Section:	5. NTEP
Subpart:	5.4. Conformity Assessment
Policy No.:	5.4.1.
Title:	Adding Device Categories to VCAP
Effective:	October 2013

Adding Device Categories to VCAP

Purpose: To establish criteria for NTEP and NTEP certificate holders who have successfully completed a VCAP audit in the proper response when a new device category is added to the VCAP.

Background: It has come to the attention of the NTEP Committee that when a new device category is added to the VCAP, the addition might create a potential problem for NTEP certificate holders who have already successfully completed a VCAP audit. The request submitted asks NTEP to recognize previous VCAP audits when adding new device types to the VCAP. It makes sense to allow certificate holders, who have already successfully completed a VCAP certification audit, to cover the new device category under their existing quality management system until the due date of their next VCAP audit. Once all the device types have been added, the question will become moot within 3 years since the next regularly scheduled audit will address all device types within that facility. Likewise, NTEP already applies the same philosophy when a new model is introduced by the same certificate holder. That is, the new model is considered covered by the audit because it is a process audit, not a device evaluation. This effectively allows a certificate holder to conduct a single audit for all device categories under the VCAP umbrella.

Policy:

1. When a new device category is added to the VCAP requirement, NTEP will recognize the current VCAP audit certification in effect, submitted by a certificate holder, for the same certificate holder and same production facility(s), to cover the new device category, continue the manufacturing process for devices covered by NTEP certificates in the newly added device category, until the due date of the next VCAP audit.

   Example: If a company had successful audits for two device types, they might submit a request for exemption from audit requirements for remaining device types, stating that they are all subjected to the same quality management system and will be included in the next audit cycle. The next VCAP audit must be done within 3 years of the last audit and address all applicable device types produced within that facility.