based.

Software which is implemented as an add-on to other NTEP-certified main elements to create a weighing or measuring system and its metrological functions are significant in determining the first indication of the final quantity. Such software is considered to be a main element of the system requiring traceability to a Certificate of Conformance. Current policy, however, prohibits NTEP from issuing a separate certificate just for the software. The certificate must be issued on the entire system.

The Software Sector considered the possibility of amending the 1998 policy to allow NTEP to issue separate Certificates of Conformance for software. This new policy would not change how NTEP evaluates software; it would simply change how the software is represented on the certificate. For example, software designed to act as a point-of-sale would be represented on the certificate as "Software" with further description as "Point-of-Sale System." The certificate would allow this software to be implemented as a main element of a weighing system using compatible hardware including scanner/scale, cash register, printer, computer processor, etc. If this fundamental approach is taken, it will allow the Software Sector to move toward the other steps in the process.

The consensus of the Sector is that the current NCWM/NTEP policy should be changed.

Recommendation from the Sector to the NTEP Committee:

Software Requiring a Separate CC: Software, which is implemented as an add-on to other NTEP-certified main elements to create a weighing or measuring system and its metrological functions, are significant in determining the first indication of the final quantity. Such software is considered a main element of the system requiring traceability to an NTEP CC.

NOTE: OEM software *may* be added to an existing CC or have a stand-alone CC with applicable applications (e.g., a manufacturer adding a software upgrade to their ECR or point-of-sale system, vehicle scale weigh-in/weigh-out software added as a feature to an indicating element, automatic bulk weighing, liquid-measuring device, loading racks, etc.) and minimum system requirements for "type P" (built-for-purpose) devices (see proposed software definition below). It may be possible for a manufacturer to submit a single application for both hardware and software contained in the same device. A single CC would be issued.

In this instance, OEM refers to a third party. The request to add software could be made by the original CC holder on behalf of the third party. Alternatively, a new CC could be created that refers to the original CC and simply lists the new portions that were examined.

As further background, the proposed definition is included for reference.

Recommendation from the Sector to the S&T Committee:

The Sector recommended that the following definition be submitted to the S&T Committee as a Developing item and be considered for inclusion in NIST Handbook 44. Please refer to the S&T Committee Interim Agenda for additional information on the proposed definition.

Add the following definition to Appendix D.

Electronic devices, software-based. Weighing and measuring devices or systems that use metrological software to facilitate compliance with Handbook 44. This includes:

(a) **Embedded software devices (Type P), aka built-for-purpose.** A device or element with software used in a fixed hardware and software environment that cannot be modified or uploaded via any interface without breaking a security seal or other approved means for providing security, and will be called a "P", or

(b) **Programmable or loadable metrological software devices (Type U), aka not built-for-purpose.** A personal computer or other device and/or element with PC components with programmable or loadable metrological software, and will be called "U." A "U" is assumed if the conditions for embedded software devices are not met.

Software-based devices – See Electronic devices, software-based.

Judy Cardin, Wisconsin, NTEP Committee Chair

Jack Kane, Montana, NCWM Chair
Randy Jennings, Tennessee, NCWM Chair-Elect
Charles Carroll, Massachusetts
Steve Malone, Nebraska

NTEP Technical Advisor: Jim Truex, NTEP Administrator

National Type Evaluation Program Committee

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Appendix A

NTETC Draft Grain Analyzer Sector Meeting Summary

This report can be viewed on the National Conference of Weights and Measures website at:

www.ncwm.net/ntep/index.cfm?fuseaction=meetings

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Appendix B

NTETC Draft Measuring Sector Meeting Summary

This report can be viewed on the National Conference of Weights and Measures website at:

www.ncwm.net/ntep/index.cfm?fuseaction=meetings

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Appendix C

NTETC Draft Weighing Sector Meeting Summary

This report can be viewed on the National Conference of Weights and Measures website at:

www.ncwm.net/ntep/index.cfm?fuseaction=meetings

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Appendix D

NTETC Draft Software Sector Meeting Summary

This report can be viewed on the National Conference of Weights and Measures website at:

www.ncwm.net/ntep/index.cfm?fuseaction=meetings

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Appendix E

Verified Conformity Assessment Program (VCAP)
Frequently Asked Questions (Emphasis on Load Cells)

National Conference on Weights and Measures/National Type Evaluation Program

What is it?
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 those devices whose 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.

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 an NTEP certificate, complete scales, automatic weighing systems, belt-conveyor scales, and automatic bulk weighing systems. The program will begin with load cells only.

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 work group was developed to assist the NCWM with this effort, which has provided feedback and recommendations to the conference. The NCWM Board of Directors thinks 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.

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.

Why two programs, SMA/PMT and NCWM/VCAP? What's different?
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 the NCWM.

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.

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.

Our company has an ISO-certified quality system. Isn't that enough for compliance with VCAP?
No. Although there are some similarities, VCAP differs in its requirements so ISO certification alone is not an acceptable substitute.

Who is going to pay for this?
The CC holder is responsible for providing proof of VCAP certification, by a Certification Body, to NTEP. NTEP will not pay any costs associated with accreditation, audits, testing or certification.

We do not produce any cells but we have private label agreements and certificates. Other than notifying the load cell manufacturers (vendors), do we need to do anything else? It appears the responsibility falls on the manufacturers.

In the eyes of NTEP, the CC holder is responsible for the product, including taking responsibility for assuring that production devices meet type. NTEP expects the CC holder to take responsibility for the integrity of the certificate and product (device, instrument, main element, component, etc.). NTEP is expecting private label certificate holders to verify with the manufacturer under contract that VCAP requirements are being met. It is expected CC holders will have QA procedures in place, including controls over the supplier, purchase and compliance of the product covered under the private label agreement.

How do I know whether my supplier complies with the VCAP or not?

You are responsible for making certain that your supplier complies with the VCAP program. If your supplier fails to conform, their NTEP CC will ultimately become inactive as well as your private label certificate (if you have one). One way to make sure your supplier complies is to ask that you receive a copy of the VCAP auditor's report.

Does this mean that the NCWM/NTEP will notify CC holders, schedule a date for review, perform the initial review of the CC holder's process, and perform the audit at the manufacturing site?

No. The CC holder is responsible for assuring a documented quality management system, meeting VCAP requirements, is in place and providing NTEP with a Certification Body audit report containing a clear statement of compliance with VCAP.

In general, what must I do to comply with VCAP?

If you are the manufacturer of the device, there are a number of requirements. You may already comply with most or all of them. They include:

a. A Quality Management System that governs the design and manufacture of the device. This Quality Management System must be documented in your Quality Manual.
b. Production and testing equipment and facilities necessary for the production and subsequent testing of the device.
c. 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 will affect the performance of the device. If the answer is yes, then the item is metrologically significant.
d. 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.
e. An appropriate sampling plan along with the required acceptance criteria for testing of the device. The sampling plan that you choose must be traceable to a nationally recognized quality standard. Optionally, you may use the sampling plan that is presented in Appendix A of the VCAP program description.
f. 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.
g. A system to deal with nonconforming material and components, whether you purchase them or build them yourself. This system must deal with the identification, control, and disposition of these items.
h. Adequate controls over suppliers to ensure the material or components they supply meet the necessary requirements.
i. A corrective action system designed and implemented to handle noncompliant or nonconforming material and components.
j. An engineering change system to control engineering design changes that affect metrologically significant components.
k. A document and data control system to document, record, and distribute to affected parties changes affecting metrologically significant components.
l. A production control system that manages changes that affect metrologically significant components.
m. A system that identifies and traces metrologically significant components.
n. A training system for personnel with documentation to verify that the appropriate training has taken place.

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 are present, are sufficient for the task, and that they are being properly calibrated and operated. The audit may 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.

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, U.S. 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.

What role does this Certification Body play in VCAP conformity?
The Certification Body is the organization that provides the auditor that actually performs the VCAP audit. It is the Certification Body that actually sends the auditor's report to the NCWM to show compliance with the VCAP. The requirements for this report are listed in Section S.1.c. of the Administrative Policy as shown in NCWM Publication 14.

I have multiple manufacturing sites. Must each one of the sites undergo a VCAP audit?
The VCAP audit is site specific. If there is more than one site where the testing of the device takes place, then each site must be audited. If the site does not perform any activities that affect the performance of the device and does not perform any device testing, it does not need to be subjected to a VCAP audit.

Who or what organization is going to test NTEP devices in or from a manufacturing arena 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.

What test equipment accuracy do you need to test devices for NTEP compliance? For many companies, this will mean aggressive capital appropriations in order to replace old electronic indicators with resolutions of less than 20,000 divisions, temperature chambers with internal thermal differentiations, and dead weights or hydraulic loading machines with unknown or inadequate accuracies. Not to mention the real-world headaches in achieving manufacturing repeatability less than 0.01 %, which subsequently slows down the product lines?
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 linearity and repeatability, not absolute accuracy. This means that the accuracy of the applied load is not critical, but the change in performance of output of the force transducer (load cell) (or indicator) under the same load but different environmental conditions is important. Consequently, the uncertainty in the reference standard may not be significant provided the uncertainty of the linearity of the total system is within one-third of the tolerance to be applied to the force transducer (load cell)."

So it is clear what the general requirements are for test equipment.

There are many different methods to achieve quality in a load cell. This could extend from testing each device to auditing one sample from a lot. This could also extend from following the test procedures described in Publication 14 for every load cell, to reducing the time and load to a minimum value to properly characterize the device under test. NTEP is not attempting to dictate the quality management system nor the testing or auditing methods used to ensure that devices meet the requirements. This will be up to each of the NTEP CC holders to determine. It will then be up to the auditors to determine that the VCAP requirements are being met. In some cases this may require some investment in equipment upgrades, calibrations, etc.; however; it is the belief of NTEP that this equipment and quality management system should already be in place, and should not present a significant burden on the NTEP CC holders.

Since there is no such thing as 100 % NTEP manufacturing first pass yields for anyone in the scale industry, then what do you do with the product that has larger metrological division errors?
If the product does not meet applicable Handbook 44 requirements, including tolerances, it cannot be sold for use in a commercial (legal for trade) application.

The VCAP program description makes it clear that the program is focused on the device's response to environmental influences; primarily temperature but also including humidity, variations in the magnitude of the electrical supply voltage, RFI/EMI, and so on. Section 1.2. requires that the manufacturer have a documented procedure for the identification of metrologically significant components (MSCs). It is clear that there are some components that would be considered to be metrologically significant yet they are unaffected by the environmental influence factors. For example, software is unaffected by the physical environment yet it is metrologically significant. Further, some integrated circuits are metrologically significant but are not affected by changes in the environment over the operating range of the device. With this in mind, are the MSCs that are to be identified and controlled under the VCAP program ONLY those MSCs that are also affected by the physical environment or does it cover "every" MSC regardless of whether its operation is influenced by the environment or not?
VCAP does not cover every component of a device, only those that are metrologically significant and are susceptible to T.N.8. influence factors. A manufacturer can choose to consider the complete device or main element to be metrologically significant.

Some manufacturers may identify an assembly like a printed circuit board as being a metrologically significant component rather than the few components in the printed circuit board assembly that control the metrological function and are sensitive to changes in the environment. Is this practice acceptable? (It would certainly make the management and control of MSCs easier to accomplish.) Section 1.2.2. states that 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 manufacturer." It would seem that the previously mentioned practice of identifying an assembly as a metrologically significant component rather than the individual components and/or materials comprising it that are metrologically significant components under the VCAP definition is in opposition to the intent of the program authors. Is that correct? Can we identify assemblies only as metrologically significant components rather than the components and materials that are used to construct them? Examples given in Section 1.2.4. seem to disallow that practice.
It is up to the manufacturer to declare a component an MSC. That could be an individual component or the assembly in which the component is used.

The VCAP plan states that 90 days will be given to address and correct any major nonconformity identified during the audit but how many major and/or minor nonconformities are allowed before it is concluded that you are not compliant?
Any nonconformities, be it major or minor, must have corrective action taken within 90 days. The difference between the two is that a minor can be verified by the auditor via paperwork and does not require a revisit by the auditor where a major does require a revisit. Each nonconformance is unique but this is a general understanding. At the time of the audit, the auditor may advise you of whether a follow-up audit is required or if only a review of objective evidence is required to show that the non-conformities have been addressed.

When checking the effect of temperature on load cell output (span TC) what, exactly, is the minimum load that must be applied to the load cell during testing to show compliance?
Compliance testing must represent the test requirements as shown in Publication 14.

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 to 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.

What happens if the auditor identifies a non-conformity that is specific to one device type? Are all of our NTEP Certificates in jeopardy?
No. For example, if the auditor finds that you have sufficient production equipment to produce your full line of load cells but have testing equipment that can only test up to 5000 pounds, then only those load cells that require performance testing to loads greater than 5000 pounds will not comply. Failure to obtain the required testing equipment could ultimately result in the loss of the NTEP Certificate that covers the cells with capacities greater than 5000 pounds.

What happens if a CC holder fails to comply?
NCWM Publication 14, NTEP Administrative Policy, Section S.2. states the certificate(s) will be declared inactive. NTEP anticipates a certificate could also be withdrawn.

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