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## 2.3 Laboratory Audits

Auditors shall define all audit findings under one of the following categories:

- Corrective Actions
- Clarification and/or Remediation Required
- Conformance with Comments

The auditor/audit team should discuss his/her preliminary findings with the Laboratory Director and/or laboratory personnel during the audit to allow for immediate remediation of any findings. Prior to the completion of the audit document, the auditor shall discuss his/her findings with the Laboratory Director. The audit document, once completed, shall be forwarded to the Laboratory Director for review and remediation. All audit findings that require remediation shall be addressed by the Laboratory Director either through a Corrective Action workflow or via an internal memorandum. A plan to determine the effectiveness of the remediation efforts shall be included that considers the length of time necessary to conduct the remediation.

### 2.3.1 Scheduled Audits

#### 2.3.1.1 Laboratory Internal/Technical Audits

The laboratory internal audits are comprised of two main areas that include a technical discipline audit and an administrative audit. Annual audits of all laboratories shall be conducted by a team that may consist of one or more Laboratory Directors, Technical Leaders, Unit Supervisors, and/or support personnel. The Assistant Division Director-Quality Assurance Manager shall review the audits as part of the annual Management System review. Each person participating in the audit should have documented training related to auditing including the ISO/IEC 17025:2017 International Standards, ANAB AR 3125 and FBI Quality Assurance Standards, as applicable. The training may be in the form of a formal assessment course offered through external sources or through internal training from another qualified assessor.

Technical Leaders shall ensure a technical discipline audit is conducted during the Laboratory Internal Audits in accordance with the Audit Schedule ([LOM 2.3 Laboratory Audits](#)). Technical Leaders (or designees) that oversee a discipline that is performed at one or more laboratories within FSD shall conduct annual audits in their disciplines and document them on the [FS-31](#). The following categories of testing are affected:

- Biology
- Seized Drugs
- Fire Debris & Explosives
- Materials (Trace)
- Footwear/Tire
- Firearms/Toolmarks
- Friction Ridge
- Toxicology
- Crime Scene Response

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- Bloodstain Pattern Analysis
- Document Examination

The Document Examination discipline should be audited annually by an external assessor. If an external assessor cannot be arranged, an internal audit is acceptable with the approval of the Quality Assurance Manager.

If the Technical Leader conducts casework at their work location, they shall have an alternate (i.e., Unit Supervisor, examiner, or Laboratory Director with experience in that discipline from another laboratory) conduct the review of the Technical Leader's casework. The Technical Leader may conduct the remainder of the audit at their work location.

Discipline audits shall include the review of a sufficient number of cases to allow for the evaluation of the range of cases analyzed (generally 3-4 cases per analyst). The selection of cases for review shall be made by the auditor. The case review shall include the re-examination of the evidence or data from each case when practical. Internal audits shall include direct observation of a sampling of testing within each discipline. Due to the nature of the requests, direct observation of bloodstain pattern analysis and Crime Scene Response activities may occur outside of the formal internal audit activities at the discretion of the Technical Leader. The step of testing selected for direct observation shall be made by the corresponding Technical Leader and documented within the audit documentation. Risks to impartiality shall be considered as the Technical Leader conducts the audit. Risks to impartiality will be addressed through [LOM 2.11 Discrepancies and Corrective Actions](#).

The management portion of the audit shall include a review of the Health & Safety Audit, Property Audits, Corrective Actions, Competency and Authorizations, Building Security, Proficiency Testing Program, and an audit trail per discipline. The audit trail activities shall be documented on the [FS-69](#) form.

Additions to the audit scope are at the discretion of the Quality Assurance Manager and will be documented within an audit plan prior to the audit activity.

A person designated as the lead assessor shall be responsible for the timely collection and organization of the individual FS-31s, FS-69s and auditor notes into a consolidated audit report. The report shall summarize the audit activities, team members, and all audit findings. The audit report shall be provided to the Laboratory Director and posted to the document management site once completed.

#### **2.3.1.1.1 Compliance with QAS**

All Biology Units that perform DNA testing shall be audited once per calendar year, with the interval between audit dates not less than six months and not exceeding 18 months, using the current Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories. Every other year a qualified auditor from an external agency must conduct the audits ("external audit"). The DNA Technical Leader shall direct the audits on the alternate years ("internal audit").

#### **2.3.1.2 Health and Safety**

The Health and Safety Officer shall conduct an annual audit in accordance with the Audit Schedule, LOM 2.3.5, at each laboratory utilizing the [FS-55 Health and Safety Audit](#) form.

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### 2.3.1.3 Property Audits

Laboratory Directors shall ensure a property audit is conducted in accordance with the Audit Schedule, LOM 2.3.5. The Laboratory Director is responsible for taking action to resolve all discrepancies.

### 2.3.1.4 Key/Access Audits

Access to FSD facilities is controlled by the distribution of access media (e.g. keys, access cards, fobs) to authorized personnel, contractors, and visitors, per [LOM 1.7 Facilities and Security](#). Laboratory Directors shall ensure an audit of these media is conducted in accordance with the Audit Schedule, LOM 2.3.5. The Laboratory Director is responsible for taking action to resolve all discrepancies.

### 2.3.1.5 Firearms Reference Collection Audits

Each item in the Firearms Reference Collection shall be labeled with a Forensic Advantage submission label that includes a barcode. An audit of the Firearms Reference Collection utilizing Forensic Advantage shall be conducted annually. The Laboratory Director, or designee, shall be responsible for conducting the audit. The outcome of the audit shall be documented and provided to the MSP Quartermaster upon completion.

### 2.3.1.6 Professional Standards Audits

The Forensic Science Division Assistant Directors (Laboratory Operations Manager and Quality Assurance Manager) shall complete a work site inspection audit as required by the Department's Professional Standards section according to the audit schedule. The work site inspection follows the [FS-61](#) Laboratory Inspection form. The audit includes a review of the Disclosure of Interest and Supplemental Employment forms, as applicable, for evaluation of risks to impartiality of laboratory activities. Risks to impartiality will be addressed through [LOM 2.11 Discrepancies and Corrective Actions](#). Once completed, the audit form is forwarded to the Laboratory Director for any remediations and a written response. The FS-61 and audit response shall be maintained on the Division's document management site.

## 2.3.2 Quality Assurance Randomized Audits (QARA)

### 2.3.2.1 Purpose

The purpose of the QARA is to apply the auditing strategies of the Quality Assurance system to the laboratory casework, specifically targeting parts of the case workflow that are not well covered by existing audits (e.g. discipline audits, annual inspections, annual internal audits, ANAB assessments, etc.). Audits should be focused on ensuring the work was completed in compliance with applicable standards, policies, procedures, methodologies, and accepted practices.

### 2.3.2.2 Personnel Assigned

These audits will be conducted under the direction of the Quality Assurance Manager, typically by the Technical Leader or Unit Supervisor. For audits that include re-examination of evidence, the audit will be conducted only by personnel who are qualified for that examination as required by [QM 5.2.1 Personnel](#).

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## 2.3.2.3 Audit Planning

### 2.3.2.3.1 Frequency of Audits

QARA audits that target an identifiable and consistent risk area should be repeated on a schedule. In most situations, the resource commitment required for a QARA will dictate (and limit) the frequency of the audit. This audit concept is meant to spot-check the execution of procedures and adherence to policies in areas of case workflow not typically covered by other audits; it is an enhancement to the scheduled annual discipline audits conducted by Technical Leaders.

### 2.3.2.3.2 Case Selection

Cases selected for QARA audits may be randomly selected or targeted to address a specific situation. Factors that may be used in the selection of cases/evidence include:

- The availability of the case/evidence
- The impact to the customer/investigation (e.g. delaying the release of reports)
- The suitability of the evidence for additional sampling, handling and/or testing

### 2.3.2.3.3 Audit Areas and Types

The area(s) of focus for the audit will be defined in the audit plan document. Factors that might help determine those area(s) of focus include:

- The potential risk involved in the activity to be audited
- How recently (and the result) the last QARA was conducted in a specific area (e.g. laboratory, assay, evidence type, individual)
- Results of other audits
- Complaints received (either internal or external) which overlap the workflow to be audited

## Examples of audit types that may be conducted:

### 2.3.2.3.3.1 Evidence Handling and Re-examination

This audit focuses on the proper handling of evidence, and on the types of analysis selected and applied to the evidence.

#### 2.3.2.3.3.1.1 Evidence handling

- Re-opening of evidence that was sealed and stored upon completion of a case
- Check all evidence in the case for proper labeling, handling (e.g. efforts to prevent loss/damage/transfer), and documentation in the case record. This will include repeating any measurements, weights, and/or inventories of evidence items. See [LOM 4.3 Marking and Sealing of Evidence and Containers](#).
- Confirm the case record Chain of Custody for the item appears to be complete, thorough, reasonable, and in compliance with [LOM 4.4 Chain of Custody](#) and the discipline's Procedure Manual.
- Confirm, to the extent reasonable for the case and evidence type, that the processing techniques documented in the case record were actually applied to the evidence item (e.g. apparent staining, evidence of sampling/cutting, handwritten markings)

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#### **2.3.2.3.3.1.2 Re-examination**

- Depending on the nature of the case and the evidence item, a full re-examination may or may not be practical or possible.
- This audit should:
  - Evaluate the propriety of the examination methods used by the original examiner
  - Conduct a re-examination of the evidence item(s) and form a conclusion from that examination
  - Compare results from the re-examination with those from the original examination
- Depending on circumstances of the audit, the staff member conducting the re-examination might not know in advance all (or any) of the details of the first examination. This is a "blind" or "partially blind" audit.
  - An example of this situation is where a supervisor removed identifying information from a sample and assigned it to a second examiner for testing. The supervisor would then compare results of that second examination to those from the first.

#### **2.3.2.3.3.2 Efficiency Review Audit**

The purpose of an efficiency review is to study situations where casework is produced by an individual or unit in an unusually high or low number.

Specific factors that may be considered and studied as part of this audit:

- Are there special issues with the types of cases (evidence) that are being submitted/analyzed?
- Are there elements of the workflow and/or technique that cause the unusual level of case production?
- Are there ancillary duties, administrative tasks, scheduling issues, work environment, or other distractions - or an absence of those, that affects the output level?
- For unusual production levels, are there quality issue/risks introduced by the pace of production?
- Are there training or procedural issues that affect the pace of production?

#### **2.3.2.3.3.3 Blind Case Audit**

The purpose of this audit is to assess the application of procedures and techniques (possibly to specific evidence types), starting with internally prepared samples of a known value or outcome. Samples will be prepared in advance by the audit team with a documented expectation of the result before testing begins.

As this audit is "blind" it should be administered so that (as much as practical) the staff member performing the examination(s) believes it is actual casework.

#### **2.3.2.3.3.4 Direct Casework Observation Audit**

The purpose of a direct casework observation audit is to study casework currently in progress by an individual or unit, on a random or spot-check basis. This will provide the opportunity to directly monitor those things that cannot be observed by review of the case file only.

Specific factors that may be considered and studied as part of this audit:

- Are quality checks performed correctly and recorded as expected?
- Are precautionary procedures correctly followed to prevent evidence contamination or loss?

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- Are appropriate safety measures followed?
- Are methods/procedures being followed and executed correctly?
- Are appropriate supplies and equipment utilized?
- Is the appropriate work area utilized for the task at hand?
- Are there interruptions or distractions that could affect the quality or efficiency of work?
- Are there elements of the workflow and/or technique that appear to be inefficient? Conversely, are there techniques that could be shared with others that may increase efficiency?

#### **2.3.2.3.4 Discrepancy Handling**

In situations where a discrepancy noted during the audit raises a Quality Assurance issue, the discrepancy will be investigated and handled by other elements of the Quality Assurance System (e.g. Corrective/Preventive Action processes).

#### **2.3.2.3.5 Documentation**

##### **2.3.2.3.5.1 Documentation of Audit Plan**

A full written, Audit Plan will be developed before the audit begins. This planning may involve the Quality Assurance Manager, Technical Leader, Laboratory Director, Unit Supervisor, or others as the circumstances dictate. Before the audit begins, the Audit Plan will be shared with the Laboratory Director(s), Unit Supervisor(s), and the examiner(s) who originally conducted the work, as appropriate.

The Audit Plan will include at least the following:

- Which part(s) of the case workflow or operation are to be audited (see 3.3 Audit Types)
- Who will conduct the audit
- Which cases will be audited, or at least how they are to be selected (see 3.2 Case Selection)
- How long the audit will last, or how many cases will be audited
- How frequently the audit should be conducted (see 3.1 Frequency of Audits)
- Who will evaluate the results of the audit
- How and where will the audit results be documented (see 3.4 Documentation)
- The approval of the staff member(s) designing the plan
- The approval of the Quality Assurance Manager

##### **2.3.2.3.5.2 Documentation of Results**

The results of the audit will be documented in a format pre-approved as part of the Audit Plan. The results, where appropriate for the audit type, will include:

- Identifying information for any cases that were included in the audit
- Results of the audit for each case involved
- Confirmation of (or exceptions to) the original examination result
- Documentation in the case record that the quality audit (QARA) was conducted
- For exceptions to the original result, the documentation should include:
  - Any independent (e.g. 3rd party) verification of the discrepancy
  - Detailed notes and/or data specifically supporting the discrepancy
  - The policies, procedures, and/or criteria affected by the discrepancy

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- Actions taken to remediate the discrepancy (additional examination conducted, hand-off to a Corrective Action, etc.)

### **2.3.2.3.6 Notifications**

For each employee whose cases and/or workflow were audited, a short memo will be written by the auditor, with input from the Quality Assurance Manager, advising them of the scope of the audit as it pertains to their work and the results (preliminary findings). A copy of this memo will be disseminated to the employee through their Laboratory Director and Unit Supervisor.

### **2.3.3 Laboratory Response**

Every audit – even those with no findings – will be closed out with a memo authored by the Laboratory Director. All responses and remediation documentation for the Health and Safety, Laboratory Internal, Key/Access, Property and Professional Standards Audits shall be provided via memo to the Assistant Division Directors by the Laboratory Director within 30 days of receipt of results of the audit.

Upon completion of the property audit, a memorandum shall be authored from the Laboratory Director to the Assistant Division Directors to document the completion of the audit, discrepancies detected, and corrective measures performed. Discrepancies that cannot be resolved require the completion of a Corrective Action Report which shall be immediately forwarded to the Quality Assurance Manager.

The Laboratory response to the annual Internal Audit shall be addressed to the Assistant Division Directors and copied to the Technical Leaders corresponding to disciplines conducted at the laboratory. The response shall contain clarifications, all required corrective action documentation and a remediation timeline for any findings. No responses are required for those issues that were remedied prior to the Laboratory Internal Audit.

Each finding resulting from an Internal Audit shall result in a Corrective Action documented by a Corrective Action workflow initiated by the Laboratory Director or appropriate Technical Leader and immediately forwarded to the Quality Assurance Manager.

On completion, all audit response memos shall be posted to the FSD documentation management site to accompany their related audit/inspection.

### **2.3.4 Accreditation Reviews**

The FSD Quality Assurance Manager shall coordinate with the accrediting agency assessor during the annual surveillance activity for each laboratory. This will generally occur near the accreditation anniversary. The completed audit surveillance activity shall be posted to the document management site.

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### 2.3.5 Audit Schedule

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Responsibility	Comments	
<b>Audits/Inspections</b>															
Health/Safety Audits					May 1								Health/Safety Officer	QM 8.8.1, LOM 2.3	
Health/Safety Audit Remediations						Jun 1							Lab Directors	QM 8.8.1, OO 87 Sec 5	
Property Audits (Complete)			Mar 1						Sep 1				Lab Directors	QM 1.6	
Key/Access Audits		Feb 1										Dec 1	Quality Manager	QM 4.15	
Quality Management Review										Oct 1			Lab Directors	due w/in 30 days of acc. cycle	
Annual Report to ASCLD/LAB													Asst. Div. Dirs.	OO 87 Sec 5	
Internal Audit								Aug 15					Lab Directors		
Internal Audit Remediation									Sep 1				Lab Directors	QM 8.8.1, LOM 2.3	
Internal Audit (ISO)									Sep 15	Oct 1			Lab Directors	QM 8.8.1, LOM 2.3	
Internal (ISO) Audit Remediation					May 1	Jun 1							Lab Directors	QM 8.8.1, LOM 2.3	
Discipline Audits													Technical Leaders		
Discipline Audit Remediations													Lab Directors		
FA Admin Override usage audit		Feb 1						Aug 1					Quality Manager		
FA User Access Audit		Feb 1			May 1			Aug 1			Nov 1		Lab Ops Manager		
<b>Other Requirements</b>															
Client Feedback Survey							Jul 1						Div. Cmd, Lab Dirs	QM 8.6.2	
Policy/Procedure Manual Reviews						Jun 1							Technical Leaders	LOM 2.12.6	
Operations Manual Review													Lab Ops Manager	LOM 2.12.6	
Quality Manual Review											Nov 1		Quality Manager	LOM 2.12.6	
SOQ's up to date						Jun 1							Lab Directors	QM 6.2.5	
Proficiency Test Results up to date						Jun 1							Technical Leaders	LOM 2.4	
CARS up to date						Jun 1							Quality Manager	LOM 2.11, QM 8.8.1	