

Corrective Action Reports

Why are they important?

ISO/IEC Guide 43-2

“6.4 For laboratories reporting unsatisfactory results, the laboratory accreditation body should have policies to:

- a) Have the laboratory investigate and comment on its performance within an agreed time-frame.”*



CAEAL PT related Policy # 7

Remedial Action

“Each time an accredited lab receives a failing PT score (<70) for any given parameter, a CAR showing the completed action items must be submitted...”



Benefits of Corrective Action Reports

- ❖ Improves the quality of laboratory data.
- ❖ Minimizes inclusion of poor data in PT program.
- ❖ Demonstrates a commitment to continual improvement.

Corrective Action Report



❖ Header

**CAEAL PROFICIENCY TESTING PROGRAM
CORRECTIVE ACTION REPORT (CAR) FORM
January 2004 Study**

MEMBERSHIP	123	MATRIX:	Water (Inorganic)
LABORATORY:	ABC	TEST GROUP:	C-01
CONTACT:	John Doe	PARAMETER:	Alkalinity
TELEPHONE	(555)555-5555	APPENDIX NO:	13
EMAIL	John.doe@abc.com	STATUS:	Possible Suspension

Corrective Action Report

❖ Section A

A **DETAILS OF PROFICIENCY TESTING FAILURE/ANALYSIS**
CONDITIONS:

(identify analyst, instrument, analytical technique, sample preparation, media type etc.)

Jane Doe
Radiometer VIT90, ABU80, SAC90
Automated titration
Results biased high

Signed (lab

John Doe

Date:

April 6 2004

Corrective Action Report

❖ Section B: Root cause identified

B **CORRECTIVE ACTION PLAN:** *(identify root cause and action to prevent reoccurrence)*

Investigated: Analytical QC, training, reagent preparation, method validation, calculations, reporting, ...

Root Cause: Air bubble occasionally observed in acid delivery line. Resulted in high estimate of result.

Corrective Action: Modify SOP to require two empty/fill cycles rather than flush cycle in instrument preparation.

Plan Completed By: Jane Doe

Date: April 4 2004

Signed (lab John Doe

Date: April 6 2004

Corrective Action Report

❖ Section B: Root cause not identified

B CORRECTIVE ACTION PLAN: *(identify root cause and action to prevent reoccurrence)*

Investigated: Analytical QC, training, reagent preparation, method validation, calculations, reporting, volume and weight traceability, sample storage, sample reception...

Root Cause: Unable to clearly identify a root cause.

Corrective Action: Closely monitor performance of method over next three months. Participate in additional QC studies.

Plan Completed By: Jane Doe

Date: April 4 2004

Signed (lab John Doe

Date: April 6 2004

Corrective Action Report

❖ Section C

C	<u>ACCEPTANCE OF CORRECTIVE ACTION PLAN/ REQUIRED FOLLOW-UP:</u>	
	More evidence required? (Y)	Due Date: <u>April 30 2004</u>
	Details Requested clarification on corrective action. Received clarification on April 18 2004. Clarification acceptable.	
	Site Visit required? (N) Revoke Accreditation? (N)	
	Signed (CAEAL representative) <u>Ken Middlebrook</u>	Date: <u>April 23 2004</u>
	Signed (Advisory Panel) _____	Date: _____

Corrective Action Report

❖ Incomplete/Unacceptable CAR

- Further information requested.
- Advisory panel may be involved.
- Site visit may be requested
- Status advanced to next level.



Corrective Action Report

❖ No CAR submitted or unacceptable CAR

- Warning notice given.
- Status advanced to next level.



Discussion
