VCAP Internal Sampling Plan for Device Auditing

How to Determine Sample Size

NCWM *Publication 14, Administrative Policy,* Verified Conformity Assessment Program (VCAP) informs the manufacturer of the need for a product sampling plan as repeated below.

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

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

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

21.1.1.1.2.1 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.

21.1.1.1.2.2 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.

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

21.1.1.1.2.4 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.

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

The following information and examples are intended to help you develop your sampling plan. The device type used in these examples is a complete Instrument.

Example #1 – One Certificate of Conformance Listing One Model with One Capacity:

In this first example the CC lists only one model with a single capacity and increment size. To aid in the determination of the number of samples needed we also need to know the projected sales volume for the current year's production for the model listed on this certificate. After reviewing the CC and collecting the projected annual sales volume we know the following:

- Number of models listed on the CC: **1**
- Model designation: **Scale-1**
- The CC lists a single capacity and increment size: **15 x 0.005 lb**
- Current years projected sales volume: **4200 units**

Using this information we can determine that we need to test 5 samples. Since there is only one model listed on the CC with a single capacity and increment size, the sampling plan tells us to randomly select and test five samples to comply with the sampling plan requirements.

Example #2 – One Certificate of Conformance Listing More Than One Model:

In this second example the CC lists 3 different models, each with a different capacity and increment size. To aid in the determination of the number of samples needed we also need to know the projected sales volume for the current year's production for each of the models listed on this certificate. After reviewing the CCs and collecting the projected annual sales volume we know the following:

- Number of models listed on the certificate: **3**
- Model designations: **ABC, DEF and GHI**

- Each model has a different capacity and increment size: Model ABC is **6 x 0.002 lb**; DEF is **15 x 0.005 lb**, and GHI is **30 x 0.01 lb**
- Current years expected combined sales volume: **2400 units**

Using this information we can determine that we need to test 5 samples. Since these three models are on a single certificate the sampling plan tells us to randomly select and test five sample units to comply with the sampling plans requirements. We could pick two samples of the model ABC, two samples of the model DEF and one sample of the model GHI for testing. Your actual selection could be different however, selecting samples which cover the range of capacities listed on the certificate is important to provide a picture of your ongoing product compliance.

Example #3 – Multiple Certificates of Conformance for this Device Type

In this third example the CC holder has multiple CCs for this single device type; some CCs list only a single unit as mentioned in Example #1 while the other CCs list multiple models as mentioned in Example #2. To determine the total number of samples that must be tested the CC holder should determine the number of samples for each of the CCs. Let us assume that the CC holder has three CCs for this device type. After reviewing the CCs and collecting the projected annual sales volume we know the following:

- CC#1 lists two models with multiple capacities and increments sizes with a projected combined annual sales volume of 470 units
- CC#2 lists a single model with a single capacity and increment size with a projected annual sales volume of 2140 units
- CC#3 lists three models with multiple capacities and increments sizes with a projected combined annual sales volume of 3800 units

By applying the sample selection criteria for the examples we find that CC#1 requires three samples, CC#2 requires five samples, and CC#3 requires five samples; giving us a total number of 13 samples to be randomly selected and tested to comply with the sampling plans requirements.

In Summary

The number of samples to be included in your internal audit plan is determined by summing the sample size based on the annual sales volume for all models listed on each Certificate of Conformance you hold for the device type being discussed.

The VCAP Policy does not instruct you as to how or when the samples should be selected and tested. However, an effective Quality Management System would guide you to spread the selections across the one year audit time line and, if possible, to select samples with different capacities and increment sizes than were audited in previous years. Following these two guidelines will provide you with the best picture of your ongoing product compliance level.

If you would like additional information on determining audit sample size, the sample selection processes, or the testing and reporting requirements of the internal auditing plan required for VCAP compliance, please contact me using the email address shown below.

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