Virginia Division of Consolidated Laboratory Services

ENVIRONMENTAL LABORATORY CERTIFICATION PROGRAM (1VAC30-45 and 1VAC30-46)

GUIDANCE DOCUMENT

ONSITE ASSESSMENT CLOSURE

March 4, 2014 (Revised July 28, 2016)

The Division of Consolidated Laboratory Services (DCLS) is issuing the following guidance on laboratory responsibility following a Virginia Environmental Laboratory Accreditation Program (VELAP) onsite assessment of a laboratory.

The key staff (responsible official, lead technical director or lab manager, and quality assurance officer) for each certified or accredited laboratory signs a certificate of compliance. This certificate states that the laboratory "understands and acknowledges that the laboratory is required to be continually in compliance" with the regulation (1VAC30-45-70 F 3 b and 1VAC30-46-70 F 3 b). VELAP uses the onsite assessment along with review of the required proficiency test studies to determine whether a laboratory continues to be in compliance with the regulation, standards, and methods.

A laboratory therefore must correct any deficiencies found during the onsite assessment to maintain its certification or accreditation status and adhere to the certificate of compliance signed by the laboratory's key staff. Corrective actions taken by a laboratory must be done in accordance with program regulations and this guidance.

VELAP provides its findings in a final onsite assessment report to the laboratory within 30 calendar days following the final day of the onsite assessment. The laboratory must do the following once it receives the final onsite assessment report:

- Begin implementation of corrective actions to bring the laboratory into compliance immediately upon receipt of the onsite assessment report;
- Complete corrective action within 90 days of its receipt of the report; and
- Provide documentation to VELAP of all implemented corrective actions.

The laboratory must provide justification to VELAP for a request for an extension beyond 90 days.

The laboratory is responsible to provide a corrective action plan or CAP to VELAP in response to the findings set out in the VELAP assessment report. The laboratory must send this plan to VELAP within 30 calendar days following the laboratory's receipt of the final assessment report (1VAC30-45-390 B and 1VAC30-46-220 L 2).

The laboratory must respond to each finding in the final assessment report. The laboratory should provide specific information in the CAP on how it will correct and prevent recurrence of each finding and should specify a deadline for the laboratory to make the corrective action (1VAC30-45-390 D and 1VAC30-46-220 L 3). If the laboratory feels the finding is incorrect, then a response that shows the laboratory was in compliance with the standard may be included with the CAP. If VELAP agrees that the laboratory has demonstrated compliance with the regulation, standard, or method, the finding will be removed from the assessment report.

VELAP will review the laboratory's initial CAP and determine whether the corrective actions specified are appropriate and acceptable. If some or all of these corrective actions are not acceptable, VELAP will notify the laboratory and provide an additional 30 days for the laboratory to produce acceptable corrective actions (1VAC30-45-390 E and F and 1VAC30-46-220 L 4). The laboratory has two opportunities to provide VELAP with an acceptable CAP. (1VAC30-45-100 B 5 and 1VAC30-46-100 B 5).

The laboratory must submit documentation of implemented corrective actions for all findings at the completion date specified in the laboratory's CAP. It is important to note that a finding sets out an observation of noncompliance with a regulation, standard, or method made during a small sampling of time or data review. The laboratory is responsible for assuring that the finding will be addressed globally throughout the quality system (i.e., all methods, all records, all training files, all SOPs, etc.) and not just in the instance(s) observed by the assessor. Implementing corrective actions globally improves the overall quality system of the laboratory and reduces the likelihood of repeat findings during future onsite assessments.

The regulations (1VAC30-45-100 B 5 and B 6; 1VAC30-46-100 B 5 and B 6) provide that DCLS may decertify a laboratory or withdraw accreditation from a laboratory under either of the following conditions:

- If the laboratory does not submit an acceptable corrective action plan after two opportunities.

- If the laboratory does not implement corrective action specified in the laboratory's corrective action plan.