Corrective Action Report ("CAR") FAQ

Disclaimer: The information in this FAQ does not supplant the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code Chapter 252, or the TNI Standard. This document is a tool to help laboratories understand and comply with the requirements for preparation and submission of a corrective action report ("CAR") resulting from deficiencies found during an on-site assessment. If there is any disagreement between the contents of this document and any of the USEPA or Department's laws, regulations, or methods, the laws, regulations and methods shall prevail. The examples given in this document are for illustrative purposes only, meant to aide individuals in visualizing applications of the regulatory requirements.

It is also important to note that laboratories are not permitted to be in violation of the accreditation regulations. Should the Department find that a laboratory's violations are so severe that the public health, safety, or welfare are in danger, the Department has the authority and responsibility to suspend the laboratory's accreditation immediately in accordance with 25 Pa. Code, § 252.703(b)(1).

Examples within this FAQ:
For the purposes of this FAQ, please refer to the following deviation as the basis for the examples provided in the whole of this document. This deviation and all examples of corrective action listed in this document are provided for illustrative purposes only. All examples are formatted in *italics*.

Deviation C5 *Initial Calibration* ***252.402(c)(5)***
Initial calibrations shall be verified with a standard obtained from a second manufacturer or with a standard from the same manufacturer if the verification standard is documented by the manufacturer as prepared independently of the standard used during initial calibration.

Example(s) of this deficiency include:
1. *The laboratory does not verify the calibration of the spectrophotometer used during the analysis of ammonia with a second source calibration verification standard. The laboratory uses the same source as the calibration standard to perform the initial calibration verification.*

Question: What is a Corrective Action Report?
Answer: A Corrective Action Report ("CAR") is a document that a laboratory must prepare and submit to the Department's Laboratory Accreditation Program ("LAP"), usually in response to the LAP's "Report of an Assessment". A CAR explains how the laboratory corrected the deviations that the Department found during an on-site assessment. A CAR includes the following items:

- Summary of investigations that you performed to find similar problems in the other areas of the laboratory that the Department did not include as examples.
- Summary of the corrective actions taken by the laboratory to correct the deviation found by the Department during the on-site. Corrective action must include the actions taken to correct both the examples of the deviation found by the Department AND any additional examples found by the laboratory after performing the investigations into all other areas of the laboratory.
- Summary of the root-cause analysis to determine WHY the deviation occurred. This is required to be performed by NELAP laboratories and strongly recommend for State accredited labs.
- Summary of training that occurred as a result of the investigations, root-cause analysis, and corrective actions to ensure that the deviations will not recur.

The CAR should be written in a paragraph form explaining how the laboratory corrected the deviations. Each correction, investigation summary, and root-cause analysis should be identified to specific deviation numbers from the Report of an Assessment.

Using the deviation provided above, the deviation number is C5.

Question: What's the difference between a deviation and an example of where the Department found the deviation?

Answer: The Department's assessment reports are structured such that the deviation is the first paragraph listed under the Header identifying the Deviation Number, Deviation Description, and Regulatory Citation. The deviation is the laboratory's failure to follow the regulatory requirement as described in this first paragraph. The Department will then provide examples of where this deviation was found or what the Department observed that supports the deviation. The examples could include, but are not necessarily limited to data packages, test reports, training records, methodology, SOPs, sections of the quality manual, reagent records, employee interviews, etc.

The laboratory must correct the actual deviation in addition to the individual examples provided by the Department. So, to correct the deviation, and not just the examples, the laboratory must investigate all areas of the laboratory that are not specifically included as examples.

The deviation provided at the beginning of this document is that the laboratory does not verify all initial calibration curves with a second source check standard. The example of where the Department found this deviation is in the calibration curve prepared for spectrophotometer used in the analysis of ammonia.

Question: What does it mean when the Department instructs me to "perform investigations into all other areas of my laboratory for similar deviations?"

Answer: The LAP does not review 100% of each laboratory's SOPs, data, training files, records, etc., nor does the LAP interview every analyst for every method that he or she performs. The LAP reviews a sampling of the laboratory's accredited activities and provides examples of where the deviation was observed in the laboratory. It is the laboratory management's responsibility to be in compliance with the accreditation requirements and to investigate all areas of the laboratory to ensure compliance. The laboratory management, or designee, must investigate all areas of the laboratory for similar problems and implement corrective action based on these investigations. This investigation must be documented, and the findings of the investigation must be described in the laboratory's CAR.

To use the example provided above: The LAP finds that the laboratory does not perform a 2nd source calibration verification when analyzing ammonia by spectrophotometer. The LAP cited 252.402(c)(5) as the deviation. The ammonia method was an example of where the LAP found that the laboratory does not verify its calibration curves correctly. This does not mean that only the ammonia curve hasn't been properly verified or that every other method is being correctly verified with a second source check standard. The laboratory must investigate all of the other analytical methods that require a calibration curve to determine if they are all being verified with a second source.

Question: Why do I have to investigate other areas of my lab? Doesn't the LAP find all of my problems for me?

Answer: The LAP employs about 9 individuals that are responsible to assess approximately 300 laboratories. On-site assessments are usually performed by 1-4 people for 1-4 days about once every 2-3 years depending on the size of the laboratory. It is impossible for the LAP to review 100% of any laboratory's activities and records. It is the laboratory management's responsibility to be in compliance with the accreditation regulations. If the laboratory management does not investigate

other areas of the laboratory, then there is a high probability that the laboratory will be found to have repeat deviations at the next on-site assessment. Repeat deviations may be a cause for revocation of accreditation.

Question: Whose responsibility is it to perform the investigations into the other areas of the laboratory?

Answer: The laboratory supervisor is ultimately responsible for compliance with the accreditation requirements. The laboratory supervisor may assign the investigations to a quality assurance officer, analyst, or other appropriately trained laboratory employee. The laboratory supervisor would then follow-up with the individual assigned to perform the investigation to ensure that it has been properly performed.

Question: What is a "Corrective Action"?

Answer: A corrective action is the action taken to correct a deviation or violation. An acceptable corrective action will ensure that the correction actually corrects the deviation in a manner that will ensure that the deviation does not recur. The laboratory must use the information it obtained during the investigations into all other areas of the laboratory to determine what corrective action is necessary. Corrective action includes training of all applicable laboratory personnel to ensure that they understand what the problem is/was, know what the new procedure or policy is in the laboratory, and will follow these new procedures and policies. This training must be documented, and the Department strongly suggests that the laboratory require the trainees to sign-off that they understand and agree to follow the procedures and policies that were presented at the training session.

Keep in mind that there is a difference between "correction" of the examples of a deviation and "corrective action" taken to correct a deviation.

Question: What is the difference between "Correction" and "Corrective Action"?

Answer: "Correction" will correct the examples that the LAP listed in the assessment report and go no further. "Corrective Action" is the entire process that the laboratory uses to ensure correction of the examples, the deviation itself, and prevention of reoccurrence. The best corrective action will include a root-cause analysis. A root-cause analysis is required to be performed by NELAP accredited laboratories but recommended for State accredited labs.

Correction of the deviation provided above would be to have the analyst begin to analyze a 2nd source check standard after every initial calibration for ammonia.

Corrective Action includes:

1. *Review of all SOPs for compliance with the requirement to verify all initial calibrations with a 2nd source check standard.*
2. *Interview all analysts and review data for all methods to determine if any other analyses were not being verified with a 2nd source check standard.*
3. *Establish the root-cause of the violation.*
4. *Update all SOPs and train all laboratory personnel in the requirement to analyze a 2nd source check standard after all initial calibrations, document this training, the contents of the training, and have the attendees sign-off that they attended and understood the expectations of the training,*
5. *Have all analysts read the amended SOPs and sign-off that they understand and agree to follow the SOPs.*
6. *Establish a timetable to follow-up on the implementation of the corrective action and verify the effectiveness of the corrective action.*

Question: What is a root-cause analysis?

Answer: A root-cause analysis is an investigation to find out why the deviation or violation occurred. Consider this similar to dealing with a young child that does not accept the answer given and continues to ask "Why?" The laboratory management, or individual responsible for performing the root-cause analysis, should continue to ask the question, "Why?" until the question cannot be answered further, thus getting to the "root" of the problem.

Most often, the root-cause of a problem will involve flaws in training and failure of management to provide proper oversight or commitment to continued compliance. So, it is unlikely that the root-cause of the problem is a log-book, SOP, or other inanimate object.

To use the example above, ask the first "Why" question, and then continue from there (all "Steps" and "Answers" are shown as examples only, and are not representative of every root-cause analysis):

1. *"Why did the analyst not use a 2nd source calibration verification?"*
    - *Step 1: Interview the analyst.*
    - *Answer: The analyst was not aware that a 2nd source verification was required.*
2. *"Why wasn't the analyst aware of the 2nd source check standard requirement?"*
    - *Step 2: Interview the individual that trained the analyst, if available*
    - *Step 3: Read the SOP; was this requirement part of the SOP?*
    - *Answer: The SOP did not include the requirement to analyze a 2nd source check standard. The trainer did not know that a 2nd source check standard was required either.*
3. *"Why wasn't the 2nd source check standard included in the SOP? Why was the trainer unaware of the 2nd source check standard?"*
    - *Step 4: Review the revision history of the SOP. Was the requirement ever in the SOP or was it removed and who removed it?*
    - *Step 5: Identify who was responsible for training the trainer and interview him or her. When was the trainer trained, maybe he or she was trained the same way as the current employee.*
    - *Answer: The requirement to analyze the 2nd source check standard was removed by a QA officer that was a new hire after the last DEP on-site assessment and he didn't know that the 2nd source check was a requirement. The trainer was the QA officer, so he was training under his own amendments.*
4. *"Why didn't the new QA officer know that the 2nd source check standard was a requirement?"*
    - *Step 6: Interview the QA Officer*
    - *Step 7: Interview the individual who trained the QA officer*
    - *Answer: The QA officer began employment after the original QA officer quit. He was never asked to demonstrate his knowledge or sign off that he read the Chapter 252 regulation. He was checking the SOP against method requirements and did not compare the SOP to Chapter 252 requirements. The trainer did not tell the new QA officer about the Chapter 252 regulation.*
5. *"Why wasn't the new QA officer trained in the requirements of Chapter 252?"*
    - *Step 8: Investigate the training procedures used for new employees, especially those for laboratory supervisors and QA officers.*
    - *Answer: The laboratory doesn't have documented training procedures that cover all aspects of the accreditation requirements.*
6. *"Why doesn't the lab have documented training procedures for new employees that cover all of the accreditation requirements?"*
    - *Step 9: Interview the laboratory supervisor*

- *Step 10: Investigate the training procedures to determine which items of the accreditation regulation are missing from the training procedures.*
- *Answer: The laboratory supervisor did not make the training of the new QA officer his responsibility. The training plans do not include the Chapter 252 requirements; all training has been limited to the methods and the lab's SOPs.*

7. *"Why didn't the laboratory supervisor take responsibility for training the new QA officer?"*
    - *Step 11: Interview the laboratory supervisor*
    - *Answer: The laboratory supervisor was busy with other responsibilities and assumed that the previous QA officer had documented all of the requirements for accreditation.*

<u>Final Root-Cause Analysis:</u> The laboratory supervisor relied on the previous QA officer's documentation for training and did not provide the necessary guidance and oversight to the new employee. The laboratory supervisor did not ensure that the training procedures and plans for new employees included all requirements for accreditation.

Question: What do I do after I determine the root-cause of the deviation?

Answer: After you determine the root-cause of the deviation (aka: identify the root of the problem), you want to develop a proposed corrective action to correct it. By correcting the root of a single deviation, you will not only correct this single deviation, but you are likely going to be able to prevent a whole host of potential deviations. Thus, you will be able to identify areas for improvement, implement preventive action, and become an overall better laboratory.

Often, during a root-cause analysis, you will identify other non-conformances that will require corrective action. Make sure that you document each of these additional findings, establish and implement corrective action, include these in your corrective action documentation, and summarize these in the CAR.

In the example above, the root-cause analysis identified that the laboratory supervisor had not taken responsibility for training new quality assurance personnel. Additionally, the root-cause identified a failure in the training plans for new employees. The laboratory supervisor also did not follow-up on the activities of the new QA officer to ensure that the changes being made to the laboratory's procedures adhered to ALL of the accreditation requirements. An effective corrective action would include, but not necessarily be limited to the following:

<u>Corrective Action:</u>

- *Review of the QA manual and associated training documents to ensure that all accreditation requirements are documented as requirements.*
- *Develop a policy and procedure for training employees and develop a training SOP that includes specific information that is included in the training and what types of documentation will be kept to document that the training occurred.*
- *Perform an internal audit of all laboratory procedures using the PA-DEP's assessment checklist for Chapter 252 accreditation.*
- *Perform an internal audit of all SOPs on the Chapter 252 requirements, the method requirements, and any other State or Federal regulatory requirements, such as Chapter 109 for drinking water and specific permit requirements within a defined amount of time.*
- *Pay particular attention to those methods that require calibration and verification with a 2nd source.*
- *Train all laboratory personnel in the new SOPs and will require them to sign-off that they understand and agree to follow the new SOPs.*

Question: How do I determine what will be an effective and acceptable corrective action?
Answer: After you implement your corrective actions, for both the deviations and the root-cause of the deviations, you need to follow-up on these corrective actions. The follow-up should include a minimum amount of time before you check on the effectiveness of the corrective actions and what types of checks are to be performed.

To use the example above: After the corrective action is implemented, the laboratory supervisor would establish a timeframe for a follow-up audit to perform a data audit of several data packages for the methods that require initial calibration to verify that the analysts are performing the 2nd source check as required. Document this internal audit, the findings of the audit, and determine if the corrective action was effective or if a second round of investigations and root-cause analyses are required.

Question: Are Corrective Actions only required after an on-site assessment and report from the LAP?
Answer: No. Corrective action procedures are not limited to responses from on-site assessments. Laboratories are required to have procedures for detecting their own deviations from the accreditation requirements. These procedures are described in 252.401(i) and the laboratory must establish corrective action procedures that include the following:

- The person that is responsible for evaluating each quality control type,
- The person that is responsible for initiating and recommending corrective actions,
- The procedures for handling results that do not meet the accreditation requirements,
- The procedure for documenting the corrective actions,
- The procedure for the laboratory supervisor to review and follow-up on corrective actions.

Question: What does the LAP expect to see in a CAR, and how can I make sure that I submit an acceptable CAR?
Answer: The laboratory must prepare a corrective action report that clearly describes all of the activities that you performed to correct all of the deviations, the examples of the deviations, and any additional examples that you found during your investigations. Use complete sentences that answer the following questions:

- What investigations did you perform?
- What other areas of the laboratory did you uncover as problematic during these investigations?
- What corrective actions did you implement?
- When were the corrective actions implemented?
- What training did you perform?
- What SOPs did you update?
- What was the root-cause of the deviation? (Required for NELAP)
- What follow-up investigations did you perform to verify the effectiveness of the corrective actions?

After you answer each of the questions above for each deviation, or group of deviations, you must provide the requested documentation that will demonstrate implementation of the corrective actions.

Question: What do I have to do to prove that I have implemented my corrective actions?
Answer: You must correct all deviations, but you are not necessarily required to provide evidence that proves correction of all of the deviations. The LAP provides laboratories with a document called, “Corrective Action Required,” that outlines the minimum documentation that the laboratory must provide to the Department. The “Corrective Action Required” will depend on the type and severity of the deviation, but will include submission of the following:

- A summary of the corrective actions, root-cause analysis (required for NELAP labs), and investigations into all other areas of the laboratory,

- Data packages and supporting documentation for the associated data,
- Updated SOPs,
- Other documents, such as temperature logs, reagent logs, quality manual, reporting SOPs, training records, etc.

The Department will outline when this supporting documentation/evidence of correction must be submitted. Typically, the Department will require submission of the evidence within 60 calendar-days of receipt of the assessment report. If the deviations/violations are more severe, the Department may require correction and evidence of correction to be provided sooner. The due dates will be outlined by the Department when you receive your assessment report.

Remember that all deviations and all examples of the deviations must be corrected regardless of whether or not the LAP requests evidence of their correction. The Department may request the submission of additional evidence of correction or other documentation at any time to verify compliance.

Question: When does the CAR need to be submitted?
Answer: Typically, laboratories have a standard amount of time to provide a CAR to the LAP, and the standard amount of time for submission depends on the type of accreditation sought by the laboratory.

NELAP accredited laboratories are usually required to provide the CAR within 30 calendar-days of receipt of the assessment report.

State accredited laboratories are usually required to provide the CAR within 60 calendar-days of receipt of the assessment report.

As stated above, the LAP may require correction of violations sooner than the typical CAR submission time-frames outlined here. In these cases, the LAP will outline the specific time-frames for submission of the evidence of correction.

Question: I'm a NELAP accredited laboratory, you said that my CAR must be submitted within 30 calendar-days, but the documentation for "Corrective Action Required" isn't required for 60 days. Why?
Answer: The TNI Standard requires that NELAP laboratories provide a CAR within 30 calendar-days after receipt of the assessment report. Chapter 252 requires that a NELAP accredited laboratory submit a CAR within the timeframes required by the TNI Standard. So, NELAP laboratories must submit their CAR within 30 days.

The LAP encourages NELAP laboratories to continue to evaluate, review, and improve their CAR during the 30 days between the initial submission and the 60 day due date for the required documentation.

Question: Why does the LAP require the submission of the evidence of correction within 60 days, or sometimes sooner?
Answer: Laboratories are not permitted to be in violation of the accreditation regulation. The LAP evaluates each deviation for severity and impact to the public health and the environment. Based on this evaluation, the LAP will assign a due date for completion of the corrective action and submission of the evidence of correction. The LAP will evaluate the CAR and supporting documentation to determine effectiveness of the corrective action. Most laboratories will be given 30 calendar days to amend the first CAR and provide a revision to the LAP. However, the LAP does

reserve the right to take any necessary action, including suspension, revocation, or denial, based on the severity of the deviation or lack of correction.

Question: What if I cannot get everything fixed within the timeframe that the Department requires?

Answer: Laboratories may request an extension for submission of the evidence of corrective action. A laboratory can only request an extension to submit the evidence of correction. The LAP does not grant extensions for submission of the CAR. Extension requests for submission of the evidence of correction must be received at least 15 calendar-days before the due date and must be filed to eplabaccredit@pa.gov. Extension requests must include the following:

- Your Laboratory ID# and Laboratory Name
- A justification/explanation why you cannot correct the deviation(s) and submit evidence of correction with the specified time-frame
- A proposed date for completion and submission of the required documentation to the LAP

Please note that an extension request is not guaranteed to be approved and the Department reserves the right to suspend, revoke, or deny accreditation for failure to comply with the accreditation regulations.

Alternatively, laboratories may choose to withdraw accreditation, either temporarily or permanently. The laboratory may then determine its own timeline for corrective action and submission of the evidence.