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 Division of Scientific Services operations are in compliance with the Management System, and the ASCLD/LAB International Standard. Additionally for the DNA Unit, that FBI Quality Assurance Standards are met. These internal audits address all elements of the Management System.

Beyond internal audits, the DSS laboratory is subject to audits by the accrediting body (ASCLD/LAB International). The DNA laboratory is also externally audited to the FBI DNA Quality Assurance Standards (QAS).

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.

Assistant Director: will aid in the support of annual audits and in making improvements to the Quality and Management systems as deficiencies or opportunities for improvement are identified.

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

FB/DNA Quality Assurance Manager (or AQM): the AQM is responsible to work with the QM to perform the annual internal quality audit of all DSS Units. Each Unit 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 FBI DNA QAS audit training (or other ISO audit preparatory courses). Any 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 ensure that audit teams (internal and external) meet the requirements of the FBI DNA 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 Assurance Manager and FB/DNA Quality Assurance Manager will perform audits. The QM may utilize other individuals to assist in this function depending on need. Every attempt will be made to ensure that audits are performed by those independent of the activities of the specific Unit 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 ensure 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 and 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. Ensure each aspect of the Management system is audited.

      iv. Identify 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 Units the Quality Section will work with the Deputy Director (or their designee) to resolve/improve the issue.

      v. Prepare an Audit report and any required documentation. Note that the annual audit will ensure 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 be in the form of a summary document and the notes and/or other documents created during the audit will be maintained in support of the summary document.

      vi. The Audit report should include:

         (a) Documentation of the review of management system elements.

(b) Cases reviewed per Unit.

(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) 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.

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

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.

viii. 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 Units 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 to ensure that needed guidelines are followed. The QM may wish to develop audit checklists to use as guidance in performing and documenting internal audits.

2. External Audits:

a. For the Division of Scientific Services:

i. ASCLD/LAB *International* will perform surveillance visits and a full audit based on the criteria of the ASCLD/LAB International accreditation program requirements (ISO/IEC:17025 and the ASCLD/LAB Supplemental Requirements). 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 the DSS management System and ASCLD/LAB.

3. DNA Unit: An audit of the DNA Unit will be performed annually, this may be either internal or external (refer to DNA Unit specific SOPs) this will meet the requirements of the FBI DNA QAS.

   a. The DNA Unit (Casework and Database) will receive an external audit once every two years (at minimum) to the respective FBI DNA QAS. The DNA Technical Leader and the FB/DNA Quality Assurance Manager will work together to ensure that the records needed for the external audit are provided per the requirements of the auditors. The DNA TL will work with laboratory management to identify an appropriate external audit team/organization based on the criteria of the FBI DNA QAS document.

      (a) Top Management may choose to require external audits more frequently based 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. The TL will review and document the review of the external audit documents and if applicable, approve corrective actions.

   i. When an internal audit of the DNA Unit (Casework and Database) is to be performed, the DNA TL is responsible to direct the performance of the audit. At minimum, an internal DNA Unit audit will be performed in years that no External DNA Unit audit is performed. Where allowed by the FBI DNA QAS, the TL can utilize employees trained in the DNA 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 Unit SOPs and all work instructions.

      (c) To document the audit, the current FBI DNA QAS audit document will be completed by the TL (or designee). The TL will review and document the review of the internal audit documents and if applicable, approve corrective actions.

      (b) Upon completion of the audit the TL, Quality Section and others as appropriate will review the audit; if necessary they will meet to review remediation.

      (c) 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.

   ii. If issues are identified during an audit (internal or external) the Technical Leader 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/AQM will be informed of all remediation that are required when they are discovered.

4. Audits of Reference Collections and Evidence Receiving:

a. Controlled Substances: The Controlled Substance Unit 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 ensure 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 witnesses 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, however, laboratory management requires this to be performed annually. The audit will be performed so that one analyst from the Controlled Substance Unit and one employee from another Unit perform the audit.

b. Firearms: The Firearms Unit maintains a collection of firearms. This reference collection will be audited every year to account for all the firearms in the collection. The Firearms Unit maintains a database for the Firearms collection. This audit will be performed by 2 individuals working as witnesses for each other. Documentation of each audit will be maintained by the Unit for no less than 10 years. The audit will be arranged so that one analyst from the Firearms Unit and one employee from another Unit perform the audit. The Unit Lead will report the outcome of the audit to the Deputy Director through email or memo. Any identified problems will be investigated accordingly. A copy of the audit findings will be forwarded to the Quality Section for storage.

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 witnesses for each other. The audit will be arranged so that one ECO and a second employee from a separate unit or 2 employees not assigned to ER will 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 Unit Lead 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 Quality Assurance Standards