



QP 12

Corrective Action

ISO 7.10

I. Purpose

The purpose of corrective action is to generate continuous improvement within the management system as a whole, in a laboratory, in a specific discipline or in an individual. A correctable incident involves issues within the management system that have already occurred. This process is not punitive; rather, the details set forth in this policy will ensure that the nonconformity is identified and corrected, that any effect on previous, current or future cases is remediated and that reoccurrence of the nonconformity is minimized or eliminated.

II. Scope

This policy applies to any nonconformity identified through all facets of casework, database work and proficiencies performed by CBI-FS personnel, regardless of who identifies the nonconformity. In this sense, a nonconformity refers to a departure from policy and/or procedure, or where the accuracy and/or reliability of the test results are in question.

III. Policy/Procedure

A. Determination of a Corrective Action

The process of Quality Incident Review (QP11) may identify some form of departure from conformance. Once the Quality Incident Review process determines that the departure from conformance is a correctable incident, this policy will apply.

B. CBI-FS Corrective Action Report Process

The CBI-FS Corrective Action Report (CAR) workflow in Qualtrax, will be used to track, document, monitor and close-out a corrective action.

1. During a quality incident review, the Quality Manager will make a determination if the incident being reviewed meets the criteria for a corrective action. Once this determination has been made, the Quality Manager will initiate the next steps.
2. The corrective action plan will state the steps to prevent reoccurrence, who will be responsible to implement the steps, and a proposed time for completion of the steps.



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- a. The action plan will need to determine if there is a halt to work, withholding of reports and impact analysis on previous casework to include calling cases back or repeating work.
 - b. Time must be allocated in order to accurately establish and verify the cause or causes of the quality incident. The description of the cause or causes must be specific, rather than verbiage that is vague. Someone will be assigned the responsibility to determine the cause or causes, the steps taken to ascertain the cause(s) and the most likely contributing source(s). The individuals involved in the cause analysis will fluctuate.
 - c. Those individuals involved in the corrective action plan will discuss possible corrective actions and how each of these actions may correct the cause(s).
 - d. A main consideration in determining the appropriate corrective action(s) is the assessment of whether the actions selected will eliminate the issue and prevent a reoccurrence of the problem in the future.
 - e. Where the identification of nonconformities or departures cast doubts on the CBI-FS compliance with its own established policies and procedures or with compliance of the International Standard, the Quality Manager will ensure an audit is conducted.
 - f. An audit of a particular activity can be used to determine if the problem may exist system wide.
 - g. If an audit is completed, the particulars for the audit will be documented either directly in the workflow or on a separate document that will be attached to the CAR.
3. The plan to monitor the effectiveness of the corrective action along with who will be responsible for this step and the proposed timeline to complete the monitoring plan will be stated.
- a. The monitoring plan should be long enough to observe enough data to determine if the corrective actions were successful. Several factors should be considered when determining the monitoring period. These include the amount of work generated in the time period or the number of the same type of circumstances occurs that could have caused the original issue.
 - b. If the expected results are not achieved in the chosen corrective action plan, the situation must be reevaluated and either the root cause must be reassessed or an alternative corrective action plan must be proposed and implemented. These additional steps will be documented on the workflow.



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- c. As part of the monitoring plan, an audit may be conducted in order to determine conformance, specifically in all situations where the nonconforming work was a failure to comply with established policies and/or procedures or accreditation requirements. If an audit occurs it will be documented either directly in the workflow or on a separate document attached to the CAR.
4. If the corrective action resulted in a work stoppage, the individual responsible for approving the resumption of work along with the specifics of who can resume work will be stated.
 - a. In all cases, the approval to resume work will be authorized by the Quality Manager or designee or the Forensic Services Director or designee.
 - b. Prior to the resumption of work, the Quality Manager or designee or the Forensic Services Director or designee will verify that all necessary steps of the Corrective Action to continue work have been fulfilled.
 - c. All members of Forensic Services management along with the CBI Director will be notified that work has resumed.
5. DNA Technical Leader Authorization—Per the requirements stated in the FBI Quality Assurance Standards, the DNA Technical Leader will be responsible for the corrective action process in all situations involving inaccuracies or nonconforming DNA casework and database sample work.
6. Measuring the effectiveness and overall success of the corrective action plan is vital in minimizing the occurrence of similar issues or the reoccurrence of the same concern. It may take additional time to monitor the effectiveness of the corrective action plan; as such, this section may need to be completed at a later date or information added to adequately finalize the CAR.
7. The Quality Manager and the Forensic Services Director retain the authority to direct those involved in the corrective action process to conduct and document additional cause analysis, to determine alternate corrective action plans and/or revise how the plan is monitored.

C. Corrective Action Workflow

Once the initial information has been entered into the Quality Incident Review workflow and it has been determined that the quality incident constitutes a Corrective Action, instructions will appear in the text boxes for each required piece of information in that part of the workflow. As information is submitted, the appropriate individual(s) will be notified that a CAR has been created and requires their attention. Records will be retained in Qualtrax.



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IV. Links

A. Corrective Action Workflow--Qualtrax