21. 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 certificate holder requesting a re-evaluation. The content and format of a Certificate of Conformance will also evolve over time.

Conformity Assessment is a responsibility of the certificate holder. 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 5 through 7 of this document, the steps below outline the measures NTEP will use to keep the Certificate of Conformance accurate and to ensure conformance.

21.1. Main Elements

1. 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.

2. Administrative Review of a NTEP Certificate of Conformance

NTEP will periodically conduct an Administrative Review of all NTEP Certificates of Conformance to help ensure that:

2.1. The NTEP Certificate of Conformance accurately reflects current Metrological Characteristics of the device as well as Standard Features and Options.

2.2. 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.

2.3. 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 Certificates will be an ongoing process relying on feedback received from the Initial Verification and VCAP.

2.4. 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.

3. NTEP Verified Conformity Assessment Program Procedures

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*.

It is important for NTEP to know the types of devices included in the VCAP audit and it is for this reason that the certificate holder shall prepare a controlled quality management system (QMS) document listing the range of parameters that cover the devices included in the audit. The certificate holder shall include in this document all certificates and device parameters (For example: different models, capacities, e-min, n-max, sizes etc.) for the applicable device category. For example, in a load cell audit, a range of capacities of the load cells included in the audit shall be listed in the report. This document shall be available for the VCAP auditor and NTEP upon request and may be included as an annex to the audit report if desired.

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

- Load Cell (T.N.8.)
- Indicating Elements (T.N.8.)
- Weighing/Load Receiving Elements 2000 lb capacity and less with non-NTEP Load Cells (T.N.8.)
- Complete Scales 2000 lb capacity and less (T.N.8.)
- Automatic Weighing Systems 2000 lb capacity and less (T.7.)
- Belt-Conveyor Scales (weigh-belt systems only) 2000 lb capacity and less (T.3)
- Automatic Bulk Weighing Systems 2000 lb capacity and less (T.7.)

3.2. Requirements, The NTEP CC Holder's Control Facility Responsibilities:

3.2.1. A documented Quality Management System governing the design and manufacture of the device.

3.2.1.1. 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.

3.2.1.2. The NTEP CC holder shall have appropriate testing facilities and equipment necessary to verify Influence Factor compliance. *See also 21.1.3.2.14*.

3.2.1.3. 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*.

3.2.1.4. 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.

3.2.1.4.1. 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.

3.2.1.5. 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.

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

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

3.2.2.1. 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).

3.2.2.2. 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.

3.2.2.3. 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. Verification can also take place by testing of the finished device to verify that it is unchanged from the device certified.

3.2.2.4. 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.

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

3.2.2.4.2. 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.

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

3.2.2.4.4. 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.

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

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

3.2.4.1. 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., Acceptable Quality Level AQL or equivalent, or meet the minimum requirements as defined in Section 21.1.3.5 of this document.

3.2.4.2. The NTEP CC holder shall maintain a controlled document listing all the devices, their estimated annual production quantity, the CC number of the device and the date that the device was added to or removed from the sampling plan.

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

3.2.4.4. 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.

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

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

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

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

3.2.6.2. 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).

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

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

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

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

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

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

3.2.8.1. 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.

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

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

3.2.8.4. 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.

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

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

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

3.2.10. 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):

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

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

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

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

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

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

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

3.2.13. Documentation that personnel have been properly trained.

3.2.13.1. 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.

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

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

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

3.2.14. 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.

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

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

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

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

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

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

3.2.16. Subsequent audits will be held on-site to verify conformance to these standards. Subsequent audits will be conducted every three years.

3.2.16.1. 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.

3.2.16.2. 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.

3.2.16.3. 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.

3.2.16.4. 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.

3.3. Certification Body's Responsibilities and NCWM Technical Employee Responsibilities:

3.3.1. The selected Certification Body is to be accredited by ANSI-ASQ National Accreditation Board (ANAB) or by a Signatory of the International

Laboratory Accreditation Cooperation (ILAC) Mutual Recognition. The ANSI, ANAB and ILAC are accreditation bodies for management systems. ANAB and ILAC accredit certification bodies (CBs) for ISO 9001 quality management systems (QMS), ISO 17025 laboratory testing facilities and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements.

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

Sequence Number	2012 NAICS, U.S. Code	2012 NAICS U.S. Title
847	333997	Scale and Bench Manufacturing

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

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

3.3.5. The Certification Body or NCWM technical employee 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.

3.4. NCWM Responsibilities:

3.4.1. 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).

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

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

3.5. Sample Sizes:

3.5.1. 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

NTEP Verified Conformity Assessment Program Procedures for Private Label Certificate Holders

Many NTEP certified devices must meet *NIST Handbook 44, Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices*, 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.

For weighing devices that are subject to influence factors, traceable to a private label NTEP Certificate of Conformance, NTEP will require the private label certificate holder 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 certificate is active.

It is important for NTEP to know the types of devices included in the VCAP audit and it is for this reason that the certificate holder shall prepare a controlled quality management system (QMS) document listing the range of parameters that cover the devices included in the audit. The certificate holder shall include in this document all certificates and device parameters (For example: different models, capacities, e-min, n-max, sizes etc.) for the applicable device category. For example, in a load cell audit, a range of capacities of the load cells included in the audit shall be listed in the report. This document shall be available for the VCAP auditor and NTEP upon request and may be included as an annex to the audit report if desired.

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

- Load Cell (T.N.8.)
- Indicating Elements (T.N.8.)
- Weighing/Load Receiving Elements 2000 lb capacity and less with non-NTEP Load Cells (T.N.8.)
- Complete Scales 2000 lb capacity and less (T.N.8.)
- Automatic Weighing Systems 2000 lb capacity and less (T.7.)
- Belt-Conveyor Scales (weigh-belt systems only) 2000 lb capacity and less (T.3)
- Automatic Bulk Weighing Systems 2000 lb capacity and less (T.7.)

3.7. Requirements: The Private Label NTEP CC Holder's Responsibilities:

3.7.1. Documentation is available to show that all private label certificates are traceable back to a parent certificate holder(s).

3.7.2. All parent certificates are active.

3.7.3. The private label certificate holder shall maintain a controlled document listing all the private label devices, the suppliers' name and the date the private label agreement was initiated or cancelled.

3.7.4. Records are available to show the private label certificate holder has confirmed that the supplier has a current VCAP audit meeting applicable requirements.

3.7.5. The private label certificate holder's purchase and sales records verify that no other supplier is providing the product listed on the NTEP certificate.

3.7.6. The supplier's sales records agree with the private label certificate holder's purchasing records.

3.7.7. The private label certificate holder has a plan in place to report non-conformance to the supplier.

3.7.8. The private label certificate holder has a plan in place to address non-conforming devices already sold or in stock.

3.7.9. The private label certificate holder has a plan in place to conduct internal audits to verify non-conformance action. Internal audits shall be conducted at established intervals, not to exceed one year.

3.7.10. Surveillance audits for VCAP conducted by an outside auditor representing a certification every three years.

3.7.11. The NTEP private label CC holder shall take corrective action within 90 days on 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.

3.7.12. All records and plans shall be made available to the VCAP auditor.

3.8. Certification Body's Responsibilities:

3.8.1. The selected Certification Body (auditor) shall be accredited to the ISO 9001:2008 standard for providing audits and certifications of management systems.

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

3.8.3. The Certification Body shall submit a completed "VCAP Systems Audit Checklist for Private Label Certificate Holders" to NCWM. Submitted documentation must contain a clear statement of compliance as a result of the VCAP audit.

3.9. NCWM Responsibilities:

3.9.1. 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).

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

3.9.3. Ensure that an appeals process is in place and made available to Certificate holders. *Note: The appeal and review process contained in Section 22 of this document shall be used.*