

ORELAP

On-Site Assessment Report

Strategies for an Acceptable
Corrective Action Response

2003 NELAC Standards

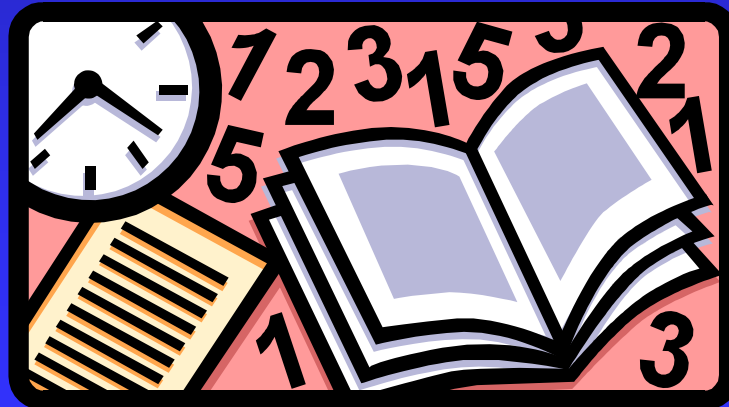
On-site assessments are a requirement of the Accreditation Process (4.1.2)

2003 NELAC Standards

- Labs have 30 calendar days from receipt of assessment report to provide a corrective action report (4.1.3.b)
- Failure to provide such a report within 30 days shall result in:
 1. Denial of accreditation (4.4.1.a.5), or
 2. Total revocation of accreditation (4.4.3.c.1)

Step 1

Determine deadline for
laboratory's report



Step 2

Read report checking for :

- Errors
- Ambiguity

If found:

Contact ORELAP immediately!



2003 NELAC Standards

4.4.3 Revocation

- b) Reason's for revocation in part or in total include a laboratory's:
 - 1) Failure to submit an acceptable corrective action report, in response to an assessment report...

Step 3

Plan the response by reviewing the entire report carefully and preparing schedule for completion by the deadline .



“Immediate”

These deficiencies are judged to affect data quality and must be addressed prior to accreditation (or for maintenance of accreditation)

“Corrective Action Plan”

These deficiencies are judged not to affect data quality directly and may be addressed in the corrective action plan. (If not corrected sooner.)

Step 4

Preparing the Response

The lab must:

1. Address each and every deficiency appropriately
2. Report in a way that is clear to the ORELAP Assessors

Preparing the Report

- Cite the original deficiency by section title, question number, and in order as they are listed in the on-site report ,

or,



- Obtain an electronic copy of the assessment report and respond directly under each finding

Preparing the Report

- Whenever possible, submit evidence of corrective action as attachments to the lab's report
- When corrections are document revisions, reference or highlight each revision that corrects the specific cited deficiency

Preparing the Report

- If at all possible, try to avoid revising parts of documents that have previously been deemed acceptable.
- Only state that the lab will correct a deficiency if the correction will take additional time to correct and this statement is followed by a date of expected completion that is mutually agreeable.

Preparing the Report

- Avoid multiple submittal dates of completed corrective actions.
- Withdrawal of one or more methods can be an acceptable response for certain method specific deficiencies.

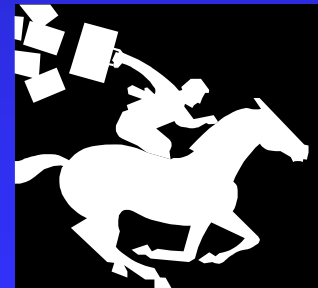
Step 5

Review final report prior to submittal checking:

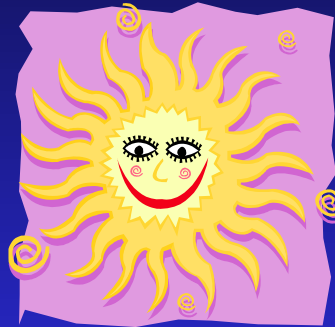
1. That all deficiencies have been addressed in an clear and concise manner
2. All attachments included and identified
3. All future corrections have reasonable deadlines
4. Document has been approved and signed by the labs's QA Officer

Step 6

- Submit original report to the ORELAP Administrator after making a copy for the lab's file
- Send it by method of choice



ORELAP's CA Report Review



Corrective Action Report is Acceptable:

1. No further action is required.
2. Lab is accredited or accreditation is maintained.

ORELAP's CA Report Review



Corrective Action Report is Unacceptable:
Begin again with Step 1

2003 NELAC Standards

4.1.3.d – If the corrective action report (or a portion) is deemed unacceptable to remediate a deficiency, the lab shall have an additional **30** calendar days to submit a revised corrective action report.

2003 NELAC Standards

4.4.3.b – Reason's for revocation in part or in total include a laboratory's:

- 1) Failure to submit an acceptable corrective action report ...The laboratory may submit two corrective action reports within the time limits specified in Section 4.1.3.

Summary

- Step 1: Determine deadline for lab's report
- Step 2: Check for errors & ambiguity
- Step 3: Plan response (corrections)
- Step 4: Prepare report
- Step 5: Review report
- Step 6: Submit report

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On-Site Assessment Report

The End

