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 a Capacity ≤ 2000 lb and using Non-NTEP Load Cell(s) (T.N.8.)
4. Complete Scales with a Capacity ≤ 2000 lb (T.N.8.)
5. Automatic Weighing Systems with a Capacity ≤ 2000 lb (T.7.)
6. Belt-Conveyor Scales (Weigh-Belt Systems only) with a Capacity ≤ 2000 lb (T.3.)
7. Automatic Bulk Weighing Systems with a Capacity ≤ 2000 lb (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CC holder has the right to appeal to the National Conference on Weights and Measures if a VCAP certificate has been withdrawn due to the results of the on-site audit.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 daysof 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:** Click to select audit type | | |
| **Name and Address of Facility being Audited:** | **Name and Affiliation of Auditor:** | | |
| **AUDIT CHECKLIST Note: Include supporting evidence if required. If not, explain in the comments column.** | | | |
| **REQUIREMENTS** | | **REQUIREMENT**  **SATISFIED** | **VCAP Policy, Paragraph Ref#** |
| **Quality Management System:** | | | |
| 1. Does your facility have a documented quality system? | | **Click To Select** | Section 21.1.3.2.1 |
| Comments: | |  |  |
| 1. Is your quality system ISO 9000 registered?   If so, what is the registration level, date of certification and certificate number?  Comments: | | **Click To Select** | None |
| 1. Are written procedures, work instructions, forms, drawings and/or visual aids in place supporting your quality system?   Comments: | | **Click To Select** | Sections 21.1.3.2.1.1  & 21.1.3.2.5 |
| 1. Is there a non-conforming material system in place to control non-conforming/non-compliant devices and components thereof (either manufactured or purchased)?   Comments: | | **Click To Select** | Sections 21.1.3.2.6 21.1.3.2.6.1 & 21.1.3.2.6.2 |
| 1. Are records of non-conformance available for review by the VCAP auditor?   Comments: | | **Click To Select** | Section 21.1.3.2.6.4 |
| 1. Are there documented quality system procedures that ensure adequate control over subcontractors and sub-tier suppliers that supply metrologically significant components?   Comments: | | **Click To Select** | Section 21.1.3.2.7.1 |
| 1. Are there records of such control available to the VCAP auditor for review?   Comments: | | **Click To Select** | Section 21.1.3.7.2 |
| 1. Is there an engineering change system to control engineering/design changes affecting any MSC including appropriate methods to ensure changes are released to production?   Comments: | | **Click To Select** | Section 21.1.3.2.9.1 |
| 1. Are records of design/document changes available to the VCAP auditor for review of changes to any MSC?   Comments: | | **Click To Select** | Section 21.1.3.2.9.2 |
| 1. Is there objective evidence of engineering evaluations of substitution of components that affect the instrument or module's response to environmental factors?   Comments: | | **Click To Select** | None |
| 1. Is there review and approval for accuracy, completeness and adequacy of documents prior to release?   Comments: | | **Click To Select** | Section 21.1.3.2.10.1 |
| 1. Is there identification and availability of current/appropriate version levels of documents?   Comments: | | **Click To Select** | Section 21.1.3.2.10.2 |
| 1. Are obsolete/superseded versions prevented from unintended use?   Comments: | | **Click To Select** | Section 21.1.3.2.10.3 |
| 1. Are there processes in place to ensure the engineering changes are properly implemented throughout production?   Comments: | | **Click To Select** | Section 21.1.3.2.11.1 |
| 1. Are internal audits of your quality system conducted on a regular basis?   Comments: | | **Click To Select** | Section 21.1.3.2.15 |
| 1. Are internal audit results of the quality system in place recorded and available for review by VCAP auditor?   Comments: | | **Click To Select** | Sections 21.1.3.2.15.4 & 21.1.3.2.15.5 |
| **VCAP Specific Documentation:** | | | |
| 1. Does your facility maintain documented procedures on equipment sufficient to ensure credible influence factor testing and results?   Comments: | | **Click To Select** | Section 21.1.3.2.1.5 |
| 1. 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.  Comments: | | **Click To Select** | Sections 21.1.3.2.2 & 21.1.3.2.2.2 |
| 1. 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   Comments: | | **Click To Select** | Section 21.1.3.2.2.3 |
| 1. 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?   Comments: | | **Click To Select** | Section 21.1.3.2.3 |
| 1. 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?   Comments: | | **Click To Select** | Section 21.1.3.2.4.1 |
| 1. Does the manufacturer have a controlled document that lists all 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?   (Refer to Item #14 in the VCAP Checklist Supplemental Guide or paragraph 21.1.3.2.4.2 in *NCWM Publication 14, Administrative Policy* for more details on the contents of this controlled document.)  Comments: | | **Click To Select** | Section 21.1.3.2.4.2 |
| 1. Are the testing methods used to test the selected device or component in accordance to the appropriate device selection(s) of *NCWM Publication 14*?   (**Note:** At a minimum the auditor shall witness data collection at one temperature,)  Comments: | | **Click To Select** | Section 21.1.3.2.4.3 |
| 1. 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?   Comments: | | **Click To Select** | Section 21.1.3.2.4.4 |
| 1. Are records available to the VCAP auditor of test results?   Comments: | | **Click To Select** | Section 21.1.3.2.4.5 |
| 1. Is review of non-conforming VCAP devices and disposition approval, performed by authorized and qualified personnel?   Comments: | | **Click To Select** | Section 21.1.3.2.6.3 |
| 1. Is there an appropriate corrective/preventive action system in place to deal with non-conforming/non-compliant devices?   Comments: | | **Click To Select** | Sections 21.1.3.2, 21.1.3.2.8.1, 21.1.3.2.8.2 & 21.1.3.2.8.3 |
| 1. Are the results of corrective/preventative actions retained, readily available and easily retrievable by testing facility personnel?   Comments: | | **Click To Select** | Section 21.1.3.2.8.4 |
| 1. Are corrective/preventative action records available and easily retrievable by testing facility personnel?   Comments: | | **Click To Select** | Section 1.8.4 |
| 1. Is there a document of data control (including software and firmware) system in place to control any MSC or components of the VCAP program?   Comments: | | **Click To Select** | Section 21.1.3.2.10 |
| 1. Is there an identification and traceability system (including serialization and/or lot/batch control as applicable) in place for MSC's?   Comments: | | **Click To Select** | Section 21.1.3.2.12 |
| 1. Are VCAP (self-assessment) internal audits conducted at least once a year as required per VCAP certification requirements?   Comments: | | **Click To Select** | Sections 21.1.3.2.15.1, 21.1.3.2.15.2 & 21.1.3.2.15.3 |
| 1. Are records available of VCAP internal audits for the VCAP auditor to review?   Comments: | | **Click To Select** | Section 21.1.3.2.15.5 |
| **Testing Environment:** | | | |
| 1. 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*?   Comments: | | **Click To Select** | Sections 21.1.3.2.1.2, 21.1.3.2.1.3 & 21.1.3.2.14 |
| 1. Do test procedures exist that cover the testing of metrologically significant components and/or the instrument or module?   Comments: | | **Click To Select** | None |
| 1. Are there test records available for review of these tests?   Comments: | | **Click To Select** | None |
| 1. Does your facility maintain control/calibration records on equipment used to test influence factor compliance on devices?   Comments: | | **Click To Select** | Sections 21.1.3.2.1.4. & 21.1.3.2.1.6 |
| 1. Are results of calibration activity available to the VCAP auditor for review?   Comments: | | **Click To Select** | Section21.1.3.2.1.6 |
| 1. Is there documentation available to show that personnel whose functions/activities affect the VCAP, have been properly trained?   Comments: | | **Click To Select** | Section 21.1.3.2.13.1 |
| 1. Do training records show that personnel are qualified to perform their respective functions?   Comments: | | **Click To Select** | Section 21.1.3.2.13.2 |
| 1. Are training records available to the VCAP auditor for review?   Comments: | | **Click To Select** | Section 21.1.3.2.13.4 |
| 1. Was the VCAP audit scheduled during testing to ensure that VCAP auditor witnessed devices being tested, data being recorded, actions being taken, etc.? (**Note:** At a minimum the auditor shall witness data collection at one temperature.)   Comments: | | **Click To Select** | Section 21.1.3.2.16.2 |
| **RESULTS** | | | |
| Corrective Action Required? **Click To Select**  Explain: | | | |
| Preventive Action Required? **Click To Select**  Explain: | | | |
| Audit Findings: | | | |