



Intermountain Forensics

SOP #

ADM-106

Revision #

04

Forensic DNA Technical Leader Approval

Issue Date

043/1143/2023

Audits

1. Purpose

To provide timing, types and documentation of audits.

2. Summary

An annual review by the DNA Technical Leader of the Quality Management System is required. Additionally, a yearly audit of the laboratory against the FBI Quality Assurance Standards must be performed with an external audit occurring at least every other year. The laboratory will ensure we remain compliant with ISO/IEC 17025, the accrediting body's accreditation requirements, and our own internal management system through the performance of an annual internal audit.

3. Procedure

Annual Quality System Review

1. The Annual Quality System Review is completed as part of the annual management review, which is directed by the DNA Technical Leader.
 - a. Refer to ADM-115 Management Review for the Management Review policy.

FBI Quality Assurance Standards Audits (FBI QAS)

1. An external audit is at minimum is performed every other calendar year, alternating with the internal audit.
 - a. These audits will be scheduled to ensure they are a minimum of 6 months and a maximum of 18 months in timeframe from the previous FBI QAS audit.
 - b. The audit is conducted by a team from an external agency with at least one team member successfully completing the FBI DNA Auditor training and is or has been qualified in the specific DNA technology used by IMF.
 - c. A record and a summary report, prepared by the Leader auditor, will be maintained which includes:
 - i. Date of inspection
 - ii. Names of the members of the inspection team
 - iii. Findings and problems identified by the team
 - iv. Remedial action taken to resolve existing problems
 - d. Any findings of non-conforming work will be addressed through corrective action report processes.
 - e. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process, after evaluation by the DNA Technical Leader.
 - f. The DNA Technical Leader is responsible for initiating all corrective and preventative actions resulting from the audit.
2. An internal audit is performed every other calendar year, alternating with the external audit.
 - a. These audits will be scheduled to ensure they are a minimum of 6 months and a maximum of 18 months in timeframe from the previous FBI QAS audit.
 - b. The FBI QAS internal audit may be performed in conjunction with the annual ISO/IEC 17025 internal audit.



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- c. The performance of an external FBI QAS audit will replace the requirement for an internal QAS audit.
 - i. The laboratory will consider external audits more transparent, unbiased, and comprehensive and will utilize external audits in lieu of internal audits if financially feasible without impact to the vision and mission of the laboratory.
- d. The audit is conducted by at least one qualified auditor, under the direction of the DNA Technical Leader.
- e. A record of each internal audit will be maintained which includes:
 - i. Date of inspection
 - ii. Names of the members of the inspection team
 - iii. Findings and problems identified by the team.
- f. Any findings of non-conforming work will be addressed through corrective action processes.
- g. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process, after evaluation by the DNA Technical Leader.
- h. If the DNA Technical Leader is not a member of the audit team, the technical leader must, review the documentation completed by the internal audit team and the associated findings.
- i. The DNA Technical Leader is responsible for initiating or reviewing all corrective and preventative actions and corrections resulting from the audit.

ISO/IEC 17025 Internal Audits

1. Internal Audits will be performed annually to ensure conformance to:
 - a. The requirements of IMF's Management System
 - b. The requirements for ISO/IEC 17025 standards
 - c. The requirements in ANAB's AR3125
 - d. The FBI's Quality Assurance Standards
2. The DNA Technical Leader is responsible for preparing the audit plan and overseeing the audit, as well as generating any appropriate corrective and preventative actions which may result from audit findings.
3. Documentation for an internal audit will include:
 - a. A plan for the audit which has been disseminated to members of management prior to the commencement of the audit.
 - i. The plan will include the criteria and scope for the audit.
 - b. Documentation to act as evidence of the completion of the internal audit and the results of the internal audit.
4. The internal audit will include direct observation of a portion of accredited laboratory activities within the disciplines included on the scope of accreditation.
 - a. Documentation for the observation must include, at a minimum:
 - i. The activity observed
 - ii. Identification of the individual observed
 - iii. The date of the observation
 - iv. Identification of the individual performing the observation
 - b. Processing of controls, contrived samples, or proficiency test samples may be performed in lieu of casework, if casework is not available during the time period of the internal audit.
5. Any findings of non-conforming work will be addressed through correction or corrective action processes, depending on the severity of the issue.
 - a. If correction is pursued instead of proceeding through the corrective action process, documentation of the correction will be maintained.



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6. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process, after evaluation by the DNA Technical Leader.
7. The outcome of the internal audit will be communicated to relevant management, at minimum, as part of the annual Management Review.
8. The DNA Technical Leader is responsible for initiating all corrective and preventative actions resulting from the internal audit.

4. References

<https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

<https://www.fbi.gov/file-repository/qas-audit-for-forensic-dna-testing-laboratories.pdf/view>

[ANAB Accreditation Requirements for Forensic Testing and Calibration](#)

5. Definitions

Federal Bureau of Investigation Quality Assurance Standards (FBIQAS): Refers to the "THE FBI QUALITY ASSURANCE STANDARDS AUDIT FOR FORENSIC DNA TESTING LABORATORIES" audit document.

ISO/IEC 17025: Refers to ISO/IEC 17025:2017- FORENSIC SCIENCE TESTING AND CALIBRATION LABORATORIES Accreditation Requirements (specifically as it refers to Forensic Accreditation)