National Type Evaluation Program (NTEP) Committee
Interim Report

Judy Cardin, Chairman
Chief
Wisconsin, Weights and Measures

Reference
Key Number

500 INTRODUCTION

The National Type Evaluation Program (NTEP) Committee (hereinafter referred to as "Committee") submits its Interim Report for consideration by the National Conference on Weights and Measures (NCWM). This report contains the items discussed and actions proposed by the Committee during its Interim Meeting in Daytona Beach, Florida, January 11 - 14, 2009.

This report contains many recommendations to revise or amend National Conference on Weights and Measures (NCWM) Publication 14, Administrative Procedures, Technical Policy, Checklists, and Test Procedures or other documents. Proposed revisions to the publication(s) are shown in **bold face print** by ~~**striking out**~~ information to be deleted and **<u>underlining</u>** information to be added.

Table A
Index to Reference Key Items

Table B
Appendices

*NTETC Sector Meeting Summaries are included in the online version of the NCWM Publication 16 but will not be included in hard copies of the publication distributed at the NCWM Annual Meeting.

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. I 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: NTEP will continue to review progress and work on improvements during the NTEP lab meetings. The Committee was asked to consider expanding the MRA to higher capacity scales. The NTEP Administrator will discuss the possibilities with Measurement Canada and the NTEP labs.

2. I 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 that 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 were 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.

A meeting of the MAA Committee on Participation Review (CPR) is scheduled for June 17 - 19, 2009, in Berne, Switzerland. This will include a two-day joint meeting of both the R 60/R 76 CPR and the R 49 (water meters) CPR, to discuss matters of common interest. Single-day meetings of the CPRs will then be held to discuss the individual specialty areas, including review of documentation in order to decide on the acceptance of additional countries into the respective Declarations of Mutual Confidence (DoMCs). The joint meeting will feature a presentation on how the acceptance of "manufacturer's test data" works in some European countries. NCWM will be represented at the CPR meeting by Jim Truex. Ken Butcher and Charles Ehrlich of NIST will also attend as Secretariats of OIML TC 9 and TC 3/SC 5 respectively.

3. I 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 workflow? 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.

The NCWM Board discussed a strategic plan for NTEP as part of the NCWM Strategic Plan. The Board is working on a strategy to insure NTEP services are available at an adequate level. The Board is seeking input from State Directors with NTEP labs, NTEP labs and manufacturers that utilize NTEP.

2009 Schedule of Meetings:

NTETC Belt-Conveyor Sector	February 25 - 26, 2009	St. Louis, MO
NTETC Software Sector Meeting	March 11 - 12, 2009	Reynoldsburg, OH
NTEP Laboratory Meeting	March 31 - April 2, 2009	Reynoldsburg, OH
NTETC Grain Analyzer Sector	August 19 - 20, 2009	Kansas City, MO
NTETC Weighing Sector	August 25 - 27, 2009	Columbus, OH
NTETC Measuring Sector	October 2 - 3, 2009	Clearwater Beach, FL

4. I 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 - 21, 2008. A draft of the final summary was provided to the Committee prior to the 2009 NCWM Interim Meeting for review and approval.

The next meeting of the Grain Moisture Meter and NIR Protein Analyzer Sectors is scheduled for August 19 - 20, 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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100 Bureau Drive, Stop 2600
Gaithersburg, MD 20899-2600
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Jack Barber
J.B. Associates
10349 Old Indian Trail
Glenarm, IL 62536
Phone: (217) 483-4232
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Measuring Sector: The NTETC Measuring Sector met October 3 - 4, 2008, in Atlanta, Georgia. A draft of the final summary was provided to the NTEP Committee prior to the 2009 NCWM Interim Meeting for review and approval.

The next meeting of the Measuring Sector is scheduled for October 2 - 3, 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
Gaithersburg, MD 20899-2600
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Software Sector: The NTETC Software Sector met May 20 - 21, 2008, in Columbus, Ohio. A final draft of the meeting summary was provided to the Committee prior to the 2009 NCWM Interim Meeting for review and approval.

The 2009 Software Sector meeting was held March 11 - 12, 2009, in Reynoldsburg, Ohio. For questions on the current status of sector work or to propose items for a future meeting, please contact the sector chairs and NTEP Administrator:

Jim Pettinato
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FMC Technologies
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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 was provided to the Committee prior to the 2009 NCWM Interim Meeting for review and approval.

The next Weighing Sector meeting is scheduled for August 25 - 27, 2009, in Columbus, Ohio. 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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Current Comment: During the Interim Meeting, the NTEP Committee approved the 2008 reports of the NTETC Sectors. The NTEP Committee is working to correct the sector report process to ensure the reports are posted for members on the NCWM website prior to the Interim Meeting.

5. I 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 Participating 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.

There was no new information for this item during the Interim Meeting. The NTEP Committee plans to move this item to be included with the report of other OIML activities.

6. I 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 (WG) 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 (CC) since the inception of NTEP. A WG 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 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.

Jim Truex updated the NTEP Committee and the NCWM Board regarding progress of Conformity Assessment issues. The VCAP/Load Cell Project is progressing. The NTEP Administrator attended the fall SMA meeting to explain the details of the project. At this point in time, it appears the primary issue facing manufacturers is identifying certified registrars and auditors. The NTEP Administrator is expecting a large volume of contacts (e-mail, phone, fax) in 2009 pertaining to VCAP load cell requirements and certified bodies (registrars). It is anticipated many questions may come from the certified bodies and their auditors.

The NTEP Committee has decided to use the current process in Publication 14, Administrative Policy, Section T, "Appeal and Review Process" for all VCAP appeals. To make it clear, the NTEP Committee plans to add a bullet to Section T to read: "A certificate holder may appeal a certificate made inactive due to non-compliance with VCAP. However, the decision of the Certification Body or VCAP auditor cannot be appealed to the NCWM."

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

Source: Load Cell VCAP WG

Background: During discussions the VCAP WG identified sections of the VCAP section of NCWM Publication 14 that needed to be addressed. Based upon decisions of the WG, recommendations were forwarded to the NTEP Committee. Based on feedback at the Interim Meeting open hearings, the NTEP Committee is striking the language published in Publication 15 and inserting the language submitted by the load cell WG. The intent of the Committee is not to change the proposal from the WG, but rather to make it clear and understandable, as it appears the format

used in Publication 15 confused many members. The proposal below will be voted on by the Board after open hearings conclude at the July 2009 NCWM Annual Meeting.

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

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 a site-specific verification that will focus on the site that controls 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 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. Identify the applicable Metrologically Significant Components (MSCs) 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 are 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 Appendix A of this document.

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 devices and components (either manufactured or purchased).

1.6. A Nonconforming Material system to control non/conforming/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., nonconforming) 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 MSCs.

1.9.1. An engineering change system to control engineering/design changes affecting any MSCs 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 MSCs 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 version are prevented from unintended uses (unless otherwise approved),

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

1.11. A production control system to control changes affecting any MSCs.

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 MSCs.

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.

1.14. 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.

1.15. 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.

1.16. 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.

1.16.1. 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 the 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.

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 would be 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.

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. V NTEP Policy for Issuing Certificates of Conformance (CC) for Software

Source: NTETC Software Sector

Proposal: Change current NCWM/NTEP policy applicable to software.

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.

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 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 CC 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 CC. 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.

As further background, the proposed definitions forwarded to the S&T Committee from the Software Sector are printed below.

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.

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