



<b>ATF-LS-4.11 Corrective Action</b>	Published Online: <b>March 2018</b>
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## 1. Purpose

- 1.1. This procedure defines authorities and provides Laboratory Services with a mechanism to investigate the cause of nonconformities in the laboratory and to implement, document, and monitor corrective actions. The purpose of corrective actions is to prevent recurrences of a nonconformity by addressing its root cause.

## 2. Scope

- 2.1. This procedure is applicable to nonconformities and departures from policies or procedures for which the preliminary investigation and evaluation conducted in accordance with ATF-LS 4.9 Control of nonconforming work determined that a corrective action is required. It does not apply to minor incidents that were resolved with a simple correction.

## 3. Reference Documents

ATF-LS-4.9 Control of nonconforming work  
ATF-LS-4.11-FA Corrective action report  
ATF-LS-4.12 Preventive action  
ATF-LS-4.13 Control of records

## 4. Procedure

### 4.1. Authorities and responsibilities

- 4.1.1. The Deputy Assistant Director, Forensic Services is responsible for approving all corrective action reports that relate to Quality Programs or that are Division-wide in scope. This authority may be delegated to a Laboratory Chief or the Quality Manager.
- 4.1.2. Laboratory Chiefs are responsible for approving all corrective action reports within their laboratory.
- 4.1.3. The DNA Technical Leader is responsible for approving all corrective action plans related to or affecting casework or proficiency tests in their discipline prior to their implementation. The DNA Technical Leader is authorized to initiate, suspend and resume analytical operations for their discipline or for an individual's work in their discipline.
- 4.1.4. Quality Programs is responsible for providing guidance as needed throughout the process. The Quality Manager is responsible for reviewing the corrective action report and ensuring its adherence to accreditation and management system requirements.
- 4.1.5. Responsibility for managing and implementing corrective actions may be assigned to a Section Chief, Technical Leader, the Quality Manager or other personnel based on the nature and scope of the corrective action.

## 4.2. Root cause analysis and assignment of a level

- 4.2.1. All nonconformities identified and documented via ATF-LS-4.9 Control of nonconforming work that require a corrective action shall begin with a root cause analysis. The root cause analysis shall seek to determine the most fundamental cause(s) of the nonconformance so that the corrective actions put into place are appropriate for minimizing the likelihood of recurrences.
- 4.2.2. The person assigned responsibility for managing the corrective action shall evaluate the significance of the nonconformity and classify it as Level 1 or Level 2 based on the following criteria:
  - 4.2.2.1. Level 1: The nature or cause of the nonconformance directly affects and has a fundamental impact on the work product of the laboratory or the integrity of evidence: or there is a concern that if the nonconformance continues for an extended period the work product of the laboratory or integrity of evidence could be negatively affected.
  - 4.2.2.2. Level 2: The nature or cause of the nonconformance does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of evidence, and allowing the laboratory to implement corrective action over an extended period does not raise an immediate concern.
- 4.2.3. When a nonconformity is determined to be Level 1, the Laboratory Chief and Quality Manager shall be notified as soon as possible. In addition, interested parties shall be notified in accordance with accreditation and ATF legal/ investigative requirements.
- 4.2.4. It is recommended that the status of corrective actions be communicated to the Quality Manager, relevant managers and affected parties throughout the process regardless of the level.

## 4.3. Development of corrective action plan

- 4.3.1. The employee assigned responsibility for managing the corrective action will work with the appropriate Technical Leader, Section Chief, Laboratory Chief or Quality Programs representative to develop and document a plan of action appropriate to the magnitude of the nonconformity and based on the root cause analysis. This plan will include the action or series of actions that are believed to address the root cause(s) of the nonconformity, eliminate the problem and prevent recurrences. It shall also include a plan to monitor the effectiveness of the corrective action.
- 4.3.2. Monitoring plans may include assignments of responsibility, random checks, interim audits or other means of assessing the effectiveness of the actions. Additional interim audits may be necessary as part of the monitoring process, but generally are only required for especially serious cases, such as when there is a significant risk to operations.

4.3.3. If the corrective action is related to or affects DNA casework or proficiency tests, the corrective action plan shall be approved by the DNA Technical Leader prior to its implementation.

#### 4.4. Implementation, review and approval

4.4.1. The actions proposed in the corrective action plan shall be implemented. Modifications to the plan may take place as deemed necessary during the implementation process and shall be documented. If the corrective actions are covered by other laboratory procedures, all applicable procedures shall be followed.

4.4.2. The Quality Manager shall review the corrective action report to ensure adherence with accreditation and management system requirements. When appropriate, the Quality Manager shall provide recommendations to the responsible party for further action. When satisfied that the corrective action is in compliance with requirements the Quality Manager shall document their review and concurrence and forward the corrective action report to top management for approval.

4.4.3. When it is demonstrated that the corrective action has addressed the problem and, insofar as possible, minimized the likelihood of future occurrences, the relevant top manager shall approve the corrective action report. For corrective actions that relate to Quality Programs or that are Division level (laboratory system), the reports shall be approved by the Deputy Assistant Director, Forensic Services or Quality Manager. The active corrective action shall then be closed.

#### 4.5. Monitoring effectiveness

4.5.1. The monitoring plan described in the corrective action report shall take place to determine the effectiveness of the corrective actions following their implementation. If an additional audit was determined to be necessary due to an especially serious issue or risk to casework or projects, then an audit covering the affected areas shall be scheduled and conducted as soon as possible.

4.5.2. When the monitoring plan is completed successfully and the corrective actions have been determined to be effective, the process is complete. If the monitoring process determined that the corrective actions were less than fully effective, it may be necessary to see if ATF-LS-4.12 Preventive action is appropriate or a nonconformity has occurred, in which case ATF-LS-4.9 Control of nonconforming work applies.

#### 4.6. Records

4.6.1. Corrective action records shall include the following:

- description of the nonconformity
- reference to the requirement
- immediate actions taken
- level assignment
- summary of the root cause analysis process and determination of the root cause

- recommended corrective actions and actions taken
- monitoring plan
- required review and approval

4.6.1.1. The first three items listed as required are generally completed as part of the ATF-LS-4.9 Control of nonconforming work process.

4.6.2. ATF-LS-4.11FA Corrective Action Report provides a template for recording the required documentation.

4.6.3. Corrective action records will be retained by the Laboratory Chief or their designee if the corrective action is the responsibility of the individual laboratory. For corrective actions at the Division level (laboratory system), the records shall be maintained by the Quality Manager. All records shall be maintained in accordance with ATF-LS-4.13 Control of records.

## 5. Controls

### 5.1. Section Chiefs

5.1.1. Section Chiefs shall review corrective actions originating from their section and ensure that monitoring plans are followed.

### 5.2. Laboratory Chiefs

5.2.1. Laboratory Chiefs will review all corrective action records as part of the approval process and during the annual review of the management system.

### 5.3. Quality Manager

5.3.1. Corrective action records will be reviewed during the annual internal audits.

Appendix I: Corrective actions workflow

