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

## Technical Assistance Document

### Effective Corrective Action

**CORRECTIVE ACTION** is defined by 1VAC30-45 and 1VAC30-46 as "the action taken to **eliminate the causes** of an existing nonconformity, defect or other undesirable situation **in order to prevent recurrence**."

The term **CORRECTIVE ACTION** is used in 1VAC30-45 *57 times* and in 1VAC30-46/2009 TNI Standard *109 times*. CORRECTIVE ACTION, **eliminating the causes** of an existing nonconformity **in order to prevent recurrence**, is ONE OF THE MOST CRITICAL ELEMENTS OF A VELAP-COMPLIANT QUALITY SYSTEM.

## THE 'A.I.M.' APPROACH TO EFFECTIVE CORRECTIVE ACTION

### 1. ANALYZE The PROBLEM

***The problem is clearly defined against the requirements; immediate correction is made; and the most probable root cause is determined.***

- **Determine and Document the "REQUIREMENT" that has not been met.** The requirement may be in the regulation or standard, in a published method, or in the laboratory's own procedures and policies. By citing the REQUIREMENT, you confirm that there is indeed a documented requirement. (If there is no REQUIREMENT, there is no need for CORRECTIVE ACTION!)
- **State the EVIDENCE of a failure to meet the requirement.** Stating exactly what has been observed as EVIDENCE of failure is important for accurately communicating the issue in the Corrective Action (CA) documentation.
- **Describe the PROBLEM.** A clear description of the PROBLEM will help in the later evaluation of the problem's solution.
- **CORRECT the problem.** A correction is an immediate fix for an immediate problem. (A correction is not corrective action but is one step in the process of lasting corrective action.) Look for long-term solutions after the immediate issue is corrected. *For example, a correction may include re-preparation of an analysis batch or contacting a customer to discuss failure to analyze a sample. This step is critical for addressing the immediate situation but has not addressed recurrence of the situation.*
- **Perform a ROOT CAUSE ANALYSIS.** This is a brainstorming opportunity and typically all involved parties should be engaged in the process (analysis staff, supervisory staff, quality assurance staff, management). Brainstorm the possible CAUSES of the failure, and then focus on selecting one (or more) most probable cause(s). This cause will be the focus of corrective action to be implemented.

## 2. IMPLEMENT CORRECTIVE ACTION

***The laboratory selects a solution(s) likely to eliminate the recurrence of the problem, and implements the solution(s) which includes updating policy and procedures as well as providing staff training of the changes.***

- SELECT potential solution(s) for addressing the root cause(s) of the problem.
- IMPLEMENT the solution(s) selected to eliminate recurrence of the problem.
    - The laboratory frequently will need to update its Quality Manual and/or Standard Operating Procedure(s) as a result of policy or procedure updates made as a corrective action. [Remember: Corrective Action is performed when a REQUIREMENT is not met. A requirement is documented in the regulation or standard, in a published method, or in the laboratory's own procedures and policies.]
    - The laboratory frequently will need to provide communication and/or training to staff members affected by the corrective action. (Always document staff training.)
    - The laboratory must assure that other regulatory or method requirements are continually met when any policy or procedure is changed.
- REVIEW the REQUIREMENT against the SOLUTION and assure that updates to policy bring the laboratory into full regulatory compliance throughout the laboratory.

## 3. MONITOR And MAINTAIN

***An effective corrective action eliminates the cause of a nonconformance in order to prevent its recurrence; a laboratory evaluates the effectiveness of corrective action by follow-up monitoring.***

- EVALUATE the effectiveness of the corrective action by monitoring to assure that it brings the laboratory into full compliance with the REQUIREMENT.
- FOLLOW-UP to assure that the corrective action is continually implemented and that the problem has been addressed in a lasting manner through out the laboratory. Typically the laboratory will establish date(s) for future evaluation and will assure that the issue is also reviewed in a future internal audit. (If the corrective action is found to be NOT effective, then a different root cause or corrective action solution must be selected and implemented.)
- CLOSE-OUT the corrective action only after evaluation and follow-up have demonstrated the corrective action's effectiveness.

## Some examples of when CORRECTIVE ACTION is required include, but are not limited to:

- After failed quality control
- After trending of data begins to show positive or negative bias or loss of precision, with potential for future failure
- After nonconformance is identified during an internal audit
- After a failed ("not acceptable") proficiency testing (PT) study
- After deviations to policies, procedures, or quality system requirements are identified during management review
- After findings are identified by a VELAP on-site assessment
- After laboratory staff or management identifies a non-compliant issue

- After a laboratory's customer (including DEQ) complains about a data quality or customer service issue

## Additional tips for implementing effective corrective action:

- ***A STRONG CORRECTIVE ACTION ADDRESSES THE THREE KEY ELEMENTS IN THE "A.I.M. APPROACH" – Analyze the Problem, Implement Corrective Action, and Monitor and Maintain the Corrective Action throughout the laboratory in a lasting manner.***

- ***VELAP REQUIRES DOCUMENTATION OF THE IMPLEMENTATION OF A LABORATORY'S CORRECTIVE ACTION IN RESPONSE TO EACH FINDING IDENTIFIED IN AN ON-SITE ASSESSMENT. TYPICAL DOCUMENTATION INCLUDES:***
  - ***Evidence of update to policy or procedure(s). [Quality Manual, Standard Operating Procedures, etc.]*** *Failure to update policy and procedure with updates to a method or quality system requirement sets the laboratory up for future failure. When policies and procedures are current and reflect the laboratory's requirements, current staff members have a reliable guidebook and future staff have a reliable training source.*
  - ***Evidence of update to day-to-day practice. [Bench sheets, invoice for purchased supplies, calibration certificate, maintenance log, demonstration of capability data, etc.]*** *The laboratory provides evidence that it is DOING what it says in the updated policies and procedures.*
  - ***Evidence of training. [Signed meeting agenda, signed review of latest version of SOP or Quality Manual, e-mail to staff, etc.]*** *The laboratory assures that all involved staff has information about changes and opportunity to ask questions or clarify understanding. Training is always documented; once management has documented training, then the staff member is accountable to uphold the change.*

- ***VELAP EVALUATES THE ACCEPTABILITY OF A CORRECTIVE ACTION PLAN BASED ON WHETHER THE PLAN HAS TAKEN ACTION TO ELIMINATE THE CAUSE(S) OF AN EXISTING NONCONFORMITY IN ORDER TO PREVENT FUTURE RECURRENCE.***

- ***VELAP EVALUATES THE ACCEPTABILITY OF CORRECTIVE ACTION DOCUMENTATION BASED ON WHETHER THE DOCUMENTATION HAS DEMONSTRATED THAT AN ACTION WAS TAKEN TO ELIMINATE THE CAUSE(S) OF AN EXISTING NONCONFORMITY IN ORDER TO PREVENT FUTURE RECURRENCE. "If it's not documented, it's not done."***

**DCLS FORM 6984 for ON-SITE ASSESSMENT CORRECTIVE ACTION PLANS**, available on the VELAP web page at www.dgs.virginia.gov/dcls, or a substitute including all of the form's elements, is required for all corrective action plans submitted in response to on-site assessment findings. The VELAP web page also contains examples of this form's use.

**DCLS FORM 6980 for CORRECTIVE ACTION (CA),** also available on the VELAP web page, is an optional tool for laboratories to use for any corrective action. The laboratory may develop an alternate approach to documentation of corrective action.