Division of Consolidated Laboratory Services (DCLS)
Virginia Environmental Laboratory Accreditation Program (VELAP)

Technical Assistance Document

Repeat Findings:
Potential Impact on Certification or Accreditation Status

Findings observed at a VELAP on-site assessment are non-conformances with the regulation or Standard which have potential to impact the laboratory's ability to consistently produce data of known and documented quality. A laboratory responds to **findings** by providing evidence of implemented **corrective action**.

Corrective action is the action taken to *eliminate the causes* of an existing nonconformity, defect or other undesirable situation *in order to prevent recurrence*.

Quality system non-conformances, or findings, must be addressed globally throughout the laboratory to prevent recurrence of a non-conformance; the ultimate goal is one of continual quality improvement. Multiple facets of a VELAP-compliant quality system are available to help prevent recurrence of non-conformances, including but not limited to management review, internal audit, data review, Quality Manual and SOPs, training (including data integrity training), corrective action documentation, and corrective action follow-up.

Repeat findings observed at a subsequent on-site assessment *indicate a weak and often ineffective quality system of the laboratory.* The regulations for non-commercial and commercial laboratories, 1VAC30-45 and 1VAC30-46, respectively, contain specific language regarding the potential impact of repeat findings on a laboratory's certification or accreditation status:

> **1VAC30-45-100, Decertification: "B 6: *DGS-DCLS may decertify an environmental laboratory in part or in total when the laboratory has failed to do any of the following: Implement corrective action specified in the laboratory's corrective action report as set out under 1VAC30-45-390."***
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> **1VAC30-46-100, Withdrawal of accreditation: "B 6: *DGS-DCLS may withdraw accreditation from an environmental laboratory in part or in total when the laboratory has failed to do any of the following: Implement corrective action specified in the laboratory's corrective action report as set out under 1VAC30-46-220."***

VELAP will assess the seriousness of repeat findings on a case by case basis in determining whether to move forward with a recommendation for decertification or withdrawal of accreditation in total or in part.

Repeat findings are avoided by implementing effective corrective action. See the Technical Assistance Document on Effective Corrective Action on the VELAP web page, and additional resources under "Corrective Action", at www.dgs.virginia.gov/dcls.

Reminders for Laboratories for Avoiding Repeat Findings:

- Invest time to investigate root cause of a non-conformance BEFORE selecting a corrective action. Failure to address the root cause will most likely allow the non-conformity to recur.
- Implement corrective actions fully and thoroughly. Look at the entire quality system and make changes globally; look beyond the example(s) of non-conformance noted by the assessors to see if the non-conformance occurs elsewhere.
- Assure that corrective actions which include a policy or procedure update are made in quality system documents (Standard Operating Procedures, Quality Manual, forms, etc.). Failure to include procedural updates in quality system documents creates a training vulnerability for future staff members, as well as vulnerability for current staff to repeat the non-conformance.
- Hold a training meeting, with documentation of the material communicated and signatures of all present, to communicate updates to procedures.
- Create a schedule of those tasks which are done outside of a typical daily routine (i.e., proficiency tests, pipette verifications, thermometer calibrations, internal audits, management reviews, LOQ verifications, etc.) to assure that no deadlines are missed. Implement electronic reminders or use the laboratory's preferred scheduling aids.
- Schedule a follow-up date to review the effectiveness of each corrective action.
- Use the VELAP on-site assessment report as a tool in future internal audits; assure all corrective actions are being continually implemented.
- Use the laboratory's internal audit as a tool for self-improvement. A laboratory that identifies weaknesses and non-conformances in its internal audit and makes effective corrective action communicates to staff and VELAP that continuous quality improvement is important to the organization. Remember: the annual internal audit is for the lab to identify any non-conformance issues, and not wait for VELAP to discover them upon an assessment.
- Encourage staff members to be knowledgeable about all regulatory requirements and pro-active in their efforts to improve the laboratory's quality system.

Reminders for laboratories regarding manual integration practices:

Please note the following caution regarding manual integration from EPA's document, QA-G8, "Guidance on Environmental Data Verification and Data Validation, EPA/240/R-02/004, November 2002, which states: ***"[M]anual integration is one of the most commonly abused aspects of GC/MS analyses. Instances of falsification have begun with manipulations of the peak areas, often with practices known as "peak shaving" or "peak juicing" where integration points are moved to decrease (shaving) or increase (juicing) peak area to meet specification. Thus, it is critical that the laboratory have written procedures that describe how and when the analyst should perform manual integrations. These written procedures should also describe how to note in the laboratory records and data that manual integrations were performed. GC/MS data systems have the ability to "flag" the electronic and hard-copy records of manual integrations. Therefore, the data verifier should review procedures, records, and any bench notes from the analyst to make sure that when the electronic records indicate that a manual integration was performed, it was done in accordance with the laboratory's stated procedures, and that it is clearly evident to the data user."***

The EPA document describes the **critical** need for:

- laboratory procedures that describe how and when manual integration is performed, and
- detailed documentation of manual integration, and
- thorough review by a data verifier for manual integration.

VELAP may recommend immediate withdrawal of certification or accreditation in part or in full for repeat findings related to manual integration. Any laboratory with a weakness or vulnerability in its manual integration practices, as demonstrated by any observance of non-conformance by VELAP assessors during an on-site assessment, must take aggressive corrective actions to assure that repeat findings do not occur.