



ATF-LS-4.14 Internal Audits	Published Online: March 2018
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1. Purpose

1.1. The process of self-evaluation is a valuable management tool. The assessment process and the system review that follows is a means to promote and encourage the quality and efficiency of operations. It is a learning process which demonstrates that management practices, operational procedures, personnel, instruments, physical plant, security systems, and personnel safety meet certain identified standards. Review findings in no way imply that a laboratory is inadequate or that its results cannot be trusted. The intent of the review is to sustain and improve operational quality and efficiency. The atmosphere of conducting audits will be open, cooperative, and constructive. This policy and procedure provides direction on performing and documenting annual internal audits.

2. Scope

2.1. This policy is applicable to all Laboratory Services laboratories and the office of Quality Programs. Internal reviews will be conducted on an annual basis and coordinated by Quality Programs. Each laboratory shall submit an annual report to ASCLD/LAB.

3. References

ATF-LS-4.9 Control of nonconforming work

ATF-LS-4.11 Corrective action

ATF-LS-4.11-F-A Corrective action report

ATF-LS-4.13 Control of records

ATF-LS-4.15 Management reviews

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, 2005.

ASCLD/LAB - *International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, 2011.

National Quality Assurance Standards for Forensic DNA Testing Laboratories, 2011.

4. Procedure

4.1. Internal audits

4.1.1. An internal audit will be conducted annually for each ATF laboratory by teams selected by the Laboratory Services management team and approved by the Deputy Assistant Director, Forensic Services. All auditors shall be trained by Quality Programs prior to fully participating in a review, and when feasible, by shadowing an internal audit. If resources permit, the team selected will comprise members from outside the laboratory being audited. For purposes of the National Quality Assurance Standards for Forensic DNA Testing Laboratories audit, a qualified auditor as defined in that document will be involved in all internal audits of Forensic Biology. An external expert will be involved in

the audit to ensure compliance with the National Quality Assurance Standards for Forensic DNA Testing Laboratories no less frequently than every other year, as mandated by the standard. These audits will be used to verify that the laboratory operations continue to comply with the requirements of its management system; with the National Quality Assurance Standards for Forensic DNA Testing Laboratories; and with accreditation criteria. Laboratory Chiefs will be notified of audit dates a minimum of one month in advance. The notification package will contain the audit scheme and instructions on preparing for the audit.

- 4.1.2. The Quality Manager will convey any findings that require a stop work order to the Laboratory Chief and to the Deputy Assistant Director, Forensic Services as soon after the observation as possible.
- 4.1.3. Audit reports, including any findings of nonconformance, will be prepared by Quality Programs and provided to the respective Laboratory Chief with a copy to the Deputy Assistant Director, Forensic Services within 30 days of the completion of the audit.

4.2. External audits

- 4.2.1. Assessments conducted by external experts or personnel, i.e., accrediting body, will be coordinated by Quality Programs on the schedule determined by the external agency. Internally, coordination and communication with laboratory management will follow the same general process, including chain of command, as internal audits addressed in Section 4.1. Any external audit findings and corrective actions will be handled according to the requirements of the external body.

4.3. Records

- 4.3.1. The results of the annual internal audits will be formally documented in a report to the Laboratory Chief. These reports will serve as the official record of the audits. A completed National Quality Assurance Standards for Forensic DNA Testing Laboratories audit document, signed by qualified participants and acknowledged by the DNA Technical Leader's signature will be used to record the audits of Forensic Biology.
- 4.3.2. Completed checklists and on-site review notes will be maintained as working notes until the reports are issued and Laboratory Chiefs have identified appropriate corrective actions at which time these working notes will be destroyed.
- 4.3.3. Records of nonconforming work and corrective actions resulting from internal audits will be generated and maintained according to ATF-LS-4.9 Control of nonconforming work and ATF-LS-4.11 Corrective action.
- 4.3.4. Audit reports shall be maintained in accordance with ATF-LS-4.13 Control of records.

5. Controls

- 5.1. To ensure that these tools continue to be effective in meeting the needs of laboratory management, the Deputy Assistant Director, Forensic Services and/or the Quality Manager will

solicit feedback following each audit. Feedback will be solicited from auditors, Laboratory Chiefs, Section Chiefs, and examiners by way of a formal written survey.