Purpose

The purpose of this procedure is 1) to describe the internal and external audits used to assess the Biology/DNA Division technical activities and quality system and 2) to describe the process of the annual Management Review.

Scope

This SOP applies to all technical personnel at LSDFC.

Guidelines & Requirements

- ISO/IEC 17025: 2017 (E) Standards
- R104 - A2LA General Requirements – ISO/IEC 17025:2017 Accreditation of Field Testing and Field Calibration Laboratories
- P113- A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies (CABs)
- P102a – A2LA Policy on Metrological Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies for all Calibrations and Verifications of Measurement and Test Equipment
- AABB's Guidelines "Guidance for Standards for Relationship Testing Laboratories", 12th Edition.

Reagents/Materials/Equipment

Management & Technical Systems of LSD&FC

Procedure

1. LSDFC shall conduct systematic internal audits to 1) monitor and determine compliance with the requirements of the Quality System and Standards and 2) to evaluate the technical activities and work product of employees

2. ***External Audits*** are under the control of, and performed by, an auditing body external to LSD&FC.

3. ***Internal Audit*** are under the control of LSD&FC and conducted by qualified and trained auditors employed at LSD&FC. At least one person independent of the section being audited shall participate in the audit.

4. The management system at LSD&FC is designed to conform to the following sets of standards:

   a. ISO/IEC 17025:2017
   b. A2LA Supplemental Requirements to ISO/IEC 17025:2017
   c. AABB Standards for Relationship Testing Laboratories
   d. Supplemental Requirements to the above listed standards

External Audits: Forensic & Databasing

1. LSD&FC is subject to external accreditation assessments/surveillance visits as required by A2LA.
2. Assessment scheduling and the assessment process are the responsibility of A2LA.
3. The audit must be conducted with the ISO/IEC 17025:2017 and A2LA Supplemental Requirements
4. A Qualified Auditor is a current or previously qualified DNA analyst and is a certified ISO/IEC 17025 Auditor.
5. The audit document and any non-conformities identified during the audit are submitted to the Section Director, the Quality Manager, and the Center Director for review and for approval of proposed follow-up actions.
6. The laboratory retains the following records from external DNA audits for a period of five years or a full accreditation cycle:

   a. Audit reports
   b. Any corrective and preventive actions

7. An external audit outside of normal accreditation schedule may be required in unique situations.
8. The results of the audit and any corrective and preventive actions shall be included in the annual management review.
9. The Quality Manager shall be the point of contact with the accrediting body.
10. Upon notice by the accrediting body, the Quality Manager shall notify the Center Director of all external audits.

External Audits: Relationship Testing

1. LSD&FC is subject to external accreditation assessments/surveillance visits as required by AABB (formerly American Association of Blood Banks).
2. Assessment scheduling and the assessment process are the responsibility of AABB.
3. An external DNA audit to ensure the conformance with the Standards for Relationship Testing Laboratories is conducted at least once every two (2) calendar years.
4. The audit must be conducted with the edition of the Standards for Relationship Testing Laboratories in effect at the time of the audit.

5. The audit document and any non-conformities identified during the audit are submitted to the Quality Manager, Section Director and Center Director for review and for approval of proposed follow-up actions.
6. Corrective and/or preventive actions shall be implemented to address any deviations or nonconformities discovered within the audit.
7. Follow-up action shall document the implementation and effectiveness of the corrective and preventive action.
8. The results of the audit and any corrective and preventive actions shall be part of the annual management review.
9. The laboratory retains the following records from external DNA audits for a period of five years or a full accreditation cycle:
    a. Audit reports
    b. Any corrective and preventive actions
10. The Quality Manager shall be the point of contact with the accrediting body.
11. Upon notice by the accrediting body, the Quality Manager shall notify the Center Director of all external audits.

Internal Audits

1. The internal audit program is a critical component of the management system at LSD&FC. It is designed to ensure that the management system is functioning correctly and that the Biology/DNA Division is operating in compliance with its own procedures as well as accreditation requirements.
2. The internal audit program evaluates the laboratory's conformance with respect to the management system, including the testing activities, and with the ISO/IEC 17025:2017 and any Supplemental requirements.

Internal Audit Schedule and Procedure

1. The Quality Manager is responsible for scheduling and planning the internal audits of the laboratory.
2. Scheduling is done in consultation with the Section Director.
3. The Quality Manager will take into consideration the schedule and availability of laboratory staff prior to agreeing to a date.
4. Audits are generally scheduled in the fourth quarter of the year.
5. The Quality Manager selects auditors to ensure that an audit team is qualified as per the requirements for each type of audit.
6. The Quality Manager develops an audit plan that, at a minimum, contains the audit schedule, the activities to be audited, and personnel assigned to audit the specified activities.
7. The general process for any internal audit is as follows:
    a. The Quality Manager notifies the laboratory that an internal audit will be conducted, the general scope of the audit, and provides an approximate timeframe.

b. The Quality Manager schedules an opening conference with the auditors to discuss the audit objectives, assignments, timing, and report format and distribution.
c. For an internal audit covering all section activities and quality system, the audit team shall use the A2LA C025 Checklist: ISO/IEC 17025:2017 Laboratory Accreditation Program and the A2LA C221 (2017) – Specific Checklist: Forensic Examination Accreditation Program Testing.
d. A modified checklist may be used if an audit covers a specific criteria or section. These audits may be required as a follow-up to determine the effectiveness of a corrective action but shall not be used in lieu of a full-scope audit.
e. The audit teams provide the Quality Manager with their audit findings, including potential non-conformities and observations.
f. The Quality Manager 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. They can be corrected on-the-spot prior to the completion of the audit. The correction is documented in the audit records, but is not included in the final audit report.
g. The Quality Manager, Section Director and Center Director shall review the audit results submitted by the audit teams and verify if the findings are true non-conformities supported by objective evidence.
h. The Quality Manager finalizes the audit report and notifies the appropriate LSD&FC personnel.
i. Any non-conformities identified in the audit report shall be evaluated and corrective action or preventive action initiated.
j. 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.
k. The internal audit assessment report, findings and follow-up documentation will be retained for a period of 5 years or a full accreditation cycle.

Auditor Qualification

1. Auditors are qualified in any of the following ways:

a. Documented completion of an ISO/IEC assessor training course.
b. Auditors are qualified to conduct DNA audits if they have successfully completed an FBI-sponsored DNA Auditing Workshop/Course.
c. The DNA audit team must include 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 or YSTR*) 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.
d. 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.

Assessments: Management Review

1. Management Review shall be performed annually after all annual internal audits have been completed.
2. The Management Review is a planned activity that assesses the LSD&FC Quality Management System and Operational Activities, and determines if it meets the standards set by the Center and ISO 17025. This review also serves as a guide for future determinations regarding the effectiveness and potential improvements of the Quality System.
3. The Center Director plans, schedules, and leads the Management Review
4. The Quality Manager shall provide any needed information and/or records for the review.
5. Top Management shall participate in this review. Top Management is defined as:
   - The Center Director
   - The Business Manager
   - The ICT Director
   - Section Director(s)
   - Section Quality Manager(s)
   - Section Technical Leader(s)

6. The management review shall include, but not be limited to, the following:
   - suitability of policies and procedures;
   - fulfilment of overall objectives of the management system;
   - outcome of internal audit(s) and external assessments performed during the year;
   - corrective and preventive actions undertaken during the year;
   - incident reports;
   - status of actions from previous management reviews;
   - feedback from customers;
   - complaints from customers and employees;
   - recommendations for improvements and effectiveness of any implemented improvements;
   - adequacy of resources;
   - changes in volume and type of work;

- personnel training;
- outcomes of the assurance of the validity of results;
- results of risks identification and opportunities for improvement;
- review of subcontractors and suppliers;
- evaluation of new suppliers or service providers;
- health and safety program.

7. The Management Review report, findings and follow-up documentation will be retained for a period of 5 years or a full accreditation cycle.

Procedure History

Procedure History			
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Shelley Johnson		September 1, 2017	
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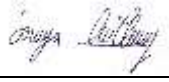
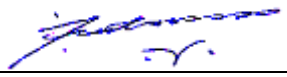
11/29/2018		***Soraya McClung, MFS Director, DNA Technical Leader***	
11/29/2018		***Richard I. Somiari, PhD Center Director***	
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11/29/2018	Updated Guidelines & Requirements Updated qualifications of internal auditor Updated Footer	Soraya McClung	v1.0
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