Organisation Internationale de Métrologie Légale
International Organization of Legal Metrology

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NTEP/VCAP (USA) Documentation

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S. Conformity Assessment Process

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

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

S.1. Main Elements

a. Initial Verification

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

b. Administrative Review of a NTEP Certificate of Conformance

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

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

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

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

c. NTEP Verified Conformity Assessment Program Procedures

Introduction

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

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

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

Devices that Must Meet this Requirement <u>are Limited</u> to the List Below:

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

Requirements:

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

1.1. A documented Quality Management System governing the design and manufacturer of the device.

1.1.1. The NTEP CC holder shall prepare documentation of its various quality activities and practices required by this document and by NCWM's Verified Conformity Assessment Program policy and procedures; and shall demonstrate the effective implementation of those activities and practices. This should include (and/or reference) the manufacturer's quality manual, written procedures and work instructions, flowcharts, diagrams, drawings, etc., as appropriate.

1.1.2. The NTEP CC holder shall have appropriate testing facilities and equipment necessary to verify Influence Factor compliance. *See also 1.14.*

1.1.3. The NTEP CC holder shall utilize testing facilities and equipment to ensure that certified devices meet the influence factors appropriate for the device type as designated in *NIST Handbook 44*.

1.1.4. The NTEP CC holder shall ensure that test equipment used either to: 1) directly perform influence factor testing or 2) calibrate other equipment that may be used to directly perform influence factor testing; is controlled.

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

1.1.5. The NTEP CC holder shall ensure that all applicable equipment shall have appropriate operating procedures and shall be accurate and repeatable to a degree sufficient to ensure credible influence factor testing and results.

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

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

1.1.7. The NTEP CC holder shall ensure that there are processes in place for identification of those components, materials, parts, or assemblies that affect the device's response to the influence factors appropriate to the device type (MSC's).

1.1.8. A metrologically significant component is a part, assembly, material, design or procedure that has a direct influence on the performance or operation of a device or component thereof as identified by the device manufacturer.

1.1.9. Metrological integrity is maintained by verification that the applicable characteristics of those components identified as metrologically significant are unchanged from those used in the device certified. Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified.

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

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

1.1.10.2. **Load Cell, Digital** – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type

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

1.1.10.4. **Indicating Element, Electronic** – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components

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

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

1.3.1. The NTEP CC holder shall establish a random sampling plan appropriate for the production quantity of the device that is traceable to a nationally recognized quality standard, i.e., Acceptable Quality Level AQL or equivalent, or meet the minimum requirements as defined in Section 4 of this document.

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

1.3.3. Results of the testing, along with values of pertinent control parameters (e.g., time, temperature, humidity, etc.), shall be recorded and shall clearly identify whether the test passed or failed.

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

1.4. Required operator's manuals and calibration procedures or other controlled documentation for all appropriate devices and components (either manufactured or purchased).

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

1.5.1. The NTEP CC holder shall control devices that do not meet specified requirements (i.e., nonconforming) to prevent their unintended use.

1.5.2. This control shall include (as a minimum): identification, recording, segregation or isolation (as practicable), review, disposition approval, and notification to appropriate personnel at the manufacturing site(s).

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

1.5.4. Records shall be made available to the VCAP auditor.

1.6. Adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components.

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

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

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

1.7.1. The NTEP CC holder shall identify, implement and record corrective actions needed to remedy the cause(s) of nonconformities and problems as a result of influence factor testing, and to prevent their recurrence.

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

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

1.7.4. Results of corrective actions shall be retained and be readily available and easily retrievable by testing facility personnel. Records shall be made available to the VCAP auditor.

1.8. An Engineering Change system to control engineering/design changes affecting any MSCs.

1.8.1. An engineering change system to control engineering/design changes affecting any MSCs including appropriate methods to ensure changes are released to production.

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

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

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

1.9.2. identification and availability of current/appropriate version levels,

1.9.3. obsolete/superseded version are prevented from unintended uses (unless otherwise approved),

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

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

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

1.11. An Identification and Traceability System (including serialization and lot/batch control as applicable) applied, as a minimum, to MSCs.

1.12. Documentation that personnel have been properly trained.

1.12.1. The NTEP CC holder shall identify training needs, and provide training for personnel whose functions/activities affect the VCAP and particularly for those personnel performing influence factor testing.

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

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

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

1.13. If the NTEP CC holder contracts with an outside testing facility to conduct the influence factor testing, that facility will be subject to all pertinent VCAP requirements.

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

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

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

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

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

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

1.15. Subsequent audits will be held on-site to verify conformance to these standards. Subsequent audits will be conducted every three years until objective evidence is obtained to move to a maximum of every five years.

1.15.1. Audits shall be scheduled as a stand-alone audit; not part of ISO, FM, UL, etc. The audit may be in conjunction with but not part of these audits.

1.15.2. Audits shall be scheduled during testing to ensure that the VCAP auditor witness's devices that are being tested, data being recorded, actions being taken, etc.

1.15.3. The NTEP CC holder has the right to appeal to NCWM if a VCAP certificate has been withdrawn due to the results of the on-site audit.

1.15.4. The NTEP CC holder shall take corrective action within 90 days of non-conformances sited during the on-site audit. It shall be determined during the audit whether a follow up audit is needed or a review of objective evidence is necessary to close any non-conformances.

2. Certification Body's Responsibilities:

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

2.2. With accreditation to Standard Industry Classification (SIC) codes (3596/3821) or equivalent.

Sequence Number	2007 NAICS, U.S. Code	2007 NAICS U.S. Title
847	333997	Scale and Bench Manufacturing

2.3. The selected Certification Body shall have international auditors available.

2.4. The Certification Body is required to notify NCWM when a major breakdown of the NTEP CC holder's VCAP program is found.

2.5. The Certification Body shall submit a completed "Systems Audit Checklist" to NCWM. Submitted documents must contain a clear statement of compliance as a result of the VCAP audit.

NCWM Responsibilities:

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

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

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

3. Sample Sizes:

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

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

S.2. Consequences

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

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

National Conference on Weights and Measures / National Type Evaluation Program

Verified Conformity Assessment Program

Frequently Asked Questions

1. ***What is VCAP?***

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

2. ***What devices fall under the VCAP?***

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

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

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

4. ***Who must comply with the VCAP?***

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

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

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

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

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

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

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

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

12. How can I show compliance with VCAP?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

National Conference on Weights and Measures / National Type Evaluation Program

VCAP Systems Audit Checklist
For Private Label Certificate Holders

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

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

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

Devices That Must Meet This Requirement Are Limited To:
1. Load Cell (T.N.8.)
2. Indicating Element (T.N.8.)
3. Weighing/Load Receiving Elements with Non-NTEP Load Cells (T.N.8.)
4. Complete Scales (T.N.8.)
5. Automatic Weighing Systems (T.7.)
6. Belt-Conveyor Scales (T.3.)
7. Automatic Bulk Weighing Systems (T.7.)

NOTES:
1) The NTEP CC holder has the right to appeal to the National Conference on Weights and Measures if a VCAP certificate has been withdrawn due to the results of the on-site audit. 2) The NTEP CC holder shall take corrective action within 90 days of non-conformances 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.

GENERAL INFORMATION		
Date of Audit:	Audit Type: ☐ Internal (self-assessment) ☐ Surveillance (certification body)	Name and Affiliation of Auditor:

AUDIT CHECKLIST Note: Include supporting evidence if required. If not, explain in the comments column.			
REQUIREMENT	**YES**	**NO**	**COMMENTS**
1. Is the private label certificate holder's NTEP certificate traceable back to a parent certificate holder and an active NTEP certificate?	☐	☐	
2. Are records available to show the private label certificate holder has confirmed that the supplier has a current VCAP audit meeting applicable requirements	☐	☐	
3. Do the private label certificate holder's purchase and sales records verify that no other supplier is providing the product listed on the NTEP certificate?	☐	☐	
4. Do the supplier's sales records agree with the private label certificate holder's purchasing records?	☐	☐	
5. Does the private label certificate holder have a plan in place to report non-conformance to the supplier?	☐	☐	
6. Does the private label certificate holder have a plan in place to address non-conforming devices already sold or in stock?	☐	☐	
7. Does the private label certificate holder have a plan in place to conduct internal audits to verify non-conformance action?	☐	☐	
8. Do internal audit records exist?	☐	☐	

RESULTS
Corrective Action Required? ☐ Yes ☐ No
Preventive Action Required? ☐ Yes ☐ No
Audit Findings:

Submit VCAP Audit Reports to NCWM:
1135 M Street, Suite 110 / Lincoln, Nebraska 68508
P. 402.434.4880 **F.** 402.434.4878 **E.** info@ncwm.net **W.** www.ncwm.net

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National Conference on Weights and Measures / National Type Evaluation Program

VCAP Systems Audit Checklist For Manufacturers

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

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

Devices That Must Meet This Requirement Are Limited To:

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

NOTES:

1) The NTEP CC holder has the right to appeal to the National Conference on Weights and Measures if a VCAP certificate has been withdrawn due to the results of the on-site audit. 2) The NTEP CC holder shall take corrective action within 90 days of non-conformances 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.

GENERAL INFORMATION		
Date of Audit:	Audit Type: ☐ Internal (self-assessment) ☐ Surveillance (certification body)	Name and Affiliation of Auditor:

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

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

metrologically significant or completed module or instrument are unchanged from those used in the device certified? **Note:** Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified. Manufacturer may choose to identify the completed module/instrument as the ONLY metrologically significant component. The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list shall not be considered exhaustive and is included as examples. • **Load Cell, Analog** – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design • **Load Cell, Digital** – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type • **Weighing/Load Receiving Element** – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell • **Indicating Element, Electronic** – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components			
12. Are there appropriate statistical methods implemented to ensure that the process is in control as defined by the NTEP CC holder's quality management system?	☐	☐	
13. Is there an appropriate sampling plan appropriate for the production quantity of the device that is traceable to a nationally recognized quality standard and acceptance criteria in place and operating?	☐	☐	
14. Are devices selected and tested in accordance to *NCWM Publication 14* as designated by the established sampling plan? The following sample sizes are to be used based on annual production. **Units Per Year (total of sample production)** — **Minimum Number Per Year** 2-50 — 2 51-500 — 3 501-35,000 — 5 35,001+ — 8	☐	☐	Attach appropriate sample plan for devices tested.
15. Are results of the testing, along with values of pertinent control parameters (i.e., time, temperature, humidity, etc.) recorded and do they clearly identify whether the test passed or failed?	☐	☐	
16. Are records available to the VCAP auditor of test results?	☐	☐	
17. Is there a non-conforming material system in place to control non-conforming/non-compliant devices and components thereof (either manufactured or purchased)?	☐	☐	
18. Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?	☐	☐	

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

22. Is there an appropriate corrective/preventive action system in place to deal with non-conforming/non-compliant devices?	☐	☐	
23. Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?	☐	☐	
24. Are corrective/preventative action records available and easily retrievable by testing facility personnel?	☐	☐	
25. Is there an engineering change system to control engineering/design changes affecting any MSC including appropriate methods to ensure changes are released to production?	☐	☐	
26. Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?	☐	☐	
27. Is there objective evidence of engineering evaluations of substitution of components that affect the instrument or module's response to environmental factors?	☐	☐	
28. Is there a document of data control (including software and firmware) system in place to control any MSC or components of the VCAP program?	☐	☐	
29. Is there review and approval for accuracy, completeness and adequacy of documents prior to release?	☐	☐	
30. Is there identification and availability of current/appropriate version levels of documents?	☐	☐	
31. Are obsolete/superseded versions prevented from unintended use?	☐	☐	
32. Are there processes in place to ensure the engineering changes are properly implemented throughout production?	☐	☐	
33. Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?	☐	☐	
34. Is there documentation available to show that personnel whose functions/activities affect the VCAP, have been properly trained?	☐	☐	
35. Do training records show that personnel are qualified to perform their respective functions?	☐	☐	
36. Are training records available to the VCAP auditor for review?	☐	☐	
37. Are internal audits of your quality system conducted on a regular basis?	☐	☐	
38. Are internal audit results of the quality system in place recorded and available for review by VCAP auditor?	☐	☐	
39. Are VCAP (self-assessment) internal audits conducted at least once a year as required per VCAP certification requirements?	☐	☐	
40. Are records available of VCAP internal audits for the VCAP auditor to review?	☐	☐	
41. Was the VCAP audit scheduled during testing to ensure that VCAP auditor witnessed devices being tested, data being recorded, actions being taken, etc.?	☐	☐	

RESULTS
Corrective Action Required? ☐ Yes ☐ No
Preventive Action Required? ☐ Yes ☐ No
Audit Findings:

National Conference on Weights and Measures / National Type Evaluation Program

VCAP Checklist Supplemental Guide

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

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

1. **Does your facility have a documented quality system?**
   A Quality Management System governs the design and manufacture of the device(s). This Quality Management System must be documented in your Quality Manual. (section 1.1 & 1.1.1)

2. **Is your quality system ISO 9000 registered? If so, what is the registration level, date of certification and certificate number?**
   The ISO 9000 series quality standards and VCAP share a number of common features, however ISO certification is not required. Although there are some similarities, VCAP differs in its requirements. Therefore, ISO certification alone is not an acceptable substitute.

3. **Are written procedures, work instructions, forms, drawings and/or visual aids in place supporting your quality system?**
   Do you possess the required operators' manual and calibration procedures for all appropriate production and testing equipment? Of course, you must not only possess these manuals, you must also ensure that your operators are familiar with them and follow the procedures contained within them. This would include a training system for personnel with documentation to verify that the appropriate training has taken place. (section 1.1.1 and 1.5)

4. **Does your facility have the appropriate testing facilities and equipment to verify influence factor compliance for the device type as stated in *NIST Handbook 44*? Attach a list of equipment.**
   (sections 1.1.2, 1.1.3 and 1.14)

5. **Do test procedures exist that cover the testing of metrologically significant components and/or the instrument or module?**
   Test procedures may be more than just the operator's manual for the equipment being used in the test. There may be preparation or other steps involved prior to using the test equipment that also need to be documented as part of the test procedure with training to cover the entire test procedure.

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

7. **Does your facility maintain control/calibration records on equipment used to test influence factor compliance on devices?**
   Such control shall include calibration using nationally traceable standards, and shall extend to equipment calibrated internally, and/or to equipment calibrated by an external service provider. (section 1.1.4.1 & 1.1.6)

8. **Are results of calibration activity available to the VCAP auditor for review?**
   (section 1.1.6)

9. **Does your facility maintain documented procedures on equipment sufficient to ensure credible influence factor testing and results?**
Do you have the required operators' manual and calibration procedures for all appropriate production and testing equipment? Of course, you must not only possess these manuals, you must also ensure that your operators are familiar with them and follow the procedures contained within them. (section 1.1.5)

10. **Are there processes in place for identification of Metrologically Significant Components (MSC's), materials, parts or assemblies that affect the device's response to the influence factors appropriate to the device type?** Note: Manufacturer may choose to identify the completed instrument or module as the only metrologically significant component. Attach a list of metrologically significant components.
You must identify those metrologically significant components (MSC) used in the device. These are the components, materials, processes, and software that have an effect on the performance of the device. It is up to you as a manufacturer to identify these items. To determine whether an item is metrologically significant or not you must ask whether a change in the characteristics of that item (such as temperature) will affect the performance of the device. If the answer is yes, then the item is metrologically significant. (sections 1.2.1 and 1.2.2)

11. **Are procedures in place to ensure that metrological integrity is maintained by verification and that the applicable characteristics of those components identified as metrologically significant or completed module or instrument are unchanged from those used in the device certified?**
(section 1.2.3)

    Note: Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified. Manufacturer may choose to identify the completed module/instrument as the ONLY metrologically significant component.
    The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list shall not be considered exhaustive and is included as examples.
    - **Load Cell, Analog** – Sensor spring element design, sensor material and heat treat, strain gauge, temperature compensating means, environment sealing design
    - **Load Cell, Digital** – Components listed in load cell, analog, bridge excitation voltage regulation components, temperature sensitive components used to establish gain of amplification stage or reference voltage(s), metrologically significant embedded software, temperature sensing component, analog to digital converter type
    - **Weighing/Load Receiving Element** – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell
    - **Indicating Element, Electronic** – Excitation voltage regulation components, temperature sensing elements, metrologically significant embedded software, reference voltage components, analog to digital converter, temperature sensitive components in amplification stage used to establish gain or offset, active filter components, some clock components

    (section 1.2.4.x)

12. **Are there appropriate statistical methods implemented to ensure that the process is in control as defined by the NTEP CC holder's quality management system?**
You must possess and use appropriate statistical tools or methods to ensure that the processes used to manufacture the device are in control. This is often referred to as statistical process control and is a means to determine whether your processes are consistent and repeatable. (section 1.3)

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

14. **Are devices selected and tested in accordance to *NCWM Publication 14* as designated by the established sampling plan?**
(section 1.4.2)

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

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

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

15. **Are results of the testing, along with values of pertinent control parameters (i.e., time, temperature, humidity, etc.) recorded and do they clearly identify whether the test passed or failed?**
(section 1.4.3)

16. **Are records of test results available to the VCAP auditor?**
(section 1.4.4)

17. **Is there a non-conforming material system in place to control non-conforming/non-compliant devices and components thereof (either manufactured or purchased)?**
This system must deal with the identification, control, and disposition of these items. (sections 1.6, 1.6.1 and 1.6.2)

18. **Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?**
(section 1.6.3)

19. **Are records of non-conformance available for review by the VCAP auditor?**
(Section 1.6.4)

20. **Are there documented quality system procedures that ensure adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components?**
(section 1.7.1)

21. **Are there records of such control available to the VCAP auditor for review?**
(section 1.7.2)
22. **Is there an appropriate corrective/preventive action system in place to deal with non-conforming/non-compliant devices?**
Identify, implement and record corrective actions needed to remedy the cause(s) of nonconformities and problems as a result of influence factor testing, and to prevent their recurrence. (sections 1.8, 1.8.1 and 1.8.2)

23. **Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?**
(section 1.8.4)

24. **Are corrective/preventative action records available and easily retrievable by testing facility personnel?**
(section 1.8.4)

25. **Is there an engineering change system to control engineering/design changes affecting any MSC including appropriate methods to ensure changes are released to production?**
(section 1.9.1)

26. **Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?**
(section 1.9.2)

27. **Is there objective evidence of engineering evaluations of substitution of components that affect the instrument or module's response to environmental factors?**

28. **Is there a document of data control (including software and firmware) system in place to control any MSC or components of the VCAP program?**
(section 1.10)

29. **Is there review and approval for accuracy, completeness and adequacy of documents prior to release?**
(section 1.10.1)

30. **Is there identification and availability of current/appropriate version levels of documents?**
(section 1.10.2)

31. **Are obsolete/superseded versions prevented from unintended use?**
These documents are marked as "obsolete," "not official copy" or similar terminology, or simply removed from use/access entirely. (section 1.10.3)

32. **Are there processes in place to ensure the engineering changes are properly implemented throughout production?**
(section 1.11.1)

33. **Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?**
(section 1.12) How are MSCs marked or otherwise identified and how can they be tracked throughout supply/manufacturing/distribution system.

34. **Is there documentation available to show that personnel, whose functions/activities affect the VCAP, have been properly trained?**
(section 1.13.1)

35. **Do training records show that personnel are qualified to perform their respective functions?**
(section 1.13.2)

36. **Are training records available to the VCAP auditor for review?**
(section 1.13.4)

37. **Are internal audits of your quality system conducted on a regular basis?**
(section 1.15)

38. **Are internal audit results of the quality system in place recorded and available for review by VCAP auditor?**
(sections 1.15.4 and 1.15.5)

39. **Are VCAP (self-assessment) internal audits conducted at least once a year as required per VCAP certification requirements?**
This is an internal audit involving testing to VCAP requirements, where internal audits of the quality system under question 37 could be of the manufactures or distributer's own design and content. (sections 1.15.1, 1.15.2 and 1.15.3)

40. **Are records available of VCAP internal audits for the VCAP auditor to review?**
(section 1.15.5)

41. **Was the VCAP audit scheduled during testing to ensure that VCAP auditor witnessed devices being tested, data being recorded, actions being taken, etc.?**
The auditor is not expected to the witness complete testing of a device/component. The auditor wants to witness the processes: Are testing and operating procedures followed? Do employees appear to be trained as records may indicate? If there is a failure on a test are follow-up procedures or processes followed? A failed test result does not mean a failed audit. (section 1.16.2)