National Conference on Weights and Measures / National Type Evaluation Program

VCAP Checklist
Supplemental Guide

This document is meant to compliment the VCAP 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 21.1.3* 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 21.1.3.2.1)

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. (Sections 21.1.3.2.1.1 and 21.1.3.2.5)

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 21.1.3.2.1.2, 21.1.3.2.1.3 and 21.1.3.2.14)

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. (Sections 21.1.3.2.1.4. and 21.1.3.2.1.6)

8. **Are results of calibration activity available to the VCAP auditor for review?**
   (Section21.1.3.2.1.6)

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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 21.1.3.2.1.5)

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 21.1.3.2.2 and 21.1.3.2.2.2)

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 21.1.3.2.2.3)

    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 (Section 21.1.3.2.2.4.1)
    - **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 (Section 21.1.3.2.2.4.2)
    - **Weighing/Load Receiving Element** – Suspension type, restraint system, bearing design, weighbridge construction load cell type, load application to load cell (Section 21.1.3.2.2.4.3)
    - **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 21.1.3.2.2.4.4)

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 21.1.3.2.3)

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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.

Are devices selected and tested in accordance to *NCWM Publication 14* as designated by the established sampling plan? (Section 21.1.3.2.4.1)

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 21.1.3.5.1 and *may* be used as an alternative to meet Section 21.1.3.2.4.1.

14. Is there a controlled document available listing all devices included in the sampling plan?

The controlled list shall identify all devices, by model designation, included in the sampling plan, the date the device was added and/or removed from the sampling plan and the annual production quantities for the current year. (Section 21.1.3.2.4.2)

Note: 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.

15. Are the testing methods used to test the selected device or component in accordance to the appropriate device section(s) of NCWM Publication 14?

(**Note:** At a minimum the auditor shall witness data collection at one temperature.)
(Section 21.1.3.2.4.3)

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16. **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?**
    Note: The auditor may make comments or suggestions for improvement in your procedures including the test methods used. In spite of that, both the manufacturer and auditor must understand that the test methods used to verify compliance with VCAP are clearly defined in NCWM Publication 14. Any departure from the procedure listed in this document must first be evaluated and accepted by NTEP before implementing the change(s).
    (Section 21.1.3.2.4.4)

17. **Are records of test results available to the VCAP auditor?**
    (Section 21.1.3.2.4.5)

18. **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 21.1.3.2.6, 21.1.3.2.6.1 and 21.1.3.2.6.2)

19. **Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?**
    (Section 21.1.3.2.6.3)

20. **Are records of non-conformance available for review by the VCAP auditor?**
    (Section 21.1.3.2.6.4)

21. **Are there documented quality system procedures that ensure adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components?**
    (Section 21.1.3.2.7.1)

22. **Are there records of such control available to the VCAP auditor for review?**
    (Section 21.1.3.7.2)

23. **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 21.1.3.2., 21.1.3.2.8.1,21.1.3.2.8.2 and 21.1.3.2.8.3)

24. **Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?**
    (Section 21.1.3.2.8.4)

25. **Are corrective/preventative action records available and easily retrievable by testing facility personnel?**
    (Section 1.8.4)
26. **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 21.1.3.2.9.1)

27. **Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?**
    (Section 21.1.3.2.9.2)

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

29. 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 21.1.3.2.10)

30. Is there review and approval for accuracy, completeness and adequacy of documents prior to release?
(Section 21.1.3.2.10.1

31. Is there identification and availability of current/appropriate version levels of documents?
(Section 21.1.3.2.10.2)

32. 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 21.1.3.2.10.3)

33. Are there processes in place to ensure the engineering changes are properly implemented throughout production?
(Section 21.1.3.2.11.1)

34. Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?
How are MSCs marked or otherwise identified and how can they be tracked throughout supply/manufacturing/distribution system. (Section 21.1.3.2.12)

35. Is there documentation available to show that personnel, whose functions/activities affect the VCAP, have been properly trained?
(Section 21.1.3.2.13.1)

36. Do training records show that personnel are qualified to perform their respective functions?
(Section 21.1.3.2.13.2)

37. Are training records available to the VCAP auditor for review?
(Section 21.1.3.2.13.4)

38. Are internal audits of your quality system conducted on a regular basis?
(Section 21.1.3.2.15)

39. Are internal audit results of the quality system in place, recorded and available for review by VCAP auditor?
(Sections 21.1.3.2.15.4 and 21.1.3.2.15.4)

40. 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 21.1.3.2.15.1, 21.1.3.2.15.2 and 21.1.3.2.15.3)

41. Are records available of VCAP internal audits for the VCAP auditor to review?
(Section 21.1.3.2.15.5)

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42. 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. (**Note:** At a minimum the auditor shall witness the data collection at one Temperature.) 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 21.1.3.2.16.2)