A. **PURPOSE**:

Laboratory Audits are utilized as a tool to determine the effectiveness of the Quality system and overall Management System and thereby to identify needed or potential improvements to the systems. This process is used to verify that all Laboratory operations are in compliance with the Management System, and the ASCLD/LAB International Standard. Additionally for the DNA section, that FBI Quality Assurance Standards are met. These internal audits address all elements of the Management System.

Beyond internal audits the DSS laboratories are subject to audits by the accrediting body (ASCLD/LAB International). The DNA laboratory is also audited to the FBI Quality Assurance Standards Audit standards on an biennial basis.

B. **RESPONSIBILITY**:

Top Management: will support the Quality Section in performing annual audits and in making improvements to the Quality and Management systems as deficiencies or opportunities for improvement are identified. Top management will continue to support travel and education to external auditor training courses as funds are available.

Quality Manager (QM): is responsible to schedule internal audits (with the exception of the DNA section) and to work to lead the audit teams through the audit process. The QM is also responsible to review the individual section audits and write the final audit documents to present to top management.

Assistant Quality Manager: the AQM is responsible to work with the QM to perform the annual internal quality audit of all Laboratory sections. Each section will be audited by the internal audit team. The team shall be composed of laboratory personnel who have attended ISO, ASCLD/LAB Legacy or International or DAB audit training (or other ISO audit preparatory courses). Additional lab personnel must be trained internally by a member of the Quality Section and deemed qualified before participating in an internal audit. Every attempt will be made to assign audit teams so that they are independent of the activity being audited.

DNA Technical Leader: is responsible to work with laboratory management to schedule/approve all DNA internal and external audits. The Technical Leader will assure that audit teams (internal and external) meet the requirements of the FBI QAS document.

Audit Team Members: Members are to perform audits in an unbiased manner, per the direction of the QM and this SOP.

C. **PROCEDURE**:

1. Internal Audits:

a. Audits of the Management System will be conducted no less than once annually under the direction of the QM. In general the Quality Manager and Assistant Quality Manager will perform audits. The QM may utilize other individuals to assist in this function depending on need. ~~The QM will identify employees who have had audit training to be Audit team members.~~ Every attempt will be made to assure that Audits ~~teams will consist of individuals that~~ are performed by those independent of the activities of the specific laboratory being audited. The QM with key management will review all suspected non-conformities to determine if they are truly non-conformities or rarely occurring instances. Items identified as true non-conformities will be followed up using the QAR procedure. Note that items identified during the audit process may require follow up but the follow-up may not rise to the level of a QAR.

b. The Quality Section, as appropriate, will:

   i. Schedule audits annually to assure that they are completed by the anniversary date of the ASCLD/LAB accreditation (no sooner than 10 months from prior internal audit unless deemed necessary). Audits performed throughout the year may be used as components to the Annual Internal Audit. Generally audits will be performed continuously throughout the year the documentation of each will be used to compile a full annual audit.

   ii. Identify members of the staff that qualify as Audit team members, when audit teams are used.

   iii. ~~Form Audit teams to~~ Assure each aspect of the Management system is audited.

   iv. Identify (through the audit teams) system deficiencies and assign QARs as required for the deficiencies.

      (a) For non-conformities relating to General Laboratory SOPs the QM will work with Key Management to resolve/improve the issue

      (b) For non-conformities relating to specific laboratories the Quality Section will work with the section supervisor or lead to resolve/improve the issue.

   v. Prepare a final Audit report and any required documentation for ASCLD/LAB International. Note that the annual audit will assure that the laboratory is in compliance with the current ASCLD/LAB *International* program (that which is in affect at the time of the audit). The Audit report may include:

      (a) The management system review of all elements

      (b) A list of case numbers from the cases submitted for review by each examiner

      (c) Problems or deficiencies noted, and recommendations for addressing them

      (d) Record(s), Quality Action Request (QAR), of the actions taken for any non-conformities during the audit year

(e) ~~A completed copy of~~ The ASCLD/LAB *International* 2011 Field Assessment Guide for Testing Laboratories may be used in its entirety or in portions to assist in the audit documentation.

vi. The QM will work with Key Management to finalize the audit, follow through on any QARs performed as a result of the audit and work to file the audit documentation with ASCLD/LAB International.

(a) Not all items suggested from the annual audit will require QARs. When an issue is identified that is in conflict with ASCLD/LAB International policy or the Divisions own policy a QAR will be required.

vii. The QM will maintain a copy of the Audit report and supporting documentation for not less than 10 years.

c. Audit Teams (when used):

i. Whenever possible Audit teams will consist of employees who:

(a) Have audit training

(b) Are independent of the activities of the specific laboratory being audited

ii. Teams will be formed to audit:

(a) Management system procedure adherence including:

(i) Management issues

(ii) Document Control

(iii) Review of Requests, tenders and contracts

(iv) Purchasing

(v) Service to customers

(vi) Complaints

(vii) Control of non-conforming tests

(viii) QARs (Corrective actions/Improvements/Preventive Actions and monitoring/follow through)

(ix) Record Control

(x) Audits

(xi) Management Reviews

(b) Individual Laboratories adherence to appropriate SOPs including the following:

(i) Technical Records

(ii) Personnel Qualifications

(iii) Competency Tests

(iv) Accommodations and Environmental Conditions

(v) Methods (selection/validation/non-standard)

(vi) Uncertainty of measurement

(vii) Data control

(viii) Instrumentation/Equipment

(ix) Traceability

(x) Testing (reference materials/standards/sampling)

(xi) Evidence handling

(xii) Quality Assurance

(xiii) Reporting (Reports/Report Amendments)

iii. Teams, when used, will utilize this SOP ~~and associated appendixes~~ to assure that needed guidelines are followed. The QM may wish to develop audit checklists to use as guidance in performing and documenting internal audits.

iv. ~~Review a minimum of 2 cases per analyst per discipline to assure adherence to section SOPs.~~

v. ~~Assist in the completion of the ASCLD/LAB International Field Assessment Guide~~

2. External Audits:

a. All DSS Laboratories:

i. ASCLD/LAB *International* will perform ~~an annual~~ surveillance visits and a full audit ~~every five years~~ based on the criteria of the ASCLD/LAB International accreditation program requirements (ISO/IEC:17025 and the Supplemental Requirements). ~~for the International program.~~ These audits will be performed by assessors designated by ASCLD/LAB.

ii. If non-conformities are identified during any audit or surveillance visit the QM will work with Key Management to address the issues and satisfy the requirements of ASCLD/LAB.

b. DNA Laboratories:

i. The DNA laboratories (Nuclear, Database and Mitochondrial) will receive an external audit once every two years (at minimum) to the FBI /QAS standards. The DNA technical lead and section QM will work together to ensure that the records needed for the external audit are provided per the requirements of the auditors. The TL will work with laboratory management to identify an appropriate external audit team/organization based on the criteria of the FBI QAS document.

(a) Top management may choose to require external audits more frequently bases on the needs of the Laboratory.

(b) The DNA TL (or designee) will maintain the original audit documents for a period of no less than 10 years. The DNA TL may designate the Quality Section as the keeper of the original audit documentation.

(c) The Division Quality Manager will maintain a copy of the audit documents (or the original if the TL designates this) for a period of no less than 10 years.

ii. An internal audit of the DNA laboratories (DNA Nuclear, Database and mtDNA) will be performed annually. The DNA TL is responsible to direct the performance of the audit. Where allowed by the FBI QAS program the TL can utilize employees trained in the QAS audit process to perform the audit, other audit trained individuals can be used for specific audit tasks if required by the TL.

(a) The audit will include a review of all section SOPs and all work instructions.

(b) To document the audit, the FBI QAS audit document will be completed by the TL.

(c) Upon completion of the audit the TL, Quality Section and Director will meet to review the audit.

(d) The DNA TL (or designee) will maintain the original audit documents for a period of no less than 10 years. A copy will be filed with the MQ.

(e) The Quality Manager will maintain a copy of the audit documents for a period of no less than 10 years.

iii. If issues are identified during an audit (internal or external) the Technical lead will work with the Quality Section to satisfy the requirements of the audit. Any issues that are identified that demonstrate non-compliance to a specific criteria will require documentation using the QAR process. The Director and QM will be informed of all remediation that are required when they are discovered.

3. Audits of Reference Collections and Evidence Receiving:

a. Controlled Substances: The Controlled Substance Laboratory maintains a collection of drug standards for use as reference materials for unknown identification. These are maintained in a safe and a locked refrigerator within the section. An audit of the drug standards will be

performed every year. This audit is to assure that all substances are accounted for, at the expected quantity. The audit guidelines for this are outlined in SOP CS-11 'Storage and Use of Controlled Substance Standards'. This audit will be performed by 2 individuals working as witness for each other. Documentation of this audit will be maintained for no less than 10 years. Note that to maintain a Federal Drug license an audit is required every two years, laboratory management requires this to be performed annually. The audit will be performed so that one analyst from the Controlled Substance section and one employee from another section perform the audit.

b. Firearms: The Firearms Laboratory maintains a collection of guns for use as references when analyzing case submissions. The reference guns will be audited every year to account for all the weapons. A current inventory of reference guns is maintained on the "T" drive within he Firearms section. This audit will be performed by 2 individuals working as witness for each other. Documentation of each audit will be maintained by the section for no less than 10 years. The audit will be arranged so that one analyst from the Firearms section and one employee from another section perform the audit. The section Supervisor will report the outcome of the audit to the Deputy Director through email or memo. Any identified problems will be investigated accordingly.

c. Evidence Receiving Storage: Evidence stored in the Evidence Receiving storage area will be audited every year. This will be performed by 2 individuals working as witness for each other. The audit will be arranged so that one ECO for the ER section and a second employees from a separate section perform the audit. Documentation of the audit will be maintained by the Quality Section for no less than 10 years.

During an audit if a discrepancy is found it must be reported to the section Supervisor who is responsible to report it to the appropriate Deputy Director and the Quality Section. The Quality Section will aid in documenting the remediation if required.



D. **REFERENCES**:

1. ASCLD/LAB *International* 2011 Field Assessment Guide for Testing Laboratories
2. ISO/IEC 17025:2005
3. DNA Advisory Board Standards