Audits and Assessments		
Status:Published		Document ID: 1190
DATE EFFECTIVE 06/29/2020	APPROVED BY Quality Assurance Manager	PAGE 1 OF 7

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 ANAB Accreditation 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 an 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 **ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories:** These requirements are assessed by ANAB under their *ASCLD/LAB International* accreditation program.

2.3 **ANAB** ISO/17025 Forensic Science Testing and Calibration Laboratories Accreditation requirements**:** These standards are **based on the ISO/IEC 17025 standards, but are made specific to Forensic Science laboratories. These standards are also** assessed by ANAB under their *ASCLD/LAB International* accreditation program.

2.4 **FBI Quality Assurance Standards for Forensic DNA Testing: These standards are** issued by the FBI Director and **are** a set of standards specific to Forensic DNA Testing (mitochondrial and autosomal). ANAB 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 (on-site and off-site) as required by ANAB.

3.1.1 Assessment/surveillance activity scheduling and the assessment/surveillance process are the responsibility of ANAB.

3.1.2 Any findings of nonconformance (as defined by ANAB) identified during the assessment/surveillance activity are submitted to the Quality Assurance Manager and/or laboratory Director for review and approval and must be corrected to the satisfaction of ANAB before a recommendation for accreditation is made. A proposed remediation action plan is submitted to the lead assessor, typically within 30 days of the assessment/surveillance activity. Once the action plan has been approved, the remediation actions should be completed within 60 days of the assessment/surveillance activity.

3.1.3 The laboratory maintains the following records from external assessments/ surveillance visits:

3.1.3.1 Written audit plan

3.1.3.2 Audit reports

3.1.3.3 Summary of assessment/ surveillance visit results and remediations

3.1.3.4 Records of communication with the audit team/ ANAB/ DCJS

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 ANAB assessment activity or could be a stand-alone DNA audit.

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 nonconformances 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 nonconformances is provided to the Laboratory's CODIS Custodian as well as 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 Written audit plan

3.2.6.2 Audit reports

3.2.6.3 Summary of audit results and remediations

3.2.6.4 Records of communication with the audit team/ ANAB/ DCJS/ FBI

3.2.6.5 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.

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

3.3 The Quality Assurance Manager (QAM) is the point of contact for any external audit or assessment 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 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/IEC 17025 and ANAB Accreditation 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 Internal "ISO" Audits are performed each calendar year, even if an external audit has been performed.

5.1.3 DNA audits using "The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories" are performed each calendar year. However, internal audits are optional in calendar years when external DNA audits have been conducted.

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

5.1.5 Each audit team has a lead auditor/team leader. The QAM and the lead auditor/ team leader develop a written audit plan that, at a minimum, contains:

5.1.5.1 The standards that will be used during the audit.

5.1.5.2 The audit schedule.

5.1.5.3 The scope of activities to be audited.

5.1.5.4 The number of Forensic Biology casefiles the audit team must review to ensure that the laboratory is in conformance with all accreditation requirements and its own management system.

5.1.5.5 Instruction for the audit team to observe at least one benchwork analysis performed in real-time. This can be done by the individual auditors, or may be assigned to one auditor acting on behalf of the team.

5.1.5.6 The expected manner in which conformance with accreditation requirements and the laboratory's own management system will be documented by the audit team (ex. Excel spreadsheets, Field Guides, audit trails, etc)

5.1.5.7 The names of the audit team(s) members assigned to audit the specified activities

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

5.1.6.1 The QAM notifies the laboratory that an internal audit will be conducted, the general scope of the audit, and provides an approximate timeframe. This information may be disseminated during lab meetings or via email.

5.1.6.2 The QAM schedules an opening conference with the auditors to discuss the audit objectives, assignments, timing, documenting of conformance, observations and the final report format.

5.1.6.3 The auditors perform their audit activities to assess the soundness of the quality

system, management system, and technical operations.

5.1.6.4 The audit teams provide the QAM with a final report with their audit findings, including potential nonconformances and all recorded observations.

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

5.1.6.5.1 Nonconformances 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.

5.1.6.5.2 The correction is documented in the audit records, but is not included in the final audit report.

5.1.6.6 The QAM, Technical Leaders, and other manager(s) as requested by the QAM review the audit results submitted by the audit teams, verify whether any noted findings are true nonconformances supported by objective evidence and approve appropriate remediation actions as needed. These reviews may take place during Management huddles (as the audit process is on-going) or as a final discussion at the next Management weekly meeting which occurs after the audit has been completed.

5.1.6.7 The CONTROL OF NON-CONFORMING WORK procedure and/or the QUALITY INCIDENT REVIEW procedure may be used for follow-up on audit non-conformances identified in the audit report. The laboratory seeks to remediate any nonconformances within 60 days of the completion of the audit.

5.1.6.7.1 Typically, audit activities, including findings and remediation actions, are summarized by the QAM for dissemination to the laboratory's CODIS Custodian, the NYS Commission on Forensic Science, ANAB, or the board members of the National DNA Indexing System (NDIS) (as applicable).

5.1.6.7.2 Findings and remediation actions are sent to accrediting bodies and the general laboratory via email.

5.1.6.7.3 If audit non-conformances 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.

5.1.6.8 Audit reports and affiliated auditing documents, including a summary of audit results and remediations 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.

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

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

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

6.2.3 Documented completion of ISO/IEC 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.

8 Annual Review of the Laboratory's Quality System

8.1 An annual review (calendar year) of the quality system is important for ensuring that measures are being taken by the laboratory to continually provide the highest quality of service. The annual review is intended to identify areas in need of attention and provide the basis for any potential changes to the quality system.

8.2 The annual review of the laboratory's quality system is performed under the direction of the

technical leader(s) and the completion of the review is documented and approved by the technical leader(s).

8.3 The review of all quality system documents that are updated or revised in the calendar year is exempt from this additional annual review, as that review is addressed in the yearly Management System review.

8.4 This annual review of the quality system is independent of internal and external audits

8.5 A case file review, including a sampling of cases that include DNA database analysis, must be conducted as part of the annual quality system review in order to evaluate the products of forensic DNA analysis. The scope of the review must be defined and approved by the technical leader and address both the representative sample and the time period of the case files under review. For example, the time period may include case files from the previous calendar year or for a specified period of time. The technical leader will determine what will be used as the representative sample for the annual review, and the representative sample may vary from year to year. The technical leader may select the sampling based on corrective actions, perceived analytical gaps, and/or at random. The sampling may be based on a percentage or a specified number of cases. Additionally, the representative sample may be selected based on the forensic samples tested, technology, conclusions reported, complexity of the typing results, or cases where testimony has occurred and transcripts were available for review. As examples, a representative sample may be a percentage of all sexual assault cases, a percentage of all YSTR cases, a specific number of random cases from each analyst, or a specific number of complex mixture cases.

8.6 This annual review of case records cannot be used to replace the review of case records that occurs during internal and external audits or the technical review process.