1. Purpose

1.1. This procedure outlines the activities and responsibilities involved when any aspect of laboratory operations does not conform to Laboratory Services' policies or procedures or to accreditation or customer requirements.

2. Scope

2.1. This procedure applies to all work performed by ATF Laboratory Services. It is applicable to technical and administrative policies and procedures as well as to Laboratory Services' management and quality systems.

3. References

ATF-LS-4.11 Corrective action

ATF-LS-4.12 Preventive action

ATF-LS-4.13 Control of records

4. Procedure

4.1. Authorities and responsibilities

4.1.1. All personnel are authorized to report nonconforming work and to stop work if necessary.

4.1.2. The DNA Technical Leader is authorized to initiate, suspend and resume analytical operations or an individual's work for their discipline and to withhold reports and to release withheld reports for their discipline.

4.1.3. Section Chiefs are responsible for assigning responsibility for the management of nonconforming work that falls within their span of control. They are authorized to withhold reports and to approve corrections and referrals to the corrective action

process for such nonconformities. For disciplines other than DNA, they are authorized to resume work and release reports for their respective disciplines.

4.1.4. Quality Programs is responsible for providing guidance as needed throughout the process. The Quality Manager is responsible for assigning responsibility for the management of nonconforming work that relates to Quality Programs or that is division-wide in scope. The Quality Manager is authorized to approve corrections and referrals to the corrective action process for such nonconformities.

4.1.5. Laboratory Chiefs are responsible for assigning responsibility for the management of nonconforming work that affects more than one section of the laboratory. They are authorized to withhold reports and to approve corrections and referrals to the corrective action process. These authorities may be delegated to a member of the management team.

4.2. Identification and initial documentation of nonconforming work

4.2.1. Detection and identification of nonconforming work may originate from a variety of sources. All employees are authorized to report potential nonconformities and have the responsibility for doing so. When a nonconformity is identified, a manager shall be notified and the nonconformity shall be documented. Documentation shall include a reference to the requirement, policy or procedure that was not met and a description of the observed nonconformity. Responsibility for addressing the nonconformity shall be assigned by a member of the management team based on the nature and scope of the nonconformity.

4.2.2. If the potential issue does not violate a specific requirement, policy or procedure but raises awareness of a potential improvement, this procedure does not apply. A preventive action may be applicable; refer to ATF-LS-4.12 Preventive action.

4.3. Preliminary investigation and immediate action

4.3.1. A preliminary investigation shall be conducted to determine if casework or projects have been adversely affected or if the nonconforming work could adversely affect future casework or projects. Based on the preliminary investigation, it may be necessary to stop work or withhold reports. All ATF Laboratory Services staff are authorized to stop work when the quality of technical work has the potential to be adversely affected. When possible, the Section Chief and Technical Leader will be consulted prior to stopping work; however, the Section Chief must be notified as soon as possible. A determination shall be made if reports need to be withheld.

4.3.2. Immediate corrections to address the nonconformity or to prevent additional recurring nonconformities are made at this step. If DNA work was stopped or reports withheld and the immediate correction addressed the problem, then the DNA Technical Leader shall authorize the resumption of technical work and release of reports for their discipline. For other disciplines, the Section Chief shall authorize the resumption of technical work and release of reports.

4.4. Evaluation

4.4.1. Following the preliminary investigation, an evaluation shall be conducted to determine the significance of the nonconformity. The evaluation process should consider the effect on the work product; any impact on the integrity of evidence; if customer service is affected; the frequency of occurrence; the impact on the laboratory's ability to meet its mission; and any other relevant factors. It may involve consultations with appropriate personnel, such as a Section Chief, Laboratory Chief, Technical Leader, Quality Manager, Primary Instrument Operator or other relevant personnel, depending on the nature and scope of the nonconformity.

4.4.2. As part of the evaluation, an assessment will be made as to whether further short term measures, such as notifying the customer, laboratory personnel, attorneys or others, need to be taken. If it is determined that notifications outside of Laboratory Services are warranted, then the Laboratory Chief and Quality Manager shall be notified prior to contacting the customer.

4.4.3. For a minor issue such as an administrative error on a report that has been issued, notification of the Section Chief may take the place of Laboratory Chief and Quality Manager notifications. This notification shall occur through the normal process of issuing the replacement (amended) report and is documented by the Section Chief's signature on the amended report.

4.4.4. Based on this evaluation of the nonconformity's significance and its likelihood of recurrence, a determination shall be made if further action and documentation (a corrective action) is required or if the nonconformity has been satisfied with a simple correction. Some minor incidents may be resolved at this point and require no further action. This decision shall be approved by a member of the management team.

4.4.5. If the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures described in ATF-LS-4.11 Corrective action shall be followed. If the evaluation indicates that the nonconformity will likely be classified as a Level 1 nonconformity then the corrective action procedures described in ATF-LS-4.11 Corrective action shall be followed.

4.5. Records

4.5.1. The records associated with nonconforming work, including corrective action reports described in ATF-LS-4.11 Corrective action, will be retained by the Laboratory Chief or their designee if the nonconformity is the responsibility of the individual laboratory. For nonconformities 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.

4.5.2. When the nonconformity is addressed by a simple correction, the documentation may be brief, such as a line in a spreadsheet or table. It shall include the following, at a minimum:

- description of the nonconformity
- reference to the requirement
- correction
- approval

4.5.3. When a corrective action is required, the documentation procedures described in ATF-LS-4.11 Corrective action shall be followed.

5. Controls

5.1. Laboratory Chiefs

5.1.1. Laboratory chiefs will review all reported nonconforming work and any resulting corrective actions during their annual review of the management system.

5.2. Quality Manager

5.2.1. Nonconforming work records and any resulting corrective actions will be reviewed during the annual internal audits.

Appendix I: Nonconformance workflow