CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: _____ EPA ID: _____

DEPARTMENT OR ANALYSIS TYPE: _____

EVENT NAME / CATEGORY___ _____LOG # _____
Example names / categories: QC failure; PT failure; customer complaint; sample mishandled by lab; instrument malfunction; reporting error, deviation from procedure, etc. THE LOG NUMBER IS A UNIQUE IDENTIFIER ASSIGNED BY THE LABORATORY.

RESPONSIBLE SUPERVISOR / MANAGER: _____

PERSON COMPLETING CA FORM (NAME, TITLE): _____ DATE: _____

The QA Manager retains all Corrective Action reports in an organized system. The Log # is used to ensure all CAs are uniquely identified. Filing records by Log # is recommended; complete records will account for all Log #s. The Event Name/Category is used to track CAs for trends/patterns.

RECORD INFORMATION BELOW OR ATTACH ADDITIONAL SHEETS. PROVIDE DOCUMENTATION WHENEVER POSSIBLE.

EVENT DESCRIPTION:
State the REQUIREMENT in regulation, method, or laboratory procedure that was not met. Describe the EVIDENCE of the nonconforming event or analysis result. Fully describe the PROBLEM. Attach any documentation that supports and/or supplements this description. (If PT Failure, attach copy of PT report.)

EVENT RESPONSE / INVESTIGATION STEPS:
Indicate the response(s) to the nonconformance, including the immediate CORRECTION taken, all processes or raw data reviewed, QA or Management staff notified, analysis repeated, analysis halted, etc. (Include details of staff member notified, date and time of notification, customer or outside involvement, analysis data, etc.)

ROOT CAUSE DETERMINATION:
State the ROOT CAUSE (reason) for the nonconformance with the analysis or process. (Root cause determination is generally a 'brainstorming' process – first list all possibilities, then select the most probable cause or causes.)

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ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, staff training, purchase of standards or equipment, document/form revision, etc.*

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion

Additional Comments/Supplemental Information:

Submitted By:		Date:
Reviewed By:	Responsible Supervisor or Manager	Date:

By signature and comments below, the QA Manager and Laboratory Director or Technical Manager approve this corrective action plan and the proposed implementation date(s) given. The QA Manager or designee will provide follow-up until the corrective action is closed with documentation/evidence of completion as noted above.

Approved By:	Quality Assurance Manager	Date:
Approved By:	Laboratory Director or Technical Manager	Date:

Reviewer Comments or Additional Actions Recommended:

Closing the Corrective Action: The QA Manager is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.

Follow-up Review Notes: _____

_____

_____ Date:_____

Corrective Action Closed By QA Manager: Signature: _____ Date:_____