



Intermountain Forensics

SOP #

ADM-106

Revision #

01

Forensic DNA Technical Leader Approval

Issue Date

5/29/20

Audits

1. Purpose

To provide timing, types and documentation of audits.

2. Summary

A yearly review by the DNA Technical Leader of the Quality Assurance Program is required. Additionally, a yearly audit of the laboratory against the FBI Quality Assurance Standards must be performed with an external audit at least every other year. The laboratory will obtain and remain compliant with ISO 17025 and will be assessed/audited as per the accrediting body's requirements.

3. Procedure

Forensic DNA Technical Leader Annual Review

1. The Forensic DNA Technical Leader conducts and documents an annual review of the DNA Quality Assurance Program including at a minimum:
 - a. Standard Operating Procedures
 - b. Corrective and Preventive Action Reports
 - c. Proficiency Testing
 - d. Validations
 - e. Training and Competency
2. This assessment will be documented with an audit summary document and approval of continued technical operations by the Forensic DNA Technical Leader (AUD-300).
 - a. Any findings of non-conforming work will be addressed through corrective action report processes.
 - b. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process

FBI Quality Assurance Standards Audits (FBIQAS)

3. An external audit is at minimum is performed every other year, alternating with the internal audit.
 - a. The audit is conducted by a team from an external agency with at least one team member successfully completing the FBI DNA Auditor Workshop and is or has been qualified in the specific DNA technology used.
 - b. A record and a summary report prepared by the DNA Technical Leader of each external 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
 - iv. Remedial action taken to resolve existing problems
 - c. Any findings of non-conforming work will be addressed through corrective action report processes.
 - d. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process
4. An internal audit is performed every other year, alternating with the external audit.
 - a. An external FBIQAS audit will replace the requirement for an internal audit.
 - i. The laboratory will consider external audits more transparent, unbiased, and comprehensive and if financially feasible without impact to the vision/mission, the laboratory will utilize external audits in lieu of internal audits whenever possible.
 - b. The audit is conducted under the direction of the DNA Technical Leader by at least one qualified auditor and one qualified (or previous qualified) DNA Analyst.
 - c. A record and a summary report prepared by the DNA Technical Leader of each external audit will be maintained which includes (AUD-301):
 - 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 processes.
 - e. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process

ISO 17025 Accreditation



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5. The laboratory will obtain and sustain ISO 17025 accreditation by an external accrediting body that is authorized and capable of providing inspection and accreditation services.
 - a. The laboratory will adhere to the assessment schedule that is required by the accrediting body.
 - b. Any audit or assessment will be recorded and a summary report will be issued by the Laboratory Director or Forensic DNA Technical Leader 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
 - c. Any findings of non-conforming work will be addressed through corrective action processes.
 - d. Any suggestions/recommendations by the audit team will be addressed through the preventative action report process
 - e. This process will include both full assessments and any surveillance assessments that are required by the auditing body.

4. References

AUD-300 Forensic DNA Technical Leader Annual Review Summary
AUD-301 Audit Summary
<https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>
<https://www.fbi.gov/file-repository/gas-audit-for-forensic-dna-testing-laboratories.pdf/view>

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