



Assessment Corrective Action Plans (alias POCs) The Good, The Bad, and The Ugly

<http://www.doh.state.fl.us/lab/EnvLabCert/WaterCert.htm>

<http://www.NELAC-Institute.org>

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un film di
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The Assessment Process

- Preliminary preparations
 - Gather (among other things) the last assessment report, deficiencies (if applicable), and Plans of Correction
- Assessment
 - Verify that the previous deficiencies have been corrected
- Post-assessment activities
 - Report the findings
 - Evaluate proposed Plans of Correction



POC Evaluation

- Renewed emphasis on detail
- Looking for what will be done and how
- Keeping an eye toward improvement

TNI V1M2 4.10 - The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.



The Good

Follow Instructions

- The back of Form DH 1137



The Good

Understand the Deficiency

- Take notes during the assessment
- Refer to available resources
 - Read the standard in context
 - Read the test method
 - Use the internet
- If you are still unsure, ask the lead assessor (or me if necessary)



The Good

Address the Deficiency

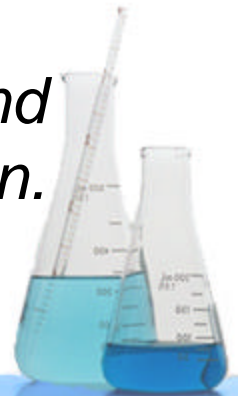
- Correct the problem
 - Is it isolated?
 - Is it systematic?
 - Find the root cause
 - Monitor the results
- Prevent recurrence
- Improve the quality system
- Follow up



Root Cause Analysis

- The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.
(**NELAC** 5.4.10.2, **TNI** V1M2 4.11.2)

Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.



Root Cause Analysis

Basics

- Identifies what, how, and why
- RCs are underlying, preventable, controllable
- Methodology
 - Data collection
 - Cause charting (5 Whys)
 - Root Cause identification
 - Recommendations and implementation



The Good

Respond Appropriately

- Reply within 30 days
- Sign and return the form
- Present a specific plan
 - Be complete
 - Be concise
- Include timely completion dates
- Submit any required documentation
 - Reference the deficiency
 - Highlight the corrections



The Bad

- “I do not understand this deficiency”
- “We disagree with this deficiency”
 - Might be acceptable or might not
 - Should be raised at closing
- “Completed”
 - Not a plan
 - Especially bad for an annual requirement



The Bad

- POC that does not address the deficiency
- Promises to write or revise an SOP
 - No guarantee of correction or implementation
- Chronically bad POCs for deficiencies related to Corrective/Preventive action (**NELAC** 5.4.10, 5.4.11; **TNI** V1M2 4.11, 4.12)



The Bad

- Unnecessary documentation
 - Bound books
 - Non-Conformance Reports
 - Repeating the deficiency in the response
 - A sheet of paper per deficiency
- Poor writing skills
 - Unclear English
 - Typos
 - Not peer-reviewed before mailing



The Ugly

- Late
- “Please provide guidance”
- Any that prompt us to “write a novel”
- POCs that require more time to review than the assessment took to conduct
- Unacceptable second POC
- Corrective Actions completed at the last minute before the next assessment (!)



The Ugly

- Documentation with no explanation and/or that cannot be read (e.g., raw chromatography data files on a CD)
- Self-justification
 - We're "doing good science"
 - "We've always done it this way – why is it a problem now?"
- "We don't agree with the standard!"



So – Back to the Good

- Follow the instructions
- Make sure you understand
- Address the deficiencies
- Respond completely, concisely and on time
- Relax!





***Thank You!
Questions?***

