Audits and Assessments		
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Audits and Assessments

1 Guiding Principles and Scope

1.1 Audits and assessments are conducted to improve the quality of the laboratory, as well as to maintain compliance with accreditation standards such as ISO 17025, the ASCLD/LAB-*International* Supplemental Requirements, and the FBI Quality Assurance Standards for Forensic DNA Testing.

1.2 An ***Internal Audit*** is an audit conducted by qualified and trained auditors employed by the Department of Forensic Biology. An ***External Audit or Assessment*** is an audit conducted by qualified and trained auditors/assessors employed by agency external to the Department of Forensic Biology.

1.3 This document describes the external audits/assessments to which the Department of Forensic Biology is subject and the internal audit program of the Department.

2 Procedure

2.1 The management system of the Department of Forensic Biology is designed to conform to the following sets of standards:

2.2 **ASCLD/LAB-*International* Standards:** The ASCLD/LAB-*International* Standards encompasses the ISO/IEC 17025 requirements and the ASCLD/LAB-*International* Supplemental Requirements.

2.3 **FBI Quality Assurance Standards for Forensic DNA Testing:** The FBI Quality Assurance Standards for Forensic DNA Testing is issued by the FBI Director and is a set of standards specific to Forensic DNA Testing (mitochondrial and autosomal). ASCLD/LAB-*International* also requires compliance with these standards as a condition of accreditation.

3 External Audits/Assessments

3.1 The Department is subject to **external accreditation assessments/surveillance visits** as required by ASCLD/LAB.

3.1.1 Assessment scheduling and the assessment process are the responsibility of ASCLD/LAB.

3.1.2 Level 1 non-conformities (as defined by ASCLD/LAB) must be corrected to the satisfaction of ASCLD/LAB before a recommendation for accreditation is made.

3.1.3 Corrections for Level 2 non-conformities may commence immediately upon discovery. Otherwise, the Department shall obtain approval from ASCLD/LAB to correct the non-conformity prior to the next, annual on-site Surveillance Visit.

3.2 An **external DNA audit** to ensure the Department's conformance with the FBI DNA Quality Assurance Standards for Forensic DNA Testing is conducted at least once every two (2) calendar years.

3.2.1 An external DNA audit could occur as part of an ASCLD/LAB accreditation assessment or could be a stand-alone DNA audit such as those provided through the DNA laboratory audit program of the National Forensic Science Technology Center (NFSTC).

3.2.2 For an external DNA audit to "count," it must occur at least 6 months, but no more than 18 months, after an internal or external DNA audit conducted during the prior calendar year.

3.2.3 The audit must be conducted with the version of the FBI DNA QAS audit document in effect at the time of the audit.

3.2.4 The audit document and any Quality Incident Reviews stemming from non-conformities identified during the audit are submitted to the Quality Assurance Manager and the DNA Technical Leader(s) for review and for approval of proposed follow-up actions.

3.2.5 A copy of the DNA audit documentation and laboratory responses to non-conformities is provided to the NDIS Custodian at the FBI within 30 days of the laboratory's receipt of the audit report.

3.2.6 The laboratory maintains the following records from external DNA audits:

3.2.6.1 Audit reports

3.2.6.2 Self-verification forms completed by the members of the audit team to certify their qualifications as auditors and experience with the DNA technologies and platform(s) used by the Department.

3.3 External audits outside of normal accreditation assessment or external DNA audit schedules may be required by ASCLD/LAB or the New York State Commission on Forensic Science as a response to very serious quality incidents.

3.4 The Quality Assurance Manager (QAM) is the point of contact for any external audit of the laboratory that concerns the technical operations of the laboratory.

4 Internal Audits

4.1 The internal audit program is a critical component of the Department's management system. It is designed to ensure that the Department's management system is functioning correctly and that the Department is operating is in compliance with its own procedures as well as regulatory and accreditation requirements.

4.2 The internal audit program consists of two parts: (1) audits to evaluate the laboratory's conformance with respect to the management system, including the testing activities, and with the ISO 17025 and ASCLD/LAB-*International* Supplemental requirements and (2) DNA audits to evaluate the laboratory's conformance with respect to the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

5 General Internal Audit Information

5.1 The Quality Assurance Manager (QAM) is responsible for scheduling and planning the internal audits of the laboratory. Scheduling is done in consultation with the Technical Leaders, Deputy Director(s), and the Director.

5.1.1 Should an audit require personnel from external organizations, the QAM will take into consideration the schedule and availability of these external auditors prior to agreeing to a date.

5.1.2 "ISO" audits and DNA audits are scheduled to occur each calendar year.

5.1.3 The QAM selects auditors to ensure that an audit team is "qualified" as per the requirements for each type of audit.

5.1.4 Each audit team has a lead auditor/team leader. The QAM and the lead auditor/ team leader develop an audit plan that, at a minimum, contains the audit schedule, the activities to be audited, and the audit team(s) assigned to audit the specified activities.

5.1.5 The general process for any internal audit is as follows:

5.1.5.1 The QAM notifies the laboratory that an internal audit will be conducted, the general scope of the audit, and provides an approximate timeframe.

5.1.5.2 The QAM schedules an opening conference with the auditors to discuss the audit objectives, assignments, timing, and report format and distribution.

5.1.5.3 The auditors perform their audit activities to assess the soundness of the quality system, management system, and technical operations.

5.1.5.4 The audit teams provide the QAM with their audit findings, including potential non-conformities and observations.

5.1.5.5 The QAM discusses preliminary observations (if any) with management.

- Non-conformities that are non-systemic, are easily corrected, and do not indicate serious deficiencies in the management system can be corrected prior to the completion of the audit.
- The correction is documented in the audit records, but is not included in the final audit report.

5.1.5.6 The QAM, Technical Leaders, and other manager(s) as requested by the QAM review the audit results submitted by the audit teams and verify the findings that are true non-conformities supported by objective evidence.

5.1.5.7 The lead auditor/ team leader writes the audit report. The QAM reviews the audit report. The laboratory managers are informed.

5.1.5.8 The CONTROL OF NON-CONFORMING WORK procedure and/or the QUALITY INCIDENT REVIEW procedure is used for follow-up on audit non-conformities identified in the audit report.

5.1.5.9 If audit non-conformities show that laboratory results may have been affected, the laboratory must notify its customers and accreditation agency of the results, in writing, within thirty (30) days of discovery.

5.1.5.10 Audit reports may need to be submitted to the NYS Commission on Forensic Science, ASCLD/LAB, or the board members of the National DNA Indexing System (NDIS). The Quality Assurance Manager shall ensure timely submission of audit reports when necessary.

5.1.5.11 Audit reports are a form of records and shall be retained according to the guiding principles of the laboratory. See CONTROL OF RECORDS for further information.

6 Information Specific to Internal "ISO" Audits

6.1 The scope of the internal audit must ensure that all elements of the management system are addressed. The QAM or designees may develop checklists to be used by the audit teams.

6.2 Auditors are "qualified" in any of the following ways:

6.2.1 Documented completion of an ASCLD/LAB-International assessor training course.

6.2.2 Documented completion of an external ISO 17025 training course and auditor training conducted in-house by a qualified auditor such as the QAM.

6.2.3 Documented completion of ISO 17025 and auditor training conducted in-house by a qualified auditor such as the QAM.

6.3 Only qualified auditors will be selected to lead an internal audit team. Staff that has not completed the required training may be used as team auditors, but they must report directly to a qualified auditor.

7 Information Specific to Internal DNA Audits

7.1 DNA internal audits are conducted using "The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories."

7.2 Auditors are "qualified" to conduct DNA audits if they have successfully completed an FBI-sponsored DNA Auditing Workshop/Course.

7.3 The DNA audit team must contain at least one qualified auditor and at least one person that is, or has previously been, a qualified analyst for each specific DNA technology (***technology*** *is used to describe the type of forensic DNA analysis performed in the laboratory, such as STR, YSTR, or mitochondrial DNA*) performed in the laboratory. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of various members of a multi-person audit team.

7.4 Internal DNA audits are optional in calendar years when external DNA audits have been conducted.