Appendix E

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

National Conference on Weights and Measures/National Type Evaluation Program

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

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

Why is NTEP initiating this program now?
The National Conference on Weights and Measures (NCWM) and National Type Evaluation Program (NTEP) have been concerned about production meeting type, protecting the integrity of the NTEP 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.

Who must comply with the VCAP?
Any holder of an NTEP CC for a device type listed above must comply with the program. Again the program will begin with load cells.

Why two programs, SMA/PMT and NCWM/VCAP? What's different?
The PMT and VCAP are administered by two different organizations. Although similar, PMT is a manufacturer program developed by manufacturers, where VCAP is a regulatory requirement developed by the NCWM.

Is it enough for a manufacturer to submit a PMT compliance certificate?
No. The Certification Body report must state compliance with VCAP. The PMT and VCAP are similar but not identical.

Must I have my quality system ISO-certified to comply with VCAP?
No. While the ISO 9000 series quality standards and VCAP share a number of common features, ISO certification is not required.

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

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

We do not produce any cells but we have private label agreements and certificates. Other than notifying the load cell manufacturers (vendors), do we need to do anything else? It appears the responsibility falls on the manufacturers.
In the eyes of NTEP, the CC holder is responsible for the product, including taking responsibility for assuring that production devices meet type. NTEP expects the CC holder to take responsibility for the integrity of the certificate and product (device, instrument, main element, component, etc.). NTEP is expecting private label certificate holders to verify with the manufacturer under contract that VCAP requirements are being met. It is expected CC holders will have QA procedures in place, including controls over the supplier, purchase and compliance of the product covered under the private label agreement.

How do I know whether my supplier complies with the VCAP or not?
You are responsible for making certain that your supplier complies with the VCAP program. If your supplier fails to conform, their NTEP CC will ultimately become inactive as well as your private label certificate (if you have one). One way to make sure your supplier complies is to ask that you receive a copy of the VCAP auditor's report.

Does this mean that the NCWM/NTEP will notify CC holders, schedule a date for review, perform the initial review of the CC holder's process, and perform the audit at the manufacturing site?
No. The CC holder is responsible for assuring a documented quality management system, meeting VCAP requirements, is in place and providing NTEP with a Certification Body audit report containing a clear statement of compliance with VCAP.

In general, what must I do to comply with VCAP?
If you are the manufacturer of the device, there are a number of requirements. You may already comply with most or all of them. They include:

a. A Quality Management System that governs the design and manufacture of the device. This Quality Management System must be documented in your Quality Manual.
b. Production and testing equipment and facilities necessary for the production and subsequent testing of the device.
c. You must identify those metrologically significant components (MSC) used in the device. These are the components, materials, processes, and software that have an effect on the performance of the device. It is up to you as a manufacturer to identify these items. To determine whether an item is metrologically significant or not you must ask whether a change in the characteristics of that item will affect the performance of the device. If the answer is yes, then the item is metrologically significant.
d. You must possess and use appropriate statistical tools or methods to ensure that the processes used to manufacture the device are in control. This is often referred to as statistical process control and is a means to determine whether your processes are consistent and repeatable.
e. An appropriate sampling plan along with the required acceptance criteria for testing of the device. The sampling plan that you choose must be traceable to a nationally recognized quality standard. Optionally, you may use the sampling plan that is presented in Appendix A of the VCAP program description.
f. Possess the required operators' manual and calibration procedures for all appropriate production and testing equipment. Of course, you must not only possess these manuals, you must also ensure that your operators are familiar with them and follow the procedures contained within them.
g. A system to deal with nonconforming material and components, whether you purchase them or build them yourself. This system must deal with the identification, control, and disposition of these items.
h. Adequate controls over suppliers to ensure the material or components they supply meet the necessary requirements.
i. A corrective action system designed and implemented to handle noncompliant or nonconforming material and components.
j. An engineering change system to control engineering design changes that affect metrologically significant components.
k. A document and data control system to document, record, and distribute to affected parties changes affecting metrologically significant components.
l. A production control system that manages changes that affect metrologically significant components.

m. A system that identifies and traces metrologically significant components.
n. A training system for personnel with documentation to verify that the appropriate training has taken place.

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

Where do I find an auditor? Can any quality auditor perform the VCAP audit?
To perform a VCAP audit, the auditor must meet certain requirements. First, the auditor must be part of a Certification Body that is accredited by ANSI-ASQ National Accreditation Board (ANAB). The Certification Body must have accreditation to Standard Industry Classification (SIC) codes 3596 and 3821 or Sequence Number 847 NAICS, U.S. Code 333997, Scale and Balance Manufacturing defined in the 2007 North American Industry Classification System or equivalent accreditation. There are several Certification Bodies that have auditors qualified to perform VCAP audits. We cannot make any specific recommendations.

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

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

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

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

What test equipment accuracy do you need to test devices for NTEP compliance? For many companies, this will mean aggressive capital appropriations in order to replace old electronic indicators with resolutions of less than 20,000 divisions, temperature chambers with internal thermal differentiations, and dead weights or hydraulic loading machines with unknown or inadequate accuracies. Not to mention the real-world headaches in achieving manufacturing repeatability less than 0.01 %, which subsequently slows down the product lines?
NCWM Publication 14, Weighing Devices, Load Cells describes the testing accuracy required in Section C. In part it states:

> "The error in the test process for force transducer (load cell) evaluations may not exceed one-third of the tolerance applied at the force transducer (load cell) (0.7 times the tolerance for the weighing system). The important characteristics for the test process for force transducers (load cells) (and indicators) for compliance with the influence factors requirements is linearity and repeatability, not absolute accuracy. This means that the accuracy of the applied load is not critical, but the change in performance of output of the force transducer (load cell) (or indicator) under the same load but different environmental conditions is important. Consequently, the uncertainty in the reference standard may not be significant provided the uncertainty of the linearity of the total system is within one-third of the tolerance to be applied to the force transducer (load cell)."

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

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

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

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

Some manufacturers may identify an assembly like a printed circuit board as being a metrologically significant component rather than the few components in the printed circuit board assembly that control the metrological function and are sensitive to changes in the environment. Is this practice acceptable? (It would certainly make the management and control of MSCs easier to accomplish.) Section 1.2.2. states that a metrologically significant component "is a part, assembly, material, design, or procedure that has a direct influence on the performance or operation of a device or component thereof as identified by the manufacturer." It would seem

that the previously mentioned practice of identifying an assembly as a metrologically significant component rather than the individual components and/or materials comprising it that are metrologically significant components under the VCAP definition is in opposition to the intent of the program authors. Is that correct? Can we identify assemblies only as metrologically significant components rather than the components and materials that are used to construct them? Examples given in Section 1.2.4. seem to disallow that practice.
It is up to the manufacturer to declare a component an MSC. That could be an individual component or the assembly in which the component is used.

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

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

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

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

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

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