

## DOM06 – Practices for Internal/External Audits and Reviews

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### 1. Background

- 1.1 The Department of Forensic Sciences (DFS) will periodically conduct internal audits and management reviews in accordance with a predetermined schedule documented on the DFS Quality calendar. DFS will also submit to audits, assessments, and/or inspections administered by external organizations to assure ongoing compliance with accreditation requirements in accordance within an appropriate/agreed upon timescale.
- 1.2 Periodic audits and reviews are used to evaluate and continually improve the effectiveness of the management system through the use of the quality policy, quality objectives, audit results, analysis of data, quality corrective and preventive actions, and management review of the DFS division entities, specifically Crime Scene Sciences (CSS), the Forensic Science Laboratory (FSL), and the Public Health Laboratory (PHL). External audits assure compliance with the appropriate industry standards, as well as department policies and procedures. Internal audits verify that operations conform to the requirements of the Division Quality Assurance Manuals and the accreditation standards under ISO/IEC 17025:2005 and supplemental standards.
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### 2. Definitions

- 2.1 For purposes of this document, the following terms shall have the designated meanings:

**CSS:** Crime Scene Sciences

**DFS:** Department of Forensic Sciences

**DOM:** Departmental Operation Manual

**FSL:** Forensic Sciences Laboratory

**PHL:** Public Health Laboratory

**SOP:** Standard Operation Procedures

### 3. Scope

- 3.1 These practices are applicable to the internal audit program and management reviews performed in the DFS. They involve all elements of the management system and testing activities to verify that operations continue to comply with DFS requirements and the International Standard, to ensure continued suitability and effectiveness, and to introduce necessary changes to improvements.
- 3.2 The internal audit program will address all elements of the management system including testing activities. This will be achieved through annual assessments of all elements of the management system, operations affecting quality, quality system requirements, internal quality policies and procedures, standard operating procedures, records, equipment, and facilities by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited.
  - 3.2.1 Findings from internal audits and actions that arise from them will be recorded and carried out within an appropriate/agreed timescale.
- 3.3 The management reviews with top management will include an annual account of the suitability of policies and procedures, reports from managerial and supervisory personnel, the outcome of recent internal audits, quality corrective and preventive actions, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, changes in the volume and type of the work, client feedback, complaints, recommendations for improvement and other relevant factors, such as quality control activities, resources and staff training.
  - 3.3.1 Findings from management reviews and actions that arise from them will be recorded and carried out within an appropriate/agreed timescale.
- 3.4 The external audit program will address those criteria specified by the organization conducting the audit, assessment or inspection. Typically, a representative sampling of elements of the management system, including testing activities, are reviewed during external audits. This is achieved through assessments of elements of the management system, operations affecting quality, quality system requirements, internal quality policies and

procedures, standard operations procedures, records, equipment, and facilities by trained/qualified personnel who are independent of the DFS.

3.4.1 Findings from external audits and actions that arise from them will be recorded and carried out within an appropriate/agreed timescale.

## 4. Responsibilities

4.1 The Laboratory Manager will:

4.1.1 Approve all audit reports before they are issued.

4.1.2 Receive responses to all external audit reports.

4.1.3 Implement quality corrective action procedures when nonconformity is identified through an audit.

4.1.4 Submit an Annual Accreditation Audit Report to applicable ISO/IEC 17025 accreditation vendor and/or other certifying body within thirty (30) calendar days following the applicable laboratory's accreditation and/or certification anniversary date.

4.2 The Lead Auditor(s) will:

4.2.1 Prepare and organize an audit schedule.

4.2.2 Read the standards and understand the requirements that are being covered in the audit.

4.2.3 Ensure that trained/qualified auditors are selected, as necessary.

4.2.4 Provide training and instruction to auditors, as needed.

4.2.5 Coordinate audit activities of the assigned auditors and DFS Division managers to accomplish the portion of the audit as assigned.

4.2.6 Conduct pre-audit conference with the audit team selected.

4.2.7 Collect audit data through reviewing documentation, interviewing personnel, observing operations and observing conditions and facilities.

4.2.8 Receive team responses and ensure an audit report is prepared for every audit conducted.

4.2.9 Ensure a post-audit conference is conducted.

4.2.10 Implement corrective action procedures in accordance with DOM07 Practices for Quality Corrective Actions and/or preventive action procedures in accordance with DOM08 Practices for Preventive Actions with the guidance of the Deputy Director of Quality or Division Quality Assurance Liaison as needed.

4.2.11 Write the Summary and Findings audit report.

4.2.12 Provide a completed checklist and supporting materials.

4.2.13 Ensure audit activities are documented on the Internal Audit Lead Auditor Checklist, the Internal Audit Observation Form, and a Summary and Findings Report, and provide a copy to the Deputy Director of Quality.

4.2.14 Close out the audit, when appropriate.

4.3 The Division Quality Assurance Specialist or designee will:

4.3.1 Ensure that an audit schedule is prepared.

4.3.2 Ensure that audits are organized and conducted as required by the schedule and requested by management.

4.3.3 Implement quality corrective action procedures when nonconformity is identified through an audit.

4.3.4 Ensure that the audit reports are presented to the appropriate management personnel.

4.3.5 Retain appropriate documents generated from audit for appropriate time periods as dictated.

4.3.6 Ensure external audits are conducted in the time and manner required.

4.4 The Deputy Director of Quality will:

4.4.1 Ensure the DFS Quality calendar is updated to reflect the periodic internal audits and management reviews for the Agency.

4.4.2 Select the Lead Auditor(s) and provide a list of certified ISO/IEC 17025 trained/qualified personnel who are eligible to serve on the audit team.

4.4.3 Track the audit schedule and monitor the progress of all audits and reviews to ensure compliance with DFS requirements and International Standards.

4.4.4 Schedule, organize, and conduct annual management reviews with top management.

4.4.5 Document findings from annual management reviews and actions that arise from them.

4.4.6 Initiate quality corrective and/or preventive actions as needed pursuant to annual management reviews.

4.4.7 Retain a copy of all internal and external audit and annual management review documents.

## 5. Practices

### 5.1 External audits or Inspections

5.1.1 A yearly internal audit of all Divisions will be conducted. Every other year, an external audit of the FSL Forensic Biology Unit (FBU) must be conducted by qualified auditors. External audits of the appropriate Division's Quality system shall follow the schedule determined by the contracted ISO/IEC 17025 accreditation vendor and/or certifying body.

5.1.2 For the FSL, the auditor(s) will assess the quality system requirements against the ISO/IEC 17025:2005 standards and supplemental guidelines.

5.1.2.1 For the FSL FBU, the auditor(s) will assess the quality system requirements and the DNA testing process utilizing the FBI Quality Assurance Standards (QAS) Audit for Forensic DNA Testing Laboratories document and the ISO/IEC 17025:2005 standards and supplemental guidelines to ensure compliance.

5.1.2.2 At a minimum, every other year an external audit of the FSL FBU must be conducted by qualified auditors using the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document.

5.1.3 External audits or inspections relating to licensing, certifications or accreditation will be conducted in accordance to the standards set forth by the respective licensing, certifying or accreditation agencies.

5.1.4 Quality corrective and preventive actions regarding any finding/nonconformance will be taken in accordance with the appropriate procedure and, when required, a report/nonconformance response will be sent to the external auditor or to the agency within the specified time.

5.1.4.1 Whenever an external DNA QAS audit is conducted, the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document along with the laboratory responses must be submitted to the FBI within thirty (30) days of receipt of the completed audit document from the external audit team. Review of this document under the direction and documented approval of the FBU Manager/Technical Leader prior to submission to the FBI is required.

5.1.5 If appropriate quality corrective and preventive actions could not be completed within the specified time, the external auditor or agency

will be notified in writing and an extension date will be requested to complete the corrective actions.

## 5.2 Internal Audits

5.2.1 Internal Audits of the entire laboratory shall be conducted at least once per calendar year. These audits may include, but are not limited to security, unit quality manuals and standard operating procedures (SOPs), evidence tracking and proper seal, training records, instrument calibration and maintenance, case files, court testimony monitoring and proficiency testing. Additionally, periodic laboratory inspections of selected areas may be conducted at the discretion of management.

### 5.2.2 Scheduling the Audits

5.2.2.1 Throughout the year, the Deputy Director of Quality will ensure the appropriate Division Director and Quality personnel are notified to schedule audits in accordance with the DFS Quality calendar and contact appropriate management to determine a mutually agreeable date(s) for the audit(s).

### 5.2.3 Preparation

5.2.3.1 The Laboratory Manager or Quality Assurance Liaison may serve as the Lead Auditor or may select an auditor when necessary based on the magnitude of the audit. The Lead Auditor may select others, as needed, with appropriate qualifications to assist in performing the audit. Additionally, the Lead Auditor will furnish any assistants with the appropriate training, instructions, guidance, and materials so that they can prepare and conduct the audit.

5.2.3.2 The Lead Auditor will ensure that a checklist is prepared. This list may include interview questions and should be organized in such a way as to prompt the auditor(s) to observe operations and review necessary documentation.

5.2.3.3 The auditors should read and familiarize themselves with the audit checklist as well as any additional documents containing requirements for which conformance is being audited.

5.2.3.3.1 The FSL FBU's DNA processes will also be assessed by qualified auditors against the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document during internal audits.

- 5.2.3.4 The Lead Auditor will inform the appropriate manager(s) of the date and time of the audit(s) and the Deputy Director of Quality.
- 5.2.4 Conducting the Audit
  - 5.2.4.1 The Lead Auditor should conduct a pre-audit conference with the unit to introduce the auditor(s), explain the scope of the audit, and establish the times for future meeting(s), as needed. The pre-audit conference may be conducted in person, by email or by telephone.
  - 5.2.4.2 The auditor(s) will, as necessary, review documentation, interview personnel, and observe operations, conditions, and facilities to collect data on conformance with requirements and effectiveness of quality control measures. The audit checklist, and additional sheets of paper, as necessary, will be used to record the audit data.
    - 5.2.4.2.1 The qualified auditors conducting the audit of the FSL FBU will also complete the FBU Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document.
  - 5.2.4.3 If necessary, the audit team will meet to review the progress of the audit and any issues that need to be discussed.
  - 5.2.4.4 The Lead Auditor will conduct a post-audit conference to inform the unit of the preliminary audit data. This conference should be held as soon as possible following the audit. The unit should inform the Lead Auditor of any disagreements that s/he has with the preliminary data. These issues will be considered by the Lead Auditor and, if possible, resolved before the audit report is written. The post-audit conference may be conducted in person, by email or by telephone.
- 5.2.5 Internal Audit Report
  - 5.2.5.1 The Lead Auditor will write an audit report for every audit conducted to formally notify the unit and management of the audit results. An audit report will include any proficiencies and nonconformities. If the unit satisfactorily corrects a nonconformity before the audit report is issued, that nonconformity will not be included as a finding in the audit report [DOM07 – Practices for Quality Corrective Action].

- 5.2.5.2 The audit report is approved by the Laboratory Manager and issued by the Lead Auditor. The approval and issuance are documented on the audit report by their respective signatures and dates.
- 5.2.5.3 If an audit report contains one or more nonconformities, a Quality Corrective Action Report will be attached for each nonconformity. If the audit report identifies needed improvements and/or potential sources of nonconformity, a Quality Preventive Action Request will be attached.
- 5.2.5.4 Copies of the audit report will be provided to the Laboratory Manager and Deputy Director of Quality.
  - 5.2.5.4.1 Following review under the direction and documented approval of the FBU Manager/Technical Leader, the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document with responses will be maintained in the FSL.
- 5.2.6 Responding to the Audit Report
  - 5.2.6.1 The unit will acknowledge receipt of the audit report by signing and dating the report where designated and returning the original report to the Lead Auditor.
  - 5.2.6.2 If a Quality Corrective or Preventive Action Report is made, it must be completed and returned to management for approval. For instructions on completing these forms and remediation procedures see the appropriate DOM07 or DOM08 sections.
- 5.2.7 Nonconformities
  - 5.2.7.1 The unit staff will each receive a copy of the approved and verified Quality Corrective Action Report(s) from the Lead Auditor when all nonconformities for that audit have been adequately remediated. When all nonconformities associated with the entire audit are remediated and all associated Quality Corrective and Preventive Action Reports are closed out, that audit will be closed.
- 5.2.8 Audit Closure Memo
  - 5.2.8.1 If there are follow-up audit activities, the verification implementation and effectiveness of the corrective action taken shall be recorded in the Audit Closure Memo.
  - 5.2.8.2 The unit staff will each receive an audit closure memo from the Lead Auditor to inform him/her that the audit is closed. An audit is considered closed when each of the

unit staff has acknowledged receipt of the audit report and all nonconformities have been addressed.

### 5.3 Accreditation Annual Report

- 5.3.1 Management (to include at a minimum, the Laboratory Manager and Quality Assurance Specialist/Liaison) will annually review the accreditation inspection checklist. Any area(s) of noncompliance will be noted as NO on the checklist and appropriate action(s) to be taken will be reported to the accrediting body. The Laboratory manager will submit the written report to the accrediting body within thirty (30) calendar days following the laboratory's accreditation anniversary date and to the Deputy Director of Quality.
- 5.3.2 Final audit reports summarizing the prior year's internal and/or external audits will be provided to the Laboratory Manager, the Deputy Director of Quality and the accrediting body, as necessary.

## 6. Documentation

- 6.1 The following records will be generated as a result of these practices. Originals will be retained by each Division, with electronic copies provided to the Deputy Director of Quality.
  - 6.1.1 Annual audit schedule will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.
  - 6.1.2 Completed audit checklists will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.
  - 6.1.3 Audit reports and any associated responses will be retained permanently.
  - 6.1.4 When necessary, Quality Corrective Action Reports will be retained according to the requirements in the [DOM07 – Practices for Quality Corrective Action].
  - 6.1.5 When issued, Quality Preventive Action Requests will be retained according to the requirements in the [DOM08 – Practices for Quality Preventive Action].
  - 6.1.6 Audit closure memos will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.
  - 6.1.7 Annual final audit reports will be retained permanently.

## 7. References

- 7.1 ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland (current revision)
- 7.2 ASCLD/LAB-International Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, ND (current revision)
- 7.3 Forensic Quality Services Supplemental Requirements for Forensic Testing, FQS ANSI-ASQ Accreditation Board, Tampa, FL (current revision)
- 7.4 Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation (current revision)
- 7.5 Unit-specific Quality Assurance Manual (current revision)
- 7.6 Division-specific Quality Assurance Manuals (current revision)
- 7.7 DOM07 – Practices for Quality Corrective Action Reports
- 7.8 DOM08 – Practices for Quality Preventive Action Reports