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# **FBI Laboratory Quality Assurance Manual**

## **Introduction**

Quality performance is the most important goal of the Federal Bureau of Investigation (FBI) Laboratory. As new and improved methods of forensic analysis are developed to meet the expanding needs of the criminal justice system and intelligence matters, the laboratory quality system must progress in parallel. The FBI Laboratory is committed to diligently implementing policy and procedure changes to ensure quality in all facets of laboratory operations.

The FBI Laboratory quality system, represented by the Quality Assurance Manual and the Laboratory Operations Manual, provides a mechanism for identifying and implementing the practices that support excellent performance. All units, disciplines, and/or categories of testing within the FBI Laboratory are responsible for the incorporation of quality practices and procedures consistent with the requirements of the quality system. All FBI Laboratory personnel share responsibility for the overall success of the quality system by adhering to established quality measures.

The continued development and improvement of the FBI Laboratory quality system serves to increase confidence in the resulting work product while strengthening the professional integrity of the FBI Laboratory and its personnel. Through the use of recognized quality practices and procedures, the FBI Laboratory will continue to meet the challenges of future laboratory missions.

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Deputy Assistant Director/Laboratory Director  
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## 1 Purpose

This FBI Laboratory Quality Assurance Manual (QAM) contains or references the policies, practices, procedures, and accompanying forms of the FBI Laboratory quality system that ensure technical competence and valid forensic examination and DNA database results. The QAM and the FBI Laboratory Operations Manual (LOM) facilitate meeting the requirements of the applicable accrediting body(ies).

## 2 Scope

The QAM and the LOM apply to FBI Laboratory personnel that could influence the laboratory activities<sup>1</sup>. This includes personnel responsible for receiving, breaking down, handling, and examining evidence; DNA databasing; reviewing and issuing *Laboratory Reports* (7-1, 7-1 LIMS, 7-273, 7-273 LIMS); providing testimony with respect to those examinations in legal proceedings; and maintaining the quality system. Personnel that examine digital evidence are not included in the scope of the FBI Laboratory's quality system.

For terms used in this document and the LOM, refer to the LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual.

## 3 Quality Initiatives

### 3.1 Forensic Examinations and Services

Forensic examinations of evidence are performed in the FBI Laboratory to support FBI and other federal, state, local, and foreign investigations as well as intelligence matters. The FBI Laboratory provides expert witness testimony on a national and international level. Additionally, FBI Laboratory personnel participate in ongoing field investigations by assisting with crime scene searches, providing DNA databasing services, as well as other scientific and/or technical services as necessary. The Handbook of Forensic Services contains a general listing of forensic services offered by the FBI Laboratory and is available on BUNET, LABNET, and the internet.

### 3.2 Environmental Health and Safety

FBI Laboratory operations are performed in a safe manner and in accordance with the standards established by applicable regulatory agencies. The FBI Laboratory Safety Manual prepared by the FBI Laboratory Health and Safety Group is available on BUNET and LABNET.

### 3.3 Accreditation

The FBI Laboratory is accredited to the requirements of the applicable accrediting body(ies). The FBI Laboratory is committed to maintaining accreditation.

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<sup>1</sup> Laboratory activities at the FBI Laboratory refers to testing and sampling.

### 3.4 Security and Access

It is the policy of the FBI Laboratory that all personnel, evidence, DNA database samples, and case records are secure in the FBI Laboratory facilities. Access to an FBI Laboratory building is restricted to FBI Laboratory personnel, authorized non-FBI Laboratory personnel, and others when escorted by an FBI Laboratory person.

**3.4.1** Due to security, classification issues, and the sensitivity of cases within the FBI Laboratory, the integrity of evidence is of utmost importance. The Laboratory Director does not allow any unauthorized personnel to have access to the laboratory areas for the purpose of viewing forensic examinations or DNA databasing.

## 4 General Requirements

### 4.1 Impartiality

**4.1.1** The FBI Laboratory performs and manages its laboratory activities in an impartial and structured manner to ensure impartiality.

**4.1.2** FBI Laboratory management is committed to impartiality.

**4.1.3** The FBI Laboratory has policies to ensure that all personnel are free from any undue pressures and influences that may negatively impact the quality of their work. FBI Laboratory personnel encountering situations or conditions that could affect the impartiality of their laboratory activities inform their Unit Chief and/or the Quality Manager. Additionally, FBI Laboratory personnel annually review and sign the *American National Standards Institute (ANSI) National Accreditation Board (ANAB) Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* and the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science*.

**4.1.3.1** The FBI Laboratory management:

- a) is committed to the *ANAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* and the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science*.
- b) ensures the *ANAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* and the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science* are reviewed annually with FBI Laboratory personnel. A record of the reviews are maintained by each Supervisor, Unit Chief, and/or Executive Management, as appropriate. These reviews may be conducted and recorded during each employee's annual performance review.
- c) ensures appropriate actions are taken when necessary

**4.1.4** The Laboratory Director is a Deputy Assistant Director in the FBI. The FBI Laboratory is part of the FBI Science and Technology Branch, led by the FBI Executive

Assistant Director for the Science and Technology Branch. This ensures the independence of the FBI Laboratory from the rest of the organization, including the investigative branches of the FBI. Risks to impartiality are brought to the attention of the Quality Manager, who evaluates the risk.

**4.1.5** If a risk to impartiality is identified, FBI Laboratory personnel eliminate or minimize the risk.

## **4.2 Confidentiality**

**4.2.1** The FBI Laboratory is responsible for the management of all information obtained or created during the performance of laboratory activities. It has policies and practices to protect contributors' confidential information. These policies and practices include guidance for protecting the electronic storage and transmission of *Laboratory Reports* as well as access to test data in examination areas. The FBI has additional policies and procedures regarding security and records management. [See LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases, LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), LOM - Practices for the Security of Evidence Storage Rooms]

**4.2.2** FBI Laboratory personnel only share information on cases with individuals who have a need to know (e.g., contributors, case agents, prosecutors).

**4.2.3** Information about a contributor received by the FBI Laboratory is kept confidential between the contributor and the FBI Laboratory. The FBI Laboratory keeps the source of the information confidential and is not shared with the contributor, unless agreed to by the source.

**4.2.4** FBI Laboratory personnel keep all information obtained or created during the performance of laboratory activities confidential, except as required by law.

## **5 Structural Requirements**

**5.1** The FBI is the principal investigative arm of the United States Department of Justice. The FBI Laboratory is located in Quantico, Virginia and Huntsville, Alabama.

**5.2** The Laboratory Director has overall responsibility for the FBI Laboratory. Technical management has overall responsibility for the technical operations and for providing the necessary resources to ensure the reliability and integrity of FBI Laboratory operations. Each category of testing has a designated Technical Leader that is technically responsible for Quantico, Virginia and Huntsville, Alabama facilities. Each sub-category of testing that falls under 4.15 General Physical and Chemical Analysis on the FBI Laboratory's Scope of Accreditation also has a designated Technical Leader. These positions and roles are defined in the LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual.

**5.2.1** The Laboratory Director's duties are defined in the FBI Deputy Assistant Director job description.

**5.3** The laboratory activities conducted by the FBI Laboratory are defined on its ANAB scope of accreditation and its American Association for Laboratory Accreditation (A2LA) scope of accreditation. Additionally, laboratory activities in cryptanalysis, illicit business records, and anthropology conform to FBI Laboratory quality system documents.

**5.4** The FBI Laboratory provides forensic services to address a contributor's request for the examination of evidence and/or a request to confirm a DNA database match. These laboratory activities are conducted in such a way as to conform to the requirements of the applicable accrediting body(ies). Personnel performing DNA analysis comply with the National DNA Index System (NDIS) Operational Procedures Manual, the Quality Assurance Standards for Forensic DNA Testing Laboratories, and/or the Quality Assurance Standards for DNA Databasing Laboratories, as appropriate. The FBI Laboratory quality system covers forensic examinations and DNA databasing conducted at the FBI Laboratory in Quantico, Virginia, Huntsville, Alabama, and at any other facility(ies) or site(s) where FBI Laboratory personnel perform forensic services.

**5.4.1** The FBI Laboratory conforms to the requirements in the current ANAB policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

**5.4.2** The FBI Laboratory performs laboratory activities under the authority of 28 Code of Federal Regulations Section 0.85 Subsection G, which is available on the Government Publishing Office website ([www.govinfo.gov](http://www.govinfo.gov)).

**5.5** The FBI Laboratory:

- a) Organizational Chart shows the structure and the relationships between Executive Management, the Quality Manager, technical operations (i.e., caseworking and DNA databasing units), and support services. The Laboratory Director manages the Quantico, Virginia and Huntsville, Alabama facilities. The FBI Laboratory's position in the FBI is shown in the FBI Organizational Chart.
- b) Defines the responsibility, authority, and interrelationship of all FBI Laboratory personnel who manage, perform, or verify work affecting the results of laboratory activities for the quality system in QAM - Section 5.6 and appropriate quality system documents.
- c) Has procedures to ensure the consistent application of its laboratory activities and the validity of the results.

**5.6** The FBI Laboratory provides its personnel the authority and resources needed to carry out their duties including the implementation, maintenance, and improvement of the quality system. FBI Laboratory personnel support and promote the quality system and the continual improvement of the system.

The Forensic Analysis Support Unit (FASU) Chief serves as the FBI Laboratory Quality Manager for Quantico, Virginia and Huntsville, Alabama facilities and has direct access to the Laboratory Director.

FBI Laboratory Executive Management:

- ensures conformance to requirements of the applicable accrediting body(ies).
- ensures that the policies, practices, procedures, training manuals, and accompanying forms within the quality system are implemented and followed in the FBI Laboratory.
- ensures that nonconformities are appropriately addressed and recorded.

The Quality Manager:

- ensures the implementation, maintenance, and improvement of the quality system
- provides reports and/or updates, as necessary, to Laboratory management on the performance of the quality system and any need for improvement.

Unit Chiefs:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure that the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed within their unit.
- ensure that any controlled quality system document used by personnel within their unit are reviewed annually and revised when necessary.
- ensure the appropriate Technical Leader(s) is consulted when necessary. This includes approval of technical procedures, deviations, and corrective actions.
- ensure that all unit personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure that all unit personnel receive appropriate continuing education.
- ensure approval for the selection and use of technical procedures within the unit; criteria establishment for technical procedure validation; and as necessary, review and update of technical procedures.
- stop, suspend, and resume operations in the discipline and/or category of testing under their authority, when appropriate.
- ensure the completeness of *Laboratory Reports* and supporting case records through technical and administrative reviews.
- ensure that nonconformities are appropriately addressed and recorded.

Personnel designated as Technical Leaders:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure that the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed within their discipline and/or category of testing.
- ensure that technical personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure approval for the selection and use of technical methods and procedures within the discipline and/or category of testing; criteria establishment for



technical procedure validation; and as necessary, review and update of technical procedures.

- ensure the examinations conducted are technically sound for each discipline and/or category of testing.
- stop, suspend, and resume operations in a discipline and/or category of testing under their authority, when appropriate.
- ensure that nonconformities are appropriately addressed and recorded.

Personnel designated as Training Program Managers:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure that the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed as applicable to the training program.
- coordinate training programs for their discipline(s)/category(ies) of testing.

Supervisors:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure that the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed by their unit personnel.
- ensure that their unit personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure the completeness of *Laboratory Reports* and supporting case records through technical and administrative reviews.
- ensure that nonconformities are appropriately addressed and recorded.

Quality Assurance (QA) Specialists:

- coordinate the continued development and revision of the quality system.
- assist units, disciplines, and/or categories of testing in the development of specific quality system documents.
- support proficiency test administration for each category of testing.
- conduct periodic quality system audits to provide management with the necessary confidence that established quality system policies, practices, procedures, and objectives are being met.
- provide guidance and direction to personnel regarding conformance to accreditation standards as well as any resulting nonconformities.
- ensure that nonconformities are appropriately addressed and recorded.

Personnel designated as QA Representatives:

- ensure conformance to requirements of the applicable accrediting body(ies).
- make recommendations for improving the quality system.
- participate in revising the QAM and LOM, as requested.
- within one year of being appointed to this role, attend an approved auditor training course.
- provide assistance, as requested, in performing audits.
- ensure that nonconformities are appropriately addressed and recorded.

**Examiners:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure that procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- support management, when necessary, by reviewing validation records, technical procedures, and deviation requests and conducting technical and administrative reviews.
- ensure that nonconformities are appropriately addressed and recorded.

**Technicians, Technical Specialists, Forensic Imaging Photographers, and Personnel who Process Film or Conduct Post-Mortem Imaging:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure that procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- advise examiners or other appropriate personnel of relevant case-related or DNA databasing issues.
- ensure that nonconformities are appropriately addressed and recorded.

**Evidence Management Unit (EMU) Personnel:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure that evidence procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- ensure that nonconformities are appropriately addressed and recorded.

**5.7****Laboratory management ensures:**

- a) communication occurs with FBI Laboratory personnel and contractors by email, meetings, or other means concerning the effectiveness of the quality system and the importance of meeting the contributors' and other requirements; and
- b) the integrity of the quality system is maintained when changes are planned and implemented.

**6 Resource Requirements****6.1 General**

The FBI Laboratory has available the personnel, facilities, equipment and support systems necessary to manage and perform its laboratory activities.

## 6.2 Personnel

**6.2.1** The FBI Laboratory ensures personnel that could influence the laboratory activities act impartially, are competent, and work within the quality system.

**6.2.2** Management ensures that the competence requirements for each function influencing the results of laboratory activities<sup>2</sup>, including requirements for education, qualification, training, technical knowledge, skills and experience are documented.

FBI Laboratory personnel meet the requirements including education specified in the individual occupational requirements in the Office of Personnel Management General Schedule Qualification Standards for their position. Additionally, personnel influencing the results of laboratory activities meet the qualification, training, technical knowledge, skills and experience requirements as defined by the applicable discipline(s)/category(ies) of testing training program.

**6.2.2.1** Personnel who authorize results, opinions, and/or interpretations meet the minimum educational requirements in the table below.

**Table 1.** Minimum Educational Requirements for Personnel who authorize results, opinions, and/or interpretations in the following disciplines

Discipline	Minimum Educational Requirements
Fire Debris and Explosives Geological Materials Gunshot Residue Materials (Trace Evidence) Seized Drugs (Drug Chemistry) Toxicology	A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.
Biology	A baccalaureate or an advanced degree in a chemical, physical, or biological science. If performing DNA analysis and where applicable, meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories or Quality Assurance Standards for DNA Databasing Laboratories, as appropriate.
Document Examination Fire and Explosion Investigation Firearms/Toolmarks Footwear/Tire Tread Friction Ridge Cryptology Illicit Business Records Anthropology	Meet the educational requirement(s) specified in the individual occupational requirements in the Office of Personnel Management General Schedule Qualification Standards.

<sup>2</sup> ANAB GD 3152, ISO/IEC 17025:2017 and ANAB 3125 Matrix of Laboratory Tasks

**6.2.2.2** Each unit, discipline and/or category of testing within the FBI Laboratory has a training program(s), coordinated by a training program manager (TPM). A TPM may cover more than one category of testing. The training program includes a training manual(s) that is used to develop a person's knowledge, skills, and abilities as required to perform forensic examinations and/or DNA databasing. The training manual must contain goals and objectives, expectations, topic areas, and a general outline of the training material. Knowledge of administrative practices and job duties must be tested and can be covered in conjunction with a subject-matter Oral Board exercise. Administrative subjects to be covered include, at a minimum, the Laboratory Division organizational structure and mission, the FBI Laboratory QAM, the LOM, and the Safety Manual. Examiner trainees will also follow the requirements of the LOM - Practices for the Forensic Examiner Training Program.

When an experienced examiner, technician, or technical specialist is entering the training program, the appropriate Technical Leader is responsible for assessing the person's previous training and ensuring it is adequate and recorded. Modification to the training plan may be appropriate and is recorded by the appropriate Technical Leader for approval by the trainee's Unit Chief. Each Unit Chief and appropriate Technical Leader ensures that, at a minimum, a trainee successfully demonstrates competence according to the requirements in the relevant discipline(s), category(ies) of testing, and/or a specific task(s) prior to conducting independent casework activities or DNA databasing. [Refer to QAM - Section 6.2.2]

Training programs for each function influencing the results of laboratory activities, to the extent necessary based on job function, include:

- a) knowledge, skills, and abilities needed to perform work
- b) general knowledge of forensic science
- c) the application of ethics in forensic science
- d) where applicable, training in the criminal law, civil law and testimony.
- e) provisions for retraining
- f) provisions for maintenance of skills and expertise
- g) criteria for acceptable performance.

**6.2.3** FBI Laboratory personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

**6.2.3.1** FBI Laboratory personnel who perform testing are competency tested. Testing includes the review and authorization of results and expressing an opinion or an interpretation. The competency test includes practical examination(s) that cover the spectrum of anticipated tasks related to the testing. The competency test intended results are achieved prior to performing the tasks on evidence or DNA databasing samples. Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.

FBI Laboratory staff whose responsibility includes reporting examination results, demonstrate their competency by completing a competency test(s) that includes, at a minimum:

- a) Practical examinations that cover the spectrum of anticipated work to be performed;
- b) A written *FBI Laboratory Report* to demonstrate their ability to appropriately

- convey results and/or conclusions and their significance;
- c) A written or oral examination to assess their knowledge of the discipline, category of testing, or task being performed.

**6.2.3.2** All personnel who perform technical reviews of results or evaluate testimony satisfactorily demonstrate competency as specified in QAM - Section 6.2.3.1.

**6.2.4** FBI Laboratory management communicates to personnel their duties, responsibilities, and authorities.

**6.2.5** Each unit maintains records determining the competence requirements of its personnel. Each Unit Chief ensures the documentation of the selection of personnel in accordance with FBI Human Resource requirements. Training of personnel is described in QAM - Section 6.2.2 and training records are maintained in the appropriate unit. Each person performing casework and/or DNA databasing is accountable to only one immediate supervisor per category of testing. The authorization(s) of personnel is recorded as described in QAM-Section 6.2.6. Continued monitoring of competence of personnel can be found in the unit's proficiency test records, evaluation of testimony records, and through technical and administrative reviews of casework. For personnel no longer participating in proficiency testing, but who are authorized to perform other laboratory tasks (e.g., technical review, evaluation of testimony), continued competence is monitored each accreditation cycle by a review of continuing education of a technical nature, observation of the task, or by having another authorized person repeat the task. A record of the continued monitoring of competence is retained.

**6.2.6** Personnel are authorized to perform specific laboratory tasks, including but not limited to:

- a) development, modification, verification, and validation of methods and procedures;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) report, review, verification, and authorization of results;
- d) conducting technical reviews;
- e) evaluation of testimony.

A person's successful completion of a training program, a portion(s) of the training program, or training for a specific task(s) is recorded in a qualification and authorization Electronic Communication (EC) (FD-1057). An example qualification and authorization EC is found in Appendix A. At a minimum, the EC(s) includes:

- the person's name,
- the person's unit,
- the training program, specified portion(s) of the training program, or training for a specific task(s) that the person completed,
- the position (e.g., examiner, technician, technical specialist),
- the training requirements met, to include a reference to the appropriate manuals (e.g., Laboratory Quality Assurance Manual, Laboratory Operations Manual, and

- appropriate training manual),
- a reference to any previous qualification, if applicable,
- start and end dates of the training,
- where the training record is maintained,
- the discipline(s), category(ies) of testing, and/or a specific task(s) in which the person has been deemed competent
- a statement that the person is qualified to perform specific laboratory activities
- authorization to perform specific laboratory tasks, including use of associated equipment,
- authorization to issue *Laboratory Reports*, including providing opinions and interpretations, if applicable,
- authorization to provide alternately reported, if applicable.

Each qualification and authorization EC is approved by at least the Forensic Examiner Training Program Manager, appropriate Technical Leader(s), and the appropriate Unit Chief(s). The Section Chief(s) are on the distribution list in Sentinel.

Upon approval of each EC by all required personnel, the person is qualified and authorized to perform forensic examinations, DNA databasing, and/or the specific task(s), including using associated equipment, and when applicable, to issue *Laboratory Reports* and/or alternately reported results, including providing opinions and interpretations, or *DNA Match Confirmation Letters*.

Units have additional authorization records. Authorizations not related to the completion of training are recorded in Sentinel or a person's unit. If a person is authorized to perform a specific laboratory activity following the completion of a training program or a portion(s) of the training program, the additional authorization should be stated in the qualification and authorization EC. Additional authorizations may be formatted following the requirements in Appendix A. The above requirements also apply to contractors.

**6.2.7** FBI Laboratory personnel obtain a minimum of eight hours of continuing education each fiscal year. Management establishes objectives for the continuing education of personnel to meet the present and anticipated needs of the FBI Laboratory.

## **6.3 Facilities and Environmental Conditions**

**6.3.1** Units, disciplines, and/or categories of testing ensure that the facilities and environmental conditions are suitable for the laboratory activities and do not adversely affect the validity of the results.

**6.3.2** Any environmental or facility conditions that can affect the results of examinations or DNA databasing are recorded in the appropriate technical procedure. Examinations and DNA databasing require typical laboratory environmental conditions unless noted in a technical procedure.

**6.3.3** If environmental conditions affect the quality of an examination or DNA databasing, the affected units, disciplines, and/or categories of testing will monitor, control, and record those conditions as required by a level 2 document. Examinations and DNA databasing are stopped when the environmental conditions jeopardize the results.

**6.3.4** Measures to control the FBI facilities where laboratory activities are performed are implemented, monitored and periodically reviewed and include, but are not limited to:

- a) access to and use of areas affecting laboratory activities;
- b) prevention of contamination, interference, or adverse influences on laboratory activities;
- c) effective separation between areas with incompatible laboratory activities.

**6.3.4.1** Redacted

**6.3.5** When laboratory activities are undertaken at sites or facilities other than a permanent FBI Laboratory facility, personnel ensure that the requirements related to facilities and environmental conditions are met.

## **6.4 Equipment**

**6.4.1** The FBI Laboratory is furnished with, or has access to, all items needed for the correct performance of laboratory activities and that can influence results.

**6.4.2** Units, disciplines, and/or categories of testing ensure that the function, maintenance, and/or calibration status of any piece of equipment outside the permanent control of the FBI Laboratory used for testing activities meets the requirements for equipment as stated in the QAM, LOM - Practices for the Calibration and Maintenance of Equipment, and applicable unit, discipline, and/or category of testing documents..

**6.4.3** Units, disciplines, and/or categories of testing have procedures for handling, transport, storage, use, and planned maintenance of equipment in order to ensure proper functioning, to prevent contamination or deterioration.

**6.4.3.1** Units, disciplines, and/or categories of testing have procedures for routinely checking the reliability of reagents. Reagents prepared in the FBI Laboratory are labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records maintained by the units, disciplines, and/or categories of testing identify who made the reagents and the components used in preparation.

**6.4.3.2** Units, disciplines, and/or categories of testing utilizing reference collections for identification, comparison, or interpretation purposes have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.

**6.4.4** Equipment and its software used for the examination of evidence or DNA databasing must meet the requirements of the relevant technical procedure. Before being placed into or returned to service, equipment is calibrated and/or checked by the unit, discipline, and/or category of testing to verify that it meets the specifications. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.5** Units, disciplines, and/or categories of testing ensure the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.6** The FBI Laboratory requires that measuring equipment is calibrated as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.7** Units, disciplines, and/or categories of testing have a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

**6.4.7.1** The requirements for the program for the calibration of equipment is specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.8** FBI Laboratory equipment requiring calibration is labeled, coded or otherwise identified as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.9** Any equipment that has been subjected to overloading or mishandling, gives questionable results or has been shown to be defective or outside specified requirements is taken out of service and the effect is determined as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.10** When intermediate checks are needed to maintain confidence in the performance of the equipment, these checks are carried out according to unit, discipline, and/or category of testing procedures. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.11** Calibration and reference material data including reference values or correction factors are handled according to the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.4.12** Units, disciplines, and/or categories of testing take practicable measures to prevent unintended adjustments of equipment from invalidating test results. [LOM - Practices for the Calibration and Maintenance of Equipment].

**6.4.13** Units, disciplines, and/or categories of testing maintain records of each piece of equipment and its associated software used for forensic examinations or DNA databasing according to the LOM - Practices for the Calibration and Maintenance of Equipment.



## **6.5 Metrological Traceability**

**6.5.1** Units, disciplines, and/or categories of testing establish and maintain metrological traceability of measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.5.1.1** The LOM - Practices for the Calibration and Maintenance of Equipment documents requirements for suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability.

**6.5.1.2** If a supplier of traceable materials or services is not available Laboratory personnel follow the requirements in the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.5.1.3** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**6.5.1.4** Laboratory personnel refer to the LOM - Practices for the Calibration and Maintenance of Equipment for the requirements that are followed when a certified reference material is changed in a way that alters the traceable measurement value.

**6.5.2** Units, disciplines, and/or categories of testing ensure measurement results are traceable to the International System of Units (SI) according to the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.5.3** When metrological traceability of measurements to SI units is not technically possible, metrological traceability to an appropriate reference is demonstrated according to the LOM - Practices for the Calibration and Maintenance of Equipment for information.

## **6.6 Externally Provided Products and Services**

**6.6.1** The FBI Laboratory selects suitable externally provided products<sup>3</sup> and services that affect laboratory activities, when such products and services:

- a) are intended for incorporation into the FBI Laboratory's own activities;
- b) are provided, in part or in full, directly to the contributor by the FBI Laboratory, as received from the external provider; or
- c) are used to support the operation of the FBI Laboratory.

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<sup>3</sup> Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

**6.6.2** The FBI Laboratory's procedure for using external providers is as follows:

- a) FBI Laboratory Unit Chiefs, Technical Leaders, and where applicable, Quality Assurance Specialists, are responsible for evaluating the suitability of external providers who provide products and services affecting laboratory activities. Federal and FBI Finance Division Procurement Policies and Regulations govern the procurement of products and services from sources external to the FBI. The Planning and Budget Unit ensures compliance with all Federal, FBI, and divisional budget/accounting policies. Units, disciplines, and/or categories of testing have procedures for the reception and storage of reagents and consumable materials necessary for forensic examinations or DNA databasing. FBI Laboratory units, disciplines, and/or categories of testing ensure that purchase requests contain information describing the supplies and services ordered, if they affect the laboratory activities. These requests are reviewed and approved by the Unit Chief prior to ordering.
- b) For the purchase of products and services that affect laboratory activities, units, disciplines and/or categories of testing evaluate suppliers, maintain records of these evaluations and maintain a list identifying approved suppliers. Units, disciplines, and/or categories of testing evaluate these materials to ensure that they comply with specifications defined in the appropriate technical procedure and/or purchase request. These materials are not used until their compliance is verified and units, disciplines, and/or categories of testing maintain records of steps taken to check conformance of these materials. When an issue with a product or service that affects laboratory activities is identified the external provider is re-evaluated and a record is maintained.
- c) Externally provided products and services conform to FBI Laboratory requirements before they are used or directly provided to the contributor.
- d) Actions are taken as necessary and recorded when evaluations, performance monitoring, and re-evaluations of external providers warrant.

**6.6.3** Units, disciplines, and/or categories of testing communicate their requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that the unit, discipline, and/or category of testing, or its contributor, intends to perform at the external provider's premises.

**7 Process Requirements****7.1 Review of Requests and Contracts****7.1.1** The FBI Laboratory ensures that:

- a) requirements are adequately defined, recorded and understood. The Handbook of Forensic Services, the LOM - Practices for Processing a

Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission provide requirements for the review of requests for examinations and the contract that is entered when a contributor submits evidence to the FBI Laboratory. To meet TEDAC's mission, the information obtained from the examination of TEDAC evidence is shared with domestic and international partners. Additionally, the LOM - Practices for Assigning Cases and Conducting Examinations details the requirements for Laboratory acknowledgment of evidence receipt.

- b) it has the capability and resources to meet the requirements. Communication with contributors about the appropriateness of requested examinations is described in the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission.
- c) externally provided products and services conform to the Laboratory's established requirements. The appropriate Unit Chief and Technical Leader conduct reviews of requests on any work that is to be performed by an external provider. When external providers are used, the requirements of QAM - Section 6.6 are applied and the appropriate Unit Chief advises the contributor of the specific laboratory activities to be performed by the external provider and obtains the contributor's approval. When examinations are completed by partner laboratories or intelligence partners or are generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis & Racketeering Records Unit evidence), approval from the contributor is not required.
- d) the appropriate methods or procedures are selected and are capable of meeting the contributor's requirement(s) as described in the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission.

**7.1.2** FBI Laboratory personnel determine the appropriate technical processes to address the contributor's request for examination. [QAM - Section 7.1.1a]

**7.1.3** When the contributor requests a statement of conformity to a specification or standard for the test (e.g., pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule<sup>4</sup> is clearly defined. Unless inherent in the requested specification or standard, the decision rule is communicated to, and agreed with, the contributor.

**7.1.4** The Handbook of Forensic Services, the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission provide

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<sup>4</sup> Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

requirements for the review of requests for examinations and the contract that is entered when a contributor submits evidence to the FBI Laboratory.

**7.1.5** Any deviations from a contributor's request, such as conducting additional examinations that were not requested, are communicated to the contributor by the examiner or the EMU personnel initiating the change prior to laboratory activities commencing. This communication is recorded. The identification of an additional examination(s) not requested that may be probative and generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis & Racketeering Records Unit evidence) are not communicated to the contributor.

**7.1.6** If any changes are made to an *Examination Plan*<sup>5</sup> (7-262) or *TEDAC Examination Plan* (7-274) after work has commenced, the requirements of QAM - Section 7.1.1 are followed and the changes are communicated to all affected examiners by the assigned EMU personnel.

**7.1.7** The LOM - Practices for Assigning Cases and Conducting Examinations and the LOM - Practices for Processing a Single Unit Submission detail the requirements for personnel contacting and communicating with the contributor. [QAM - Section 7.7.1]

**7.1.8** An *Examination Plan* or *TEDAC Examination Plan*, as appropriate, records the review of the incoming communication which details the request for examination(s) for submissions. Any significant changes to an *Examination Plan* or *TEDAC Examination Plan* are recorded by the assigned EMU personnel. In addition, the contributor is contacted about the submission, according to the LOM - Practices for Processing a Submission and Evidence Breakdown and the LOM - Practices for Assigning Cases and Conducting Examinations. The *Examination Plan* or *TEDAC Examination Plan* and record of communication with the contributor are included in the FBI Laboratory file. [LOM - Practices for Assigning Cases and Conducting Examinations]

**7.1.9** The extent of database searches is communicated to the contributor and updated as needed according to the LOM - Preparing Laboratory Reports and Retaining Records for Legacy or the LOM - Preparing Laboratory Reports and Retaining Records in FA, as appropriate

## **7.2 Selection, Verification and Validation of Methods**

### **7.2.1 Selection and Verification of Methods**

**7.2.1.1** FBI Laboratory units, disciplines, and/or categories of testing have and use procedures for all examinations and DNA databasing within their scope. Where appropriate, technical procedures include the estimation of the measurement uncertainty as well as statistical techniques for the analysis of examination and DNA database data

**7.2.1.1.1** The FBI Laboratory uses appropriate methods and procedures for all associated data

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<sup>5</sup> *Examination Plans* are not required for Single Unit Submissions based on evidence that meets the requirements of, and is handled as described in, the LOM – Processing a Single Unit Submission.

analysis and interpretation.

**7.2.1.1.2** If a technical procedure involves the comparison of an unknown to a known, the procedure requires the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s)<sup>6</sup>.

**7.2.1.1.3** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**7.2.1.2** Quality system documents relevant to laboratory activities are kept up to date and are readily available according to the LOM - Practices for Document Control.

**7.2.1.3** Units, disciplines, and/or categories of testing ensure that they use the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

**7.2.1.4** Examiners select appropriate methods and procedures to meet the needs of the contributor while taking into account the nature of the evidence, the request for examination, and any pertinent case information received. These methods are published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, or are developed or modified by the FBI Laboratory.

**7.2.1.5** Units, disciplines and/or categories of testing verify that they can properly perform methods before introducing them by ensuring that the FBI Laboratory can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary. [LOM - Practices for Developing Methods and Validating Technical Procedures]

**7.2.1.6** When a unit, discipline, or category of testing develops a method, it is a planned activity and assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm that the needs of the contributor are still being fulfilled. Any modifications to the development plan are reviewed and authorized. [LOM - Practices for Developing Methods and Validating Technical Procedures and LOM - Practices for Validating Chemical Procedures]

**7.2.1.7** Deviations from quality system requirements are recorded, justified, and authorized according to the LOM - Practice for Authorizing Deviations.

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<sup>6</sup> This requirement is not focused on the process of assessing an unknown in order to identify evidence that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known sample prior to the assessment of the unknown.

## 7.2.2 Validation of Methods

**7.2.2.1** Appropriate validation studies are conducted on all new technical procedures, non-standard methods and standard methods used outside their intended scope or otherwise modified when used for the analysis of evidence. Validations for new technical procedures are performed according to the LOM - Practices for Developing Methods and Validating Technical Procedures and the LOM - Practices for Validating Chemical Procedures, as appropriate, to ensure the procedure produces reliable results.

**7.2.2.1.1** Requirements for the validation of technical procedures are found in the LOM - Practices for Developing Methods and Validating Technical Procedures and the LOM - Practices for Validating Chemical Procedures.

**7.2.2.2** When changes are made to a validated technical procedure, the influence of such changes is determined and where they are found to affect the original validation, a new validation is performed.

**7.2.2.3** The performance characteristics of validated technical procedures, as assessed for the intended use, are relevant to the contributor's needs and consistent with specific requirements

**7.2.2.4** Units, disciplines, and/or categories of testing maintain records of the validation including:

- a) the procedure used;
- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- d) the results obtained;
- e) a statement on the validity of the method, detailing its fitness for intended use.

## 7.3 Sampling

**7.3.1** Each unit, discipline, and/or category of testing, when they carry out sampling (i.e., selection of a sample for testing according to a procedure) has sampling plans and sampling procedures included in the appropriate SOPs. The approach to sampling can be either non-statistical or statistical. Sampling plans are based on statistical methods when appropriate and address the factors to be controlled to ensure the validity of the examination results. The sampling plan and procedure is available at the site where sampling is undertaken.

**7.3.2** The sampling procedure describe:

- a) the selection of samples or sites;
- b) the sampling plan;
  - 1. Statistical sampling at a stated level of confidence is used if an inference is made to report on the whole population.
- c) the preparation and treatment of a sample(s) from a substance, material, or product to conduct the appropriate examinations.

**7.3.3** Units, disciplines, and/or categories of testing, as applicable, record appropriate sampling data and activities relating to the examination. Records are maintained in the FBI Laboratory and include, where relevant:

- a) the sampling procedure(s) used;
- b) date and time of sampling;
- c) data to identify and describe the sample;
- d) identification of the personnel performing the sampling;
- e) identification of the equipment used;
- f) environmental or transport conditions;
- g) diagrams or other equivalent means to identify the sampling location, when appropriate;
- h) deviations from the sampling procedure and sampling plan.

## **7.4 Handling of Items of Evidence**

**7.4.1** The FBI Laboratory maintains practices for the transportation, receipt, handling, protection, storage, retention, and disposal or return of items of evidence. These practices specify requirements for protecting the integrity of evidence, protecting the interests of the FBI Laboratory and the interests of the contributor. The FBI Laboratory ensures the integrity of evidence by protecting items from loss, cross-transfer, or deleterious change during storage, handling, and preparation for examination. Appropriate handling instructions provided with an item are followed. The DNA units maintain procedures for the transportation, receipt, handling, protection, storage, retention, and disposal of DNA databasing samples. [LOM - Practices for the Security of Evidence Storage Rooms, LOM - Practices for Processing a Submission and Evidence Breakdown, LOM - Practices for Assigning Cases and Conducting Examinations, LOM - Practices for Transferring and Storing Evidence, and LOM - Practices for Shipping and Returning Evidence]

**7.4.1.1** For all test items received except known origin individual characteristic database samples:

- a) the evidence is stored, packaged, and sealed according to the LOM - Practices for the Security of Evidence Storage Rooms, LOM - Practices for Processing a Submission and Evidence Breakdown, LOM - Practices for Assigning Cases and Conducting Examinations, LOM - Practices for Transferring and Storing Evidence, and LOM - Practices for Shipping and Returning Evidence. Evidence is resealed as soon as practicable.
- b) the evidence is secured when unattended according to the LOM - Practices for Transferring and Storing Evidence. Unit, discipline, and/or category of testing quality manuals define active examination for all evidence in the process of examination. The time period for active examination cannot be open-ended and is based upon a justifiable expectation of frequent examination.
- c) the evidence is recorded on a Chain-of-Custody log according to the LOM - Practices for Transferring and Storing Evidence. Secondary evidence and subdivided items of evidence are tracked on the appropriate Chain-of-Custody

Log. When evidence, such as latent prints and impressions, can only be recorded or collected by lifting, photography or digital capture and the print or impression itself is not recoverable, the lift, photograph, negative or digital image of the print or impression is treated as evidence and tracked on the appropriate Chain-of-Custody Log.

- d) the evidence is securely and accurately identified on the appropriate Chain-of-Custody Log according to the LOM - Practices for Transferring and Storing Evidence.
- e) the disposition of that evidence requires communication to the contributor regarding disposition. [LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA)] and
- f) any items collected or created and preserved for future testing are addressed according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.4.2** The FBI Laboratory identifies all items of evidence according to the LOM - Practices for Processing a Submission and Evidence Breakdown, and the LOM - Practices for Assigning Cases and Conducting Examinations. The identification of evidence remains in place while the items are in the FBI Laboratory. These practices ensure that items of evidence are uniquely identified and provide requirements for subdivided and secondary evidence. Evidentiary items are transferred within and from the FBI Laboratory according to the LOM - Practices for Transferring and Storing Evidence and the LOM - Practices for Shipping and Returning Evidence. Each item of evidence is marked to ensure that it is uniquely identified and traceable to the FBI Laboratory number. If the evidence does not lend itself to marking, its proximal container or identifying tag is marked. The DNA units maintain procedures for the unambiguous identification of DNA databasing samples. [LOM - Practices for Processing a Submission and Evidence Breakdown and LOM - Practices for Assigning Cases and Conducting Examinations]

**7.4.2.1** FA is utilized to identify all evidence received. Refer to the LOM - Practices for Processing a Submission and Evidence Breakdown or the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases for Office of Professional Responsibility (OPR) investigations or prohibited cases.

**7.4.3** Upon receipt of the evidence, the condition of the evidence is evaluated and any conditions adverse to quality are recorded as described in the LOM - Practices for Processing a Submission and Evidence Breakdown. When the suitability of an item of evidence for examination is questionable, or there is a discrepancy between the evidence and the request for examination, or the request for examination is unclear, the assigned EMU personnel or examiner will contact the contributor for clarification prior to proceeding with any testing. This communication is recorded in a Case Record/Case Communication Logs in FA or *Activity and Communication Log* (7-245) according to the LOM - Practices for Processing a Submission and Evidence Breakdown, and the LOM - Practices for Assigning Cases and Conducting



Examinations. The DNA units maintain procedures for received DNA databasing samples that do not meet specified conditions and/or when there is a doubt about the suitability of a DNA database sample.

**7.4.4** When evidentiary items have to be stored or handled under specified environmental conditions, these conditions are maintained, monitored, and recorded. The LOM - Practices for the Handling of Drug and Valuable Evidence describe how drug and valuable evidence are stored and handled.

## **7.5 Technical and Case Records**

**7.5.1** The FBI Laboratory retains technical records for each laboratory activity. These records contain adequate information to facilitate, if possible, the identification of factors affecting uncertainty and to enable the examination to be repeated under conditions similar to that of the original examination. Technical records include the date and identity of personnel responsible for each laboratory activity. The FBI Laboratory also retains case records. Original observations, data, and calculations are recorded at the time they are made and are identifiable with the specific task. Records are generated and retained according to the LOM - Practices for the Calibration and Maintenance of Equipment; LOM - Practices for Assigning Cases and Conducting Examinations; LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Case; and, LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). The DNA units maintain procedures for DNA *Match Confirmation Letters* and retaining technical records for DNA databasing.

The FBI Laboratory number is on each page of administrative records or on at least the first page of bound administrative records. For electronic administrative records, the FBI Laboratory number can be applied electronically. The FBI Laboratory number is on each page of the examination records. Examination records reflect, at a minimum, the starting and ending date(s) of the examinations. The examiner's initials are on each page of the examination records. When examination records are prepared by a person other than the reporting examiner(s), the person's initials are on the page(s) of the examination records representing his/her work. The FBI Laboratory number for each case for which data is generated is appropriately recorded on the printout when data from multiple cases is recorded on a single printout. When information is recorded on the front and back of an examination record, each side is identified as an individual page, signed or initialed, and labeled with the FBI Laboratory number. [LOM - Practices for Assigning Cases and Conducting Examinations].

**7.5.1.1** The FBI Laboratory retains all technical records. The LOM - Practices for Assigning Cases and Conducting Examinations, the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and level 2 documents identify what records are maintained in the FBI Laboratory file.

**7.5.1.2** Abbreviations and/or symbols specific to the unit, discipline, and/or category of testing are acceptable if they are clearly defined in a level 2 document.

**7.5.1.3** Technical records are such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data. [LOM - Practices for Assigning Cases and Conducting Examinations, LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), and LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases]

**7.5.1.4** Technical and case records are of a permanent nature. Any exceptions to this are noted in the LOM - Practices for Assigning Cases and Conducting Examinations.

**7.5.1.5** If an observation, data, or calculation is rejected, the reason, the identity of the person taking the action and the date are recorded in the technical record.

**7.5.1.6** If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data is retained.

**7.5.2** Changes to physical case records or DNA databasing records are made with an initialed single strike-out, date of the change, and the change entered alongside. Nothing in the case records or DNA databasing records is erased or otherwise made illegible.

For electronic case records or DNA databasing records, sufficient information to determine what was changed, the date of the change, and who made the change is maintained (e.g., track changes, maintaining both the original and amended data and files). For electronic records, measures are taken to avoid loss or change of original data.

Contemporaneous changes (i.e., those made before reaching a decision point) are not considered amendments.

## **7.6 Evaluation of Measurement Uncertainty**

**7.6.1** Units, disciplines and/or category of testing identify in each appropriate SOP, the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are taken into account using the appropriate methods of analysis.

**7.6.1.1** Technical procedures, when applicable, include considerations for estimating the measurement uncertainty. The method of analysis for evaluation of measurement uncertainty:

- a) requires the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
- b) includes the process of rounding the expanded uncertainty;
- c) requires the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
- d) specifies the schedule to review and/or recalculate the measurement uncertainty.

**7.6.2** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**7.6.3** Estimation of measurement uncertainty is based on an understanding of the theoretical principles or, practical experience of the performance of the method. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method.

**7.6.3.1** Units, disciplines, and/or categories of testing evaluate or estimate measurement uncertainty when applicable, for all reported quantitative results.

**7.6.4** Unit, disciplines and/or categories of testing maintain the following records for each evaluation and measurement uncertainty:

- a) statement defining the measurand;
- b) statement of how traceability is established for the measurement;
- c) the equipment (e.g., measuring device(s) or instrument[s]) used;
- d) all uncertainty components considered;
- e) all uncertainty components of significance and how they were evaluated;
- f) data used to estimate repeatability, intermediate precision, and/or reproducibility;
- g) all calculations performed; and
- h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

## **7.7 Ensuring the Validity of Results**

**7.7.1** Units, disciplines, and/or categories of testing have procedures for monitoring the validity of forensic examinations and DNA databasing. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the review of the results. Monitoring is planned and reviewed and will include the following, where appropriate:

- a) use of certified reference materials, secondary reference materials and/or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replication of tests using the same or different procedures;
- g) retesting of retained items;

7.7.1.g).1 When a verification of a result is carried out, it is conducted by a person who is currently qualified and authorized to perform the testing; a record of the verification is made identifying who performed the verification, when it was performed, and the result of the verification. The resolution of

any discrepancy is also recorded. [LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in FA; LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Legacy Cases; LOM - Practices for Resolution of Scientific or Technical Disagreement]; .

- h) correlation of results for different characteristics of an item of evidence;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s);
- l) technical review of examination records, including *Laboratory Reports*, and evaluation of testimony. These procedures are described in LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Legacy Cases, and LOM - Practices for Testimony Related Activities.

**7.7.2** The FBI Laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. The FBI Laboratory participates in proficiency testing. Proficiency testing applies to personnel that perform testing activities in each discipline and/or category of testing in which casework, or DNA databasing, is performed.

**7.7.2.1** The FBI Laboratory's proficiency testing program is administered according to the LOM - Practices for Open Proficiency Testing.

**7.7.3** Data from monitoring activities is analyzed, used to control and, if applicable improve the FBI Laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, units, disciplines, and/or categories of testing will take appropriate actions to prevent incorrect results from being reported.

**7.7.4** Personnel who perform testing activities complete proficiency testing according to LOM - Practices for Open Proficiency Testing.

**7.7.5** The FBI Laboratory proficiency testing program is documented in the LOM - Practices for Open Proficiency Testing. In addition, each quality manual contains procedures, for both internal and external proficiency testing, as appropriate.

**7.7.6** The FBI Laboratory proficiency testing plan is addressed in the LOM - Practices for Open Proficiency Testing.

**7.7.7** Proficiency testing requirements are addressed in the LOM - Practices for Open Proficiency Testing. To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b), the FBI Laboratory uses proficiency test providers for each discipline that are accredited to ISO/IEC 17043 or by an accreditation body that is a signatory to the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement or Inter American Accreditation Cooperation Multilateral Recognition Arrangement. Additionally, the proficiency test providers have the applicable proficiency test on their scope of accreditation.

**7.7.8** The FBI Laboratory maintains proficiency testing records according to the LOM - Practices for Open Proficiency Testing.

## **7.8 Reporting of Results**

### **7.8.1 General**

**7.8.1.1** *Laboratory Reports* are issued according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). These practices ensure the *Laboratory Reports* have been reviewed and authorized prior to issuance. The DNA units have procedures for DNA *Match Confirmation Letters*.

**7.8.1.1.1** The authorizer of results reviews the technical record and records the review according to the LOM - Practices for Assigning Cases and Conducting Examinations; LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA); and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Legacy Cases.

**7.8.1.2** FBI Laboratory personnel accurately, clearly, unambiguously, and objectively report the results of each examination according to the LOM - Practices for Preparing, Reviewing and Issuing Reports of Examination and Retaining Records for Legacy Cases, the LOM - Practices for Preparing, Reviewing and Issuing Reports of Examination and Retaining Records in Forensic Advantage (FA), and level 2 documents. *Laboratory Reports* include information regarding the work conducted and any information necessary for the interpretation of the results. All issued *Laboratory Reports* are retained as technical records.

**7.8.1.2.1** The FBI Laboratory generates a written and/or electronic *Laboratory Report* for every request for examination, unless an alternate reporting option has been approved.

**7.8.1.2.2** Results are reported according to the LOM - Practices for Preparing, Reviewing and Issuing Reports of Examination and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Reports of Examination and Retaining Records in Forensic Advantage (FA).

**7.8.1.2.3** The FBI Laboratory does not perform calibrations as part of its scope of accreditation.

**7.8.1.3** A simplified *Laboratory Report* is prepared to improve the contributor's ability to understand the report. The Handbook of Forensic Services provides the contract that is entered when a contributor submits evidence to the FBI Laboratory.

The Laboratory Director and Quality Manager must approve an alternate reporting format for an initiative and/or intelligence matters. The approval of alternate reporting is recorded in an EC. Alternate reporting, including any alternate requirements for generating and/or retaining case

records, is specified in a level 2 document. Alternately reported results undergo the same reviews as a *Laboratory Report*.

Any information required by ISO/IEC 17025:2017 and ANAB AR 3125 not covered in the *Laboratory Report* or alternate reported results is maintained in the FBI Laboratory.

**7.8.1.3.1** All *Laboratory Reports* are prepared in a simplified way. The *Laboratory Report* omits the following information:

- contact info for the contributor
- date of receipt of the evidence item
- statement that the results apply to the sample as received, when the FBI Laboratory does not perform the sampling (e.g., the sample is provided by the contributor)
- sampling information including the date of sampling, location of sampling, the sampling plan and method, environmental conditions during sampling, and information to evaluate measurement uncertainty for subsequent examination, when the FBI Laboratory does perform the sampling
- date examinations were conducted
- statement that results relate to items examined
- additions to, deviations, or exclusions from examination methods
- identification of data provided by the contributor
- disclaimer when the information is supplied by the contributor and can affect the validity of results.

## **7.8.2 Content of *Laboratory Reports***

**7.8.2.1** Requirements for the content of a *Laboratory Report* are found in the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases, the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) and level 2 documents.

### **7.8.2.2 Format of *Laboratory Report***

A *Laboratory Report* is prepared according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). The FBI Laboratory is responsible for all the information provided in a *Laboratory Report*, except when information is provided by the contributor.

## **7.8.3 Specific Requirements for *Laboratory Reports***

**7.8.3.1** A *Laboratory Report* includes additional information, when it is necessary for the interpretation of the examination results. Additional information is described in the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.3.1.1** When a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, FBI Laboratory personnel have objective evidence of the regulation, statute, case law or other legal requirement and have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

**7.8.3.2** When the FBI Laboratory is responsible for sampling, a simplified *Laboratory Report* can be prepared or the *Laboratory Report* includes additional information regarding sampling or sample selection. when it is necessary for the interpretation of the examination results (refer to QAM - Section 7.8.5).

## **7.8.4 Specific Requirements for Calibration Certificates**

The FBI Laboratory does not issue calibration certificates.

## **7.8.5 Reporting Sampling-Specific Requirements**

When the FBI Laboratory is responsible for sampling, personnel will retain the following information in the FBI Laboratory. The information may additionally be included in the *Laboratory Report*.

- a) the date of sampling
- b) unique identification of the item or material sampled
- c) the location of sampling, including any diagrams, sketches, or photographs
- d) a reference to the sampling plan and sampling procedure.
  - 1. If statistical sampling is used the *Laboratory Report* contains the confidence level and corresponding inference regarding the population.
- e) details of any environmental conditions during sampling that affect the interpretation of the results
- f) information required to evaluate measurement uncertainty for subsequent examination.

## **7.8.6 Reporting Statements of Conformity**

**7.8.6.1** When a statement of conformity to a specification or standard is provided in the *Laboratory Report*, the units, disciplines, and/or categories of testing have procedures for recording the decision rule<sup>7</sup> employed. These procedures ensure the decision rule takes into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and describes how to apply the decision rule.

**7.8.6.2** The statement of conformity in the *Laboratory Report* will clearly identify:

- a) to which results the statement of conformity applies;
- b) which specifications, standards, or parts thereof are met or not met;

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<sup>7</sup> A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

- c) the decision rule applied (unless it is inherent in the requested specification or standard).

## **7.8.7 Reporting Opinions and Interpretations**

**7.8.7.1** Authorized qualified examiners provide opinions and interpretations, when applicable in *Laboratory Reports* or *DNA Match Confirmation Letters* and record the basis upon which the opinions and interpretations have been made.

**7.8.7.2** The opinions and interpretations in a *Laboratory Report* and/or alternately reported results are based on the results obtained from the tested item. Opinions and interpretations are identified in *Laboratory Reports* according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.7.3** When opinions and interpretations are directly communicated by dialogue with the contributor, a record of the dialogue is retained in the appropriate communication log. The LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) contain requirements for providing expedited results to a contributor.

## **7.8.8 Amendments to Laboratory Reports**

**7.8.8.1** When an issued *Laboratory Report* needs to be changed, amended, or reissued, any change of information is clearly identified, and, where appropriate, the reason for the change is included in the amended, supplemental, or superseding *Laboratory Report*.

**7.8.8.2** Once a *Laboratory Report* has been issued, any amendments or supplements are made in the form of another *Laboratory Report* according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.8.3** An amended, supplemental, or superseding *Laboratory Report* is uniquely identified and contains a reference to the original *Laboratory Report(s)*.

## **7.9 Complaints**

**7.9.1** As part of the FBI Laboratory's commitment to provide reliable forensic examinations, personnel take appropriate steps to address valid complaints regarding their services. The FBI Laboratory's process to receive, evaluate, and make decisions on complaints, including complaints received in a *Customer Satisfaction Assessment* (FD-1000), is documented in QAM - Sections 7.9.3 through 7.9.7.



**7.9.2** The process for handling complaints is available to any interested party upon request. Upon receipt of a complaint, personnel notify their Unit Chief in writing. The Unit Chief confirms whether the complaint relates to laboratory activities that the FBI Laboratory is responsible for and, if so, investigates the complaint. The Unit Chief ensures that other laboratory management is made aware of the complaint, if appropriate. The FBI Laboratory is responsible for all decisions at all levels of the handling process for complaints.

**7.9.3** When handling complaints, the FBI Laboratory:

- a) receives, validates, investigates and decides what actions are to be taken in response to the complaint. If the Unit Chief determines the complaint identifies a nonconformity, the FBI Laboratory addresses the complaint as described in the LOM - Practices for Addressing a Nonconformity.
- b) tracks and records complaints, including actions undertaken to resolve them. Records are maintained by the appropriate Unit Chief(s) of all complaints, any relevant investigations, and responses by the affected unit(s).
- c) ensures that any appropriate action is taken.

**7.9.4** The appropriate Unit Chief is responsible for gathering and verifying all necessary information to validate the complaint.

**7.9.5** When practicable, the appropriate Unit Chief acknowledges receipt of the complaint, provides the complainant with progress reports, and provides the outcome.

**7.9.6** The outcomes to be communicated to the complainant are made by, or reviewed and approved by, personnel not involved in the original laboratory activities in question.

**7.9.7** When practicable, the appropriate Unit Chief gives formal notice of the end of the complaint handling to the complainant (i.e., stating that a given message is the final communication regarding the complaint).

## **7.10 Nonconforming Work**

**7.10.1** The QAM - Section 8.7 and the LOM - Practices for Addressing a Nonconformity are followed when any aspect of laboratory activities or results of the work do not conform to the quality system. These practices ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the FBI Laboratory;
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
- d) a decision is taken on the acceptability of the nonconforming work;
- e) where necessary, the contributor is notified and work is recalled;
- f) the responsibility for authorizing the resumption of work is defined.

**7.10.2** The FBI Laboratory retains records of nonconforming work and actions regarding nonconforming work.

**7.10.3** Where the evaluation indicates that the nonconformity could recur or there is doubt about the conformity of the operations of the FBI Laboratory with its quality system, QAM - Section 8.7 and the LOM - Practices for Addressing a Nonconformity are followed.

## **7.11 Control of Data and Information Management**

**7.11.1** The FBI Laboratory has access to the data and information needed to perform laboratory activities.

**7.11.2** The FBI Laboratory's laboratory information management system(s) used for the collection, processing, recording, reporting, storage, or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the FBI Laboratory before introduction. Whenever there are any changes, including software configuration or modifications to commercial off-the-shelf software, they are authorized, recorded, and validated before implementation.

**7.11.2.1** Units, disciplines, and/or categories if testing have a plan for the validation of computer software developed in-house and retain records of the validation.

**7.11.3** The laboratory information management system(s):

- a) is protected from unauthorized access;
- b) is safeguarded against tampering and loss;
- c) is operated in an environment that complies with provider or laboratory specifications;
- d) is maintained in such a manner that ensures the integrity of the data and information; and
- e) failures are recorded and appropriate immediate and corrective measures are taken.

**7.11.4** The laboratory information management system(s) is maintained at an FBI facility.

**7.11.5** The FBI Laboratory ensures instructions, manuals, and reference data relevant to the laboratory information management system(s) are readily available to personnel.

**7.11.6** Units, disciplines, and/or categories of testing ensure that calculations and data transfers are checked in an appropriate and systematic manner<sup>8</sup>.

**7.11.6.1** Technical records indicate the check was performed and who performed the check. When possible, the check is not conducted by the person who performed the calculation(s) or data transfer(s)<sup>9</sup>.

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<sup>8</sup> This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

<sup>9</sup> This check may be part of a technical review.

## **8 Quality System Requirements**

### **8.1 Options**

**8.1.1** The FBI Laboratory has an established quality system that supports and demonstrates the consistent achievement of the requirements in ISO/IEC 17025:2017 and ANAB AR 3125 and assures the quality of the laboratory results. The FBI Laboratory's quality system is in accordance with Option A of ISO/IEC 17025:2017.

**8.1.2** The FBI Laboratory quality system addresses, at a minimum:

- management system documentation (see QAM - Section 8.2);
- control of management system documents (see QAM - Section 8.3);
- control of records (see QAM - Section 8.4);
- actions to address risks and opportunities (see QAM - Section 8.5);
- improvement (see QAM - Section 8.6);
- corrective actions (see QAM - Section 8.7);
- internal audits (see QAM - Section 8.8);
- management reviews (see QAM - Section 8.9).

### **8.2 Quality System Documentation**

**8.2.1** The FBI Laboratory quality system establishes, documents, and maintains policies and objectives for the fulfillment of the requirements of the applicable accrediting body(ies). The quality policies and objectives are acknowledged and implemented at all levels of the FBI Laboratory.

**8.2.1.1** The following words (to include forms of the same word) used in ISO/IEC 17025:2017, the requirements issued by the accrediting bodies, and those in quality system documents require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

**8.2.2** The quality policies and objectives address the competence, impartiality and consistent operation of the FBI Laboratory.

The management of the FBI Laboratory is dedicated to good laboratory practice and to the quality of the forensic services provided to contributors. The quality system of the FBI Laboratory ensures that functions are performed as intended and conform to the requirements of applicable accrediting body(ies). FBI Laboratory personnel are responsible for ensuring that they understand and apply the quality system to their daily activities.

All quality system documents are reviewed annually and updated as necessary to continuously improve the effectiveness of the quality system. If conditions or situations having an adverse impact on the quality system are identified, appropriate changes are made and/or corrective actions are implemented.

The FBI Laboratory quality system goals and objectives are as follows:

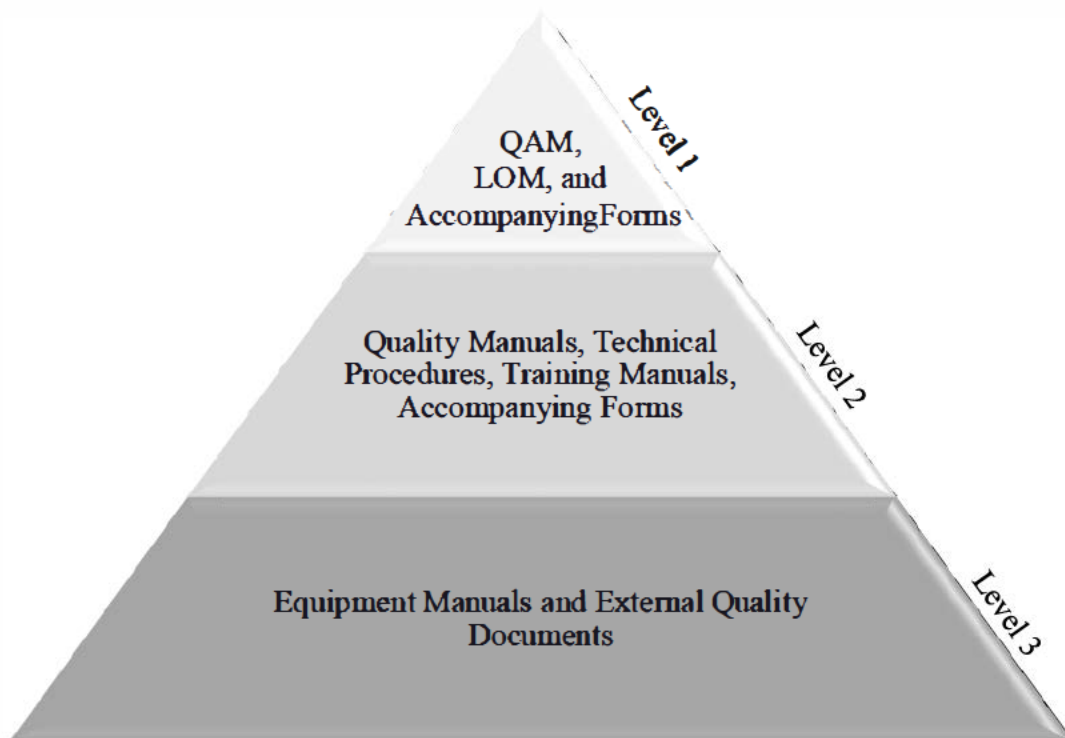
- To ensure that FBI Laboratory results provided to contributors and other laboratories are reliable and scientifically sound.
- To establish formal methods of quality assurance within the FBI Laboratory through the implementation of recognized standards for good laboratory practice.
- To ensure procedures are valid, dependable, reproducible, and are adequate for the intended purpose.
- To ensure the routine operational performance of units within the FBI Laboratory are monitored.
- To ensure all areas of the quality system are periodically audited to demonstrate that policies, practices, and procedures are being followed and where applicable, accompanying forms are being used.
- To maintain quality, excellence, and integrity.
- To conform to the requirements of the applicable accrediting body(ies).
- To ensure necessary training is provided for personnel to carry out the provisions of the quality system.

**8.2.3** Management is committed to the development, implementation, and continuous improvement of the quality system. This is communicated via policies, the QAM and LOM, FBI Laboratory News emails, targeted issue emails, and meetings with FBI Laboratory personnel. With the support of the FBI Laboratory's management and input from personnel, new policies, practices, and procedures are developed, revised, and implemented when necessary.

#### **8.2.4 Document Hierarchy**

The FBI Laboratory's quality system is comprised of the QAM, LOM, quality manuals, technical procedures, training manuals, accompanying forms, and controlled equipment manuals. Within the quality system, a document that applies to the entire FBI Laboratory (i.e., QAM, LOM, their accompanying forms) is referred to as a level 1 document. A document that applies to a specific unit(s), discipline(s), and/or category(ies) of testing (i.e., quality manual documents, technical procedures, training manuals, their accompanying forms) is referred to as a level 2 document. A level 3 document applies to a specific unit(s), discipline(s), and/or category(ies) of testing, but does not require approval by the Quality Manager (e.g., controlled equipment manuals, externally produced standards).

The QAM provides requirements to meet the standards of the applicable accrediting body(ies) and other requirements based on the needs of the FBI Laboratory. FBI Laboratory practices and accompanying forms are found in the LOM. Practices are used to implement FBI Laboratory requirements defined in the QAM. The QAM and LOM are supplemented by quality manuals, technical procedures, training manuals, and accompanying forms. Technical procedures cover all relevant examinations and DNA databasing conducted by the FBI Laboratory. Training manuals cover appropriate training requirements for personnel responsible for receiving and breaking down evidence and performing laboratory tasks. Additionally, appropriate controlled equipment manuals are available to refer to, when necessary, for equipment used in examinations and DNA databasing.



**Figure 1: FBI Quality System Document Hierarchy**

**8.2.5** All personnel involved in laboratory activities have access to the quality system documents and related information necessary for their responsibilities.

### **8.3 Control of Quality System Documents**

**8.3.1** The documents that comprise the FBI Laboratory quality system are controlled according to the LOM - Practices for Document Control. The official versions of the QAM, LOM, quality manuals, technical procedures, training manuals, and accompanying forms are posted on BUNET and LABNET.

**8.3.2** The LOM - Practices for Document Control ensures:

- a) all FBI Laboratory quality system documents are approved for adequacy prior to issuance by authorized personnel.
- b) documents are annually reviewed, and revised as necessary.
- c) changes in FBI Laboratory prepared quality system documents are identified and the current revision status of documents is identified.
- d) current versions of FBI Laboratory prepared quality system documents are available at points of use and, where necessary, their distribution is controlled.
- e) quality system documents are uniquely identified.

- f) invalid and/or obsolete documents are promptly removed, and archived quality system documents are marked appropriately to preclude their use.

## **8.4 Control of Records**

**8.4.1** The FBI Laboratory quality system documents address the legible records that are generated and/or retained.

**8.4.2** The FBI and FBI Laboratory have policies, practices, and procedures for the identification, access, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records.

## **8.5 Actions to Address Risks and Opportunities**

**8.5.1** The FBI Laboratory considers the risks and opportunities associated with laboratory activities in order to:

- a) give assurance that the quality system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the FBI Laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in laboratory activities; and
- d) achieve improvement of the quality system.

**8.5.1.1** The FBI Laboratory considers risks and opportunities related to health and safety through the Health and Safety Program.

**8.5.2** The FBI Laboratory plan includes:

- a) determination of risk associated with detected nonconformities;
- b) opportunities for improvement;
- c) the review of quality system documents, at a minimum on an annual basis, and revisions when needed. Reviews and revisions consider risks and opportunities for improvement;
- d) consideration of the risks and merits of requested deviations;
- e) a comprehensive evaluation of quality system activities, including the effectiveness of these actions, during the Annual Management Review of the quality system. The Annual Management Review determines the plan for improvement of the quality system in the coming year.

**8.5.3** FBI Laboratory management ensures actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

## **8.6 Improvement**

**8.6.1** FBI Laboratory personnel, identify opportunities for improvement and implement any necessary actions.

**8.6.2** The FBI Laboratory encourages feedback from its contributors according to the LOM - Practices for Customer Satisfaction Assessment of FBI Laboratory Services. The feedback is analyzed and used to improve the quality system, laboratory activities, and customer service.

## **8.7 Corrective Actions**

**8.7.1** Any FBI Laboratory personnel may identify a situation or condition where a concession, correction, or corrective action is required. The LOM - Practices for Addressing a Nonconformity describes how the FBI Laboratory:

- a) reacts to the nonconformity and, as applicable, takes action to control and correct it, and addresses the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity, determining the cause(s) of the nonconformity, and determining if similar nonconformities exist or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) establishes a reasonable timeframe for completion.

The FBI Laboratory updates risks and opportunities determined during the Annual Management Review and makes changes to the quality system, if necessary. [QAM - Section 8.5.2]

**8.7.2** FBI Laboratory personnel ensure the response to a nonconformity is appropriate to the effect of the nonconformity encountered according to The LOM - Practices for Addressing a Nonconformity.

**8.7.3** The LOM - Practices for Addressing a Nonconformity describes the records that are generated and/or retained with respect to nonconformities.

## **8.8 Internal Audits**

**8.8.1** The LOM - Practices for Internal Audits are followed when conducting scheduled audits to verify that operations conform to the requirements of the FBI Laboratory quality system and the ISO/IEC 17025:2017, ANAB AR 3125, and/or ISO/IEC 17020:2012 requirements, as applicable. Audits are performed to provide information on whether the quality system is effectively implemented and maintained.

**8.8.1.1** Internal audits are conducted, at a minimum, on an annual basis according to the LOM - Practices for Internal Audits.

**8.8.2** The FBI Laboratory plans, establishes, implements, and maintains an audit program as described in the LOM - Practices for Internal Audits.

## **8.9 Management Reviews**

**8.9.1** The FBI Laboratory's Executive Management in conjunction with the Quality Manager evaluate the quality system and laboratory activities to ensure their continued suitability, accuracy and effectiveness. Additionally, the quality policies and objectives are reviewed. This management review is used as the foundation for future development of FBI Laboratory goals and objectives as well as any necessary changes or improvements to the quality system.

**8.9.1.1** Management reviews are conducted on an annual basis.

**8.9.2** The management review inputs are recorded and assess:

- a) changes in internal and external issues that are relevant to the FBI Laboratory;
- b) fulfillment of objectives;
- c) the suitability, adequacy, and completeness of quality system documents for meeting the quality objectives of the FBI Laboratory and ISO/IEC 17025:2017 and ISO/IEC 17020:2012 standard (as applicable);
- d) status of actions from previous management reviews;
- e) outcome of any recent internal audits;
- f) corrective and preventive actions, including their status;
- g) external audits and/or assessments;
- h) changes in the volume and type of work being performed or in the range of laboratory activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of the organizational structure, staff training, and resources to implement the FBI Laboratory quality system and fulfill its objectives;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

**8.9.3** Records of management reviews are serialized in Sentinel and record all decisions and actions related to:

- a) the effectiveness of the quality system and its processes; improvement of the laboratory activities related to the fulfillment of the accrediting bodies' requirements;
- b) provision of required resources;
- c) any issues identified and actions taken to address them. Laboratory management and the Quality Manager will ensure the actions are carried out within an appropriate and agreed upon timescale.



## 9 References

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Handbook of Forensic Services, Federal Bureau of Investigation, Laboratory Division, latest revision.

International Vocabulary of Basic and General Terms in Metrology, International Organization for Standardization, Geneva, Switzerland, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17020 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection, International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Security Reference Guide for Laboratory Division Personnel, Federal Bureau of Investigation, Laboratory Division, latest revision.

[www.anab.org](http://www.anab.org) for policies and guidance.

Rev. #	Issue Date	History
12	06/08/18	Sections 4.1.4 and 4.2.6.1 revised to designate the Deputy Assistant Director as the Laboratory Director. Updated title of <i>ANAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists</i> throughout. Clarified location where position descriptions are maintained and where educational requirements can be found throughout. In section 4.1.6.1, added that Technical Leaders are included in the QAWG. In sections 4.2.6.3, 4.2.6.4 and 4.2.6.6 added authorization. Clarified that DNA databasing records meet all requirements for technical records in sections 4.13.2.1, 4.13.2.3 and 4.13.2.3.1. Updated sections 5.2.5, 5.9.4.2 and Appendix A to require authorization to perform technical reviews.
13	06/03/19	Entire document revised to conform to new accreditation requirements.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **Appendix A: Example Language to use in a Forensic Examiner, Technician, or a Specific Task(s) Qualification and Authorization EC**

The following provides guidance for preparing a Qualification/Authorization EC. The information in *italics* must be included in the Qualification/Authorization EC for FBI Laboratory personnel. There is also example language provided for each required heading (**in bold**). Language can be modified to cover whether the person has completed the entire training program for a discipline/category(ies) of testing, is being authorized to perform a specific task(s) such as conduct technical reviews, testimony evaluations, and/or was previously qualified and authorized and being re-qualified and authorized in same and/or new discipline/category(ies) of testing. For questions about the EC requirements, contact the Forensic Examiner Training Program Manager or the Quality Manager.

**Case ID#:** *Refer to Forensic Examiner Training Program Manager for the file number*

**Title:** *Provide a brief title that appropriately reflects:*

- *The training the person has completed (e.g., entire training program, specific task(s)).*
- *Include “Qualification” and “Authorization” as well as the person’s name in the title.*

**Title Example language:**

Completion of Forensic Examiner training for Forensic Examiner (Full Name), Qualification, and Authorization

**Synopsis:** *Briefly describe:*

- *The training the person has successfully completed (e.g., entire training program, specific task(s)).*
- *Include the person’s name, unit, and the official date of the training completion.*

**Synopsis Example language:**

To record (Examiner’s Full Name) successful completion of the Forensic Examiner Training Program in the (Unit) on (insert official date of training completion).

**Details:** *Describe in detail:*

- The training requirements the person has met, to include referencing the appropriate manuals.*
- Reference any previous qualification file number for a person in cases of re-qualification or additional qualifications.*
- Include the training period beginning and end dates.*
- State where the training record will be maintained.*
- State that the person is qualified as an FBI Examiner, Technician, and/or in a specific task(s) and in what unit.*
- State that the person is authorized to conduct work in a specific discipline/ category(ies) of testing, and/or task(s), such as conducting technical reviews and/or testimony evaluations. When referring to the discipline, also specify the category(ies) of testing as listed on the FBI Laboratory’s Scope of Accreditation.*

Details Example language:

(Examiner's Full Name) has successfully completed all training requirements as outlined in the Laboratory Quality Assurance Manual, Laboratory Operations Manual, and (Title) Training Manual. The training period began on (date) and was completed on (date). A complete record of (Ms/Mr\_\_\_\_\_'s) training is on file in the (Unit). Upon approval of this EC, (Ms/Mr\_\_\_\_\_) is recognized as a qualified FBI (Examiner title) in the (Unit). (Ms/Mr\_\_\_\_\_) is authorized to perform examinations in the (specify the discipline(s)/category(ies) of testing as stated on Scope of Accreditation, or the specific tasks), operate all associated equipment as defined by (Unit), and when applicable, issue FBI *Laboratory Reports* including providing opinions and interpretations.

*The final sentence is only needed for personnel that have completed training as a Forensic Examiner. If personnel will provide alternately reported results, the final sentence will include that authorization. If personnel will be authorized to conduct technical reviews and/or perform testimony evaluations upon completion of training, authorization to perform that task will be included. If personnel will be authorized to conduct technical reviews and/or perform testimony evaluations following other requirements, a separate authorization EC will be generated.*

## **FBI Laboratory Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual**

### **1 Purpose**

To define terms used in the FBI Laboratory Quality Assurance Manual (QAM) and the FBI Laboratory Operations Manual (LOM).

### **2 Scope**

The definitions in this document apply to FBI Laboratory personnel who follow FBI Laboratory quality system documents.

### **3 Terms and Definitions**

1A - Physical and/or electronic records supporting an FBI case. FBI Laboratory physical and/or electronic records are placed in a *Supporting Documentation Envelope* and/or serialized in Sentinel, as appropriate.

1B - Physical evidence that is submitted by an FBI contributor.

1C - Records of the same nature as 1A material but that are physically too large to be filed in the 1A section of the FBI Laboratory file.

A2LA - An accrediting body; American Association for Laboratory Accreditation.

ANAB - An accrediting body; American National Standards Institute (ANSI) National Accreditation Board .

Accreditation Cycle - Period of time between the date that accreditation is granted and the date accreditation expires.

Accreditation - A process by which an accrediting body, such as ANAB or A2LA, gives formal recognition that an entity is competent to carry out specific tasks.

Accrediting Body - An authoritative body that provides accreditation to various standards and programs for public and private organizations such as laboratories, inspection bodies, proficiency test providers, and reference material producers.

Acknowledgement Email - An email sent to acknowledge receipt of a request for examination and the associated evidence.

Acknowledgement Letter (7-3 or 7-3 LIMS) - A form that may be used to acknowledge receipt of a request for examination and the associated evidence. [obsolete]

Activity and Communication Log (7-245) - A physical form used to record activity or communication related to a legacy case or to record classified activity or communication.

Administrative Error - A non-technical error such as a typographical error in a *Laboratory Report* or associated with a proficiency test. An administrative error may also be a nonconformity.

Administrative Records - Records related to a case, whether electronic or physical, that do not constitute data or information resulting from examinations and DNA databasing (e.g., Communication Log, Chain-of-Custody Log, *Activity and Communication Log*, *Chain-of-Custody Log*, *Laboratory Worksheet*).

Administrative Review - An evaluation to ensure that an FBI Laboratory file record is complete and that the *Laboratory Report* uses correct spelling, is grammatically accurate, properly classified, complete, and complies with FBI Laboratory requirements and practices, and relevant level 2 documents.

Administrative Reviewer - A Unit Chief, Technical Leader, or designee who conducts an administrative review. An administrative reviewer is someone other than the person(s) authoring the report being reviewed.

Alternate Reporting - An approved format used in lieu of a *Laboratory Report* to present case-related information to a contributor (e.g., record email, Summary Sheet) for an initiative and/or intelligence matters. Alternate reporting must be approved by the Laboratory Director and Quality Manager.

Analytical/Interpretive Inconsistency - A discrepancy of a technical nature identified in a proficiency test, to include the processing and interpretation of data.

Analytical/Interpretive Error - A technical error such as an incorrect conclusion in a *Laboratory Report*. It also pertains to technical errors associated with a proficiency test.

Approved Proficiency Test - A proficiency test approved by the appropriate Technical Leader and Quality Manager to ensure it is appropriate for the testing conducted in the FBI Laboratory.

Archive (FA) - A terminal transfer used to place evidence into a storage area for indefinite detention. This transfer type is used for request only and electronic submissions as well as for submissions with physical evidence that will not be returned to the contributor.

Archived Storage - A physical location for long term storage of evidence.

Association - A determination that a relationship exists between persons and/or objects.

Audit - A systematic, independent, documented process for obtaining records, statements of fact, or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

Audit Program Manager - A Quality Assurance Specialist in the Forensic Analysis Support Unit who manages the FBI Laboratory internal audit program.

Audit Team - One or more auditors conducting an audit.

Audit Team Leader - An auditor who coordinates a portion of an audit.

Auditor - A person with demonstrated competence who conducts Forensic Analysis Support Unit directed audits. In the FBI Laboratory, auditors performing internal audits must successfully complete an approved training course.

Authorized - The conclusion of a process of reviewing pertinent records related to a person, technique, document, or other entity, including approval by appropriate personnel.

Biohazard Evidence - Materials that may include, but are not limited to, liquid and dried body fluids such as blood, saliva, urine, human tissue, body parts, and organs or medical diagnostic packs, regardless of content.

Blank - A control where a specified component(s) is not present.

Blind Verification - An independent examination of an item(s) of evidence by another examiner qualified and authorized in the same category of testing, who does not know the conclusion of the original examiner.

BUNET - The intranet platform located on the FBI's classified network (i.e., FBINET).

Calibration - The adjusting or standardizing of equipment to ensure agreement of a measurement with a reference standard.

Case (FA) - FBI investigation designated in FA with a Laboratory Number. Contains case-related data including submissions, Case Records, listing of evidence, and *Laboratory Reports*.

Case Communication Log (FA) - Data entry fields used to record activity or communication related to a case.

Case ID - A unique alphanumeric case identification number that is assigned to an FBI investigation.

Case Notes - The record of standards, controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other records generated which are used to support conclusions.

Case Record (FA) - Instance of work within a unit or discipline resulting in an acknowledgement email and/or *Laboratory Report* or completion of an assignment of work in FA.

Case Record Communication Log (FA) - Data entry fields used to record activity or communication related to a case record.

Case Record Number (FA) - FA generated identifier for a case record within a case.

Case Records - All administrative and examination records, whether electronic or physical, generated or received by the FBI Laboratory for a given case. These records may be stored in one or more locations/facilities.

Casework - FBI Laboratory activities concerning the examination of evidence and/or request(s) for examination of evidence.

Category of Testing - A specific type of analysis within an accredited discipline of forensic science. In the FBI Laboratory, anthropology, cryptology, and illicit business records, are also considered categories of testing. Additionally, the General Physical and Chemical Analysis category of testing for the FBI Laboratory has sub-categories of testing (e.g., bank dye, lubricants, inks, oleoresin capsicum, cyanide, polymers, metallurgy, explosives and hazardous devices, and soil). The use of the term category of testing in the FBI Laboratory Quality System documents includes sub-category where one is available unless otherwise specified.

Certified Reference Material - Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Chain-of-Custody Log (7-243, 7-243a, or equivalent in FA or EXPeRT) - A form or data entry fields in FA or EXPeRT used to record all transfers of evidence, including non-evidentiary items, over which the FBI Laboratory has control.

Check-In Notes - A mechanism to record the items received, including evidentiary and non-evidentiary items, and the condition of these items as well as the container/packaging.

Comparative Examination - Testing performed on two or more items for the purpose of determining whether an association between the items exists.

Competency Test - The evaluation of a person's knowledge, skills, and/or ability to perform work.

Competent - Possessing the requisite knowledge, skills, and abilities to perform a job.

Complaint - The expression of dissatisfaction by any person or organization to the FBI Laboratory, relating to the activities or results of the FBI Laboratory, where a response is expected.



Concession - An acknowledgement that a nonconformity has been detected, and the nonconformity will not be corrected.

Condition Adverse to Quality - A situation or condition such as failure, malfunction, deficiency, or defective item that results in a nonconformity that requires corrective action for resolution.

Container - A vessel intended to secure the integrity of the item.

Container (FA) - FA evidence type used to designate a container.

Continual Improvement - Recurring activities that are carried out to enhance the performance of the quality system.

Contract - The agreement between the FBI Laboratory and the contributor.

Contractor - A person performing work for the FBI Laboratory on a contractual basis who meets the applicable provisions of the FBI Laboratory quality system.

Contributor - A person or organization that submits evidence to and/or requests the testing services of the FBI Laboratory. Equivalent to “customer” as used in ISO/IEC 17025 and AR 3125. (See External Contributor and Internal Contributor)

Contributor, External - Any non-FBI entity that submits evidence to and/or requests the testing services of the FBI Laboratory.

Contributor, Internal - Any FBI entity that submits evidence to and/or requests the testing services of the FBI Laboratory.

Contributor Portal - Law Enforcement Enterprise Portal (LEEP) service managed by the Laboratory Division that allows non-FBI law enforcement contributors to submit a Request for Laboratory Examination (RFLE), check status of casework, and retrieve released *Laboratory Reports*.

Control - A sample analyzed in parallel with evidentiary and DNA database samples and designed to demonstrate that a procedure worked correctly and that data are valid.

Correction - Action to eliminate a detected nonconformity.

Corrective Action - Process to eliminate the cause of a detected nonconformity or other undesirable situation adverse to quality. This may include the affect or impact on the quality of the work, the integrity of the evidence, or the quality of the testimony.

Corrective Action Request (7-254) - A form used to identify and record the resolution of a corrective action.

Corrective Maintenance - Actions taken on equipment to restore it to proper operation.

Crime Scene - An area, object, or person, from which evidence is identified, recorded, collected, and/or interpreted; excluding said activities that routinely occur within FBI Laboratory facilities.

Custody - The care and control of an item of evidence implying responsibility for its protection and preservation.

Decision Rule - A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

Deputy Assistant Director - A person who is responsible for managing multiple sections within the FBI Laboratory. (See Laboratory Director)

Designee - A person designated in writing to perform a task by the person (or his/her manager) who is assigned responsibility for that task.

Deviation - Authorization to depart from a requirement(s) prior to its occurrence. A deviation can be major or minor depending on the circumstances. (See Major Deviation and Minor Deviation)

Deviation, Major - A deviation that has the potential to significantly impact the quality system, may affect multiple cases/DNA database samples, and/or is applicable over an extended period of time. (See Deviation)

Deviation, Minor - A deviation that is not expected to significantly impact the quality system and does not have an extended duration. (See Deviation)

Digital Evidence - Information of probative value stored or transmitted in binary form. Personnel that examine digital evidence are not included in the scope of the FBI Laboratory's quality system.

Discipline - A major area of activity in forensic science which may appear on a scope of accreditation.

DNA Database Sample - A DNA sample obtained from a person who is legally required to provide a DNA sample for DNA databasing purposes and whose identity is established at the time of collection of the sample.

DNA Databasing - The analysis of DNA database samples for entry into the Combined DNA Index System (CODIS) and, if eligible, for upload to the National DNA Index System (NDIS) (e.g., offenders, arrestees, detainees). The term DNA databasing constitutes part of the term "test" as used in this manual, ISO/IEC 17025 and AR 3125. (See Examination)

DNA Databasing Records - Equivalent to Case Records.

DNA Match Confirmation Letter - The official notification that presents written confirmation to a caseworking laboratory to communicate the database match and the identity of the person who

provided the DNA database sample. A *DNA Match Confirmation Letter* is not a *Laboratory Report*.

Document - In the FBI Laboratory quality system, this term applies to the QAM, LOM, quality manuals, technical procedures, accompanying forms, training manuals, and controlled equipment manuals. (See Controlled Document, Level 1 Document, Level 2 Document, Level 3 Document)

Document Control - The process of ensuring that controlled documents prescribing quality-affecting activities or specifying quality requirements, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and distributed for use to the personnel performing the prescribed activities.

Document Control Program Manager - A Quality Assurance Specialist in the Forensic Analysis Support Unit who manages the FBI Laboratory document control program.

Document, Controlled - A document that is issued and distributed in a trackable manner. (See Document)

Document, Level 1 - A document that applies to the entire FBI Laboratory (i.e., QAM, LOM, accompanying forms).

Document, Level 2 - A document that applies to a specific unit(s), discipline(s), and/or category(ies) of testing (i.e., quality manual documents, technical procedures, SOPs, training manuals, accompanying forms).

Document, Level 3 - A document that applies to a specific unit(s), discipline(s), and/or category(ies) of testing, but does not require approval by the Quality Manager (i.e., controlled equipment manuals, externally produced quality documents).

Document, Uncontrolled - Any document that is not issued or distributed in a trackable manner (e.g., documents printed for personal use, electronic files sent outside the FBI Laboratory).

Drug and Valuable Evidence Label (FD-723) - A combined drug and valuable label affixed to packages containing drug or valuable evidence submitted by FBI personnel. The combined label became obsolete on 02/24/2016. (See Drug Evidence Label, Valuable Evidence Label)

Drug Evidence - Controlled substances, drug paraphernalia, prescription and nonprescription drugs.

Drug Evidence Label (FD-723) - A label affixed to packages containing drug evidence submitted by FBI personnel. (See Drug and Valuable Evidence Label)

eLAB Help Desk - Personnel who may assist FBI Laboratory personnel with FA-related tasks, including specialized functions that only limited personnel may be permitted to perform (e.g., modification to previous evidence transfer).

Electronic Communication (EC) (FD-1057) - A standardized form typically used to record information as an FBI official record in Sentinel.

Electronic Evidence - Evidence received in an electronic format such as email attachments or evidence serialized in Sentinel by FBI contributors.

Environmental Conditions - Any characteristic of the FBI Laboratory facilities that could reasonably be expected to impact the quality of the FBI Laboratory's work.

Evaluation of Testimony (7-256) - A form used to record the evaluation for a person who testifies for the FBI Laboratory.

Evidence - An item submitted for examination(s).

Evidence Breakdown (FA) - Process of taking inventory of submitted evidence types to include containers, packaging, items, and requests.

Evidence Management Unit (EMU) Personnel - Personnel who initially accept and inventory evidence, manage cases, maintain liaison with contributors, and package and/or ship evidence. Authorized personnel may also write *Laboratory Reports*. In certain cases, other appropriately trained personnel may perform the duties of EMU personnel.

Evidence Storage Room (ESR) - Any secured room, cabinet, warehouse, or other area with multi-person access used for the storage of evidence.

Examination - The procedure(s) utilized by an examiner/technician/technical specialist to obtain information from evidence in order to reach conclusions concerning the nature of and/or associations related to evidence received by the FBI Laboratory. The term examination constitutes part of the term "test" as used in this manual, ISO/IEC 17025 and AR 3125.

Examination Plan (7-262) - A form prepared or data entry fields completed that record the anticipated examination(s) of evidence submitted to the FBI Laboratory. (See TEDAC Examination Plan)

Examination Plan, TEDAC (7-274) - A form prepared or data entry fields completed that record the anticipated examination(s) of TEDAC evidence submitted to the FBI Laboratory. (See Examination Plan)

Examination Records - Records related to a case, whether electronic or physical, that support the results and/or conclusions presented in a *Laboratory Report* or *DNA Match Confirmation Letter*, such as case notes, data, and photographs. Examination records are generated as the result of examinations of evidence or DNA databasing.

Examination Statistics - An accounting of the number and types of examinations conducted. This is recorded on a *Laboratory Statistics Sheet* or equivalent in FA.

Examiner - A person who is qualified and authorized by the FBI Laboratory to conduct, direct, and/or have responsibility for examinations or DNA databasing within his/her category(ies) of testing. Examiners also write *Laboratory Reports* or DNA Match Confirmation Letters conveying the results of those examinations/DNA databasing.

Executive Management - The Assistant Director, Laboratory Director, and Section Chiefs of the FBI Laboratory Division. The FBI Laboratory TEDAC section also has a TEDAC Deputy Director and an Assistant Section Chief.

Explosives Reference Tool (EXPeRT) - A system used for case management of TEDAC submissions and to share information with the Counter-Improvised Explosive Device (C-IED) community. Additionally, EXPeRT contains explosives-related information.

FBI Laboratory - In this manual, this term refers to personnel that may be responsible for receiving, inventorying, and/or examining evidence; DNA databasing; issuing *Laboratory Reports*; providing testimony with respect to those examinations in legal proceedings; and maintaining the quality system.

FBI Laboratory Chief Security Officer - An FBI Laboratory person who is responsible for administering the FBI Laboratory's Security Program.

FBI Laboratory Drug and Valuable Evidence Label (7-248) - A combined drug and valuable label affixed to packages containing drug or valuable evidence within the FBI Laboratory. The combined label became obsolete on 06/02/2019. (See FBI Laboratory Drug Evidence Label, FBI Laboratory Valuable Evidence Label)

FBI Laboratory Drug Evidence Label (7-248) - A label that is placed on drug evidence packaging within the FBI Laboratory.

FBI Laboratory Valuable Evidence Label (7-287) - A label that is placed on valuable evidence packaging within the FBI Laboratory.

FBI Laboratory File - A portion of an official FBI file containing records generated and/or maintained by the FBI Laboratory. Some of the electronic records may be generated and/or maintained in FA or Sentinel. Physical records consisting of a 1A(s) or 1C(s) may also be a part of the official FBI file.

FBI Laboratory Number - The FBI Laboratory's unique identifier that is assigned to each request for examination. For legacy cases, this nine-digit number indicates the year, month, day, and sequential request for examination processed on that day. For FA cases, it is generated by FA for a case. This nine-digit number indicates the year, followed by a hyphen, followed by a five-digit number assigned consecutively per year (e.g., 2019-00001).

FDDU Sample Number - The FBI Laboratory's unique identifier that is assigned to each Federal DNA Database Unit DNA database sample, generated by STACS. For DNA databasing, the FDDU Sample Number will be recorded in lieu of an FBI Laboratory Number.

File Copy (Laboratory Report) - A copy of a *Laboratory Report*, generated for a legacy case, which contains all of the text in the original *Laboratory Report* and records of the administrative review and technical review, when applicable.

Follow Up Case Record (FA) - A type of Case Record used when generating an amended, supplemental, or superseding *Laboratory Report*.

Foreign Intelligence Surveillance Act (FISA) - A legal authority by which the FBI may acquire information or evidence. Information of this type will be omitted from FA and other unclassified systems.

Forensic Advantage (FA) - The laboratory information management system (LIMS) used by the FBI Laboratory. For DNA, STACS may be used to perform equivalent functions in lieu of FA.

Good Laboratory Practice - Operating practices and procedures for promoting quality and ensuring the integrity of the FBI Laboratory's work.

Hazardous Material Evidence - Any item or agent (biological, chemical, physical) which because of its quantity, concentration, or physical or chemical characteristics, has the potential to cause harm to humans, animals, or the environment, either by itself or through interaction with other factors. Also, hazardous materials are defined by the Department of Transportation as materials that in shipment pose risk to health, safety, and property. The materials are classified as being explosive, toxic, flammable, oxidizing, radioactive, or corrosive. (See the FBI Laboratory Safety Manual)

Health and Safety Group - Personnel in the Health, Safety & Security Unit who are responsible for administering the FBI Laboratory's Health and Safety Program.

Impartiality - The presence of objectivity.

Individual Characteristic Database (ICD) - A computerized, searchable collection of features, generated from individual characteristic database samples of known origin from which individual characteristic information originates, (e.g., reference blood or biological specimens, fingerprints of known persons, electronic fingerprint records, test fired ammunition).

Initial(s) - A person's handwritten initials or the secure electronic equivalent. A signature can also be used in lieu of initials.

Initiative - A Laboratory Director and Quality Manager approved Laboratory project devised to further support the Laboratory's mission. Initiatives may differ in their requirements from other quality system documents, but they require approved procedures authored according to LOM – Practices for Document Control and specific to the initiative.

Intelligence - Information specifically tailored to serve as a prelude to a decision or action by law enforcement or intelligence personnel, program managers, executives, or policy makers. In the broadest sense, intelligence is knowledge and foreknowledge of cyber, criminal, or national

security threats and issues.

Intermediate Check - A check carried out according to defined procedures and schedules to maintain confidence in the calibration status of equipment, reference standards, and reference materials. Analysis of a working standard may be used for an intermediate check.

Internal Audit - A review conducted by FBI Laboratory personnel to compare the various aspects of the FBI Laboratory's performance with a standard for that performance.

Item (FA) - The FA evidence type used to designate evidence for analysis or secondary evidence.

Item Identifier - A designator assigned to an item submitted to the FBI Laboratory. For legacy cases, it is an alphanumeric designator (e.g., Q1, K1). For FA cases, it is a numeric designator (e.g., 1-4).

LABNET - An unclassified network in the FBI Laboratory, which includes FA.

Laboratory Activity - The testing and sampling performed by the FBI Laboratory.

Laboratory Director - The Deputy Assistant Director of the Laboratory Division.

Laboratory Examination Request (LER) (FD-1121) - A Sentinel-based form which may be completed by FBI personnel to request forensic examinations from the FBI Laboratory. (See Request for Examination)

Laboratory Report (7-1, 7-1 LIMS, 7-273, 7-273 LIMS) - An official report that presents case-related information to a contributor regarding FBI Laboratory work. (Formerly known as *Report of Examination*)

Laboratory Statistics Sheet (7-2a) - A form used by an examiner to record examination statistics for legacy cases.

Laboratory Work Sheet (7-2) or TEDAC Laboratory Work Sheet - A form that contain(s) administrative information and descriptions of the items of evidence.

Legacy Case - Evidence or a request for examination submitted to the FBI Laboratory prior to the implementation of FA.

Major Deviation Request (7-258) - A form used to record the request and authorization of a major deviation.

May - A word used when an element of the quality system is optional or discretionary.

Measurand - Quantity intended to be measured.

Measurement - Process of experimentally obtaining one or more quantity values that can

reasonably be attributed to a quantity.

Measurement Error - The difference between a measured quantity and its true value. It includes random error and systematic error.

Measurement Traceability - Property of a measurement result whereby the result can be related to a reference through a recorded, unbroken chain of calibrations, each contributing to the measurement uncertainty. Also known as metrological traceability or traceability.

Measurement Uncertainty - Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. Also known as uncertainty of measurement.

Media - Objects on which electronic data can be stored.

Method - The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.

Must - A word used when an element of the quality system is required.

Non-association - The result of an examination/analysis between persons and/or objects that is not an association.

Nonconformity - A nonfulfillment of a requirement.

Nonoriginal Evidence - A reproduction of an original item of evidence, received by the FBI Laboratory for examination, including photographs, photocopies, digital images, audio recordings, video recordings, and other electronic files.

Object Repository (FA) - A location within FA where Laboratory records can be uploaded. FA has unit, Case, Case Record, Communication Log, Submission, and evidence repositories.

Packaging - Layer(s) of packaging within the outermost container.

Packaging (FA) - FA evidence type used to designate layer(s) of packaging.

Partner Laboratory - A non-FBI laboratory which accepts, inventories, and/or analyzes evidentiary material on behalf of the FBI Laboratory.

Performance Check - A check carried out at appropriate intervals to verify that the equipment is working as expected. Analysis of a control may be used as a performance check.

Policy - A directive that embraces the general goals and acceptable processes of the FBI, FBI Laboratory, and/or units.

Practicable - If something can be done, it will be done.



Practices - The term used to identify an FBI Laboratory level process.

Preventive Action - Action intended to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Preventive Action Request (7-261) - A form used to record and track the activities related to a potential nonconformity or other undesirable potential situation.

Preventive Maintenance - Actions taken to ensure that instruments and equipment continue to operate properly.

Primary Standard - Designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Procedure - A specified way to carry out an activity or a process.

Proficiency Test - A test to evaluate the continuing capability of examiners and technicians, and the performance of the FBI Laboratory. The expected results of the test are unknown to personnel taking the test.

Proficiency Test, External - A proficiency test provided by and reported to a source external to the FBI Laboratory. A type of interlaboratory comparison as used in ISO/IEC 17025 and AR 3125.

Proficiency Test, Internal - A proficiency test prepared by and reported to FBI Laboratory personnel. A type of intralaboratory comparison as used in ISO/IEC 17025 and AR 3125.

Proficiency Test Program Manager - A Quality Assurance Specialist in the Forensic Analysis Support Unit who manages the FBI Laboratory proficiency testing program.

Prohibited Case - A designation in Sentinel whereby a case is restricted and material cannot be added to the case unless a person has been granted access.

Proper Seal - A seal that prevents loss, cross-transfer, or contamination while ensuring attempted entry into the container/package is detectable. These may include a heat-seal, tape-seal, or a lock. A proper seal includes the initials of the person creating the seal being placed on the seal or across the seal onto the container/package, when possible.

Qualified - A term used to identify FBI Laboratory personnel who successfully complete their assigned training program, demonstrate competence, and when applicable, participate in the FBI Laboratory Proficiency Testing Program.

Qualitative Analysis - Procedures that determine the characteristics or constituents of a sample or specimen without regard to quantity.

Quality Assurance - Planned or systematic actions necessary to provide sufficient confidence that

the FBI Laboratory's work or service will satisfy given requirements for quality.

Quality Control - Internal activities or activities conducted according to established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality Manager - A person designated by Executive Management who has the defined authority and obligation to ensure that the requirements of the quality system are implemented and maintained. In the FBI Laboratory, the Forensic Analysis Support Unit Chief is the Quality Manager.

Quality Records - Records pertaining to the quality system such as audit reports, corrective action requests, deviation requests, and testimony evaluations.

Quality System - The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly. Equivalent to "management system" as used in ISO/IEC 17025 and 17020 and AR 3125.

Quantitative Analysis - Analysis of a substance that determines the amount or proportion of its constituents.

Quantity Value - Number and reference together expressing magnitude of a quantity.

Reagent - A substance used because of its known chemical or biological activity.

Record - Objective evidence of a condition, work performed, and/or activity conducted.

Reference Collection - Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes.

Reference Material - Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

Reference Standard - Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization, or at a given location.

Repository - The location for the permanent retention of TEDAC materials. Items may be eligible for lending to TEDAC partners.

Request (FA) - The FA evidence type used to designate a Request Only.

Request for Laboratory Examination (RFLE) - An FBI Laboratory Contributor Portal-based form which may be completed by external contributors to request forensic examinations from the FBI Laboratory. (See Request for Examination)

Request for Examination - Source requisition, which identifies the evidence submitted and the examination(s) requested.

Request Only - A request for FBI Laboratory services that does not require the submission of evidence.

Reserve Lab Number (FA) - FA functionality allowing a Laboratory Number to be generated without entering submission details.

Resource Manager (FA) - A module within FA for tracking Laboratory equipment and calibration and specified maintenance records. Other recordkeeping software (e.g., Laserfishe, STACS), may be used to perform equivalent functions.

Root Cause(s) - The fundamental reason(s) for a nonconformity

Sample Tracking and Control Software (STACS) - The laboratory information management system (LIMS) used by DNA personnel in lieu of FA. (See Forensic Advantage)

Sampling - Selection of a sample for testing according to a procedure. The approach to sampling can be either non-statistical or statistical.

Scientific Resolution Board - Personnel selected to resolve a disagreement of a scientific or technical nature that cannot be resolved at other levels.

Secondary Evidence - Material derived from an examination process on an item of evidence and recorded on a secondary evidence log. It is not an individual item submitted by a contributor and could not have been assigned an item identifier through the evidence breakdown process.

Secondary Evidence Log - A listing of secondary evidence.

Section Chief - A person who is responsible for managing multiple units within the FBI Laboratory Division. The FBI Laboratory TEDAC section also has a TEDAC Deputy Director and an Assistant Section Chief.

Secure Electronic Equivalent - The electronic equivalent of handwritten initials or signature that can only be applied by the person whom the electronic initials or signature represents.

Secured Limited Access Area - A locked or otherwise controlled space in the FBI Laboratory with access restricted to authorized personnel.

Sentinel - The FBI's official recordkeeping, information, and case management system.

Shipping Container - The outer container that houses evidence container(s).

Shipping Invoice (7-264, 7-264 LIMS) - A form or data entry fields in FA used to record the shipping of evidence.

Should - A word used when an element of the quality system is recommended, but not required.

SI Units - System of units, based on the International System of Quantities, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference on Weights and Measures (CGPM).

Signature - A person's handwritten signing of his/her name or the secure electronic equivalent.

Standard Method - A method that specifies the steps necessary to perform a test, contains documented performance characteristics, and is published by a standards developing organization such as ASTM International. (Formerly known as the American Society for Testing and Materials.)

Sub-category of Testing - See category of testing.

Subdivided Evidence - Multiple items of evidence that were originally designated as a single item during the evidence breakdown process and have subsequently been assigned unique identifiers. Items may also be subdivided in order to group related items together to assist examinations.

Subject Matter Expert (SME) - A person having specific skills and/or knowledge of a particular topic derived from training and/or experience.

Submission (FA) - Single instance of providing evidence and/or a request for examination to the FBI Laboratory.

Submission Number (FA) - FA generated identifier for a submission within a case.

Supervisor - A person directly responsible for overseeing the work of an organizational group.

Supporting Documentation Envelope (7-251) - An envelope, commonly referred to as a 1A envelope, which contains physical administrative and examination records and is part of the FBI Laboratory file.

Supporting Records - Administrative and examination records that support the examinations and conclusions contained in a *Laboratory Report* or *DNA Match Confirmation Letter*. General technical records, such as calibration and maintenance logs, reagent logs, and calibration certificates may be retained independent of supporting records.

Systematic Error - Component of measurement error that in replicate measurements remains constant or varies in a predictable manner.

Systemic Error - An error that occurs when all appropriate procedures are followed; interpretations seem correct based on the information provided; and appropriate thoroughness, judgment, and completeness are exercised. Systemic errors may indicate an error or oversight in documented procedures or the lack of validity of those procedures for that instance. A systemic

error means that the problem is not attributable to an examiner or technician.

Technical Leader - A person who is accountable for the technical operations in a category(ies) of testing and who is authorized to stop, suspend, and resume operations in that category(ies) of testing.

Technical Management - Personnel with overall responsibility for the technical operations and who provide the necessary resources to ensure the reliability and integrity of FBI Laboratory operations. In the FBI Laboratory the Quality Manager, the caseworking/DNA databasing/evidence management Unit Chiefs, Supervisors, and Technical Leaders are technical management.

Technical Procedure - A document that specifies the steps, methods, equipment, and materials necessary to perform a task properly. Technical Procedures are written to provide instruction and standardization for activities affecting quality.

Technical Records - Accumulations of data and information that support examinations and DNA databasing and that indicate whether specified quality or process parameters are achieved. All issued *Laboratory Reports* are retained as technical records.

Technical Review - Evaluation of notes, data and other supporting records that form the basis for the scientific results and conclusions contained in the *Laboratory Report*. This review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the recorded data and are within the scope of the discipline and/or category of testing. This term may also be used to describe other reviews (e.g., document preparation).

Technical Reviewer - A person who has been competency tested and is authorized to conduct a technical review of examination and/or DNA databasing records in that category of testing. For other technical reviews (e.g., document preparation) a person must have adequate technical expertise.

Technical Specialist - A person who performs technical tasks to support laboratory activities. In various FBI Laboratory units, such personnel may be identified by other titles such as analyst, biologist, chemist, electronics technician, photographer, or physical scientist.

Technician - A person who is qualified and authorized by the FBI Laboratory to work under the direction of an examiner in conducting examinations or DNA databasing within a particular discipline or category of testing. In various FBI Laboratory units, they may be identified by other titles such as analyst, biologist, chemist, or physical scientist.

TEDAC Evidence - Evidence submitted to the FBI Laboratory with the intent of sharing information with the C-IED community.

TEDAC Item Submission Form (7-275) - A form which may be completed by contributors or FBI personnel to request TEDAC examinations when only one case is submitted to TEDAC. (See Request for Examination)

TEDAC Bulk Submission Form (7-276) - A form which may be completed by contributors or FBI personnel to request TEDAC examinations when more than one case is submitted to TEDAC. (See Request for Examination)

TEDAC QA Program Manager - A Quality Assurance Specialist in the Forensic Analysis Support Unit who manages quality assurance matters for TEDAC.

Terminate Case Record (FA) - FA functionality allowing the discontinuation of a Case Record.

Terrorist Explosive Device Analytical Center (TEDAC) - An entity within the FBI Laboratory that performs forensic examinations on IEDs and related material, primarily for intelligence purposes.

Testimony Evaluator - A person authorized to perform a review of testimony.

Testimony Tracker - A system used to record information related to providing testimony (e.g., name of person testifying; court jurisdiction; date of request, receipt, and review of transcripts; receipt of *External Evaluation of Testimony*).

Traceability - Ability to verify the history, application, or location of an item by means of recorded identification back to a reference standard or reference material.

Uncertainty of Measurement - See Measurement Uncertainty.

Unit Chief - A person who manages a unit in the FBI Laboratory.

Universal Precautions - Refer to the FBI Laboratory Safety Manual.

Validation - The process for determining whether specified requirements are adequate for an intended use.

Valuable Evidence - Money (irrespective of country of origin or condition), jewelry (irrespective of composition), medals, rare coins, works of art, antiques, furs, and other items of intrinsic value. (See FBI Field Evidence Policy Guide)

Valuable Evidence Label (FD-723a) - A label affixed to packages containing valuable evidence submitted by FBI personnel. (See Drug and Valuable Evidence Label)

Verification - In the context of examinations, the procedure used to evaluate the validity of a test/opinion reached by re-performing the comparison between the unknown and known or two unknowns. In the context of validations, confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Verification of Effectiveness - Confirmation that action steps associated with a *Corrective Action Request*, have been effective.

Verifier - An examiner qualified and authorized in the same category of testing, who performs an independent review to verify or refute the conclusion offered by the original examiner.

Virtual Transfer - Transfers that are recorded on an electronic Chain-of-Custody Log without a corresponding physical change in custody.

Will - A word used when an element of the quality system is required.

Working Standard - Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems.

Rev. #	Issue Date	History
10	06/08/18	Definitions for Deputy Assistant Director, Executive Management, and Laboratory Director revised to designate the Deputy Assistant Director as the Laboratory Director. Definitions for administrative records and examination records revised and definition added for DNA databasing records to clarify records generated from DNA databasing. Category of testing definition revised to split cryptanalysis/illicit business records into two categories of testing: cryptology and illicit business records. Updated definition for concession for consistency with LOM practice. Updated definition of DNA database sample to state that handled as reference material. Updated definitions of DNA databasing and examinations to clarify that they constitute parts of the term “test”. Simplified definition of Evaluation of Testimony, Internal. Added definition for FDDU Sample Number. Clarified that technical review also applies to documents and records. Technical reviewer definition modified to address authorization requirement.
11	06/03/19	Added definition for ANAB and changed references from ASCLD/LAB to ANAB throughout. Revised or added definitions for administrative error, administrative records, association, auditor, case notes, case record, certified reference material, competency test, complaint, contract, contributor (and external and internal), decision rule, discipline, DNA database sample, DNA Match Confirmation Letter, DNA databasing records, evaluation (internal) of testimony, evidence, evidence management personnel, examinations records, executive management, FBI Laboratory Drug and Valuable Evidence label, FBI Laboratory Drug Label and FBI Laboratory Valuable Label, Health and Safety Group, impartiality, initiative, laboratory activity, proficiency tests (and external and internal), quality records, reference collection, reference standard, request (FA), sampling, secured limited access area, supporting records, technical records, technical review, technical reviewer, technical specialist, TEDAC QA Program Manager, testimony evaluator, validation, verification, and verification of effectiveness. Removed definitions for court official, critical consumables, supplies, and services, external evaluation of testimony, facilitating, key managerial personnel, sample selection, sampling plan, sampling procedure, subcontracting, subcontractor, and top management.



**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Document Control**

### **1 Purpose**

Documents that specify quality requirements or record quality-affecting activities (i.e., forms) must be controlled to ensure that they are adequate, approved for use, and only the current revisions are in use. These practices provide requirements for properly controlling those documents. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the applicable accrediting body(ies).

In the FBI Laboratory quality system, requirements reside in the QAM and Laboratory Operations Manual (LOM). In addition, units, disciplines, and/or categories of testing will have quality manuals, technical procedures/standard operating procedures (SOPs), training manuals, and/or controlled equipment manuals. Blank forms are included in the accompanying document and are controlled documents.

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in the preparation, review, control, and/or posting of quality system documents.

### **3 Practices**

The FBI Laboratory quality system document hierarchy is defined below. Each FBI Laboratory generated document will include a scope which states the applicability of the document to include to whom it applies.

#### **3.1 Level 1 Documents**

A level 1 document applies to all FBI Laboratory personnel. The QAM, LOM, and any accompanying forms and the Laboratory Safety Manual are level 1 documents.

**3.1.1** Level 1 documents, with the exception of the Laboratory Safety Manual, are generated by Forensic Analysis Support Unit (FASU) personnel.

**3.1.2** The Laboratory Safety Manual is generated by Health, Safety, and Security Unit (HSSU) personnel.

#### **3.2 Level 2 Documents**

A level 2 document applies to a specific unit(s), discipline(s), and/or category(ies) of testing and

is generated by FBI Laboratory personnel. Types of level 2 documents are specified in each of the following subsections and include any accompanying forms.

**3.2.1** Technical procedures (e.g., examination of evidence, sampling processes, DNA databasing, operation of laboratory equipment, database searches relating to casework).

**3.2.2** Quality manual documents (e.g., identifying secondary evidence, calibration program, purchasing products and services, abbreviations and/or symbols).

**3.2.3** Training manuals.

### **3.3 Level 3 Documents**

A level 3 document applies to a specific unit(s) and/or discipline(s) and/or category(ies) of testing and/or all FBI Laboratory personnel. These documents are not generated by FBI Laboratory personnel. Types of level 3 documents are specified in each of the following subsections and include any accompanying forms.

**3.3.1** External technical instructions, procedures, or manuals that specific unit(s) and/or discipline(s) and/or category(ies) of testing personnel are required to follow for specific procedures or instructions (e.g., controlled equipment manuals, American Society for Testing and Materials [ASTM] procedures).

**3.3.2** FBI policies that all FBI Laboratory personnel are required to follow for specific procedures or instructions (e.g., FBI Security policies).

**3.3.3** Accrediting body(ies) requirements that applicable personnel are required to conform to (e.g., ISO/IEC 17025, ISO/IEC 17020, ANSI-National Accreditation Board [ANAB] AR 3125, American Association of Laboratory Accreditation [A2LA], American Board of Forensic Toxicology [ABFT] Forensic Toxicology Laboratory Accreditation Requirements, FBI Quality Assurance Standards [QAS] for Forensic Testing Laboratories, FBI QAS for DNA Databasing).

### **3.4 Level 1 and Level 2 Document Format**

Refer to sections 3.1 and 3.2 for descriptions of level 1 and level 2 documents.

Level 1 and level 2 documents, with the exception of training manuals and the Laboratory Safety Manual, will be formatted as follows (see Appendix B):

- Left justified.
- Prepared in Times New Roman 12-point font except for the title, the header of the document, and figures/tables.
- Title centered at the top of the document in Times New Roman 14-point bold.
- Have a header (See section 3.4.1 for header formatting requirements).
- Have two lines between major sections (i.e., those with a single number). All other sections or paragraphs will be separated by one line (those with two or

more numbers).

- Have section headings numbered with the title of the heading followed by two spaces after the last number. The number and the section heading will be 12-point bold.
- Numbered sections that do not have a heading will be 12-point bold. Any text that immediately follows the number will be indented with a preferred distance of 0.75" from the left margin. Subsequent paragraphs in the same section will be left justified.
- Bullets or lists will be aligned. If the list is part of a paragraph, it will be indented with a preferred distance of 1" from the left margin.
- Have a revision history (See section 3.4.2 for revision history formatting requirements).
- Have a signature block (See section 3.5.2.1 for signature block formatting requirements).
- When applicable, have forms (See section 3.4.3 for form formatting requirements).
- When figures include calculations other fonts may be used to display special characters.

### **3.4.1 Header Format**

Each page of a level 1 and level 2 document, with the exception of a form, will have a header that:

- Is right justified.
- Is in Times New Roman 8-point font.
- Includes at least the following information, in this order:
  - Title of the Manual (information to identify the type of document [e.g., quality manual, procedures manual, training manual]).
  - Document Title (can be abbreviated) or unique identifier
  - Issue Date
  - Revision Number
  - Pagination (Page \_ of \_)

### **3.4.2 Revision History Format**

The revision history for a level 1 and level 2 document, with the exception of a form, will be comprised of three columns:

- The first will consist of the revision number.
- The second will consist of the issue date of that revision.
- The third will contain a description and/or rationale of changes made from the last version of the document.

### **3.4.3 Forms**

Forms generated outside of Forensic Advantage and figures/tables in documents will use the

preferred font, Times New Roman, with the font size at the discretion of the preparer. Forms that are associated with level 1 and level 2 documents will be included for reference in the appropriate document as an appendix(ices). The appendix(ices) will be placed after the revision history and signature block. The issue date of the form will be in the upper left or right header on the form. For FBI Laboratory forms, the form number will typically appear in the upper left header on the form.

### **3.5 Level 1 and Level 2 Document Preparation**

Level 1 and level 2 documents will be prepared by personnel with adequate expertise in the subject matter and must be labeled as draft to ensure they are not used while in draft status.

The technical details of a document will correspond to the complexity of the activity being performed as well as the background of the intended user. A document must include enough detail and specificity to ensure that the activity conforms to quality system requirements.

For level 2 documents, the document preparer will initiate the *Document Review Form* (7-263) (Appendix A), including marking if the document is associated with a new or modified validation of a procedure. The document preparer will ensure the document and the *Document Review Form* are uploaded to the Document Tracker and that the applicable information is entered into Document Tracker.

#### **3.5.1 Level 1 and Level 2 Document Reviews and Records**

All level 1 and level 2 draft documents will undergo a technical and quality assurance review. Personnel cannot conduct technical or quality assurance reviews on a document where they are listed as a preparer. For level 2 technical procedures as described in section 3.2.1, the technical and quality assurance reviews can be conducted by the same person.

For level 1 documents, the technical and quality assurance reviews will be recorded. The record will include the name of the reviewer(s), the title or unique identifier of each document reviewed, its revision number, and the date(s) the document(s) was reviewed. FASU staff will coordinate these reviews, with the exception of the Laboratory Safety Manual. HSSU will coordinate the review of the Laboratory Safety Manual.

For level 2 documents, the technical and quality assurance reviews will be recorded on the *Document Review Form*. The document and the *Document Review Form* will be submitted to the reviewers. All comments from the reviewers will be addressed and/or resolved. FASU personnel will ensure validation records are complete, when applicable for technical procedures as described in section 3.2.1.

FASU personnel will ensure that the technical and quality assurance reviews have been completed for all level 1 and level 2 documents prior to posting. Technical and quality assurance review records for level 1 documents and all completed *Document Review Forms* will be maintained by FASU.

### **3.5.1.1 Technical Review**

A technical review will assess a document's accuracy, adequacy, technical sufficiency, and clarity of presentation. The technical reviewer(s) must have adequate technical expertise to evaluate the document.

### **3.5.1.2 Quality Assurance Review**

A quality assurance review will assess a document for the inclusion of quality requirements, quality sufficiency, adherence to the applicable accreditation program(s), and absence of conflicts with other quality system documents. The quality assurance reviewer(s) must have adequate quality assurance expertise to evaluate the document.

**3.5.1.2.1** For level 1 documents, with the exception of the Laboratory Safety Manual, and for level 2 documents as described in sections 3.2.2 and 3.2.3, FASU personnel will conduct the quality assurance review.

**3.5.1.2.2** For level 2 documents as described in section 3.2.1, unit and/or discipline personnel will conduct the quality assurance review.

### **3.5.2 Level 1 and Level 2 Document Approval**

Approval will be indicated by the signature and date on the appropriate signature lines of the document.

For level 1 document issuance:

For the QAM and LOM, the Laboratory Director and the Quality Manager are authorized and will approve issuance. For the Laboratory Safety Manual, the Deputy Bureau Designated Environmental, Safety, and Health Official (DESHO) and Laboratory Director are authorized and will approve issuance.

For level 2 documents as described in section 3.2.1 issuance:

The applicable Unit Chief(s) and Technical Leader(s), as determined by the unit(s) and/or discipline(s) and/or categories of testing listed in the scope, are authorized and will approve issuance.

For level 2 documents as described in sections 3.2.2 and 3.2.3 issuance:

The Quality Manager, applicable Unit Chief(s), and where applicable, Technical Leader(s), as determined by the unit(s) and/or discipline(s), and/or category(ies) of testing listed in the scope, are authorized and will approve issuance.

### **3.5.2.1 Document Signature Block**

The signature block will include all authorized personnel who approved issuance of the document. For all approvers, the person's title will be to the left of the signature line and their name will be typed below the signature line. The date will be to the right of the signature line.

The signature block will be at the end of the main body of the document before the appendix(ices).

### **3.5.3 Level 1 and Level 2 Document Posting**

**3.5.3.1** After a level 1 or level 2 document has been approved for issuance, FASU personnel will prepare the document for posting and ensure it is posted to BUNET and LABNET.

**3.5.3.2** Level 1 and level 2 documents posted on BUNET and LABNET will be the official, controlled version of the documents. Forms will be posted on BUNET and LABNET, or will be generated by Forensic Advantage, a database, or a macro.

**3.5.3.2.1** If a document is printed from BUNET or LABNET, it will be an uncontrolled copy.

**3.5.3.2.2** When a form is completed electronically and printed from BUNET or LABNET, or it is printed blank and completed by hand, it will be considered a record.

**3.5.3.2.3** A trainee may print a copy of the training manual from BUNET or LABNET to use as part of their training record.

### **3.5.4 Level 1 and Level 2 Document Revisions**

**3.5.4.1** Revisions to a level 1 or level 2 document are subject to the same review, approval, and recordkeeping requirements as the original document. Change indicators from the prior revision will be removed. New change indicators will be placed in the right margin where new or altered text is located and are not needed if the change is a minor administrative change (e.g., results of renumbering, minor typographical edit). Revisions will be summarized in the "History" column of the revision history table. At a minimum, the one preceding and current revision histories are required on each document. Older revision histories may be deleted as the archive of each document is maintained on BUNET and LABNET. Forms are not required to have change indicators and the history will indicate when a form has been revised. Forms will be archived within the document.

**3.5.4.2** Revisions to the level 1 documents may require revisions to other controlled documents. Level 2 documents will be reviewed for any required revisions during the next annual review, unless otherwise instructed by the Quality Manager, and revisions will be prepared, when necessary. The level 1 document revisions will be followed regardless of when level 2 documents are revised and issued.

### **3.5.5 Level 1 and Level 2 Document Archives**

**3.5.5.1** When a level 1 or level 2 document is superseded or discontinued, the official version of the document posted on BUNET and LABNET will be marked as superseded or discontinued, as appropriate, and posted. This document will be considered the official archived copy. A footer will be added to the document that reads "Superseded - Effective Dates xx/xx/xxxx to xx/xx/xxxx" or "Discontinued - Effective Dates xx/xx/xxxx to xx/xx/xxxx". For documents

issued prior to being required to be posted on BUNET and LABNET, the archived documents will be maintained in another format.

**3.5.5.2** If archived physical copies are maintained, the retained archived document must be labeled, for example, “archived” or “superseded” or “discontinued”, and include the signatures of the approvers/issuer. Effective dates of the document must be indicated on the archived physical copy. Alternatively, physical copies of archive controlled documents may be destroyed after a revision is issued or a document is discontinued if the official archive copy is maintained on BUNET and LABNET.

### **3.6 Other Formats for Controlled Level 1 and Level 2 Documents**

**3.6.1** Controlled documents may be maintained in physical copy form, on media, and/or networks other than BUNET or LABNET. Requests to maintain electronic level 1 and level 2 documents in locations other than BUNET or LABNET must be submitted in writing to the Quality Manager. The Quality Manager will consider the request and respond in writing.

**3.6.1.1** For controlled documents maintained in locations other than BUNET or LABNET, units will ensure that only the current revision of a document is in use. Electronic level 1 and level 2 documents, in coordination with a member of FASU, will be updated when revised. Physical copy controlled documents will be identified as controlled on at least the first page of the document.

**3.6.1.2** If a unit chooses to maintain controlled documents in locations other than BUNET and LABNET, the unit will ensure the documents are identified as controlled in the following ways, as appropriate:

- On at least the cover or first page of the manual/document for a physical copy;
- On the electronic media or its container (e.g., CD/DVD, thumb drive);
- By its inclusion on a unit’s or applicable support unit’s master list for electronic (e.g., PDF) manuals/documents.

Level 1 and 2 document records will be maintained by creating a unit or applicable support unit master list, numbering the level 1 and/or 2 document, when practicable, and assigning it to a person. This list will include each document’s title (or unique identifier), revision number and/or issue date, number of copies or electronic file location, and the name of the person(s) who is responsible for the document.

A copy of the master list will be provided to the Document Control Program Manager.

### **3.7 Control of Level 3 Documents**

Refer to section 3.3 for a description of level 3 documents.

**3.7.1** Equipment manuals and externally produced documents (e.g., ANAB accreditation manual) that are maintained for general reference purposes are not subject to document control requirements.



**3.7.2** Level 3 documents as described in sections 3.3.1 will be identified as controlled in the following ways, as appropriate:

- On at least the cover or first page of the manual/document for a physical copy;
- On the electronic media or its container (e.g., CD/DVD, thumb drive);
- By its inclusion on a unit's or applicable support unit's master list for electronic (e.g., PDF) manuals/documents.

**3.7.2.1** FBI policies as described in section 3.3.2 will be maintained, including their control, by the FBI's Internal Policy Office.

**3.7.3** If level 3 documents are posted on BUNET and LABNET they will be the official, controlled version of the document.

### **3.7.4 Level 3 Initial Document Review**

**3.7.4.1** The applicable Unit Chief(s) or Quality Manager, as applicable, will ensure that each level 3 document undergoes an initial review to check that it is the current and correct version for the needs of the FBI Laboratory. The review and date of the review will be recorded.

**3.7.4.1.1** FBI policies as described in section 3.3.2 will be maintained by the FBI's Internal Policy Office, therefore an initial review to check that it is the current and correct version for the needs of the FBI Laboratory is not required.

### **3.7.5 Level 3 Document Approval**

Level 3 documents described in sections 3.3.1 and 3.3.3 are issued outside the FBI and therefore approval for internal use is not required. Refer to section 3.7.4 for information regarding initial review.

**3.7.5.1** FBI policies as described in section 3.3.2 will be maintained, including their approval, by the FBI's Internal Policy Office.

### **3.7.6 Level 3 Document Records**

**3.7.6.1** After a level 3 document as described in sections 3.3.1 and 3.3.3 has been initially reviewed, the applicable Unit Chief(s) or when applicable, Quality Manager, will ensure the level 3 document is assigned to a specified person.

**3.7.6.1.1** Level 3 FBI policies as described in section 3.3.2 will be maintained by the FBI's Internal Policy Office and follow their requirements.

**3.7.6.1.2** Level 3 document records will be maintained by creating a unit or applicable support unit master list, numbering the level 3 document, when practicable, and assigning it to a person. This list will include each level 3 document's title (or unique identifier), revision number and/or issue date, number of copies or electronic file location, and the name of the person(s) who is

responsible for the level 3 document.

**3.7.6.1.2.1** Applicable units will maintain a master list of level 3 documents as described in section 3.3.1.

**3.7.6.2** FASU will maintain a master list of level 3 documents as described in section 3.3.3.

### **3.7.7 Level 3 Document Modifications**

New or altered text may be handwritten in a level 3 manual or document as described in section 3.3.1 only and will be initialed and dated by the applicable Unit Chief(s).

All other level 3 documents cannot be altered by hand and new text cannot be added.

### **3.7.8 Level 3 Document Archives**

A level 3 document will become superseded or discontinued when the entity that produced the manual or document issues a new version that will be used, or the manual or document becomes obsolete. For example, a controlled equipment manual becomes obsolete when it is no longer used for casework or DNA databasing. Only archived level 3 documents described in section 3.3.1 will be retained and labeled, when practicable, with the document's status (i.e., archived, superseded, discontinued) and effective dates, and the review records retained. If retained on a CD/DVD, the CD/DVD or its container will be labeled as described above. For an electronic (e.g., PDF) level 3 document as described in section 3.3.1, the document's status, (i.e., archived, superseded, discontinued) and the effective dates will be added on the record containing its review, where practicable.

## **3.8 Controlled Document Notifications**

FBI Laboratory personnel will be notified when a controlled document is issued, revised, or discontinued.

**3.8.1** For level 1 documents, all FBI Laboratory personnel will be notified by email within one business day of a change. Email notification for a level 1 document will be retained by the FASU.

**3.8.2** For level 2 documents, affected personnel that will be notified within one business day via email will be determined by the unit(s) and/or discipline(s), or category(ies) of testing listed in a document's scope. Email notification for a level 2 document will be retained by each affected unit, or by the applicable support unit.

**3.8.3** For level 3 documents as described in section 3.3.1, affected personnel will be notified within one business day when a document is adopted in the FBI Laboratory. Email notification for this type of level 3 document will be retained by each affected unit, or by the applicable support unit.

**3.8.3.1** For level 3 FBI policies as described in section 3.3.2, FBI personnel will be notified according to the FBI's Internal Policy Office guidance.

**3.8.3.2** For level 3 documents as described in section 3.3.3, all FBI Laboratory personnel will be notified by email within one business day when a document is posted.

### **3.9 Working Electronic Copies of Level 1 and Level 2 documents**

Working copies of level 1 and level 2 documents may be maintained for the preparation of document revisions. The applicable Unit Chief(s) will ensure access to these electronic files is limited to personnel preparing documents and/or are secured in a manner that prevents unauthorized editing.

### **3.10 Annual Review**

Each level 1, level 2, and level 3 document must be reviewed annually to ensure that the documents reflect current quality system requirements, that technical procedures are up to date, and/or that it is still the current and correct version for the needs of the FBI Laboratory. Annual reviews of documents can occur throughout the calendar year, do not have to be conducted at the end of a calendar year, and do not have to be reviewed all at the same time.

**3.10.1** The Quality Manager will ensure that level 1 documents, with the exception of the Laboratory Safety Manual, are reviewed annually and revised when necessary. This review will be recorded and retained in the FASU. The HSSU Chief will ensure that the Laboratory Safety Manual is reviewed annually and revised when necessary. This review will be recorded and the record will be maintained in the FASU. Records will include the name of the reviewer(s), the title or unique identifier of each document reviewed, its revision number, and the date(s) the document was reviewed. Internal or external audits and/or quality assurance reviews do not satisfy this requirement.

**3.10.2** Unit Chiefs will ensure that level 2 documents, and level 3 documents as described in section 3.3.1, used by personnel within his/her unit are reviewed annually and revised when necessary (See section 3.7.7 for level 3 modifications).

**3.10.2.1** The annual review(s) of these documents will be recorded and retained in the unit or the applicable support unit. Records will include the name of the reviewer(s), the title or unique identifier of each document reviewed, its revision number or date published, and the date(s) the documents were reviewed. Internal or external audits and/or quality assurance reviews do not satisfy this requirement.

**3.10.2.2** Personnel from multiple units may complete these annual reviews by a combined review of the applicable documents with each unit or applicable support unit retaining a record of the review.

**3.10.3** The Quality Manager will ensure that level 3 documents as described in section 3.3.3 are reviewed annually to check that they are the current and correct version for the needs of the

FBI Laboratory. Records will include the name of the reviewer(s), the title or unique identifier of each document reviewed and its revision number or date published, and the date(s) the documents were reviewed. Internal or external audits and/or initial reviews do not satisfy this requirement.

**3.10.4** Level 3 FBI policies as described in section 3.3.2 will be maintained by the FBI's Internal Policy Office and follow their guidance for periodic reviews.

### **3.11 Level 1 and Level 2 Document Requests**

Requests for level 1 and level 2 documents will be tracked by the FASU. Any quality system document that is sent outside the FBI Laboratory will be an uncontrolled copy. Alternatively, the requestor can be directed to [www.fbi.gov](http://www.fbi.gov).

**3.11.1** FBI Laboratory personnel may print a copy from BUNET, LABNET, or other media, or personnel may request electronic copies of documents according to the FASU Procedures for Responding to Quality System Document Requests. FBI Laboratory personnel will notify the FASU when they provide documents in response to a request.

**3.11.2** If the quality system document(s) is not available on BUNET or LABNET and it was a level 1 document, the FASU will provide a copy of the document(s), if available. If the quality system document is not available on BUNET or LABNET and it was a level 2 document, the requesting person should contact the appropriate unit for the document(s).

**3.11.3** Requests for copies of the level 3 documents will be handled on a case by case basis.

## **4 Records**

The following records may be generated and/or retained as a result of these practices:

- Reviews of level 1 documents and *Document Review Forms* will be retained in the FASU for at least one accreditation cycle.
- Records of completed annual review of controlled documents will be retained by the appropriate unit through one accreditation cycle.
- Superseded/archived/discontinued physical copy versions of level 1, level 2, and level 3 documents as described in section 3.3.1 will be retained permanently by the appropriate party if not archived on BUNET or LABNET.
- Email notification of issuance, revision, or discontinuance of level 1, level 2, and level 3 documents as described in sections 3.3.1 and 3.3.3 will be retained by each affected unit, or the applicable support unit through one accreditation cycle.
- Current master lists for any unit that maintains physical copies and/or electronic copies on other media.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
14	10/07/19	Revised entire document to include technical procedures will no longer be submitted to FASU for QA Review. QA Review of technical procedures must be conducted by the units/disciplines/categories of testing using the Document Review Form (7-263). Only applicable TL(s) and UC(s) will sign level 2 technical procedures. Added specification of level 3 documents to include FBI policies and accrediting body requirements. Added Appendix B.
15	10/21/19	Clarified in section 3.5.1 that FASU personnel will review validation records. Revised 3.5.1.2.1 and added 3.5.1.2.2 to state who will perform quality assurance reviews of documents. Added section 3.5.3.2.1 that was inadvertently deleted in previous version to state that a document printed from BUNET or LABNET, will be an uncontrolled copy. Added sections 3.7.5.1 and 3.8.3.2 to cover all types of level 3 documents. Minor edits throughout for clarification and numbering.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 10/18/2019

Quality Manager

Date: 10/18/2019

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## **FBI Laboratory Practices for Developing Methods and Validating Technical Procedures**

### **1 Purpose**

These practices establish the requirements for developing new methods and provide direction for validating technical procedures prior to those procedures being introduced into casework and DNA databasing. Method development is the acquisition and evaluation of test data for the determination of conditions and/or limitations of a novel method to achieve consistent results. Validation is the process for determining whether specified requirements are adequate for an intended use.. If a new method is intended to be used for the examination of evidence then it must be validated according to this practice. Refer to Appendix A for an overview of the steps required for developing methods and validating technical procedures. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are authorized to develop, modify, verify, and validate new methods and technical procedures that pertain to casework or DNA databasing. These methods and technical procedures may be developed internally or externally.

### **3 Practices**

#### **3.1 Method Development**

Method development is the acquisition and evaluation of test data for the determination of conditions and/or limitations of a novel method to achieve consistent results. A novel method may include an established procedure or technology that has not been previously utilized in a specific forensic application. Development must be a planned activity. The plan must be recorded, approved by the Technical Leader, and any changes to the plan will be communicated to all personnel involved in developing the method. External standard methods previously utilized for forensic applications that do not require modification may proceed to the validation phase.

**3.1.1** Personnel who seek to use a novel methodology or process must record and/or reference any other technical work relied upon to support the usage of the novel methodology or process. Such records may include publications, presentations at scientific meetings, symposia, or research studies generated by the FBI Laboratory or an external laboratory.

## **3.2 Method Development Review**

**3.2.1** The Technical Leader will evaluate the development plan to ensure that it is fit for the intended purpose.

**3.2.2** The Technical Leader will record agreement with the developed method with his/her name, signature or initials, and date of the review.

**3.2.3** Any resulting method that will be used for casework and/or DNA databasing will be validated prior to being used.

## **3.3 Validation**

All proposed technical procedures must be validated in the FBI Laboratory prior to use for forensic examinations and DNA databasing. Prior to beginning a validation study, a plan of action will be prepared and recorded. The Technical Leader will review the validation plan for his/her approval prior to beginning the validation study.

**3.3.1** The plan will include the test method(s), specific equipment, and sample preparation techniques(s) to be used, if necessary. Further, it will record the validation requirements of the procedure. The validation plan will provide direction for the activities that will be performed and acceptance criteria for the validation.

**3.3.2** Appropriate level 2 documents will define and/or reference the minimum requirements for a validation study. The validation study will include:

- Identifying the limitations of the procedure, reported results, opinions, and interpretations.
- Conditions under which reliable results can be obtained.
- Critical aspects of the procedure that must be controlled and monitored.
- The scope and accuracy of the procedure to meet the needs of the given application.
- The associated data analysis and interpretation.
- Establishing the data required to report a result, opinion, or interpretation.

**3.3.3** When validating a novel or existing procedure, known samples must be used.

**3.3.4** Prior to applying a novel or existing procedure to the examination of evidence or DNA database samples, validation records must demonstrate that the procedure performs as expected, or with modification performs as expected, in the FBI Laboratory.

**3.3.5** Validation of chemical procedures must additionally meet the requirements of the Laboratory Operations Manual (LOM) - Practices for Validating Chemical Procedures.

## **3.4 Validation Review and Records**

**3.4.1** Once the validation study has been completed a validation summary will be prepared.

**3.4.2** The Unit Chief(s) and Technical Leader, will evaluate the results of the validation study and the validation summary before use of the procedure in the FBI Laboratory. These persons will record agreement with the validation results and summary with his/her initials or signature and the date of the review.

**3.4.3** Once the validation study has been completed, reviewed by the Technical Leader, and approved, the technical procedure will be written according to the LOM - Practices for Writing Standard Operating Procedures if it will be used for forensic examinations or DNA databasing.

**3.4.4** When a standard operating procedure (SOP) is written, a Quality Assurance reviewer will ensure the validation records are complete prior to the SOP being approved according to the LOM - Practices for Document Control.

### **3.4.5 Previously Validated Procedure**

When a previously validated procedure is to be used in a new facility, a simplified validation will be required to ensure that technically sound results can be produced. The appropriate Unit Chief(s) and Technical Leader will record agreement with the validation results with his/her initials or signature and the date of the review before implementing the procedure.

## **3.5 Resolution of Disagreement**

If a disagreement arises between the parties involved in developing a new method or validating a procedure, and an agreement cannot be reached, resolution will be achieved following the LOM - Practices for Resolution of Scientific or Technical Disagreement.

## **3.6 Competency Tests**

**3.6.1** After the validation process on a technical procedure is completed, each examiner and/or technician who will apply the new procedure to casework or DNA databasing must successfully complete a competency test prior to applying the new procedure to casework or DNA databasing. This test will demonstrate that the examiner and/or technician can accurately perform the technical procedure. For personnel involved in the validation process, the Unit Chief and the Technical Leader, may approve the validation to serve as demonstration of competency. If approved, the approval will be recorded.

**3.6.2** Additional authorization records will be generated, when applicable.

**3.6.3** Newly validated procedures will be incorporated into the proficiency testing program, when applicable.

## **3.7 Procedure Modifications**

There are times when deviating from an established SOP is necessary. Changes to or deviations from a procedure must be within the bounds of good laboratory practice, recorded, justified, and authorized according to the LOM - Practices for Authorizing Deviations. Modifications to

validated chemical procedures have additional requirements as listed in LOM - Practices for Validating Chemical Procedures.

**3.7.1** If a significant modification (significance is determined by Technical Leader in the appropriate discipline/category of testing) has been made to a previously validated procedure, the influence of such changes will be evaluated. Where the changes are determined to affect the original validation, a new validation will be performed. Results generated by means of the change will be evaluated through comparison to the results generated using the current procedure, to include using the appropriate samples. These modifications should produce results of the same or improved quality as compared with those obtained by the previously validated procedure, or adequate for the intended use.

**3.7.2** A minor modification to an existing procedure that does not materially affect the performance of the test does not require additional validation studies. These modifications may affect the efficiency, effectiveness, and/or quality of the test without affecting the results. Minor modifications will be handled as minor or major deviations, as appropriate, and requested and authorized according to the LOM - Practices for Authorizing Deviations.

**3.7.3** All modifications will be made available to personnel within a discipline/category of testing to maintain consistency when others are faced with the same or similar circumstances.

**3.7.4** When a modification becomes routine (routine being determined by Technical Leader in the appropriate discipline/category of testing), the technical procedure will be written or revised according to the LOM - Practices for Writing Standard Operating Procedures and the LOM - Practices for Document Control.

### **3.8 Record of Procedure Development and Validation**

Appropriate level 2 documents will provide instructions regarding where the records for the reviews, approvals, development, and validation will be retained.

## **4 Records**

The following records are generated and/or permanently retained as a result of these practices:

- All records related to developing a method and the associated reviews.
- All records related to the validation study including the study plan, the results, and the associated reviews.
- All competency test records including approvals for the validation to serve as demonstration of competency.
- Additional authorization records, when applicable.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Rev. #	Issue Date	History
5	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Merged the Practices for Validating Technical Procedures into this document. Substantive changes include: clarified intent of method development, removed the Responsibilities section, added requirement for TL approval for method development plan and completion of the development process, changed from technical reviewer(s) approval for validation plans to Technical Leader, added requirement that a validation summary be written for completed validations, and added a flowchart for this practice in Appendix A.
6	06/03/19	Modified definition of validation in Section 1. Updated section 2 to reflect that personnel must be authorized to develop, modify, verify, and validate methods and procedures in casework and DNA databasing. Removed validation definition from section 3.3. Expanded validation study requirements in section 3.3.2. Modified section 3.4.3 and flowchart in Appendix A to reflect review performed by Technical Leader. Revised requirements related to significant modifications in section 3.7.1. Updated section 3.8 to cover all types of reviews. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019



**Appendix A: *Flowchart for Developing Methods and Validating Technical Procedures***

Redacted - Form on File

## **FBI Laboratory Practices for Writing Standard Operating Procedures**

### **1 Purpose**

Standard operating procedures (SOPs) specify the procedural steps and materials that will be used to ensure uniform quality of the process or product. SOPs will be used for all processes for which they exist and are applicable. SOPs should conform to accepted consensus standards, where applicable. These practices specify the required elements for preparing an SOP and when an SOP is needed. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who prepare technical procedures (e.g., examination of evidence, sampling processes, DNA databasing, operation and calibration of laboratory equipment, database searches relating to casework) that have a direct effect on the quality of the casework and DNA databasing.

### **3 Practices**

A Technical Leader will ensure that a discipline/category(ies) of testing has SOPs where required and that the SOPs are appropriate for use. A Unit Chief will ensure the personnel in their unit follow the appropriate SOPs.

#### **3.1 Applicability**

Processes for which SOPs are required are as follows:

- Examination and DNA databasing processes.
- Sampling processes, when not included in an examination SOP(s).
- Operation of equipment, when not included in an examination SOP(s) or when manufacturers' procedures do not exist or are not used.
- Database searches when related to casework.

#### **3.2 Content Detail**

Each SOP must:

- Be clear, precise, and comprehensive.
- Use language and detail appropriate to performing the tasks described.
- Be written in a manner that clearly describes the steps and ensures ease of use.
- Have adequate detail to preclude misinterpretation.
- Permit a person with an appropriate background in the science, discipline, or

category of testing to independently perform the same procedure and obtain comparable results.

### **3.3 Format**

The following sections are required in each examination SOP. If the section is addressed in a separate SOP, the title of the separate SOP will be referenced. If the section does not pertain to a procedure, the phrase “not applicable” will be listed under the section heading. Additional sections may be included as necessary for a particular SOP. Sections may appear in any order.

#### **3.3.1 Title**

Titles used in SOPs should be brief and easily associated to the content.

#### **3.3.2 Scope**

The scope will specify the applicability of the procedure to include to whom it applies.

#### **3.3.3 Equipment/Materials/Reagents**

This section will list pertinent equipment, materials, reagents, working standards, controls, reference materials, and reference standards used in performing the procedure. Each item should be specified to ensure that the proper item of the appropriate quality is identified.

#### **3.3.4 Standards and Controls**

This section will provide instructions for preparing and/or checking standards and controls, including criteria for acceptance or rejection of data based on results for standards and controls.

#### **3.3.5 Sampling**

This section will include information on sampling as described in the QAM – Section 7.3.

#### **3.3.6 Procedure**

This section will specify the steps required to perform the procedure. This section may include the use of controls, standards and blanks; instructions for performance checks; and/or precautions to be taken to minimize contamination and/or degradation.

#### **3.3.7 Calculations**

This section will provide example calculations used for statistical or other evaluation of data. This may include criteria for acceptance or rejection of data based on results for controls, standards, blanks, or other quality control checks.

### **3.3.8 Measurement Uncertainty**

This section will detail how measurement uncertainty for examinations described in the QAM - Section 7.6 was determined and will be reported.

### **3.3.9 Limitations**

This section will specify under what circumstances, including environmental conditions, that the procedure may not provide accurate results, when it should not be used, and any other limitations specific to the procedure.

### **3.3.10 Safety**

This section will document hazards associated with performing the procedure. See the FBI Laboratory Safety Manual.

### **3.3.11 References**

This section will identify documents used in developing an SOP or sources for further information. References may include relevant national or international standards and technical publications, operating manuals supplied by an equipment manufacturer, relevant technical documents, and established in-house methods.

### **3.3.12 Approval**

This section will be formatted according to the Laboratory Operations Manual (LOM) - Practices for Document Control.

## **4 Records**

Records generated and/or retained by these practices will be specified in the LOM - Practices for Document Control.

## **5 References**

FBI Laboratory Operations Manual, Practices for Document Control, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
7	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section, changed from unit based structure to a mixture of unit/discipline/category of testing based structure, assigned Technical Leader and Unit Chief responsibilities in regards to SOPs, and added requirements for content detail.
8	06/03/19	Updated section 3.3.5 on sampling and adding reference to QAM 7.6 in section 3.3.8. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Authorizing Deviations**

### **1 Purpose**

There are times when deviating from FBI Laboratory issued quality system document requirements is necessary. These practices specify the actions required to request and authorize deviations. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in requesting and/or authorizing deviations from FBI Laboratory issued quality system documents.

### **3 Practices**

Deviations must be requested and authorized prior to departing from the specified requirement(s). An authorized deviation does not eliminate the requirement for validating modifications to examination or DNA databasing procedures.

#### **3.1 Minor Deviations**

A minor deviation is not expected to significantly impact the quality system and does not have an extended duration.

**3.1.1** When there is a need for a minor deviation from a specified requirement(s), the approver will consider the merits and risks of a minor deviation before approving a proposed deviation. For minor deviations of an administrative nature, the person's manager or Technical Leader will serve as the approver. For minor deviations of a technical nature, the Technical Leader will serve as the approver.

**3.1.2** A *Major Deviation Request* (7-258) will not be used for minor deviations. The record of the minor deviation will include:

- The title of the document (or unique identifier), issue date and/or revision number, and the specific requirement(s) from which a minor deviation is sought.
- A statement of the specific deviation.
- The name and initials or the signature of the approver and the date of the authorization or the electronic equivalent if retained in Forensic Advantage (FA).

**3.1.3** When the minor deviation is applicable to casework or DNA databasing, the deviation and its authorization will be included in the FBI Laboratory file (e.g., upload to the Case Object Repository, physical copy in the 1A) or be recorded in the Case Record Communication Log in FA.

**3.1.4** For minor deviations not directly applicable to examinations or DNA databasing, authorization will be maintained by the appropriate unit personnel.

**3.1.5** Units will record minor deviations in a centralized location (e.g., FA, binder, spreadsheet). Records will include specific information to allow for a unit, discipline, and/or category of testing to determine any trends. Unit Chiefs and Technical Leaders will ensure minor deviation records are reviewed, at a minimum on an annual basis, to determine what, if any, trends are occurring that may require revision to the appropriate document(s). The review of minor deviations will be recorded and will include a notation as to whether any trends were identified.

## **3.2 Major Deviations**

A major deviation has the potential to significantly impact the quality system, may affect multiple cases/DNA database samples, and/or is applicable over an extended period of time. No major deviation can be implemented until all authorizations are recorded.

### **3.2.1 Initiating a *Major Deviation Request***

When a major deviation is needed, the requestor will initiate a *Major Deviation Request* in the Deviation Request Database and specify:

- The title (or unique identifier), of the document(s), issue date and/or revision number, and the specific requirement(s) from which a major deviation is sought.
- Description of the requested deviation (i.e., what the deviation will cover).
- The specific instance(s) for which the deviation is requested (i.e., when the deviation will be needed or to which specific circumstance(s) the deviation will apply).
- The reason for the deviation (i.e., why the deviation is needed).
- The merits and the risks of the requested deviation.
- The duration of the requested deviation.

### **3.2.2 Authorization**

The requestor of the major deviation will submit the *Major Deviation Request* to the appropriate Unit Chief(s) for authorization. For major deviations of a technical nature the Technical Leader will also serve as the approver. If the requestor is a Unit Chief or Technical Leader, he/she will sign the authorization.

**3.2.2.1** The Unit Chief(s) and when applicable, Technical Leader will evaluate the merits and risks of the major deviation. Risks may include contamination, security, defensibility,



deleterious change, and safety. If he/she determines the merits of the proposed major deviation outweigh the risks, he/she will sign the *Major Deviation Request* to record his/her authorization and forward the request to the Quality Manager.

**3.2.2.2** The Quality Manager will evaluate the proposed major deviation with regard to good laboratory practice and potential impact on the quality of the work and the quality system. The Quality Manager will determine whether the *Major Deviation Request* impacts the examination or reporting process and will be referenced in the FBI Laboratory file. The Quality Manager will record his/her authorization or rejection on the *Major Deviation Request*. If the Quality Manager authorizes the major deviation, he/she will sign the *Major Deviation Request* and forward the request to the appropriate Section Chief or Deputy Assistant Director. The Deputy Assistant Director will review a major deviation when it applies to personnel in multiple sections of the FBI Laboratory.

**3.2.2.3** The Section Chief or Deputy Assistant Director will review the *Major Deviation Request* and will record his/her authorization or rejection on the *Major Deviation Request*. The Section Chief or Deputy Assistant Director will sign the *Major Deviation Request* to record his/her authorization. The Section Chief or Deputy Assistant Director will return the Major Deviation request to the Forensic Analysis Support Unit (FASU), whether it is authorized or rejected.

### **3.3 Allowable Duration of a Minor or Major Deviation**

Authorized minor deviations will be valid for only a specific instance. Authorized major deviations will be valid only for a specified time period or circumstance not to exceed six months. The specific duration must be specified on the *Major Deviation Request*.

**3.3.1** A Quality Assurance Specialist will record the expiration date following all authorizations.

#### **3.3.2 Major Deviation Renewal**

Authorized major deviations may be renewed by the Quality Manager for up to an additional six months. The renewal duration will be specified on the *Major Deviation Request*.

### **3.4 Authorized Major Deviation Records**

The original, physical copy of a *Major Deviation Request* will be retained in the FASU whether it is authorized or rejected. The FASU will post all authorized *Major Deviation Requests* to BUNET and LABNET. The *Major Deviation Request* provides a record of an authorized major deviation.

**3.4.1** If the Quality Manager determined the *Major Deviation Request* impacts the examination or reporting process, a copy of the authorized *Major Deviation Request* will be included in the FBI Laboratory file (e.g., attach to a communication log entry, upload to the Case Object Repository, physical copy in the 1A). Alternatively, the unique identifier of the *Major*

*Deviation Request* may be recorded on the appropriate communication log (e.g., *Activity and Communication Log* (7-245), Case Communication Log, Case Record Communication Log).

If the Quality Manager determined the *Major Deviation Request* does not impact the examination or reporting process it is not necessary to include or reference the *Major Deviation Request* in the FBI Laboratory file.

### **3.5 Major Deviation Notifications**

When a major deviation has been authorized, renewed, or inactivated, the Quality Manager will ensure the requestor is notified by email. The requestor will ensure the affected personnel are notified by email. The notifications will be retained.

## **4 Records**

The following records will be generated and/or retained as a result of these practices through one accreditation cycle or five years, whichever is longer.

- Minor deviations applicable to casework or DNA databasing will be retained with the FBI Laboratory file.
- Minor deviations not applicable to casework will be retained according to the retention requirements of the associated record, at a minimum of at least the current accreditation cycle.
- Centralized records of minor deviations.
- Annual review of minor deviations.
- The original of each *Major Deviation Request* will be permanently retained by the FASU.
- Notifications regarding major deviations.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev #	Issue Date	History
6	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section, changed from unit based structure to a mixture of unit/discipline/category of testing based structure, modified requirements for approval of minor deviations depending on the nature of the deviation, added requirements for centralized records and annual review of minor deviations, modified requirement for QA Specialist to record expiration date after all authorizations, and updated of the notification requirements.
7	06/03/19	In sections 3.1.2, 3.1.3, and 3.1.5 added the option to use FA for recording the use of minor and major deviations. Clarified section 3.1.5 regarding minor deviation records and their reviews. In sections 3.2.2.2 and 3.4.1 added requirement for the Quality Manager to determine whether a major deviation impacts the examination or reporting process and must be referenced in the file. Updated list of references in section 5. Revised <i>Major Deviation Request</i> in Appendix A.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

**Appendix A: *Major Deviation Request (7-258)***

Redacted - Form on File

## **FBI Laboratory Practices for Preventive Action**

### **1 Purpose**

The purpose of preventive action is to bring about continuous improvement through proactive measures, provide guidelines to identify potential nonconformities, and reduce the likelihood of nonconformities occurring. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in the preventive action process.

### **3 Practices**

#### **3.1 Preventive Action**

A preventive action is an action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Preventive actions are initiated to identify opportunities for improvement and to reduce the likelihood of a nonconformity occurring. Any FBI Laboratory personnel may identify a potential situation or condition when a preventive action would be helpful.

##### **3.1.1 Notification of Potential Situations or Conditions**

If a situation or condition exists that may be improved, the person identifying the opportunity will notify his/her Unit Chief. Additionally, for technical matters personnel will notify the Technical Leader. If the Unit Chief and/or Technical Leader determine that a preventive action is appropriate they will ensure any other impacted Unit Chief(s) and the Quality Manager are notified in writing.

#### **3.2 Initiating the *Preventive Action Request***

A *Preventive Action Request* (7-261) (Appendix A) is used to record and track preventive actions. This form identifies the potential situation or condition, the person responsible for managing the preventive action, the action step(s), and the expected date of completion of the action step(s). The *Preventive Action Request* will be initiated using the Forensic Analysis Support Unit (FASU) Corrective Action Request (CAR) database. Refer to the FASU Procedures for Entering Data in the Quality Assurance CAR Database to complete the steps listed below. The Unit Chief or Technical Leader will ensure the *Preventive Action Request* is

initiated. If a preventive action is identified through an internal audit or assessment, the Quality Manager or a Quality Assurance (QA) Specialist will initiate the *Preventive Action Request*.

### **3.2.1 Action Steps**

Depending on the nature of the potential situation or condition, action steps should target the ways to improve the potential situation or condition and/or reduce the likelihood of a nonconformity occurring.

### **3.2.2 Accepting Preventive Action Steps**

A QA Specialist will evaluate the proposed preventive action to determine its adequacy, acceptability of the planned action step(s), and the stated time frame. If the request is determined to be less than adequate, the person responsible for managing the preventive action will be required to amend the request. If the QA Specialist determines a *Preventive Action Request* is not appropriate, it may be changed to a *Corrective Action Request* (7-254) in accordance with the Laboratory Operations Manual (LOM) – Practices for Addressing a Nonconformity. If accepted, the Quality Manager will sign and date the bottom of the form in the space labeled “Reviewed and Accepted By” and forward a copy to the person responsible for managing the preventive action.

### **3.2.3 Completed Preventive Action Steps**

The assigned QA Specialist will liaise with the person responsible for managing the preventive action to determine if the action step(s) is complete. If the action step(s) has been completed, the assigned QA Specialist will review objective evidence in support of its completion. The assigned QA Specialist will sign and date the bottom of the form in the space labeled “Actions Completed.”

### **3.2.4 Closing Out a *Preventive Action Request***

The Quality Manager will sign and date the bottom of the *Preventive Action Request* in the space labeled “Closed Out” indicating approval for close out of the preventive action. The original *Preventive Action Request* will be retained in the FASU. A copy of the *Preventive Action Request* will be forwarded to the appropriate QA representative(s).

## **3.3 Tracking Progress on *Preventive Action Requests***

QA Specialists will track the progress of *Preventive Action Requests*.

## **4 Records**

The following records will be generated and/or retained through one accreditation cycle or five years, whichever is longer, as a result of these practices:

- Original *Preventive Action Requests* and associated records will be maintained

in FASU.

- Other associated records will be maintained by the units.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
6	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville. Substantive changes include: removed the Responsibilities section, updated the language for approvals and management of the Preventive Action.
7	06/03/19	Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019



**Appendix A: *FBI Laboratory Preventive Action Request (7-261)***

Redacted - Form on File

## FBI Laboratory Practices for Addressing a Nonconformity

### 1 Purpose

These practices specify steps and requirements to ensure that a nonconformity is addressed within the specified timeframe, that the effect(s) on prior work or records, if appropriate, is remediated, and that the possibility of recurrence is minimized, in order to bring about continuous improvement. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### 2 Scope

These practices apply to FBI Laboratory personnel who are involved in identifying and addressing nonconformities. Additionally, personnel may follow these practices when handling a complaint.

### 3 Practices

#### 3.1 Nonconformity

**3.1.1** A nonconformity is the non-fulfillment of a requirement. FBI Laboratory personnel, internal or external customers, and/or external auditors/assessors may identify a situation or condition where a concession, correction, or corrective action is required. The appropriate technical management will evaluate the situation or condition when it is reported. The significance of a nonconformity will be evaluated and categorized as requiring a concession, a correction, or a corrective action.

#### 3.1.2 Responses to Nonconformity

The responses to a nonconformity are defined as:

- A **concession** is an acknowledgement that a nonconformity has been detected, and the nonconformity will not be corrected.
- A **correction**<sup>1</sup> is an action to eliminate a detected nonconformity.
- A **corrective action** is an action to eliminate the *cause* of a detected nonconformity.

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<sup>1</sup> Correction as defined in these practices does not refer to a correction that occurs at the time of generation of case records involving an initialed single strikeout where the correction is entered alongside, or those similar corrections tracked in electronic case records.

## 3.2 Concessions and Corrections

If the evaluation indicates that the potential impact of the nonconformity is low and:

- the activity or work is deemed acceptable or uncorrectable and will only be acknowledged, then a **concession** is appropriate.
- the activity or work is deemed not acceptable and will be corrected, then a **correction** is appropriate.

Concessions and corrections do not require a root cause analysis of the situation or condition.

### 3.2.1 Notification, Records, and Review of Concessions and Corrections

**3.2.1.1** The person identifying a nonconformity that will be handled as a concession or a correction will notify the appropriate caseworking/DNA databasing/evidence management Unit Chief(s) and/or Supervisor(s), at the time the nonconformity is identified. The Quality Manager does not need to be notified when a situation or condition will be handled as a concession or correction.

**3.2.1.2** Units will record concessions and/or corrections in a centralized location (e.g., binder, spreadsheet). Records will include specific information to allow for a unit, discipline, and/or category of testing to determine any trends that may need to be addressed through a corrective action and/or document revisions. Unit Chiefs and Technical Leaders will ensure concessions and corrections records are reviewed, at a minimum on an annual basis, to determine what, if any, trends are occurring and may require corrective action. The review of corrections and concessions will be recorded and will include a notation as to whether any trends were identified.

## 3.3 Corrective Actions

If the evaluation of the nonconformity indicates that the situation or condition is adverse to quality (e.g., recurrence is possible, potential impact is increased), then corrective action will be taken. A *Corrective Action Request* (7-254) (Appendix A) will be initiated. Corrective actions must begin with root cause analysis of the situation or condition.

### 3.3.1 Notification of Situations or Conditions Adverse to Quality Resulting in a Corrective Action

**3.3.1.1** If a situation or condition exists that may potentially be adverse to quality and a corrective action may be warranted, the person identifying the situation or condition will notify his/her Unit Chief at the time the nonconformity is identified.

**3.3.1.1.1** For technical matters the person identifying the situation or condition will also notify the Technical Leader at the time the nonconformity is identified.

**3.3.2** If the Unit Chief and/or Technical Leader determines that the situation or condition is potentially adverse to quality and a corrective action may be warranted they will ensure other impacted Unit Chief(s) and the Quality Manager are notified in writing at that time. The

notification to the Quality Manager will be retained.

**3.3.3** The Quality Manager does not need to be notified when a situation or condition has progressed to a personnel performance issue, unless the situation also involves steps taken in accordance with these practices.

### **3.4 Completing a *Corrective Action Request***

**3.4.1** The *Corrective Action Request* is used to record the root cause analysis and subsequent corrective actions. This form identifies the situation or condition, the requirement source(s), the specific requirement(s), the person who is responsible for managing the corrective action, the root cause(s) of the situation or condition, the action step(s) and the expected completion date(s) of each action step(s).

**3.4.1.1** Upon notification to the Quality Manager, the Unit Chief will ensure their unit personnel initiate a *Corrective Action Request* in the Quality Assurance Corrective Action Request (CAR) database. Refer to the QA Program Procedures for Entering Data in the Quality Assurance Corrective Action Request (CAR) Database for entering the information described below.

**3.4.1.2** The Quality Manager and/or a Quality Assurance (QA) Specialist will evaluate the situation or condition entered into the CAR database and determine if the *Corrective Action Request* is appropriate. If the Quality Manager and/or QA Specialist determine that a corrective action is not warranted, the unit will be notified and the entry in the CAR database will be closed out. A comment will be added to the CAR database as to why the corrective action wasn't necessary.

**3.4.1.3** To minimize the impact of the nonconformity, *Corrective Action Requests* must be issued within 45 days of being identified as potentially adverse to quality. A *Corrective Action Request* will be considered issued when the root cause(s) and action step(s), with completion dates for each action step, are approved by the Quality Manager.

**3.4.2** The Quality Manager will determine when a nonconformity is significant and ensure that the notification requirements of the applicable accrediting body(ies) are met (e.g., ANAB requires notification within 30 days of Quality Manager determining it as significant).

### **3.4.3 Root Cause Analysis**

Root cause analysis is important in preventing the recurrence of a nonconformity. The person responsible for managing a corrective action will investigate and determine the root cause(s).

The root cause(s) may be determined by following a cause and effect model (e.g., 5 whys, fishbone diagram, cause map) that evaluates potential causal factors. Potential causal factors should be evaluated, as appropriate, in the broad areas of equipment, personnel (e.g., work schedules, deployments, staffing), methods, environment, evidence, materials and supplies, budget, previous occurrences, and/or customer complaints. Refer to the FBI Laboratory Division

BUNET quality system documents webpages Resources tab for the evaluation of potential causal factors.

### 3.4.4 Action Steps

Action steps must be specific, measureable, achievable, relevant, and time-bound. Action steps will also be proportional to risks and opportunities. Objective evidence of completion of each action step(s) will be collected and retained. Depending on the nature of the nonconformity, appropriate action steps may include:

- Notification to the contributor(s) or the casework laboratory.
- Review of, and correction to, any relevant casework and/or DNA databasing.
- Additional review of work before release of reports and/or DNA match confirmation letters.
- Issuance of amended, supplemental, and/or superseding reports and/or DNA *Match Confirmation Letters*.
- Reassignment of duties.
- Remedial training.
- Revisions to policies, practices, procedures, and/or forms.
- Adoption of additional quality control measures.
- Indefinite removal of the person(s) from casework or DNA databasing.

The appropriate Technical Leader and Unit Chief(s) will authorize the resumption of casework or DNA databasing.

### 3.4.5 Accepting Corrective Action Steps

**3.4.5.1** The appropriate Unit Chief(s) will sign and date the form in the space labeled “Steps Approved by Unit Chief” indicating approval of the action steps listed and the expected completion date for each action step.

**3.4.5.1.1** Additionally, for technical matters, the appropriate Technical Leader will sign and date the form in the space labeled “Steps Approved by Technical Leader (for technical matters)” indicating approval of the action steps listed and the expected completion date for each action step.

**3.4.5.2** The Quality Manager and/or a QA Specialist will review the *Corrective Action Request* to determine its adequacy, acceptability of the planned action step(s), and the expected completion date(s) of each action step(s). If the request is determined to be less than adequate, the person responsible for managing the corrective action will be required to amend the *Corrective Action Request*. When approved, the Quality Manager will sign and date in the space labeled “Reviewed and Approved By” indicating the acceptance of the root cause(s) and action step(s). A QA Specialist will forward a signed copy to the person responsible for managing the corrective action. The person responsible for managing the corrective action will ensure the action steps are implemented by the expected completion date for each step.

### **3.4.6 Completed Corrective Action Steps**

A QA Specialist will liaise with the person responsible for managing the corrective action to determine if each action step is complete by its expected completion date.

**3.4.6.1** Once all of the action step(s) have been completed, the person responsible for managing the corrective action will ensure objective evidence in support of the completion of each action step is provided to a QA Specialist. A QA Specialist will review the objective evidence. A QA Specialist will sign and date in the space labeled “Actions Completed” when the objective evidence indicates each action step is completed.

### **3.4.7 Verification of Effectiveness of a Corrective Action**

A QA Specialist will ensure that the effectiveness of the corrective action(s) is verified. This may be accomplished by reviewing objective evidence of implementation, or it may be necessary to verify the effectiveness by other methods, which may include a review of affected work, additional audits, and/or interviews of affected personnel.

**3.4.7.1** When the effectiveness of the corrective action(s) has been verified, a QA Specialist will sign and date the space labeled “Verified Effectiveness.” A notation of what records were reviewed, or a copy of the records reviewed, to verify effectiveness will be retained.

**3.4.7.1.1** For some corrective actions, the effectiveness of the action step(s) cannot be verified. In this instance, a QA Specialist will mark the space labeled “Verified Effectiveness” as not applicable.

**3.4.7.1.2** If a QA Specialist determines that an action step(s) was not effective, a course of action will be recommended to the Quality Manager who will determine the next steps taken.

### **3.4.8 Closing Out a Corrective Action**

**3.4.8.1** The Unit Chief(s), or for technical matters the appropriate Technical Leader(s), will sign and date in the space labeled “Unit Approved” indicating approval for close out of the *Corrective Action Request*.

**3.4.8.2** The Quality Manager will sign and date the *Corrective Action Request* in the space labeled “Approved” indicating approval for close out of a corrective action.

**3.4.8.3** The Laboratory Director will sign and date the space labeled “Closed Out” thereby closing the *Corrective Action Request*.

**3.4.8.4** The original *Corrective Action Request* will be retained in the FASU. A copy of the signed, closed out *Corrective Action Request* will be forwarded to the person managing the corrective action.

### 3.5 Tracking Progress of *Corrective Action Requests*

QA Specialists will track the progress of *Corrective Action Requests*.

**3.5.1** All requests for information from a QA Specialist to the person managing the corrective action or other appropriate individual must be answered in a timely manner (e.g., within one to two days) and with the appropriate information/objective evidence. Issues related to the handling of a *Corrective Action Request* including non-responsiveness to requests for information or lack of progress on a corrective action may be elevated to the Section Chief of the person managing the corrective action by the Quality Manager.

**3.5.2** The Quality Manager will provide updates on open *Corrective Action Requests* at regularly scheduled meetings with Executive Management.

## 4 Records

The following records will be generated and/or retained unless specified otherwise through one accreditation cycle or five years, whichever is longer, as a result of these practices:

- Original *Corrective Action Requests* and associated records (e.g., notification to Quality Manager, objective evidence of action step(s) completion, accrediting body notification) will be maintained in FASU.
- Other associated records will be maintained by the units.
- Unit concession and correction records including annual reviews will be maintained by the unit.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Okes, D., *Root Cause Analysis The Core of Problem Solving and Corrective Action*, American Society for Quality, Quality Press, Milwaukee (2009).

Robitaille, D. *Root Cause Analysis Basic Tools and Techniques*, Paton Professional, Chico (2004).

Rev. #	Issue Date	History
11	06/08/18	Document revised to require expected completion date for each action step, update time requirements and approvals for corrective actions. Also updated wording and added section numbers for clarification throughout. In section 3.2.12 updated annual review requirements for concession and correction records. Added that Quality Manager will determine notification to accrediting body in section 3.4.2. In section 3.4.7 added that verification of effectiveness can include interviews. Revised <i>Corrective Action Request</i> in Appendix A. Removed Appendix B and added root cause resources to FBINET.
12	06/03/19	Expanded scope in section 2 to include handling complaints. Changed from 30 to 45 days in section 3.4.1.3. In section 3.4.4 added requirement for action steps to be proportional to risks and opportunities and statement that Technical Leader and Unit Chief(s) will authorize resumption of casework or DNA databasing. Updated requirement in section 3.4.5.1 regarding appropriate Unit Chief approval of action steps. In section 3.4.7, removed "verification" to avoid conflicting with LOM definition for this term. Removed requirement for providing monthly status updates to affected Unit Chiefs. Updated list of references in section 5. Revised <i>Corrective Action Request</i> in Appendix A.

### **Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019



**Appendix A: *FBI Laboratory Corrective Action Request (7-254)***

Redacted - Form on File

## **FBI Laboratory Practices for Internal Audits**

### **1 Purpose**

Internal audits verify that operations conform to the requirements of the FBI Laboratory quality system. They also provide management with information regarding the quality system. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to the Quality Manager, Quality Assurance (QA) Specialists, and/or other FBI Laboratory personnel who conduct Forensic Analysis Support Unit (FASU) directed quality assurance audits in the FBI Laboratory.

### **3 Practices**

#### **3.1 Auditor Training**

An auditor must successfully complete an approved training course. The Quality Manager will determine if a training course will be approved and the Audit Program Manager will maintain a list of approved training courses. The Audit Program Manager will also maintain a list of auditors who have successfully completed an approved course.

#### **3.2 Long-Term Audit Planning**

Activities performed by FBI Laboratory personnel will be audited at least once per year in all elements of the quality system. The Audit Program Manager will prepare a schedule for audits on an annual basis. The schedule will identify the topics and approximate dates of the audits. This schedule is a guide and may be changed at the discretion of the Quality Manager or Audit Program Manager.

#### **3.3 Scheduling the Audits**

Throughout the year, the Audit Program Manager will ensure the QA representatives of the units to be audited are contacted to determine mutually agreeable dates for the audits.

#### **3.4 Preparing for the Audit**

**3.4.1** The Audit Program Manager will identify an audit team leader(s) when appropriate, and ensure auditors are identified, as needed, to assist in performing an audit. The Audit

Program Manager will ensure the selected auditors are on the list of internal auditors. If an audit team leader is identified, the audit team leader will coordinate the audit, as directed by the Audit Program Manager.

**3.4.2** The Audit Program Manager will ensure an audit checklist is prepared and provided to the auditee(s) and the auditor(s). The audit checklist should be organized in such a way as to prompt the auditor(s) to review records, interview personnel, and/or observe conditions and facilities when necessary. The auditor(s) may be provided with additional materials so that they can prepare for the audit.

**3.4.3** The Audit Program Manager or audit team leader will meet with the audit team(s) when necessary, to provide instruction and guidance, prior to conducting the audit.

### **3.5 Conducting the Audit**

#### **3.5.1 Pre-audit Communication**

The Audit Program Manager or audit team leader will communicate the scope of the audit and address any questions and/or concerns with the auditee.

#### **3.5.2 Auditing**

The auditor(s) will, as necessary, review records, interview personnel, and/or observe conditions and facilities to collect data on conformance with requirements and effectiveness of quality control measures. For appropriate topics, the auditor(s) will directly observe a sampling of examinations within each discipline. The audit checklist will be used to record the audit data and any pertinent questions, observations, and/or comments identified during the audit.

#### **3.5.3 Post-audit Communication**

The Audit Program Manager will inform the unit QA representative, the Unit Chief(s) and the Technical Leader(s), of the preliminary audit data in writing. This communication will include the completed audit checklist. The Audit Program Manager or audit team leader may prepare a summary checklist to consolidate multiple audit checklists. This communication should occur as soon as possible following the audit. The auditee should inform the Audit Program Manager and if applicable, the audit team leader, of any disagreements that he/she has with the preliminary audit data. These issues will be considered by the Audit Program Manager and, if possible, resolved before the audit report is written.

**3.5.3.1** The preliminary audit data will be prepared by the Audit Program Manager or the Terrorist Explosive Device Analytical Center (TEDAC) QA Program Manager, respectively, when an audit is conducted on the TEDAC QA Program or the FASU QA Program.

### **3.6 Reporting the Audit**

**3.6.1** The Audit Program Manager will provide an audit report to each unit(s) for every

audit topic conducted to formally notify the Unit Chief(s) and the Technical Leader(s) of their audit results. An audit report will record any proficiencies, potential nonconformities, potential undesirable situations, and/or nonconformities.

**3.6.2** The audit report will be issued by the Audit Program Manager and approved by the Quality Manager. The issuance and approval will be recorded on the audit report by their respective signatures and dates.

**3.6.2.1** An audit report will be prepared by the Audit Program Manager or the TEDAC QA Program Manager, respectively, when an audit is conducted on the TEDAC QA Program or the FASU QA Program. The appropriate Section Chief will approve the audit report.

**3.6.3** The Audit Program Manager will issue the audit report to the Unit Chief(s) and the Technical Leader(s). If a concession or correction was identified to address a nonconformity, the audit report will identify those actions. If an audit report contains a corrective action(s), a copy of each *Corrective Action Request* (7-254) will be provided with the audit report. If the audit report contains a preventive action, a copy of each *Preventive Action Request* (7-261) will be provided with the audit report. Any *Corrective Action Request* will be generated according to Laboratory Operations Manual (LOM) - Practices for Addressing a Nonconformity. Any *Preventive Action Request* will be generated according to the LOM - Practices for Preventive Action.

**3.6.3.1** When an audit is conducted on the TEDAC QA Program or the FASU QA Program, the audit report will be issued to the Quality Manager.

### **3.7 Responding to an Audit Report**

The Unit Chief(s) and Technical Leader(s), or when applicable, Quality Manager, will acknowledge receipt of the audit report by signing and dating the report and returning the original report to the Audit Program Manager.

### **3.8 Closing Out the Audit**

#### **3.8.1 Preventive and Corrective Actions**

When a *Preventive Action Request(s)* and/or *Corrective Action Request(s)* associated with an audit is closed out, the audit for that unit can be closed.

#### **3.8.2 Audit Closure Notification**

The unit QA representative, Unit Chief(s), and Technical Leader(s), or when applicable, Quality Manager, will receive an audit closure notification from the Audit Program Manager in writing to inform him/her that the audit is closed. An audit is considered closed when the Unit Chief(s) and Technical Leader(s), or when applicable, Quality Manager have acknowledged receipt of the audit report, all concessions and corrections have been recorded, and all preventive and corrective actions have been closed out.

## 4 Records

The following records will be generated and/or retained through one accreditation cycle or five years, whichever is longer, unless otherwise stated as a result of these practices:

- Annual audit schedule.
- Completed audit checklists and if generated, a summary checklist.
- Audit reports and any associated responses will be retained permanently.
- Preliminary audit data.
- Audit closure notifications.
- List of approved auditor training courses.
- List of approved auditors.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
9	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section, clarified that all elements of the quality system will be audited, added flexibility for audit teams and management, added requirements for audits of the QA programs, and added the requirement to observe examinations when appropriate.
10	06/03/19	Added section 3.1 describing training requirements for auditors. Generalized requirement in section 3.3 as other QA personnel may schedule an audit. In sections 3.5.3.1 added requirement regarding when audits are conducted on a QA program. Removed redundant requirement for sending a copy of PAR or CAR from section 3.8.1. Updated section 3.8.2 as Audit Program Manager will send all audit closure notifications. Updated Records section to add lists of approve auditor training courses and approved auditors. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for the Calibration and Maintenance of Equipment**

### **1 Purpose**

These practices establish requirements for calibration, performance checks, and maintenance of equipment to ensure the accuracy and reliability of testing results. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel with equipment that has an effect on the validity of forensic examinations and DNA databasing and those personnel who coordinate maintenance and calibration services. This includes equipment outside the permanent control of the FBI Laboratory, used for testing activities.

### **3 Practices**

All equipment having an effect on the accuracy or validity of forensic examination and DNA database results will be properly maintained and calibrated. Units, disciplines, and/or categories of testing ensure the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

**3.1** Equipment and its software used for the examination of evidence or DNA databasing must meet the requirements of the relevant technical procedure or applicable specifications. Before being placed into or returned into service, and when necessary, equipment (including that used for sampling) that has a direct effect on the quality of an examination or DNA databasing is calibrated and/or checked by the unit, discipline, and/or category of testing to verify that it meets the specifications. Additionally, maintenance may be performed on equipment to ensure it meets the applicable specifications or requirements.

**3.2** Units, disciplines, and/or categories of testing will have procedures for handling, transport, storage, use, and planned maintenance of equipment in order to ensure proper functioning, to prevent contamination or deterioration.

**3.3** Units, disciplines, and/or categories of testing will take practicable measures to prevent unintended adjustments of equipment from invalidating test results.

**3.4** Any equipment that has been subjected to overloading or mishandling, gives questionable results or has been shown to be defective or outside specified requirements will be taken out of service. The equipment will be isolated to prevent use or clearly labeled or marked as being out of service until it has been verified to perform correctly. Units, disciplines, and/or categories of testing will determine the effect of the defect or departure from specified

requirements and implement nonconforming work procedures as specified in the LOM - Practices for Addressing a Nonconformity when necessary.

**3.4.1** If an instrument can be affected by a power interruption, units, disciplines, and/or categories of testing will check the instrument operation after a shutdown, whether deliberate or otherwise.

### **3.5 Resource Manager in Forensic Advantage**

**3.5.1** All equipment having a direct effect on the quality of an examination or DNA databasing or are part of an internal audit will be identified in Resource Manager in Forensic Advantage (FA) (with the exception of DNA equipment that is tracked in Sample Tracking and Control Software (STACS)). When a unit needs a new piece of equipment added to Resource Manager, they will contact the Research and Support Unit Instrument Operations and Systems Support (RSU IOSS).

**3.5.1.1** Each piece of equipment in Resource Manager will receive a unique identifier and barcode that will be placed on the equipment, when practicable.

**3.5.1.2** When the equipment is entered into FA, under Resource Instance Details, the following information will be populated by RSU IOSS. Only RSU IOSS will update these fields.

- “Identifier” - Type or name of equipment
- “Asset ID” - Equipment serial number or other unique identifier
- “Entered in FA” - Date equipment added to FA
- “Owner” - Unit managing the equipment
- “Model Number” - Model number, if available
- “Manufacturer” - Vendor, if available
- “Description” - Standard RSU IOSS description for the equipment
- “Comments” - Property (F) number, if available

**3.5.1.3** Each Unit Chief will ensure the equipment used in examinations and DNA databasing that requires calibration is identified in Resource Manager or STACS, as appropriate. Additionally, each Unit Chief will ensure that the appropriate fields in Resource Manager are complete and current,

**3.5.1.3.1** Units will update equipment calibration in Resource Manager or STACS, as appropriate in a timely manner after calibration. Units will maintain calibration records including any calibration certificates. Software and firmware version records will be maintained by the units. Resource Manager is not used to track maintenance and must track maintenance via another mechanism.



## **3.6 Calibration**

### **3.6.1** Measuring equipment is calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the examination or DNA databasing results, and/or
- calibration is required to establish metrological traceability of the examination or DNA databasing results.

### **3.6.2** Units, disciplines, and/or categories of testing will have a calibration program which they review and adjust as necessary in order to maintain confidence in the status of the calibration(s).

#### **3.6.2.1** The program for the calibration of equipment will include:

- a) a list of the equipment requiring calibration;
- b) specifications for the calibration laboratory;
- c) specified requirements for the calibration; and
- d) the interval of calibration.

### **3.6.3** FBI Laboratory equipment requiring calibration will be labeled, coded, or otherwise identified to allow the user of the equipment to readily identify the calibration status, or period of validity.

### **3.6.4** Equipment that requires calibration will not be used for examinations or DNA databasing if satisfactory calibration cannot be achieved. If the calibration has expired, personnel will verify that the calibration status is satisfactory prior to using the equipment.

## **3.6.5 Calibration of Measuring Equipment , Reference Standards, and Certified Reference Materials**

### **3.6.5.1** If available, suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability will be one of the following:

- a) a National Metrology Institute that is a signatory to the International Bureau of Weights and Measures (BIPM) International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB); or
- b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) MRA, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation; or
- c) an accredited reference material producer that is accredited to ISO 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC MRA, with a scope of accreditation covering the certified reference

material to be purchased.

**3.6.5.2** In situations where a supplier that meets 3.6.5.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased will be confirmed by the unit(s), discipline(s), and/or category(ies) of testing using that supplier. Objective evidence of the confirmation will be maintained by the relevant unit(s), discipline(s), and/or category(ies) of testing.

**3.6.5.3** If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material will be evaluated by the unit(s), discipline(s), and/or category(ies) of testing using that equipment for applicability of measurement traceability accreditation requirements.

**3.6.6** Units, disciplines, and/or categories of testing will ensure measurement results are traceable to the International System of Units (SI) through:

- a) calibration provided by a competent laboratory; or
- b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

**3.6.7** When metrological traceability of measurements to SI units is not technically possible, units, disciplines, and/or categories of testing will demonstrate metrological traceability to an appropriate reference, for example:

- a) Certified values of certified reference materials provided by a competent producer;
- b) Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

**3.6.8** When calibration and reference material data will include reference values or correction factors, the units, disciplines, and/or categories of testing will have measures to ensure the reference values and correction factors are updated and implemented as appropriate to meet specified requirements.

**3.6.9** Unit Chiefs will ensure that the calibration was completed and that Resource Manager or STACS is updated to record the calibration information.

### **3.6.10 Calibration Interval**

Unit Chiefs will ensure that equipment requiring calibration are calibrated within the required intervals. The interval for equipment requiring calibration will be specified in a level 2 document. Manufacturers' operating guidelines should be consulted to determine the recommended calibration interval, if applicable. However, equipment used infrequently, such that recommendations by the manufacturer cannot be followed, will be calibrated or have its calibration status verified prior to use.

New equipment or equipment that has undergone repair or maintenance that affects calibration, will have its calibration status verified before being used in examinations or DNA databasing.

### **3.6.10.1 Intermediate Checks**

When intermediate checks are needed to maintain confidence in the performance of the equipment, these checks will be carried out according to an applicable procedure(s).

### **3.6.11 Calibration Records**

**3.6.11.1** Calibration records including any calibration certificates for all equipment will be maintained by the units.

**3.6.11.2** Resource Manager fields will be used to record the following information for balances, calipers, micrometers, pipettes, and class 1 weights (Resource Manager fields in quotes), with the exception of DNA equipment tracked in STACS.

When a Resource Action (calibration) is entered, the following fields will be populated by the unit:

- “Performance Action” - Calibration option
- “Date of Action/ Time of Action” - Date and time (separate fields) when calibration conducted
- “Performed By” - Person performing/recording the maintenance
- “Comments” - Additional information about the calibration conducted

When the equipment is calibrated, the field below on “Resource Instance Details” must be updated by the unit.

- “Expiration Date” - Expiration date for the current calibration

**3.6.11.3** If calibrations performed by an outside vendor are coordinated by the Forensic Analysis Support Unit (FASU) or the Scientific and Biometric Analysis Unit Instrument Operations Group (SBAU IOG) (e.g., balance calibrations), FASU or SBAU IOG will provide to the units the original calibration records (physical or electronic) provided by the vendor.

## **3.7 Performance Checks**

In instances where calibration is not required or appropriate, performance checks should be carried out at appropriate intervals to verify that the equipment is functioning properly. Performance check procedures will be included in the appropriate technical standard operating procedure (SOP) in which the equipment is used, in a stand-alone maintenance document, or in manufacturer-supplied procedures for maintenance. These procedures will reflect current performance requirements based on the use of the equipment and will be readily available to appropriate personnel.

### **3.7.1 Performance Check Records**

Performance check records will be maintained. If a bound notebook is used to capture the

performance check records, only the cover or first page of the notebook must be labeled with the equipment's unique identifier. Performance check records may also be maintained in case notes. These records will include, at a minimum:

- Type or name of equipment.
- Equipment serial number or other unique identifier.
- Date of the performance check.
- Results of the performance check.
- Material used for the performance check, including unique identifying information (if applicable).
- Acceptance criteria, if applicable.
- Identity of person performing the performance check.

### **3.8 Maintenance**

**3.8.1** Units, disciplines, categories of testing will have maintenance procedures for equipment that has a direct effect on the quality of an examination or DNA databasing.

#### **3.8.2 Maintenance Intervals**

Maintenance can be performed on equipment:

- according to a regular, predetermined schedule (e.g., microscope maintenance performed annually);
- based on routine monitoring of performance;
- following adjustment of common parameters (e.g., head pressure, solvent degas); and/or
- after replacement of consumable items (e.g., septa, liners, columns).

Maintenance is performed on equipment in order to ensure reproducible and uninterrupted operation, or maintenance can be corrective. Maintenance performed on a regular, predetermined schedule is based on manufacturer's recommendations (as available and relevant), historical observations of any issues, operating experience, and/or how often the equipment is used. The interval for any equipment requiring preventive maintenance will be specified in a procedure.

**3.8.3** Corrective maintenance occurs when a piece of equipment cannot be properly calibrated, fails an intermediate check, fails to meet the performance characteristics established for the procedure(s), or produces unacceptable results. The equipment will be taken out of service (Refer to Section 3.4).

#### **3.8.4 Maintenance Records**

**3.8.4.1** Maintenance records will be maintained by the units. If a bound notebook is used to capture maintenance records, only the cover or first page of the notebook needs to be labeled with the equipment's unique identifier.

**3.8.4.2** If maintenance performed by an outside vendor is coordinated by FASU or SBAU IOG (i.e., microscope maintenance), FASU or SBAU IOG will provide to the units the original

maintenance records (physical or electronic) provided by the vendor.

### **3.9 Refrigerator and Freezer Monitoring**

All refrigerators and freezers that store evidence and/or items that have a direct effect on the validity of forensic examinations or DNA databasing have their temperatures monitored and maintained as needed.

## **4 Records**

The following records will be maintained through one full accreditation cycle or five years, whichever is longer as a result of these practices:

- Entries in Resource Manager or STACS for all equipment having a direct effect on the quality of an examination or DNA databasing or part of an internal audit.
- Calibration records will be maintained by the units with specified calibration fields maintained in Resource Manager.
- Maintenance records will be maintained by the units.
- Performance check records will be maintained by the units.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
9	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removal of the Responsibilities section, the addition of CU IOSS group's entry of new equipment into Resource Manager, the addition of SAU IOG to perform calibration functions at the Huntsville, AL facility in the way FASU performs them for the Quantico, VA facility, and the requirement for monitoring the temperatures of refrigerators and freezers.
10	06/03/19	Entire document revised to conform to new accreditation requirements. Broadened scope in section 2 to include personnel who coordinate services, and equipment outside the FBI Laboratory's permanent control. Updated unit names following Laboratory realignment. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Open Proficiency Testing**

### **1 Purpose**

The open proficiency testing practices are a measure used by the FBI Laboratory to monitor performance. These practices are designed to demonstrate that FBI Laboratory personnel performing forensic examinations or DNA databasing produce reliable work and that analytical procedures are conducted within the established performance criteria. The program is designed in a manner to test examiners and technicians as well as the FBI Laboratory quality system. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who routinely perform analytical or interpretative procedures on evidentiary items and DNA database samples and are required to participate in proficiency testing. Additionally, these practices apply to other personnel who remain qualified to support FBI Laboratory needs and are subsequently required to participate in proficiency testing. These practices also apply to the Proficiency Test Program Manager (PTPM) as well as personnel responsible for various actions that occur as a result of proficiency testing. Open proficiency tests are analyzed and interpreted according to the approved standard operating procedures (SOPs) in use in each discipline/category of testing at the time of the proficiency test.

### **3 Practices**

The PTPM manages the proficiency testing program to include liaising with FBI Laboratory personnel and the accrediting body regarding proficiency testing inconsistencies, where appropriate, and when requested, generating proficiency test management reports from Forensic Advantage (FA) or requesting equivalent records from the DNA units.

#### **3.1 Participation**

**3.1.1** Each examiner and technician in forensic science disciplines accredited to the ISO 17025 standard must complete at least one proficiency test annually to cover each category of testing appearing on the FBI Laboratory's Scope of Accreditation in which the examiner and/or technician routinely performs testing, except for latent print processing. A single proficiency test may cover more than one category of testing. Each DNA examiner and technician, individually or together, must complete two DNA external proficiency tests per year. Examiners involved in the latent print processing will complete at least one proficiency test per accreditation cycle. Each examiner and technician engaged in testing activities in caseworking units that are not

accredited must successfully complete at least one proficiency test per calendar year in his/her category of testing. The test(s) may be external or internal; however, all examiners and technicians will participate in external proficiency tests where available and appropriate for the testing conducted in the FBI Laboratory. Refer to section 3.4 for information on internal proficiency tests. Each person tested must participate in the test to the extent that he/she would perform the procedures in casework or DNA databasing.

**3.1.1.1** When an examiner chooses to remain proficient in the entire examination or DNA databasing process, he/she must complete an independent proficiency test. If the examiner is also participating in an examiner/technician test in the same proficiency test series, the examiner will not begin his/her portion of the examiner/technician test until after his/her independent test is completed.

**3.1.1.2** Any person who prepares an internal proficiency test and is required to complete a proficiency test must take an external proficiency test or an internal test prepared by another person.

**3.1.1.3** Personnel who leave a position in a discipline/category(ies) of testing may continue to participate in proficiency testing for up to one year. The appropriate Technical Leader will determine the duration (not to exceed one year) in which the person will continue to participate in proficiency testing. The Technical Leader will ensure an Electronic Communication (EC) is serialized in Sentinel recording the duration. The EC will be approved, at a minimum, by the appropriate Technical Leader and affected Unit Chief(s). The proficiency testing schedule will be modified as needed.

### **3.1.2 Approved Proficiency Tests**

**3.1.2.1** Proficiency tests will be approved by the appropriate Technical Leader and the Quality Manager. The appropriate Technical Leader will evaluate the technical merits of a test to ensure that it is appropriate for the testing conducted in the discipline/category of testing within the FBI Laboratory. The Quality Manager will determine if a test meets accreditation requirements and/or the quality system requirements of the FBI Laboratory.

**3.1.2.2** The PTPM will maintain a list of approved external proficiency tests. The Proficiency Test Representative (PTR) will ensure approved external proficiency tests are purchased. An unapproved test may be purchased for evaluation purposes.

**3.1.2.3** If an approved external test is not available, an internally designed and prepared test will meet the annual proficiency testing requirement. Refer to section 3.4.

### **3.1.3 Proficiency Test Ordering and Schedule**

**3.1.3.1** The PTR will arrange for the procurement of the necessary external tests. The procurement records will be retained by the PTR.

**3.1.3.2** Each PTR will ensure the proficiency testing schedule through the next reassessment



is recorded. This schedule will be updated by December 31st of each year. This schedule will be maintained on the Proficiency Testing SharePoint site and include the following:

- Location(s) where test will be performed (if different from participant's assigned duty station)
- Unit
- Participant
- Discipline and Category(ies) of Testing
- Proficiency Test
- Proficiency Test Type
- Estimated Distribution Date

**3.1.3.3** The PTPM will ensure a proficiency testing plan(s) is prepared. The proficiency testing plan(s) will include a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation.

## **3.2 Proficiency Test Procedures**

A level 2 document will contain procedures for internal and/or external proficiency testing. These procedures will contain a program scope and a description of the proficiency test evaluation process. If a proficiency test evaluation form is used, the form and its use will be included in the relevant proficiency test procedure(s). Participants will follow appropriate SOPs when participating in proficiency tests. The results (with the exception of DNA proficiency tests) will be uploaded into the Case Record Object Repository in FA and proficiency test evaluations will be entered into FA. DNA units will have procedures for recording the results and evaluations.

### **3.2.1 Program Scope**

This statement will include a reference to the positions and categories of testing to which the program applies and whether the program includes internal and/or external proficiency tests.

### **3.2.2 Sample Retention**

Proficiency test samples must be retained through the evaluation of a proficiency test and when applicable, the resolution of corrective actions associated with that proficiency test.

## **3.3 External Proficiency Testing**

The PTR will ensure that proficiency tests are accounted for, distributed, submitted by the provider's due date, evaluated, and recorded.

### **3.3.1 Date Assigned**

The date assigned identifies the day on which the test participant was assigned a proficiency test. This date identifies the calendar year for which the test will be credited. For example, if the date assigned for a test is December 18, 2019, and the due date for that test is January 18, 2020, the

test participant is credited with participating in a 2019 proficiency test. The PTR will ensure the timely issuance of external tests. The date the proficiency test is assigned will be recorded in FA.

### **3.3.2 Internal Evaluation of External Proficiency Test for Current Cycle**

Proficiency test results not accepted by the provider do not satisfy the external proficiency test requirement for that category of testing for that calendar year in which it was assigned. With the exception of DNA, the test may be evaluated internally for the current proficiency test cycle. If this occurs, the affected Unit Chief and/or PTR will establish a new internal due date for the proficiency test(s) to be evaluated internally. This due date must precede the release of any manufacturer's information, individual reports, and/or summary reports released by the external test provider.

### **3.3.3 Preparation of Test Provider Data Sheets**

Results for external tests will be recorded on external provider data sheets according to instructions provided by the external provider. These data sheets must include the following:

- Reference to the test provider's sample identifiers.
- Legible conclusions written without using abbreviations, other than abbreviations for units of measurement.

External provider data sheets must be completed in their entirety as appropriate. Attachments may be used to supplement the data sheets, but cannot be used in lieu of completing the data sheets. Electronic data sheets or web based data entry are preferred.

### **3.3.4 Verification of Identification or Association and Technical Review**

All proficiency test identifications or associations will be verified, when appropriate, and all proficiency tests will be technically reviewed using the same procedures used for casework. DNA databasing will have procedures for the technical review of proficiency tests. The verification and/or technical review will be recorded in FA. The verification and/or technical review of DNA proficiency tests will be recorded according to DNA proficiency testing procedures.

**3.3.4.1** If a person who will verify and/or technically review a proficiency test is participating in the same test distribution, the PTR will ensure that the person has finished his/her portion of the test prior to performing a verification or technical review.

**3.3.4.2** If the PTR is participating in the test distribution and will be submitting other participants' results to the provider, the Unit Chief will ensure the PTR has finished their portion of the test prior to submitting results.

**3.3.4.3** Analytical/interpretive inconsistencies will be handled according to section 3.5.3.2.

### **3.3.5 Administrative Review**

All proficiency tests will be administratively reviewed. An administrative review will not be conducted by the participant whose data sheets/results are being reviewed. A level 2 document may further define requirements for an administrative reviewer. Completed external provider data sheets will be included in the administrative review process. The administrative review will be conducted before the proficiency tests results are submitted to the provider or internal evaluator. The administrative review will be recorded in FA. DNA databasing will have procedures for the administrative review of proficiency tests. The administrative review of DNA proficiency tests will be recorded according to DNA proficiency testing procedures.

**3.3.5.1** If the administrative reviewer is participating in the same test distribution, the PTR will ensure that the reviewer has finished his/her portion of the test prior to performing the review.

**3.3.5.2** Administrative errors will be handled according to section 3.5.3.1.

### **3.3.6 Submitting Test Results**

**3.3.6.1** Technical and administrative reviews must be completed prior to submitting test results.

**3.3.6.2** The PTR will ensure the electronic data sheets, web based data entry forms, or physical forms are submitted according to the provider's instructions by the provider's due date, and that the results are authorized for release to the accrediting body.

**3.3.6.3** After the results have been submitted to the test provider, proficiency testing records and completed provider data sheets are considered the finalized work and cannot be changed.

**3.3.7** If a problem that may impact the quality of the original test samples received from an external test provider is identified, the affected PTR will notify the PTPM in writing regarding the nature of the problem.

## **3.4 Internal Proficiency Testing**

If a proficiency testing program includes internal proficiency testing, a level 2 document will address test design, sample preparation, and test preparation. If a retained external proficiency test will be used as an internal proficiency test, refer to section 3.4.3.5.

Those categories of testing unable to comply with the requirements listed below will record a course of action. The affected Unit Chief(s), appropriate Technical Leader, PTR(s), and the Quality Manager will agree on the course of action to be taken to ensure the quality of the proficiency testing.

### **3.4.1 Internal Test Design**

An internal proficiency test design will include:

- the objective of each test or batch of tests.
- what the test is designed to measure.
- the expected outcome including the acceptable limits, when appropriate.
- how the test will be prepared, to include sufficient detail to replicate the test.

**3.4.1.1** The design of a proficiency test(s) must be approved by the Technical Leader. This approval will be recorded using the name of the Technical Leader, his/her signature or initials and the date of the approval. The approved design will be provided to the PTR.

**3.4.1.2** The PTR will forward the approved design to the PTPM. The proficiency test design will be administratively reviewed by the PTPM for appropriateness and completeness of each design relative to quality assurance. The PTPM will record the review.

### **3.4.2 Internal Sample Preparation to be Used in an Internal Proficiency Test**

Proficiency test samples will be prepared using specimens, materials, and methods that ensure their uniformity, identity, and integrity. Prior to a person other than an examiner or technician in the category of testing participating in the preparation of samples, the name and qualifications of the candidate will be submitted to the Technical Leader for approval. If approval is not granted by the Technical Leader, another candidate will be chosen. At a minimum, the following will be identified when preparing a proficiency test sample.

- Types of samples that need to be prepared and the materials necessary for their preparation.
- Steps taken to collect or prepare a sample.
- Who collected or prepared the sample.
- When the sample was collected or prepared.

**3.4.2.1** Quality control measures address the verification of the accuracy and integrity of each proficiency test sample. At a minimum, these measures will include:

- Labeling each sample with a unique identifier.
- Recording the source from which the sample was collected. The level of detail for the source identification may differ for each category of testing.
- Verifying the sample identifier for accuracy. This verification of accuracy will be recorded and conducted by another person.
- Preparing each sample that produces qualitative results in such a way that it contains sufficient class and/or individual characteristics for meaningful analysis and/or comparison.
- Preparing each sample that produces quantitative results in such a way that it will contain an amount of analyte sufficient to enable a conclusion to be drawn from the results of the analysis and/or comparison.
- Validating each sample (or lot of samples) for desired qualitative or quantitative results. The validation will be conducted by an examiner or technician qualified in the category of testing or by a person who approved by

the Technical Leader. This validation must be recorded.

**3.4.2.2** Samples must be appropriately labeled as proficiency test samples.

### **3.4.3 Internal Test Preparation**

Each internal proficiency test will be prepared by a person determined by the Technical Leader to possess sufficient knowledge of and/or experience of the category of testing for which the test is being prepared. The preparer will use the proficiency test samples that were prepared according to section 3.4.2 to create the internal proficiency test. At a minimum, the name of the person who prepared the test and when the test was prepared will be recorded.

**3.4.3.1** Quality control measures ensure the accuracy of information contained in each internal proficiency test. At a minimum, these measures will include:

- Labeling each test with a unique identifier.
- Recording all samples and sample identifiers used for each test.
- Verifying the sample and test identifiers for accuracy. This verification of accuracy will be recorded and conducted by another person.
- Validating each test (or lot of tests) to ensure the expected results can be obtained. This validation will be conducted by an examiner or technician, as appropriate, qualified in the category of testing or by a person approved by the Technical Leader. This validation must be recorded. An examiner/technician who validates the results may count this validation as an internal proficiency test for that category of testing, with the requirement that he/she does not have direct knowledge of the preparation of the samples or the test. Verification of identification or association and technical review will be required for this instance. The person who validated the test preparation may conduct the verification of any identification and association and/or the technical review of other tests of this lot.

**3.4.3.2** Expected results of each internal proficiency test will be recorded, including acceptable limits when appropriate.

**3.4.3.3** Appropriate controls among the samples submitted for each internal proficiency test will be used, where appropriate or necessary. Reference materials may be used as part of the control system (if available) for a particular examination or test.

**3.4.3.4** An additional internal proficiency test sample(s), from the same source for possible re-analysis and comparison, must be retained through the evaluation of a proficiency test and when applicable, the resolution of corrective actions associated with that proficiency test.

### **3.4.3.5 External Proficiency Test Samples Used in Internal Test Preparation**

**3.4.3.5.1** Retained external proficiency test samples may be used in the preparation of an internal proficiency test or a requalification test.

**3.4.3.5.2** Each test will be prepared by a person determined by the Technical Leader to possess sufficient knowledge of and/or experience in the category of testing for which the test is being prepared.

**3.4.3.5.3** The following will be recorded when preparing a test using retained external proficiency test samples:

- Who prepared the test.
- When the test was prepared.
- The unique identifier for the test.
- Sample(s) and sample identifier(s) used for the test.

**3.4.3.5.4** When retained external proficiency test samples are used, the PTR must ensure that the sample(s)/test identification is altered such that the test participant cannot correlate any published results with the proficiency test sample(s).

**3.4.3.5.5** The sample's new identifier must be recorded and traceable to the test provider's sample/test identifiers. The retained external proficiency test sample identifier and the sample's new identifier must be verified. This verification of accuracy will be conducted and recorded by another person for all samples used in the test.

**3.4.3.5.6** The expected results for retained external proficiency test samples do not need to be validated or verified. The manufacturer's information for the retained external proficiency test samples will be considered the expected results.

## **3.4.4 Internal Test Administration**

### **3.4.4.1 Date Assigned**

The date assigned identifies the day on which the test participant was assigned a proficiency test. This date identifies the calendar year for which the test will be credited. For example, if the date assigned for a test is December 18, 2019, and the due date for that test is January 18, 2020, the test participant is credited with participating in a 2019 proficiency test. The PTR will ensure the timely issuance of internal tests. The date the proficiency test is assigned will be recorded in FA.

### **3.4.4.2 Due Date**

The Unit Chief and/or PTR will establish the internal proficiency test due date. If a test is not completed and returned by the due date, that test does not satisfy the proficiency testing requirement for that category of testing for that calendar year in which it was assigned.

## **3.4.5 Proficiency Results Form**

Results for all internal tests will be recorded in FA and may additionally be recorded on a proficiency results form. If used, the form will be uploaded into the Case Record Object Repository in FA. The proficiency results form will include at a minimum:

- Name(s) of test participant(s).

- Test type (position type and internal/external).
- Test identification number.
- Completion date.
- Test results including conclusions where applicable.
- Records of technical and administrative reviews.

### **3.4.6 Verification of Identification or Association, Technical Review, and Administrative Review**

Verification of identification or association, technical review, and administrative review will be performed according to sections 3.3.4 and 3.3.5.

## **3.5 Evaluation of Proficiency Test Results**

**3.5.1** The PTR will obtain and review the proficiency test manufacturer's information report (when provided), individual reports, and summary reports. The PTR will evaluate the submitted results and supporting records and compare those results with the above reports. The PTR will also review the proficiency test manufacturer's information report (when provided), individual reports, and summary reports and his/her evaluation of the submitted results with the Unit Chief and/or Technical Leader.

**3.5.1.1** The PTR will ensure that the manufacturer's information report (when provided), individual reports, and summary reports are available to the test participant(s) for review.

**3.5.1.2** The PTR will ensure the following information is recorded in FA and when applicable, recorded on a unit evaluation form:

- Name(s) of test participant(s).
- Test type (position type and internal/external).
- Test identification number.
- Date assigned.
- Date returned.
- Due date.
- Evaluation date.
- Name of evaluator.
- Results: satisfactory or unsatisfactory.
- Description of discrepancy, when appropriate.

DNA will have procedures for recording the above information.

**3.5.1.3** The proficiency test evaluation will be completed within 20 calendar days after the individual and/or summary reports are received for an external test.

**3.5.1.4** The PTR will ensure the completion of the evaluation, the appropriate evaluation term (i.e., satisfactory, unsatisfactory, or discontinued), and the test participant's feedback date are entered into FA contemporaneously with the evaluation and feedback. The feedback date is the date the evaluation was reviewed by the test participant.

**3.5.1.5** If a proficiency test evaluation form is used, it will be made available to the test participant. Each test participant must record his/her receipt of the test evaluation. These records include the name and initials or the signature of the test participant and the date the evaluation was reviewed. If used, the form will be uploaded into the Case Record Object Repository in FA. For DNA proficiency tests, the unit evaluation form will be maintained with the proficiency test records.

**3.5.1.6** The PTR will ensure that the evaluation of internal proficiency tests is conducted within 20 calendar days from the administrative review.

### **3.5.2 Notification of Inconsistency**

The PTR, affected Unit Chief(s), or Technical Leader will notify the PTPM in writing, at the time of detection, of any potential analytical/interpretative proficiency test inconsistency.

### **3.5.3 Nonconformities**

#### **3.5.3.1 Administrative Errors Identified by Laboratory Personnel**

##### **3.5.3.1.1 Notification of Administrative Errors**

If an administrative error is detected it will be brought directly to the attention of the test participant.

##### **3.5.3.1.2 Action Taken**

All administrative errors detected during an administrative review will be corrected prior to the administrative review being completed. If the administrative error is detected during the evaluation of the results by the PTR, it will be corrected. The PTR will ensure any corrected data sheet(s) and examination notes or DNA database notes are maintained with the proficiency test records. The PTPM will be notified in writing if the correction requires communication with the provider.

#### **3.5.3.2 Potential Analytical/Interpretative Inconsistencies Identified Prior to Submission**

##### **3.5.3.2.1 Notification of Analytical/Interpretative Inconsistencies**

If a potential inconsistency is detected during a verification or technical review, the nature of the potential inconsistency will be brought to the attention of the Unit Chief(s) and Technical Leader. The Technical Leader will initiate the appropriate evaluation of any analytical/interpretative inconsistency and will determine whether the potential inconsistency is an analytical/interpretative inconsistency. The Technical Leader will notify the PTR, the appropriate Unit Chief(s), and PTPM in writing of her/his evaluation and resulting determination.



### **3.5.3.2.2 Action Taken**

If the inconsistency is detected during a verification/technical review, at the discretion of the Technical Leader, the test participant may address the inconsistency and complete the proficiency test.

**3.5.3.2.2.1** If necessary, the Technical Leader will initiate a corrective action according to the LOM – Practices for Addressing a Nonconformity to address the inconsistency. A Unit Chief and Technical Leader may have the item(s) re-examined and reviewed by examiners other than the original examiner and technical reviewer. The Unit Chief and Technical Leader will record the inconsistency and notify the affected test participant.

**3.5.3.2.2.2** The examiner and/or technician will not conduct examinations or DNA databasing, or issue *Laboratory Reports* (7-1, 7-1 LIMS, 7-273, 7-273 LIMS) or *DNA Match Confirmation Letters* until the appropriate corrective action steps have been completed and the examiner and/or technician is authorized to resume examinations or DNA databasing by the Unit Chief and Technical Leader.

**3.5.3.2.2.3** The Unit Chief will ensure casework or DNA databasing records are reviewed from the examiner and/or technician to ensure that the examinations or DNA databasing have been conducted properly, that the notes and results have been reviewed, and that the appropriate conclusions have been rendered. The review of casework or DNA database records will include all cases or DNA database samples that were completed since the last satisfactory proficiency test in that category of testing and are relevant to the inconsistency and/or the design of the proficiency test.

**3.5.3.2.2.4** The examiner and/or technician will complete remedial training and a requalification test in the category of testing in which the inconsistency occurred.

### **3.5.3.3 Potential Inconsistencies Identified by the PTR**

If a potential inconsistency is identified by the PTR after the initial assessment of external proficiency test results against the manufacturer's information, individual reports, and/or the summary reports, he/she will notify the affected Unit Chief(s) and Technical Leader of the potential inconsistency in writing. The Unit Chief(s) and Technical Leader will determine whether the potential inconsistency is an acceptable result or is an inconsistency that is administrative or analytical/interpretive in nature, and notify the PTPM of the type of inconsistency in writing. If it is determined to be an analytical/interpretive inconsistency, the Unit Chief(s) and Technical Leader will then follow the steps listed in sections 3.5.3.2 through 3.5.3.2.2.4.

### **3.5.3.4 Potential Inconsistencies Identified by the Proficiency Review Committee (PRC) or a Proficiency Test Provider**

#### **3.5.3.4.1 Notification of Potential Inconsistencies or Non-Consensus Results**

If a potential inconsistency or non-consensus result is identified by the PRC or a proficiency test provider, the PTR will notify the affected Unit Chief(s), Technical Leader, and the PTPM in writing. The PTR will also forward to the PTPM any communications from the PRC. The Unit Chief(s) or Technical Leader must provide a response to the PTPM regarding the PRC inquiry by the date specified in the accompanying notification. The Unit Chief or Technical Leader will notify the affected test participant.

#### **3.5.3.4.2 Action Taken**

The Unit Chief and Technical Leader will review the potential inconsistency or non-consensus result noted by the PRC or the proficiency test provider and the examination notes of the affected test participant to determine whether the potential inconsistency or non-consensus result is an acceptable result or is an inconsistency that is administrative or analytical/interpretive in nature.

**3.5.3.4.2.1** If the potential inconsistency or non-consensus result is determined to be an acceptable result, the Unit Chief or Technical Leader will communicate this in writing to the PTR and PTPM.

**3.5.3.4.2.2** If the inconsistency or non-consensus result is determined to be an administrative error, it will be corrected by the test participant. The Unit Chief or Technical Leader will communicate in writing to the PTR and PTPM detailing the resolution of the administrative error. The PTR will ensure any corrected data sheet(s) and examination notes or DNA database notes are maintained with the proficiency test records.

**3.5.3.4.2.3** If the inconsistency or non-consensus result is determined to be an analytical/interpretive error, the Unit Chief or Technical Leader will communicate in writing to the PTR and the PTPM detailing the resolution of the analytical/interpretative error or non-consensus result including a copy of any corrective action(s), if necessary. Additionally, the PTR will ensure a copy of the affected test participant's examination or DNA databasing notes, including the resulting conclusions for the proficiency test records, is maintained with the proficiency test records.

**3.5.3.4.2.4** The PTPM will forward to the unit any resulting requests from the PRC that may follow. The Unit Chief or Technical Leader must provide a response in writing to the PTR and PTPM regarding the PRC inquiry by the date specified in the accompanying notification.

### **3.5.3.5 Other Proficiency Review Committee Communications**

**3.5.3.5.1** At times, although a potential inconsistency or non-consensus result has not been identified, the PRC may need to communicate with the FBI Laboratory regarding the submitted test results. The PTR will notify the affected Unit Chief(s), Technical Leader, and PTPM in

writing and will forward to the PTPM any communications from the PRC for review. The Unit Chief(s) or Technical Leader will provide a written response to the PTR and PTPM regarding the PRC communication by the date specified in the accompanying notification.

**3.5.3.5.2** When a potential inconsistency or non-consensus result has been identified by the FBI Laboratory, the Laboratory may proactively communicate with the PRC regarding the potential inconsistency. The PTR will notify the affected Unit Chief(s), Technical Leader, and PTPM in writing and will forward to the PTPM any information to be included in the proactive communications.

## **3.6 Extended Leave**

**3.6.1** When a person is on extended leave, his/her Unit Chief and Technical Leader will ensure that that person is administered a requalification test(s) upon his/her return, to ensure continued proficiency. Successful completion of the requalification test(s) must be accomplished and recorded prior to resuming independent casework or DNA databasing responsibilities.

**3.6.2** The length of leave considered to be “extended leave” will be at the discretion of the Technical Leader. However, any leave exceeding one half of an annual proficiency test cycle will be considered “extended leave.” In the DNA units, leave that takes a person out of the semi-annual proficiency test cycle will be considered “extended leave.”

**3.6.3** Retained external proficiency test samples may be used in the preparation of a requalification test(s) to meet this requirement. If retained external proficiency test samples are used, refer to section 3.4.3.5.

## **4 Records**

Each Unit Chief will ensure that all proficiency test-related records are permanently retained in FA and/or the unit to which the participant is assigned.

**4.1** The following test information must be retained for all proficiency tests:

- Distribution records.
- Examination or DNA database records.
- External test provider data sheets or proficiency results form for internal tests.
- Test information for external tests to include test manufacturer/provider, test identifier, participant code, test type, and category of testing.
- Date assigned.
- Due date
- Examinations completed date.
- Evaluation date.
- Feedback date.
- Completed date.
- Evaluation records including completed evaluation forms, if used.
- Corrective action records, if applicable.

- PRC communications, if applicable.
- Location(s) where test performed (if different from participant's assigned duty station).

**4.2** The following information must be retained for internally prepared tests:

The records to be retained for sample preparation include:

- The unique identifier for the sample.
- Who prepared the sample.
- When the sample was prepared.
- The source of each sample.
- Who witnessed the source and sample identification accuracy.
- Who validated the quantitative and/or qualitative results.

The records to be retained for test preparation include:

- The unique identifier for the test.
- Who prepared the test.
- When the test was prepared.
- What samples are included in each test (by sample identifier).
- Who verified the sample and test identification accuracy.
- The expected results, including acceptable limits (when appropriate), of the test.
- Who validated the expected results of the test.

**4.3** The following proficiency test records will be maintained by the Forensic Analysis Support Unit through one accreditation cycle or five years, whichever is longer.

- List of approved external proficiency tests.
- Proficiency testing plan(s).
- Proficiency test schedule.
- Corrective action records, if applicable.
- PRC communications, when received.

**4.4** Procurement records related to proficiency tests will be retained by units ordering external proficiency tests through one accreditation cycle or five years, whichever is longer.

**4.5** Requalification records will be maintained in the person's unit or applicable support unit.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Rev. #	Issue Date	History
12	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Entire document revised due to decentralization of many Proficiency Test Program elements facilitated by the use of electronic test submission and provider notifications.
13	06/03/19	Added requirements regarding personnel who leave a position in section 3.1.1.3. Updated the list in section 3.1.3.2 to include location and discipline. Added section 3.1.3.3 to require a proficiency testing plan(s). In section 3.3.4.2 added a requirement to cover instances when the PTR is participating in the test. Expanded section 3.3.6.2 to include release to accrediting body. Added reference to nonconformity practice in section 3.5.3.2.2.1. In section 3.6.1, clarified that requalification must be recorded. Listed additional records in section 4 that correspond to revised content. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Handling Drug and Valuable Evidence**

### **1 Purpose**

These practices establish the requirements for handling drug and valuable evidence to conform with FBI policies and the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who handle drug and/or valuable evidence.

### **3 Practices**

Personnel handling drug or valuable evidence will take and record custody of evidence prior to opening or beginning examinations. Refer to Appendices A and B for a summary of drug and valuable evidence handling requirements.

#### **3.1 Receipt of Drug and Valuable Evidence**

##### **3.1.1 Receipt of Internal Submissions**

Drug or valuable evidence should be received from an FBI contributor in a plastic heat-sealed evidence pouch, or in a box or wrapped in brown paper and secured with fiber-reinforced packing tape. The evidence should be received bearing a completed *Drug Evidence* (FD-723), *Valuable Evidence* (FD-723a), or obsolete *Drug and Valuable Evidence* (FD-723) label.

**3.1.1.1** If the evidence is not received as described above, personnel breaking down the evidence will record the condition in which the evidence was received (e.g., check-in notes). Personnel will appropriately seal the evidence.

##### **3.1.2 Receipt of External Submissions**

Evidence received from an external contributor should be sealed. If the evidence is not sealed, personnel receiving the evidence will record the condition in which the evidence was received and appropriately seal the evidence.

#### **3.2 Opening Drug and Valuable Evidence**

Drug or valuable evidence packaging should only be opened for purposes of examination and should not be opened for other purposes, such as ensuring the contents.

**3.2.1** Personnel will open the packaging in the presence of a witness, by cutting along a different point from where the packaging was originally sealed. Personnel will ensure that the contributor's label, seal, and/or initialing remains intact, if possible. The person who opens the packaging will retain the original packaging, including any pieces removed during the opening, for return with the evidence to the contributor. If opening a box or carton, the label may be removed, if necessary, and retained.

### **3.2.2 Accounting for Drug and Valuable Evidence**

**3.2.2.1** For any item determined to be drug or valuable evidence, personnel will open and count or weigh the evidence, as appropriate, in the presence of a witness who will confirm the contents are as described (e.g., money count, weight). Prior to opening the evidence or adding any (or minimal) labels/barcodes, the gross weight of the suspected non-trace drug evidence and applicable packaging will be recorded in grams. For an evidence item(s) where only drug residue is suspected of being present (e.g., drug wrappings, pipes, scales), the drug weight will be recorded as trace.

**3.2.2.2** Personnel opening and accounting for the contents will compare the count/weight against what was stated in the request for examination or on the contributor label. If there is an unexplainable discrepancy between what was received and what was listed on the request for examination or contributor label, he/she will contact the contributor for further instructions and if necessary, notify the appropriate Evidence Management Unit personnel. Personnel will record the discrepancy and any contributor instructions on the appropriate communication log (e.g., Case Communication Log, *Activity and Communication Log* (7-245)).

### **3.3 Recording on the FBI Laboratory Drug Evidence Label or Valuable Evidence Label**

**3.3.1** The person opening and accounting for the contents and the person witnessing will record the activity on an *FBI Laboratory Drug Evidence* (7-248) (Appendix C) or an *FBI Laboratory Valuable Evidence* (7-287) (Appendix D) label, as appropriate. The label will be placed on the packaging ensuring that it does not obstruct the contributor's labeling in any way. The reverse side of the packaging may be used when necessary.

**3.3.2** For evidence submitted as suspected drugs, personnel sealing the contents will record the gross weight on the *FBI Laboratory Drug Evidence* label after sealing the packaging. The weight of non-trace drugs will be recorded in grams. For evidence where only drug residue is suspected of being present (e.g., drug wrappings, pipes, scales), the drug weight will be recorded as trace.

**3.3.3** For valuable evidence the amount may be recorded on the label (e.g., money count, weight of gemstone).

### **3.4 Storing Drug and Valuable Evidence**

Personnel storing drug or valuable evidence will ensure that the evidence is stored in a section safe, unit safe, or a secured area restricted to storing only drug and valuable evidence. Drug and



valuable evidence storage locations will be secured for dual-person entry.

### **3.5 Transferring Drug and Valuable Evidence**

Drug and valuable evidence will be separated from other types of evidence when transferred to ensure appropriate handling and storage.

#### **3.5.1 Recording Drug and Valuable Transfers**

All transfers, whether person to person or to and from storage, will be recorded by two people (e.g., in Forensic Advantage (FA), in the Explosives Reference Tool, on a *Chain-of-Custody Log* (7-243)). For transfers to and from storage, the second person will record their information in the witness field in FA.

**3.5.1.1** If FA cannot be used to record the transfer, all personnel that access the drug or valuable storage location will record their entry on an *Access Log - Evidence Storage Facility* (FD-455) specific to each drug or valuable evidence storage location.

#### **3.5.2 Transfer to Storage for Self-retrieval**

When storing drug and valuable evidence for self-retrieval, the evidence must be sealed with a proper seal to prevent loss, cross-transfer, or contamination. The evidence does not need to be affixed with a completed *FBI Laboratory Drug Evidence* or *FBI Laboratory Valuable Evidence* label each time it is stored.

#### **3.5.3 Special Circumstances for Sealing for Transfer**

For stamps, checks, or drug evidence where the weight has been recorded as trace, the item(s) may be transferred within the unit or for photographic purposes with a proper seal. The evidence does not need to be affixed with a completed *FBI Laboratory Drug Evidence* or *FBI Laboratory Valuable Evidence* label..

#### **3.5.4 Sealing Drug or Valuable Evidence for Transfer Outside the Unit**

All drug and valuable evidence will be sealed each time the item(s) is transferred outside the unit (except for photographic purposes). Additionally, when valuable evidence (except for stamps and checks) and non-trace weight drug evidence is transferred within the unit or for photographic purposes, the evidence will be sealed each time the item(s) is transferred, whether the transfer is person to person or to and from storage. The sealing will be completed in the presence of a witness. When the evidence is sealed, both persons will ensure the contents are as described (e.g., money count, weight).

**3.5.4.1** Personnel sealing evidence for transfer will package the evidence, when possible, in the original packaging. If the original packaging cannot be reused, the evidence will be packaged in a new package, with the original packaging and any pieces removed from it. When packaging the evidence, personnel will ensure that the contributor label from the original

packaging is visible.

**3.5.4.2** If the evidence is of such size as to preclude the use of heat-sealable packaging, the item(s) will be boxed or wrapped in brown paper and secured with fiber-reinforced packing tape, ensuring that the tape encircles the package and that the ends meet or overlap.

**3.5.4.3** The person sealing the contents and the person witnessing will record the activity on the *FBI Laboratory Drug Evidence* or *FBI Laboratory Valuable Evidence* label. When heat-sealed packaging is used, the heat-seal will be initialed by the person creating the seal. When the item is boxed, the *FBI Laboratory Drug Evidence* or *FBI Laboratory Valuable Evidence* label will be affixed to the packaging to ensure that it covers all ends of the packing tape.

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## 4 Records

The following records will be generated and/or retained in as a result of these practices:

- Communication Log.
- Chain-of-Custody Log.
- Record of the condition in which the evidence was received (e.g., check-in notes).
- *FBI Laboratory Drug Evidence* or *FBI Laboratory Valuable Evidence* label.
- *Access Log – Evidence Storage Facility* (for non-FA transfers).

## 5 References

FBI Field Evidence Management Policy Guide, 0780PG. Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
7	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Merged the FA drug and valuable evidence requirements from the Practices for Transferring, Storing, and Returning Evidence in Forensic Advantage into this document. Substantive changes include: removal of the Responsibilities section, updated the handling of packages received which are not sealed appropriately, added requirement for the witness to transfers to be recorded in FA and for the Access Log to only be used if FA cannot be used, separated requirements for handling drug and valuable evidence into two sections, and the addition of requirements for shipping drug and valuable evidence.
8	06/03/19	Summarized handling requirements in Appendices A and B. Replaced combined FBI Laboratory Drug and Valuable Evidence label with separate FBI Laboratory Drug Evidence and FBI Laboratory Valuable Evidence labels in Appendices C and D and throughout document. Reorganized document to improve clarity. In section 3.2.2.1, clarified that evidence is opened in the presence of a witness and that weight is recorded prior to opening or adding labels. Changed evidence management personnel to Evidence Management Unit in section 3.2.2.2. In section 3.5.1, added that person to person transfers of drug and valuable evidence do not require an additional witness. Allowed stamps or checks to be handled in a manner similar to trace weight drug evidence. Modified section 4 as some records are not retained in the FBI Laboratory file. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

**Appendix A: *Summary for Handling Stamps, Checks or Trace Weight Drug Evidence***

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**Appendix B: *Summary for Handling Non-Trace Weight Drug Evidence or Valuable Evidence***  
***(except stamps and checks)***

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**Appendix C: *FBI Laboratory Drug Evidence Label (7-248)***

Redacted - Form on File

**Appendix D: *FBI Laboratory Valuable Evidence Label (7-287)***

Redacted - Form on File

## **FBI Laboratory Practices for Transferring and Storing Evidence**

### **1 Purpose**

These practices describe the requirements for transferring and storing evidence in the FBI Laboratory to conform with the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who transfer and store evidence. Additional requirements for handling drug and valuable evidence are in the Laboratory Operations Manual (LOM) - Practices for Handling Drug and Valuable Evidence. For Laboratory Director and Quality Manager approved initiatives, a level 2 document will contain procedures for transferring and storing evidence when necessary.

### **3 Practices**

FBI Laboratory personnel will record each custody transfer from the point at which a container is identified as housing evidence (or an electronic submission is received) to the time evidence is returned to the contributor, destroyed according to existing regulations, or is retained. The transfer will be recorded at the time the transfer is made. Personnel will ensure he/she has custody of the evidence prior to opening an item or beginning examinations.

All transfers recorded on a Chain-of-Custody will include the person/location receiving or transferring the evidence, the description or unique identifier of the evidence, and the date of receipt or transfer on a *Chain-of-Custody Log* (7-243, 7-243a) (Appendix A) or the time and date of receipt or transfer on an electronic Chain-of-Custody Log.

Submissions received by the FBI Laboratory will be initiated and have records contained in Forensic Advantage (FA), unless the case must be handled outside of FA (i.e., Office of Professional Responsibility, prohibited cases). Non-Terrorist Explosive Device Analytical Center (TEDAC) legacy cases refer to any submission initiated prior to January 7, 2014. TEDAC legacy cases refer to any submission initiated prior to October 1, 2015. The generation of additional records for legacy cases may be continued in non-FA formats (e.g., *Activity and Communication Log* (7-245), *Chain-of-Custody Log*, Explosives Reference Tool (EXPeRT)). If a subsequent submission to a legacy case is received, a new FA Laboratory number will be generated and records will be maintained in FA.



### **3.1 Evidence Transfers**

**3.1.1** Custody transfers will be recorded by container until such time as the evidence is broken down. Once the evidence break down has been completed, custody transfers will be recorded by item identifier. Evidence transfers will be recorded on the appropriate Chain-of-Custody Log. All Chain-of-Custody records will be retained as part of the FBI Laboratory file.

**3.1.2** When personnel who have custody of an item(s) of evidence are unavailable or no longer with the FBI Laboratory, the appropriate Unit Chief will ensure the evidence is reassigned. The reassignment of the evidence will be recorded on the appropriate Chain-of-Custody Log.

#### **3.1.3 Evidence Received Electronically and Request Only Submissions**

When evidence received electronically (e.g., email attachments, evidence serialized in Sentinel by FBI contributors) or a request only submission is retrieved by Laboratory personnel, personnel will record the retrieval of the evidence on the Chain-of-Custody Log. A copy of the evidence received electronically will be retained (e.g., printed copy in 1A(s)/1C(s), on CD/DVD in 1A(s)/1C(s), uploaded to Sentinel). If the evidence was retrieved from Sentinel, a separate copy does not need to be retained. No further entries on the Chain-of-Custody Log are required and the evidence will be placed into an archived status if in FA prior to the completion of the submission.

#### **3.1.4 Chain-of-Custody Log for Legacy Cases**

The *Chain-of-Custody Log* and the *Continuation Page* will be used to record transfers for legacy cases. The *Chain-of-Custody Log* may be generated if a person of the FBI Laboratory takes custody of evidence while in the field performing examinations or providing case assistance.

**3.1.4.1** Any modification to the *Chain-of-Custody Log* will be initialed and dated, and a comment will be entered in the Remarks block indicating why the change occurred.

##### **3.1.4.2 Continuation Page**

The *Continuation Page* will be initiated when the transfer blocks on the *Chain-of-Custody Log* are filled. In such a case, the "Request Coordinator's Log" block will be checked and the unit managing the case will be entered as the unit name to indicate use of the *Continuation Page* as a continuation page to the *Chain-of-Custody Log*. The *Continuation Page* will be generated to track transfers within a unit. The "Intraunit" block will be checked and the unit name or acronym entered to indicate that the log will be used as a stand-alone log. The original *Continuation Page* will be retained by the assigned examiner as part of the FBI Laboratory file.

**3.1.4.3** When secondary evidence (e.g., pill boxes, slides, processed DNA) is added to the listing of what is being transferred, it will be added to the Item(s) block. A secondary evidence log is required for this transfer. The *Chain-of-Custody Log* or *Continuation Page* will reference the appropriate secondary evidence log in the Remarks block.

**3.1.4.4** When only the evidence packaging is being transferred because the evidence has been repackaged or has been consumed, assigned a new item identifier, transferred to secondary evidence during the examination process, the original item identifier will be listed in the Item(s) block. The Remarks block will reference that only the packaging for that item is being returned and any other appropriate information. The packaging will be labeled as “Packaging Only”.

Item(s)*	Delivered By	Accepted By	Date	Remarks
Q1	Signature	Signature		Optional entry
	Unit	Unit		
Q1, Q1.1, Q1.2	Signature	Signature		Q1.1, Q1.2 added
	Unit	Unit		
Q1, Q1.1, Q1.2 Secondary Evidence	Signature	Signature		See secondary evidence log
	Unit	Unit		
Q1, Q1.1, Q1.2	Signature	Signature		Q1 Packaging only
	Unit	Unit		

**Figure 1:** Example of how the *Chain-of-Custody Log* and/or the *Continuation Page* should be completed once the evidence has been broken down and how sub-divided items, secondary evidence, and packaging only should be documented.

### 3.1.5 Chain-of-Custody Log for TEDAC Legacy Cases

The Chain-of-Custody function in EXPeRT will be utilized to record transfers of evidence for TEDAC legacy cases. EXPeRT generated barcodes will be used to record the transfer of evidence. Personnel may record intraunit transfers using EXPeRT or on a *Continuation Page*. If the unit utilizes the *Continuation Page*, the “Intraunit” block will be checked and the unit name or acronym entered to indicate that the log will be used as a stand-alone record. The original *Continuation Page* will be retained as part of the FBI Laboratory file.

**3.1.5.1** Secondary evidence may be retained by the unit generating the evidence for future examinations and/or disposition at a later date if not required to be returned to the contributor. If secondary evidence is transferred for permanent storage in the repository, a secondary evidence log will be generated by the unit for inclusion in the FBI Laboratory file. A comment will be added to EXPeRT recording the receipt of the secondary evidence and its location.

### 3.1.6 FA Chain-of-Custody Log

Evidence received or generated in the FBI Laboratory will have transfers recorded on the FA Chain-of-Custody Log.

**3.1.6.1** Virtual transfers refer to transfers that are recorded on an electronic Chain-of-Custody Log without a corresponding physical change in custody. Virtual transfers may be used when switching between different chains of custody, such as between FA and Sample Tracking and Control System (STACS). Virtual transfers may be used for administrative purposes, such as

transferring items into personal custody to update breakdown records (e.g., check-in notes) and ensuring appropriate nesting after evidence breakdown. Virtual transfers may also be used to immediately fix an incorrect record, such as inadvertently selecting the incorrect storage location where physical evidence will reside. When a virtual transfer is recorded, a comment will be added noting that the transfer is virtual and provide a reason for the virtual transfer.

**3.1.6.2** If a modification is needed to the FA Chain-of-Custody Log, a ticket will be submitted to the eLAB Help Desk. The Help Desk will note the correction in the Override Comments field for the adjusted transfer. After the ticket has been resolved, the person requesting the modification will add the ticket to the FA Case Object Repository for the affected Laboratory number. If the FA Chain-of-Custody Log cannot be modified, the person will note the correction in the evidence transfer comments during the next transfer of the evidence.

**3.1.6.3** Secondary evidence (e.g., pill boxes, slides, processed DNA) will be added as a separate item in FA. The secondary evidence item description will include the discipline or category of testing and the number and type of secondary evidence. Secondary evidence that is separated from other secondary evidence for transfer will be uniquely identified.

**3.1.6.4** When only the evidence packaging is being transferred because the evidence has been repackaged or has been consumed or re-itemized as secondary evidence during the examination process, the packaging will be labeled as “Packaging Only”. The item will continue to be transferred in FA and the Evidence Comments will be updated with a “Packaging Only” notation followed by the initials of the person making the update.

### **3.1.7 Evidence Transfers Within the Same Facility**

When FBI Laboratory personnel transfer the custody of evidence to other FBI Laboratory personnel, within the same facility, personnel will place the evidence in a container, when practicable, prior to the custody transfer taking place. The evidence need not be properly sealed but will be closed, when practicable, in a manner to prevent loss, cross-transfer, or contamination of the evidence contained inside. Evidence placed in an ESR will be properly sealed each time it is stored, unless it is within an individual locker.

### **3.1.8 Evidence Transfers Outside a Facility**

FBI Laboratory personnel transferring the custody of evidence outside the facility will properly seal the container prior to the custody transfer taking place.

### **3.1.9 Transfers To and From Evidence Storage**

When a person stores evidence in an ESR and it is the intent to have another person remove the evidence, the transfer will be recorded at the time the transfer is made. When a person retrieves evidence from evidence storage, the transfer will be recorded at the time the transfer is made.

## **3.2 Physical Evidence Storage**

Personnel who have custody of the evidence will ensure that integrity of each item of evidence is maintained by protecting it from loss, cross-transfer, contamination, or deleterious change. When evidence must be stored under specified environmental conditions, these conditions will be maintained, monitored and recorded. Packages containing biohazard evidence will be stored appropriately (e.g., refrigerator, freezer), as soon as practicable. When the examination does not begin immediately, the evidence will be placed under proper seal and stored appropriately until the examination begins.

### **3.2.1 Applying a Proper Seal**

A proper seal prevents loss, cross-transfer, or contamination while ensuring that attempted entry into the container/package is detectable. A proper seal may include a heat-seal, tape-seal, or a lock, with the initials of the person creating the seal being placed on the seal or across the seal onto the container/package, when possible.

**3.2.1.1** Evidence under examination may be stored in an individually assigned evidence locker without a proper seal if the access to the locker is controlled and limited to the examiner and his/her technician, excluding emergency access controlled by the Unit Chief or designee.

**3.2.1.2** Evidence placed in an ESR will be properly sealed each time it is stored, unless it is within an individual locker. A bulky or large item of evidence that does not lend itself to sealing and does not fit in a storage locker in an ESR will be stored by placing an “Evidence Do Not Disturb” sign (or similar) on top or in front of the evidence.

**3.2.1.3** If more than one piece of tape is used to create a proper seal, each piece used will be initialed. For heat seals, personnel creating the seal will initial over the heat-seal.

**3.2.1.4** If the package houses paper evidence and the package is not rigid, the examiner’s or technician’s initials will be placed on the tape prior to the tape being placed on the package. This will protect the evidence from extraneous indentations.

### **3.2.2 During an Active Examination**

An examiner and/or technician who is in the process of conducting an examination and has to leave the evidence unattended will only do so in a secured, limited access area and will clearly identify items of evidence to distinguish them from non-evidentiary items, training materials, or supplies. This may be accomplished by placing an “Evidence Do Not Disturb” sign (or similar) on top or in front of the evidence.

### **3.2.3 Not Under Active Examination**

**3.2.3.1** Evidence that is not being examined will be stored in a secured, limited access area. Personnel storing evidence will properly seal evidence in a container/package and ensure the container/package is labeled with at least the FBI Laboratory number prior to storage.

**3.2.3.2** Drug and valuable evidence will be stored according to the LOM - Practices for Handling Drug and Valuable Evidence.

## **4 Records**

The following records will be generated and retained in the FBI Laboratory file, except as noted below, as a result of these practices:

- Appropriate Chain-of-Custody Log., with the exception of the EXPeRT Chain-of-Custody Log which will be retained in EXPeRT.
- Secondary evidence log, if generated.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Date	History
9	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Merged information about transferring and storing evidence from the Practices for Transferring, Storing, and Returning Evidence in FA into this document. Substantive changes include: removed the Responsibilities section, generalization of RC and EA to evidence management personnel throughout, and the addition and explanation of virtual transfers.
10	06/03/19	In section 3, added description of the minimum information recorded on a Chain-of-Custody. Broadened requirement regarding EXPeRT Chain-of-Custody in section 3.1.5. Modified section 3.2.3.1 to revise wording since containers are typically already labeled. Updated list of references in section 5.

**Approval**

Redacted - Signature on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

**Appendix A: *FBI Laboratory Chain-of-Custody Log (7-243)***

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**Appendix A: *FBI Laboratory Chain-of-Custody Log Continuation Page (7-243a)***

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## **FBI Laboratory Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases**

### **1 Purpose**

These practices specify the requirements for performing verifications; preparing, reviewing, and issuing a *Laboratory Report* (7-1, 7-273); and retaining case-related records for legacy cases to conform to the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who prepare or issue *Laboratory Reports* and/or generate case-related records for legacy cases. These practices also apply to FBI Laboratory personnel who perform verifications of identifications and associations, conduct technical reviews, and conduct administrative reviews for legacy cases. Appropriate level 2 documents will contain procedures for performing verifications; conducting technical and administrative reviews; preparing and issuing *Laboratory Reports*; and/or generating case-related records. When necessary, a level 2 document will also contain procedures for initiatives and/or the use of alternate reporting approved by the Laboratory Director and Quality Manager. Additionally, these practices apply to FBI Laboratory personnel generating a *Laboratory Report* for Office of Personnel Responsibility (OPR) or prohibited cases or for legacy Terrorist Explosive Device Analytical Center (TEDAC) cases.

### **3 Practices**

Every Laboratory number assigned to a request for examination must have a *Laboratory Report* (Appendix A, Appendix B) issued addressing each request associated with that number. Any information required by ISO/IEC 17025 or ANAB AR 3125 not covered in a *Laboratory Report* or alternate reported results will be maintained in the FBI Laboratory. [QAM - Sections 7.8.1.3 and 7.8.1.3.1]

#### **3.1 Formatting a *Laboratory Report***

Each *Laboratory Report* will contain administrative information about the request for examination; a listing and description of evidence; a Results of Examinations section when forensic examinations have been conducted; a Remarks section; and a name block; and will be digitally signed in Sentinel by the person issuing the *Laboratory Report*.

The report is usually generated by initiating the “REX” macro in Microsoft Word® with the appropriate *Laboratory Work Sheet* (7-2) or *TEDAC Work Sheet* open. The text entered for each

*Laboratory Report* will be Times New Roman font. Typically, the font size used in the body of the *Laboratory Report* is 12-point; however, different font sizes may be used in charts. The bold, italic, or underline functions may be used, and charts and/or images, may be included as necessary.

### **3.1.1 Administrative Information**

**3.1.1.1** All fields in the Administrative section, excluding the “Your No.” field must be completed. An external contributor number is entered in the “Your No.” field only if it is supplied to the FBI Laboratory.

#### **3.1.1.2**

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**3.1.1.3** A *Laboratory Report* being prepared for an external contributor will be addressed according to the information supplied in the request for examination.

**3.1.1.4** If an examiner has any concerns regarding the administrative information he/she will contact Evidence Management Unit (EMU) personnel to verify that information is accurate.

### **3.1.2 Listing and Description of Evidence**

The Listing and Description of Evidence section contains a listing and description of the item(s) which were submitted to, or examined in, a particular unit, discipline, and/or category of testing.

**3.1.2.1** Each *Laboratory Report* will include a listing and description of the items received by EMU personnel; or received or examined by the examiner, along with any subdivided items identified during his/her examination. If there are items in the FBI Laboratory that are not addressed in the *Laboratory Report*, the *Laboratory Report* will have a statement that items not included in the listing and description of evidence were not examined as part of this report. Alternatively, the results of examination section may provide this information.

**3.1.2.2** Items will be grouped according to the item identifier and listed sequentially within each group (i.e., Questioned, Known, Non-Evidentiary). Questioned items are listed and described first, known items are listed and described next, non-evidentiary items are listed and described next, and resubmitted items last. Headings, for example, distinguishing items from the victim and the subject, may be used.

**3.1.2.3** The person generating the *Laboratory Report* will include a statement identifying the discipline/category of testing/evidence management being reported. This statement will follow the listing and description of evidence.

**3.1.2.4** If an examiner has any concerns regarding the description of evidence, he/she will contact EMU personnel to verify that information is accurate.

### 3.1.3 Results of Examinations

The Results of Examinations section contains methods, results, opinions, limitations, interpretations, and/or conclusions of forensic examinations conducted by a particular examiner. This information may be under a separate heading(s) as specified in level 2 documents. Additionally, the requirements in QAM - Section 7.8 will be followed.

**3.1.3.1** The wording used to convey the results of examinations is left to the discretion of the examiner, in accordance with the applicable Department of Justice Uniform Language and Reports (ULTR) document(s), the applicable FBI Approved Standards for Scientific Testimony and Report Language (ASSTR) and any applicable level 2 documents regarding reporting, and is acceptable to the technical reviewer.

**3.1.3.1.1** The significance of an association will be included in the *Laboratory Report* in a statistic or a qualitative statement.

**3.1.3.1.2** When comparative examinations result in the elimination of a person or object, the *Laboratory Report* will clearly communicate the elimination.

**3.1.3.1.3** When an inconclusive result is reported, the reason(s) will be clearly stated in the *Laboratory Report*.

**3.1.3.1.4** A *Laboratory Report* will include additional information, when it is necessary for the interpretation of the examination results, such as:

- information regarding specific examination conditions;
- a statement of conformity with requirements or specifications, as described in QAM - Section 7.8.6;
- additional information that may be required by specific methods, authorities, or contributors.

**3.1.3.1.5** Measurement uncertainty will be included in the *Laboratory Report*, or as an enclosure, when it is relevant to the validity or application of the examination results; a contributor's instructions require it; it affects conformity to a specification limit; or when the measurement impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement.

**3.1.3.1.6** The measurement uncertainty will:

- include the measured quantity value,  $y$ , along with the associated expanded uncertainty,  $U$ , and the coverage of probability;
- be in the format of  $y \pm U$ ;
- be limited to at most two significant digits, unless there is a recorded rationale for reporting additional significant digits;
- be reported to the same level of significance as the measurement result.
- where applicable, be presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent).

**3.1.3.2** If evidence is received and the request for examination is to compare the submitted evidence with other items from a closed request(s), the previous FBI Laboratory number(s) will be referenced in the Results of Examinations section. If the items were submitted from different Case ID numbers, both the previous FBI Laboratory number(s) and the Case ID number(s) will be referenced in the Results of Examinations section. This does not constitute a combined report.

### **3.1.4 Individual Characteristic Database (ICD) Searches**

**3.1.4.1** If a forensic sample (e.g., latent print, test fire, DNA profile) is searched as a one-time event, then a *Laboratory Report* must be generated clearly stating the results of the ICD search. A one-time event means that the sample will not be retained in the database and automatically searched against the database on some routine basis.

**3.1.4.2** If a forensic sample is, or will be, entered into a database(s) and is repeatedly searched with negative results, a *Laboratory Report* is not required for each search. However, the first time the sample is entered into the database, written notification (e.g., email, letter of notification, *Laboratory Report*) must be generated which clearly informs the contributor that the sample was, or will be, entered into the database. Any time a positive association is made, written notification (e.g., email, letter of notification, *Laboratory Report*), must be generated. A record of the notification will be maintained.

### **3.1.5 Remarks**

The Remarks section will contain, at a minimum, the disposition of the evidence contained in the *Laboratory Report*, contact information for the examiner, contact information for submission status inquiries, the facility(ies) and/or site(s) where work was conducted, as well as a statement regarding the location of the supporting records. This section may also contain information pertinent to the request, evidence not inventoried, examination cancellations, examinations not conducted, and special evidence handling and storage instructions. Any additional information for this section will be specified in appropriate level 2 documents.

#### **3.1.5.1 Disposition of Evidence**

Each *Laboratory Report* will contain a statement that will address the disposition of the items of evidence and secondary evidence, as applicable. The disposition statement may state that the items:

- Are enclosed with the *Laboratory Report*.
- Will be returned to the contributor under separate cover from the *Laboratory Report*.
- Will be retained.
- Have been consumed during the examination process.

### **3.1.5.2 Contact Information**

**3.1.5.2.1** Each *Laboratory Report* will contain a statement providing contact information, including the title, name, and telephone number of the person issuing the *Laboratory Report*, should the contributor have questions about the content of the report.

**3.1.5.2.2** Each *Laboratory Report* will include a telephone number and/or email address of the person and/or unit to contact regarding the status of the submission.

### **3.1.5.3 Facility Statement**

Each *Laboratory Report* will contain a statement which identifies the facility(ies) and/or site(s) where any work (e.g., examination, processing, verification) was performed. The location where each task was performed does not need to be specified.

### **3.1.5.4 Opinions/Interpretations and Supporting Records Statement**

Each *Laboratory Report* that contains conclusions will contain a statement referencing the applicable Department of Justice Uniform Language and Reports document(s). Additionally, a *Laboratory Report* that contains opinions and interpretations will have a statement indicating that the report contains the opinions and interpretations of the issuing examiner(s) and is supported by records retained in the FBI Laboratory file. The *Laboratory Report* will also contain language advising contributors of the time required for discovery requests to be processed.

### **3.1.5.5 Information Pertinent to the Request**

This information may include investigative assistance information or sample collection instructions.

### **3.1.5.6 Evidence Not Inventoried**

If the evidence is being returned prior to the container(s) being opened and/or the content inventoried, the EMU person managing the case will issue a *Laboratory Report* explaining that no examinations were conducted and the evidence was not inventoried.

### **3.1.5.7 Examination Cancellations**

If instructions are received from the contributor to cancel a request for examination, all cancellation instructions and the name of the person who canceled the request for examination will be recorded on the *Activity and Communication Log* (7-245). If the cancellation instruction is provided via email, the email(s) will be retained in the 1A(s)/1C(s).

#### **3.1.5.7.1 Cancellation Prior to Any Examinations**

If instructions are received from the contributor to cancel a request for examination and no examinations have been initiated by the FBI Laboratory at the time the request was received, the

EMU person managing the case will issue a *Laboratory Report* that includes a listing and description of the evidence. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when.

#### **3.1.5.7.2 Cancellation After Examination Initiation**

If an examiner is instructed to discontinue examinations after they have been initiated, the affected examiner will determine the appropriate stopping point in the examination process. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when. All results of any completed examinations will be included in the Results of Examinations section in a *Laboratory Report*.

Additionally, if there are any remaining examinations that have not been initiated, the person who received the instruction to discontinue examinations will contact the EMU person managing the case. The EMU person managing the case will issue a *Laboratory Report* that includes a listing and description of the evidence. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when.

#### **3.1.5.8 Examinations Not Conducted**

**3.1.5.8.1** When a request for a type of examination that is not conducted in the FBI Laboratory is received, EMU person managing the case will issue a *Laboratory Report* and include a detailed explanation in the Remarks section that describes why the requested examination was not conducted.

**3.1.5.8.2** When a request for a type of examination that is conducted in the FBI Laboratory is received, but will not be conducted, the appropriate examiner will issue a *Laboratory Report* and include a detailed explanation that describes why the requested examination was not conducted. If there are results included in the *Laboratory Report* for another type of examination, then the detailed explanation may be under separate heading(s) as specified in a level 2 document.

**3.1.5.8.3** When evidence is received damaged and the integrity of the evidence has been compromised to the extent that no examinations will be conducted, the appropriate examiner will issue a *Laboratory Report* and include a detailed explanation that describes why the requested examination(s) was not conducted.

#### **3.1.5.9 Special Evidence Handling/Storage Instructions**

Instructions to the contributor may be included in the *Laboratory Report* addressing evidence handling and storage (e.g., to freeze, refrigerate the returned evidence).

#### **3.1.6 Name Block**

The name and unit of the examiner(s) responsible for the content of the *Laboratory Report* will immediately follow the Remarks section.

### **3.1.7 Enclosures**

Enclosures may be attached to the *Laboratory Report* and serialized in Sentinel or physically mailed to the contributor. If the *Laboratory Report* is being serialized in Sentinel and the enclosure is being mailed, at a minimum, the first page of the report must be printed and attached to the enclosure. For external contributors, the *Laboratory Report* and enclosures will be mailed together.

All enclosures must be accounted for on the first page of the *Laboratory Report*. The enclosure count will be placed on the bottom left margin of the first page of the *Laboratory Report*, above the page number.

### **3.1.8 Major Case and Other Cases with Multiple Examiner *Laboratory Reports***

**3.1.8.1** Multiple examiners from a caseworking unit may prepare one *Laboratory Report* for a major case or other cases as deemed appropriate by a Unit Chief.

**3.1.8.2** When a *Laboratory Report* contains the results of multiple examiners, the report will identify each examiner's results (e.g., each examiner's initials or name in parentheses at the end of each paragraph or section, or where appropriate in tables and charts). The initials or name do not need to be electronically secure on the *Laboratory Report*. Each examiner will have his/her own name block in the *Laboratory Report*. Additionally, each contributing examiner will be a co-author or approver in Sentinel, acknowledging agreement with his/her results as reported.

**3.1.8.3** When an Explosives and Hazardous Devices *Laboratory Report* is being issued and results from another examiner(s) must be included, the Explosives and Hazardous Devices examiner will identify each examiner's results (e.g., each examiner's initials or name in parentheses at the end of each paragraph or section, or where appropriate in tables and charts). The initials or name do not need to be electronically secure on the *Laboratory Report*. The Explosives and Hazardous Devices examiner will also include a statement that includes the FBI Laboratory number for the other examiner's report, the examiner's name, and the date of his/her report. Each contributing examiner will be a co-author or approver in Sentinel, acknowledging agreement with his/her results as reported.

### **3.1.9 Combined *Laboratory Reports***

An examiner may prepare a *Laboratory Report* combining the information from various open requests submitted to the FBI Laboratory under the same Case ID number.

#### **3.1.9.1 Same Contributor and Same Case ID Number**

The examiner preparing a combined *Laboratory Report* for evidence submitted by the same contributor under the same Case ID number will ensure that each listing of items received under one request is preceded by an administrative sentence that identifies the date of the request, the FBI Laboratory number, and the unit that received/examined the evidence. At a minimum, the FBI Laboratory numbers that are relevant to the results of examinations will be listed.



### **3.1.9.2 Different Contributors and Same Case ID Number**

The examiner preparing a combined *Laboratory Report* for evidence submitted by different contributors under the same Case ID number will ensure that the Case ID numbers are the same. If they are not, the *Laboratory Report* will be handled as described below. Each listing of items received under one request will be preceded by an administrative sentence that identifies the contributor, the date of the request, the FBI Laboratory number, and the unit that received/examined the evidence. The *Laboratory Report* will be addressed to the FBI office of origin, even if it was not the office contributing the evidence.

### **3.1.10 Comparison of Evidence Submitted Under Different Case ID Numbers**

An examiner must prepare separate *Laboratory Reports* when addressing a request to compare items submitted under different Case ID numbers. A file copy of each *Laboratory Report* will be generated for every Case ID number referenced in the contents of the *Laboratory Reports*.

### **3.1.11 Examination of Evidence Received Under Both Legacy and Forensic Advantage Submissions**

The examiner preparing a *Laboratory Report* for evidence received under both legacy and Forensic Advantage submissions will refer to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

### **3.1.12 Supplemental *Laboratory Report***

A supplemental *Laboratory Report* will be prepared to provide additional information pertaining to a completed request for examination. A legacy supplemental *Laboratory Report* will only be issued if needed for an OPR or prohibited case or for TEDAC legacy cases. All other supplemental *Laboratory Reports* will be generated according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**3.1.12.1** The examiner who prepares a supplemental *Laboratory Report* to provide additional information pertaining to a request for examination will reference the date of the previous *Report(s) of Examination/Laboratory Report(s)* in an introductory sentence. The introductory sentence will precede the Results of Examinations section.

**3.1.12.2** The examiner who prepares a supplemental *Laboratory Report* will ensure that a listing and description of items in the previous *Report(s) of Examination/Laboratory Report(s)* that are affected by the supplemental *Laboratory Report* are included.

**3.1.12.3** The supplemental *Laboratory Report* will clearly state what additional information is being provided. The supplemental report will be administratively and, when applicable, technically reviewed.

### **3.1.13 Amended *Laboratory Report***

An amended *Laboratory Report* will be prepared if a change must be made to the content of a previous *Report of Examination(s)/Laboratory Report(s)*.

**3.1.13.1** The examiner who prepares an amended *Laboratory Report* will reference the date of the initial *Report of Examination/Laboratory Report* in an introductory sentence. The introductory sentence will precede the Results of Examinations section.

**3.1.13.2** The examiner who prepares an amended *Laboratory Report* will ensure that a listing and description of items in the initial *Laboratory Report* that are affected by the amended *Laboratory Report* are included.

**3.1.13.3** The examiner who prepares an amended *Laboratory Report* will ensure that the amended *Laboratory Report* clearly describes the information from the *Report of Examination/Laboratory Report* being amended and how that information is being changed.

**3.1.13.4** The amended *Laboratory Report* will be administratively reviewed and, when applicable, technically reviewed.

### **3.1.14 Superseding *Laboratory Report***

**3.1.14.1** When a previously issued report requires a change or addition and an amended or supplemental report could be confusing to the contributor, the examiner may issue a superseding *Laboratory Report*. A superseding *Laboratory Report* can only be prepared with the approval of the Unit Chief. If the superseding *Laboratory Report* is being issued because a *Laboratory Report* must be removed from Sentinel due to a spillage event, Unit Chief approval is not required. A legacy superseding *Laboratory Report* will only be issued if needed for OPR or prohibited cases or for TEDAC legacy cases. All other superseding *Laboratory Reports* will be generated according to the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**3.1.14.2** The *Laboratory Report* will clearly state the Laboratory number(s) affected, the date(s) of the previous *Report of Examination/Laboratory Report*, a complete listing of the item(s) of evidence received in the unit, and, if applicable, that re-examinations were conducted. The *Laboratory Report* does not need to specify the wording that is changing; however, it will state that all information in the previous *Report(s) of Examination/Laboratory Report(s)* is superseded by the current *Laboratory Report*.

**3.1.14.3** The superseded *Laboratory Report* will be administratively and when applicable, technically reviewed.

### **3.1.15 *Laboratory Report* with Results Obtained from Outside Experts**

When a *Laboratory Report* contains results of tests performed by an expert outside the FBI Laboratory, those results will be clearly identified. If the examination results are not included in

the *Laboratory Report*, the Unit Chief will ensure that the contributor receives a copy of the outside expert's report.

### **3.1.16 *Laboratory Report for an Examiner Not Available to Testify***

A court official or contributor may request a new *Laboratory Report* for trial purposes because the examiner who issued the original *Report of Examination/Laboratory Report* is not available to testify (e.g., no longer works for the FBI, on extended leave). The court official and/or contributor will submit a request in writing according to the LOM - Practices for Processing a Submission and Evidence Breakdown. If the FBI Laboratory agrees to provide a new *Laboratory Report*, refer to LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

### **3.1.17 *Laboratory Report File Copy***

For every *Laboratory Report*, a file copy will be generated for inclusion in the FBI Laboratory file.

## **3.2 *Reviewing a Laboratory Report***

### **3.2.1 *General Requirements***

**3.2.1.1** Each identification or association rendered as a result of a comparison examination will be verified. This will occur prior to or concurrently with the technical review.

**3.2.1.2** When a *Laboratory Report* contains examination results, it will be technically reviewed prior to or concurrently with the administrative review.

**3.2.1.3** Each *Laboratory Report* will be administratively reviewed.

**3.2.1.4** FBI Laboratory personnel cannot verify, technically review, or administratively review their own work.

**3.2.1.5** The verification, technical review, and/or administrative review may be conducted by the same person and may be conducted concurrently.

### **3.2.2 *Expedited Results***

**3.2.2.1** Prior to a *Laboratory Report* being issued to the contributor and a complete technical review being conducted, an examiner may disseminate expedited results or partial results of an examination(s). The appropriate level 2 document may contain requirements that specify results that do not require verification by another examiner prior to dissemination (such as negative results or presumptive results). If a unit, discipline, or category of testing chooses not to define requirements for which results do not require verification prior to dissemination, all results must be verified according to these practices prior to dissemination. The verification(s) will be recorded in the FBI Laboratory file.

**3.2.2.2** When providing expedited results, the examiner will communicate the following dissemination information to the contributor. This communication will be recorded on the *Activity and Communication Log*.

- The examinations performed on pertinent items and the results.
- The results are subject to change.
- Final results will be provided in a *Laboratory Report* that will undergo review prior to issuance.

**3.2.2.3** If the examiner provides the contributor with the final results after a technical review has been conducted but prior to an administrative review, the examiner will record that communication on the *Activity and Communication Log*.

### **3.2.3 Verification of Identification or Association**

**3.2.3.1** A verification of identification or association will be conducted by a verifier who did not perform the initial examination.

**3.2.3.1.1** If there is a qualified and authorized person within the FBI Laboratory to verify an identification or association for the category of testing being reviewed, but that person is unavailable (e.g., deployment, on leave) to conduct the verification, an attempt will be made to obtain an expert outside the FBI Laboratory to serve as the verifier. If an expert outside the FBI Laboratory can perform the verification, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow the outside expert to verify the identification or association. If an expert outside the FBI Laboratory cannot perform the verification, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow a verification of the identification or association to not occur.

**3.2.3.1.2** If there is not another qualified and authorized person within the FBI Laboratory to verify an identification or association for the category of testing being reviewed, the appropriate Technical Leader will evaluate the qualifications of an expert outside the FBI Laboratory to serve as a verifier for a specified time. The affected unit(s) will maintain a list of approved external verifiers.

**3.2.3.2** A verification will be performed on the following as it applies to the particular examination.

- Best relevant evidence.
- Derivative information or evidence.
- Data.
- Charts.
- Images.
- Analogous information from which the first examiner based the conclusion.

**3.2.3.3** The appropriate level 2 document will contain a definition of an identification or association and the procedures used to perform the verification.

**3.2.3.4** Upon completion of the verification, the verifier will record his/her agreement with

the examiner's results in the FBI Laboratory file. Records include the date of the verification and either the verifier's signature or name and initials.

### 3.2.4 Technical Review

**3.2.4.1** A technical review will be conducted by a person who is authorized to conduct technical reviews in the category of testing being reviewed. The technical reviewer will have been competency tested in the task(s) that the review is encompassing. Additionally, the technical reviewer will have knowledge of the technical procedures used in that category of testing.

**3.2.4.1.1** If there is an authorized person within the FBI Laboratory for the category of testing being reviewed, but that person is unavailable (e.g., deployment, on leave) to conduct the technical review, an attempt will be made to obtain an expert outside the FBI Laboratory to serve as the technical reviewer. If an expert outside the FBI Laboratory can perform the technical review, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow the outside expert to conduct the technical review. If an expert outside the FBI Laboratory cannot conduct the technical review, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow a technical review to not occur.

**3.2.4.1.2** If there is not another authorized person within the FBI Laboratory for the category of testing being reviewed, the appropriate Technical Leader will evaluate the qualifications of an expert outside the FBI Laboratory to serve as a technical reviewer for a specified time. The affected unit(s) will maintain a list of approved external technical reviewers.

**3.2.4.2** Technical reviews will not be conducted by the examiner(s) who authored the examination records or the *Laboratory Report* under review.

**3.2.4.3** A technical review will be performed on all *Laboratory Reports* that contain examination results, and the supporting case records. This review will determine if:

- The examinations and supporting case records conform with appropriate technical procedures and applicable portions of the level 1 documents, appropriate level 2 documents, and technical procedures;
- The appropriate examinations have been performed;
- The examiner's conclusions are consistent with the data records, are within the limitations of the discipline/category of testing, and are supported by the applicable ULTR and/or ASSTR;
- The *Laboratory Report* is accurate and there are sufficient supporting records for the results and/or conclusions of the *Laboratory Report*;
- A verification of identification or association has been completed and properly recorded, when such a conclusion has been reached;
- Associations are put into the appropriate context in the *Laboratory Report*;
- The *Laboratory Report* contains all the required information.

**3.2.4.4** The appropriate level 2 document will contain procedures used to conduct a technical

review to include field examination review, when applicable.

**3.2.4.5** The technical reviewer will record his/her agreement with the examination process and the completion of the technical review in the FBI Laboratory file. Records include the date of the technical review and either the reviewer's signature or name and initials.

### **3.2.5 Administrative Review**

**3.2.5.1** An administrative review will not be conducted by the person(s) authoring the Laboratory Report being reviewed. A level 2 document may further define requirements for an administrative reviewer.

**3.2.5.2** An administrative review includes at a minimum:

- Spelling and grammatical accuracy of the *Laboratory Report*;
- Proper classification markings have been applied.
- The administrative and examination records conform to QAM - Section 7.5 and LOM - Practices for Assigning Cases and Conducting Examinations.
- The *Laboratory Report* conforms to these practices.
- A technical review has been completed, when applicable, and properly recorded.

**3.2.5.3** The administrative reviewer will record his/her completion of the administrative review. Records include the date of the technical review and either the reviewer's signature or name and initials. This will be the last entry on the last page of the file copy of the *Laboratory Report*. This record signifies approval for serializing the *Laboratory Report* to Sentinel.

**3.2.5.4** A level 2 document will contain procedures used to conduct an administrative review and a list of what is considered administrative records and examination records.

### **3.2.6 Resolution of Scientific or Technical Disagreement**

Personnel will follow LOM - Practices for Resolution of Scientific or Technical Disagreement to resolve any disagreement resulting from a verification, blind verification, technical review, and/or administrative review.

## **3.3 Issuing a *Laboratory Report***

A *Laboratory Report* is primarily issued to a contributor. In some instances, it may be issued to a person other than the contributor such as a prosecutor or a lead investigator. The *Laboratory Report* will be issued only after it has been reviewed and serialized in Sentinel.

A *Laboratory Report* will be issued to an FBI contributor in an electronic file serialized in Sentinel. For external submissions, a *Laboratory Report* will be emailed or physically mailed to the contributor. For TEDAC submissions, a *Laboratory Report* will be available in an electronic file in the Explosives Reference Tool (EXPeRT). A *Laboratory Report* in EXPeRT may be viewed by all partners, not just a single contributor.

**3.3.1** Multiple examiners may issue one *Laboratory Report* for a major case or other cases with multiple examiners according to these practices.

**3.3.2** A *Laboratory Report* that references more than one Case ID number will list the additional Case ID number(s) in the Additional Case field in Sentinel.

**3.3.3** In order to complete a Case Record for non-TEDAC evidence in FA, each examiner will ensure that his/her examination statistics are recorded on a *Laboratory Statistics Sheet* (7-2a) and furnished to the appropriate personnel.

**3.3.4** The *Laboratory Report* will be serialized in Sentinel. When someone other than the person issuing the *Laboratory Report* serves as the author of the *Laboratory Report* in Sentinel, the person issuing the *Laboratory Report* will serve as an approver in Sentinel.

**3.3.4.1** If the person(s) issuing the *Laboratory Report* is not available and the *Laboratory Report* must be issued immediately, a deviation will be requested as described below.

**3.3.4.1.1** If a single case requires immediate issuance of a *Laboratory Report* in the issuing person's absence (i.e., an examiner that is responsible for the examination(s)), a minor deviation will be requested according to the LOM - Practices for Authorizing Deviations to allow another person to issue the *Laboratory Report* on behalf of the issuing person (i.e., will have the issuing person's name). The minor deviation will state why the *Laboratory Report* needs to be issued immediately and why the issuing person is unavailable to be an approver in Sentinel (e.g., deployment, leave). The minor deviation will be authorized and recorded in the *Activity and Communication Log*. The issuing person will be listed for distribution in Sentinel and will acknowledge review of the issued report in the *Activity and Communication Log* upon his/her return.

**3.3.4.1.2** If multiple cases require immediate issuance of a *Laboratory Report* in the issuing person's absence (e.g., the examiner that is responsible for the examination(s)), a major deviation will be requested according to the LOM - Practices for Authorizing Deviations to allow another person(s) to issue the *Laboratory Reports* on behalf of the issuing person (i.e., will have the issuing person's name). The major deviation will state why the *Laboratory Reports* need to be issued immediately and why the issuing person is unavailable to be an approver in Sentinel (e.g., extended deployment, extended leave). A copy of the authorized major deviation will be included in the FBI Laboratory file and referenced in the *Activity and Communication Log*. The issuing person will be listed for distribution in Sentinel and will acknowledge review of the issued report in the *Activity and Communication Log* upon his/her return.

**3.3.5** The person issuing the *Laboratory Report* will ensure that the assigned serial number is placed after the Case ID number on the front page of the file copy.

### **3.3.6 Requests for a Previously Issued *Report of Examination/Laboratory Report***

**3.3.6.1** If an FBI contributor requests a previously issued *Report of Examination/Laboratory Report*, the FBI contributor will be directed to retrieve the *Report of Examination/Laboratory Report* from Sentinel.

**3.3.6.2** If an external contributor requests a previously issued *Report of Examination/Laboratory Report*, the *Report of Examination/Laboratory Report* will be retrieved from Sentinel and may be sent to an external contributor, the contributing agency, and/or the prosecutor for that specific case.

**3.3.6.3** For DNA cases involving a missing person, where a comparison is conducted with either a sample from another laboratory or a sample from a CODIS index, a copy of the *Report of Examination/Laboratory Report* may be issued to the laboratory who contributed the compared sample without authorization from the contributor.

### **3.4 Retaining Case-Related Records**

Requests for examinations, administrative records including the *Laboratory Work Sheet* and *TEDAC Work Sheet*, examination records, and *Laboratory Reports* are routinely received or generated by FBI Laboratory personnel. These records (either originals or copies) will be retained in the FBI Laboratory file.

#### **3.4.1 Request for Examination**

The person managing the case will ensure that the request for examination is retained in the FBI Laboratory file.

#### **3.4.2 Evidence Acknowledgment**

If an *Acknowledgement Letter* was generated for a case, it will be retained in the FBI Laboratory file.

#### **3.4.3 *Laboratory Report***

The person issuing the *Laboratory Report* will ensure it is serialized in Sentinel and that the file copy is placed in the FBI Laboratory file.

#### **3.4.4 Supporting Records**

Each person who issues a *Laboratory Report* will prepare a 1A(s)/1C(s) containing supporting records for serializing in Sentinel.

**3.4.4.1** Physical supporting records will be placed in a *Supporting Documentation Envelope(s)* (7-251) and serialized as a physical attachment 1A in Sentinel. Supporting records that are too bulky to fit in a physical 1A(s) may be placed in a bulky 1C(s). Physical supporting



records will be delivered to the file room. A summary of the enclosures in the 1A(s) and/or 1C(s) will be noted in Sentinel.

**3.4.4.2** Electronic supporting records will be serialized in Sentinel. If the file is larger than the largest allowed attachment size for Sentinel, personnel will save the files to electronic media and retain the media in the physical 1A(s) or 1C(s).

**3.4.4.3** Communication(s) will be recorded on the *Activity and Communication Log*. Substantive email communication(s) will be referenced on the *Activity and Communication Log* and the email(s) will be retained in the 1A(s). *Activity and Communication Logs* are not required for TEDAC legacy cases.

Redacted

### 3.4.8 Retention of an FBI Laboratory File

Long-term retention and disposition of files will be coordinated by the Information Management Division.

## 4 Records

The following records will be generated and/or retained in the FBI Laboratory file and/or in Sentinel when completed as a result of these practices:

- Request for examination
- *Acknowledgement Letter*
- *Activity and Communication Log*
- Record(s) of verification of an identification or association
- *Laboratory Report*
- *Laboratory Report* file copy
- 1A(s) and/or 1C(s), containing administrative and examination records
- Record(s) of a technical review

- Record(s) of an administrative review
- Additional request records, when necessary
- *Laboratory Statistics Sheet* for non-TEDAC evidence

Records supporting an OPR related matter or a prohibited case will be handled as requested by the contributor

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Forensic Advantage User Guide, Forensic Advantage® Systems, a division of The Computer Solution Company, Inc., latest revision.

FBI Corporate Policy Directive 0423D, Preservation and Disclosure of Electronic Communications in Federal Criminal Cases, Federal Bureau of Investigation, latest revision.

Rev. #	Issue Date	History
11	10/02/17	Document revised to include update requirements due to the addition of the satellite facility in Huntsville, AL and to address the intelligence driven mission of the TEDAC Section of the Laboratory. Merged content from four practices: Practices for the Formatting and Content of a Laboratory Report for Legacy Cases, Practices for Reviewing a Laboratory Report for Legacy Cases, Practices for Issuing a Laboratory Report for Legacy Cases, and Practices for Retaining Case-Related Records for Legacy Cases into a single document. Substantive changes include: removed the Responsibilities section, changed from unit based structure to a mixture of unit/discipline/category of testing based structure, added references to level 2 documents, added the ability to use alternate reporting formats, generalization of RC and EA to evidence management personnel, added information about ICD search reporting, added the superseding report, updated requirements for technical and administrative reviews, updated section regarding requests for a previously issued report, and added direction for issuance of a report in the absence of the issuing examiner.
12	06/03/19	Changed evidence management personnel to Evidence Management Unit throughout document. In section 3 added a statement that any information required by accreditation requirements which is not in a <i>Laboratory Report</i> or alternate reported results will be maintained in the FBI Laboratory. Modified section 3.1 to move details about listing and description of evidence section to section 3.1.2. In section 3.1.2.1, added requirement for <i>Laboratory Report</i> to include a statement regarding items not examined. Added reference to DOJ ULTR documents in sections 3.1.3.1 and 3.2.4.3. Modified and added requirements in sections 3.1.3.1 through 3.1.3.1.6 to reflect revised accreditation requirements. In sections 3.1.5 and 3.1.5.3, added requirement to also provide sites where work was conducted. Added requirement for <i>Laboratory Report</i> to reference DOJ ULTR documents and discovery requirements in section 3.1.5.4. Clarified requirements regarding exam cancellations in sections 3.1.5.7 through 3.1.5.7.2. In section 3.1.8.3, allowed contributing examiners to alternatively be co-authors in Sentinel. Clarified that supplemental <i>Laboratory Report</i> pertain to completed requests in section 3.1.12. In section 3.1.13 removed requirement for legacy amended <i>Laboratory Reports</i> to be generated in FA. Relocated requirement regarding verification to section 3.2.2.1. Revised requirements for technical reviews in section 3.2.4.1 through 3.2.4.1.2 to remove requirements for person to be qualified and have casework experience, and to add requirement to have been competency tested. In section 3.3 broadened requirements to allow emailing <i>Laboratory Report</i> . Generalized serialization requirements in section 3.4.4.2. In

section 3.4.8, updated division name. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

**Appendix A: *FBI Laboratory Report (7-1)***

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**Appendix B: *FBI Laboratory Report (7-273)***

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## **FBI Laboratory Practices for Shipping and Returning Evidence**

### **1 Purpose**

These practices establish the requirements for shipping and returning evidence to conform to the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel shipping and returning evidence to appropriate parties. These practices also apply to FBI Laboratory personnel shipping evidence between FBI Laboratory facilities.

### **3 Practices**

Personnel preparing evidence for shipment will account for all items and ensure that the evidence is returned in a timely manner unless it is destroyed according to existing regulations, is retained by the FBI Laboratory, or shipped to another FBI facility for examination. Evidence will not be shipped through internal FBI mail (i.e., Bumail). Evidence will not be shipped on Fridays or over holidays except in exigent circumstances. Personnel who have identified evidence that will be sent to an external laboratory for examinations will be responsible for packing and shipping evidence to that laboratory. Evidence received electronically (e.g., email attachments, evidence serialized in Sentinel by FBI contributors and retrieved by Laboratory personnel for examination) will be retained.

#### **3.1 Packaging Evidence for Shipment**

**3.1.1** Personnel preparing evidence for shipment will locate all evidence that needs to be shipped for a particular case and re-inventory the evidence against the evidence listing.

Personnel will cross-check the Laboratory number(s), item identifiers or numbers, and contributor identifiers (e.g., 1B number) on the records and the evidence.

**3.1.2** Personnel will package all evidence in a properly sealed evidence container and in a manner to prevent damage under normal shipping conditions. Personnel will ensure evidence packaging is labeled with the Laboratory number, item identifiers, container, and packaging designations. When possible, personnel will repackage evidence in contributor containers with contributor identifiers (e.g., 1B numbers, barcodes). The shipping records will be placed so that they are not in direct contact with the evidence and can be easily retrieved.

**3.1.3** When returning evidence to an FBI field office or resident agency, the package will be addressed to the attention of evidence control in the receiving office. Redacted

**3.1.4** When returning evidence to an external contributor, the package will be addressed according to the incoming request for examination.

**3.1.5** Evidence may be shipped to a different person and/or facility upon request from the contributor. This request will be recorded on the appropriate communication log (e.g., *Activity and Communication Log* [7-245], Case Communication Log). If the request is received in a letter, a fax, or an email, the request will be retained in the Forensic Advantage (FA) Case Object Repository, Case Communication Log Object Repository, or in the 1A for legacy cases.

**3.1.6** For evidence that was personally delivered to the FBI Laboratory, the contributor will be contacted to determine if he/she will pick up the evidence, when necessary. This communication will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, Case Communication Log).

## **3.2 Shipping Records**

### **3.2.1 Shipping Invoice**

**3.2.1.1** A *FBI Laboratory Shipping Invoice* (7-264, 7-264 LIMS) (Appendix A, Appendix B) will be generated for at least each shipment and may be generated for each shipping container within that shipment. A copy of each *FBI Laboratory Shipping Invoice* will be retained in the FBI Laboratory file. For FA cases, the copy will be uploaded into the FA Case Object Repository.

**3.2.1.2** Personnel preparing evidence for shipment will place the *FBI Laboratory Shipping Invoice* in an envelope labeled "Invoice" and include it in the shipment. If not included on the *FBI Laboratory Shipping Invoice*, a detailed description of the enclosed item(s) will also be enclosed. For legacy cases, this will typically be a copy of the *Laboratory Work Sheet* (7-2).

### **3.2.2 Secondary Evidence Log**

When secondary evidence is shipped, a copy of the secondary evidence log will be enclosed in the envelope labeled "Invoice".

## **3.3 Chain-of-Custody Records**

### **3.3.1 Chain-of-Custody Log**

Transfers of evidence for shipping purposes will be recorded on the appropriate Chain-of-Custody Log.



### **3.4 Selecting a Carrier for Shipping Evidence**

When choosing a carrier, it is essential that personnel preparing evidence for shipment are aware of each carrier's limitations for shipment, including requirements for shipping oversized evidence, overweight evidence, or hazardous material evidence. The limitations are available from carriers. When practicable, personnel preparing evidence for shipment will use a trackable carrier.

#### **3.4.1 Hazardous Material Evidence**

Any submissions containing materials defined as hazardous by the Department of Transportation must be returned by personnel who have been trained to ship packages containing hazardous materials by a certified Department of Transportation (DOT) or International Air Transport Association-approved school. DOT defines hazardous materials as materials that in shipment pose risk to health, safety, and property. The materials are classified as being explosive, toxic, flammable, oxidizing, radioactive, or corrosive. Examples of hazardous materials include ammunition, lighters, lithium batteries, pressurized containers, matches, and chlorine. For assistance in determining whether items must be treated as hazardous material evidence, personnel will contact an appropriately trained person or Evidence Management Unit personnel.

### **3.5 Returning Evidence to a Contributor**

#### **3.5.1 Contributor within the United States**

When shipping evidence within the United States, including territories, personnel preparing evidence for shipment will ensure that the evidence is shipped using a courier or an appropriate, trackable carrier, when practicable.

#### **3.5.2 External Contributor outside the United States**

Personnel preparing evidence for shipment should seek the assistance of an appropriately trained person when sending evidence outside the United States as this may result in the container being opened and inspected by customs officials.

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#### **3.5.4 Direct Return to a Contributor**

Personnel returning evidence directly to a contributor will record a hand-to-hand transfer on the

appropriate Chain-of-Custody Log. For FA cases, personnel will ensure the contributor signs the FA Evidence Return Receipt using the electronic signature pad, and upload the Evidence Return Receipt to the FA Case Object Repository.

### **3.6 Shipping Evidence Between FBI Laboratory Facilities**

Evidence shipped between FBI Laboratory facilities will be properly sealed. Personnel preparing evidence for shipment will locate all evidence that needs to be shipped for a particular case and re-inventory the evidence against the evidence listing. A *FBI Laboratory Shipping Invoice* will be generated for at least each shipment and may be generated for each shipping container. A copy of each *FBI Laboratory Shipping Invoice* will be retained in the FBI Laboratory file. For FA cases the copy will be uploaded into the FA Case Object Repository.

### **3.7 Misdirected Evidence**

If it is determined that evidence was shipped to the wrong location, it must be reported to the Quality Manager in writing. The Quality Manager will address the issue in accordance with the Laboratory Operations Manual - Practices for Addressing a Nonconformity. The evidence will be sent to the correct location, either by being returned to the FBI Laboratory or by the FBI Laboratory requesting confirmation that the evidence has been forwarded from the incorrect location to the correct one (e.g., shipping receipt). All activities to resolve the misdirection of the evidence will be recorded in the appropriate communication log (e.g., *Activity and Communication Log*, Case Communication Log).

## **4 Records**

The following records will be generated and/or retained in the FBI Laboratory file as a result of these practices:

- Appropriate Chain-of-Custody Log.
- *FBI Laboratory Shipping Invoice*.
- Secondary evidence log, if generated.
- *Laboratory Work Sheet* (for legacy cases).
- Appropriate communication log.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 20017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
7	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Merged information about shipping and returning evidence from the Practices for Transferring, Storing, and Returning Evidence in FA into this document. Substantive changes include: removed the Responsibilities section, generalization of RC and EA to evidence management personnel throughout, added requirements for shipping evidence between Laboratory facilities, added information regarding returning evidence that was delivered personally to a Laboratory facility, the allowance of multiple shipments within a container, and added requirements for addressing misdirected evidence. Added Appendix B.
8	06/03/19	Revised terminology in section 3 to refer to an external laboratory. In section 3.1.5 added reference to the Case Communication Log Object Repository. Modified section 3.1.6 to allow for instances when the contributor doesn't need to be contacted. Changed evidence management personnel to Evidence Management Unit in section 3.4.1. Updated list of references in section 5. Updated image of Shipping Invoice in Appendix B to reflect addition of portion marking.

**Approval**

**Redacted - Signatures on File**

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

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## **FBI Laboratory Practices for Resolution of Scientific or Technical Disagreement**

### **1 Purpose**

Occasionally, the technical or scientific opinion of one person may differ from another's and is referred to as a disagreement. Consultation is encouraged between personnel while performing work and does not mean there is a disagreement. The FBI Laboratory will conform to the practices in this document to ensure that disagreements are resolved. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in disagreements of a scientific or technical nature. These disagreements may occur during verification, technical review, administrative review, blind verification, casework involving an external organization, DNA databasing, or validation of a new method or technical procedure. These disagreements may occur within a unit, between units, or with an external organization. Personnel will follow these practices unless there is an approved alternative procedure for their discipline or category(ies) of testing.

### **3 Practices**

#### **3.1 Disagreements Internal to the FBI Laboratory**

##### **3.1.1 Initial Resolution Process**

The personnel involved in the disagreement will discuss the matter, refer to any applicable references, and attempt to resolve the matter. If a resolution is reached to the agreement of all parties, it will be recorded and clearly communicated to all personnel involved. If a resolution cannot be achieved by the affected personnel, the discussions will be elevated to the affected Unit Chief(s) and Technical Leader. The personnel are prohibited from discussing the matter with anyone other than the personnel described in this document.

##### **3.1.2 Unit Chief/Technical Leader Level Resolution Process**

The Unit Chief(s), Technical Leader, and the personnel involved in the disagreement, will participate in the resolution process. If a resolution is reached to the agreement of all parties, it will be recorded and clearly communicated to all personnel involved. If a resolution cannot be achieved, it will be recorded and the Unit Chief(s) will bring the matter to the attention of the appropriate Section Chief(s).

### **3.1.3 Section Level Resolution Process**

The Section Chief(s) will review the records regarding the disagreement. The Section Chief(s) will work with the personnel involved in the disagreement, the Unit Chief(s), and the Technical Leader, to resolve the disagreement. If a resolution is reached to the agreement of all parties, it will be recorded and clearly communicated to all personnel involved. The Section Chief will ensure an Electronic Communication (EC) (FD-1057) is prepared recording the resolution. If a resolution cannot be achieved, it will be recorded and the Section Chief(s) will bring this matter to the attention of the Quality Manager and Deputy Assistant Director.

### **3.1.4 Scientific Resolution Board Level Resolution Process**

The Quality Manager will convene a Scientific Resolution Board (SRB) to resolve disagreements that cannot be resolved at the Section Chief level. The Quality Manager will identify the personnel who will participate in the SRB, including a person to facilitate the SRB. The SRB will review the disagreement information and make recommendations to the Laboratory Director in an EC.

### **3.1.5 Laboratory Director Resolution Process**

The Laboratory Director will approve or reject recommendations of the SRB and/or direct other actions as needed to resolve the disagreement. The Laboratory Director's decision will be recorded in an EC and clearly communicated to all personnel involved.

## **3.2 Disagreements between the FBI Laboratory and External Organizations**

### **3.2.1 Notification**

FBI Laboratory personnel will notify their immediate supervisor, the Technical Leader, and affected Unit Chief(s) when they are aware of a disagreement of a scientific or technical nature between the FBI Laboratory and an external organization. Personnel will provide the applicable records and an explanation of the nature and extent of the disagreement. The Unit Chief(s) will notify in writing the affected Section Chief(s) and the Quality Manager of the disagreement.

### **3.2.2 Executive Level Resolution Process**

The Technical Leader, Unit Chief (s), and Section Chief(s) will review the records regarding the disagreement and attempt to resolve the disagreement with the external organization. The personnel involved in the disagreement may assist with the resolution process. If a resolution is reached to the agreement of all parties, it will be recorded and clearly communicated to all parties involved. The Section Chief will ensure an EC is prepared recording the resolution.

If a resolution cannot be achieved, all aspects of the external disagreement will be recorded including the reasons why the disagreement remains unresolved and recommendations for further action. The Section Chief will ensure an EC is prepared recording this information and routed to the Technical Leader, appropriate Unit Chief(s), Section Chief(s), Quality Manager,



and Deputy Assistant Director for approval. The approved EC will be provided to the Laboratory Director for his/her review.

### **3.2.3 Laboratory Director Resolution Process**

The Laboratory Director will review the executive level EC and approve or reject the recommendations and/or direct other actions as needed to resolve the external disagreement. The Laboratory Director will communicate the resolution of the external disagreement in writing to the external organization. The Laboratory Director's decision will be recorded in an EC and clearly communicated to all FBI Laboratory personnel involved.

### **3.3 Recording the Resolution Process**

All aspects of the disagreement resolution process will be recorded at each level. The record will include the nature of the disagreement, information and/or resources used to resolve the disagreement, the outcome, and if applicable, why the disagreement remains unresolved. The records will be placed in the FBI Laboratory file, DNA database records, or validation records as appropriate. If an EC is generated to record the resolution, a copy of the EC will be placed with the appropriate records.

### **3.4 Revision to Quality System Documents**

The Quality Manager or appropriate Unit Chief(s) will ensure any FBI Laboratory practices or procedures are revised, if needed, following the resolution of a disagreement.

### **3.5 Alternative Procedures**

A discipline or category(ies) of testing may develop alternative procedures of resolving differences, based on the technical nature of that work. In lieu of the practices described in this document, a level 2 document may have procedures for handling disagreements internal to the FBI Laboratory. These procedures will include, at a minimum, definitions regarding what will be considered a disagreement, requirements regarding issuance of final conclusions, and records that will be generated. When a situation arises where an alternative procedure for disagreements is followed, the appropriate Section Chief(s) will be notified in writing at the beginning of the process and the notification retained.

## **4 Records**

The following records may be generated and/or retained as a result of these practices:

- Records of disagreement resolution results will be retained in the FBI Laboratory file, DNA database records, or validation records, as appropriate.
- Additional information and/or resources used in the disagreement resolution.
- Any ECs generated.
- Any written notifications.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
6	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL and to allow flexibility in resolution of scientific or technical disagreements. Merged the Practices for Conflict Resolution with an External Organization into this document. Substantive changes include: removed the Responsibilities section, changed terminology from conflict to disagreement throughout, changed from the Deputy Assistant Director convening the SRB to the Quality Manager convening the SRB, and added requirements for alternative disagreement resolution procedures.
7	06/03/19	Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Testimony Related Activities**

### **1 Purpose**

These practices establish all requirements related to testimony. These practices describe the steps required prior to testimony (e.g., requesting documents for discovery, preparing Curriculum Vitae (CV) to be submitted for court purposes), information related to providing testimony, the information that must be entered into the Testimony Tracker, and steps for monitoring testimony that will aid in identifying opportunities for improving a witness' testimony. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual, the applicable accrediting body(ies), and the Department of Justice (DOJ) Testimony Monitoring requirements.

### **2 Scope**

These practices apply to FBI Laboratory personnel who provide expert testimony as part of their current and past FBI job duties and their managers. Additionally, these practices apply to personnel who conduct testimony evaluations and personnel who support testimony related activities.

### **3 Practices for Pre-Testimony Activities**

#### **3.1 Curriculum Vitae**

**3.1.1** Personnel will maintain a CV to provide to court officials upon discovery request and/or receipt of a subpoena. That CV will not contain any official seal.

**3.1.2** The previous four years of testimonies will be listed on the CV. No testimonies older than four years will be listed on the CV.

**3.1.3** Each testifying person will ensure their CV is uploaded to BUNET and that it is reviewed at least on 90 day intervals and will ensure the CV is updated appropriately at that time.

**3.1.3.1** If a person is no longer with the FBI Laboratory, the appropriate Unit Chief will ensure the CV is removed from BUNET.

**3.1.4** If personnel are scheduled to testify and a significant event occurs (e.g., additional testimony, presentation or publication that will be used in testimony) outside of the 90 day update interval, personnel will ensure an up to date CV is provided to the sponsoring attorney. See Appendix A for an example template for use in creating a CV.

## **3.2 Request for Testimony**

**3.2.1** Testifying personnel will ensure their management is aware of any request for their testimony.

**3.2.2** Upon receipt of a subpoena request to testify, personnel will notify the Office of General Counsel (OGC). Testifying personnel will ensure the subpoena is attached to the associated entry in the Testimony Tracker, located on BUNET.

**3.2.3** If the request for testimony is received in a manner other than a subpoena (e.g., verbal request, email request), testifying personnel will request a subpoena and notify OGC.

## **3.3 Discovery Requests**

**3.3.1** Discovery requests will be coordinated through OGC.

**3.3.2** Testifying personnel will ensure that all applicable level 2 documents in use at the time of their examinations are requested following the instructions provided on the Discovery Request site, located on BUNET. For discovery requests that include a request for prior transcripts for testifying personnel, the request for the testimony information will be included as part of the same request.

**3.3.3** Upon receipt of all information associated with the discovery request (e.g., document names and revisions, transcripts request), the Discovery and Testimony Monitoring Program Manager (DTMPM) will ensure that the Laboratory Quality System documents (applicable levels 1 and 2 documents) are provided in accordance with the request along with any available requested transcripts for the testifying personnel.

## **4 Practices for Testimony**

**4.1** All testifying personnel must provide testimony such that:

- Testimony is consistent with FBI Laboratory practices and procedures regarding testimony about the forensic analysis of evidence;
- Testimonial opinions, conclusions, and statements regarding the underlying case-specific facts or data are properly qualified and do not exceed the scientific limitations of the method performed or the discipline/category of testing in question; and
- Conclusions are in conformity with the applicable Approved Standards for Scientific Testimony and Reports (ASSTR) document(s), which are in accordance with the applicable DOJ approved Uniform Language for Testimony and Report document(s).

**4.2** To facilitate the receipt of transcripts by the DTMPM, testifying personnel and testimony evaluators will ensure the appropriate testimony and testimony monitoring related information is entered and saved into the Testimony Tracker, located on BUNET. All fields

indicated in the Testimony Tracker must be completed with appropriate information, when practicable.

## **5 Practices for Post-Testimony Activities**

The testimony of current FBI Laboratory personnel will be monitored. Testimony monitoring will include recording appropriate information related to testimony, requesting and retaining transcripts, and evaluating testimony. A transcript will be requested for every testimony provided.

### **5.1 Transcript Requests**

**5.1.1** After testimony, testifying personnel (i.e., witness) will ensure all post-testimony related information is properly recorded in the Testimony Tracker to best facilitate the requesting of transcripts.

**5.1.2** The DTMPM will ensure a transcript is requested for each testimony logged in the Testimony Tracker. The date of a transcript request will be recorded in the Testimony Tracker.

**5.1.3** The DTMPM will ensure that at least two additional attempts are made within one year to obtain a transcript. The interval between the attempts will be at least three months. Follow-up attempts to obtain a transcript will be recorded in the Testimony Tracker. Once a transcript is received, follow-up attempts are no longer required. When a transcript is received, the date of receipt will be recorded in the Testimony Tracker.

**5.1.4** When a transcript will not be made available (e.g., sealed testimony, court official responds that a transcript will not be created, grand jury), the person who received the notification that the transcript will not be created will ensure a comment is added to the Testimony Tracker noting that the transcript will not be created. Follow-up attempts are no longer required.

**5.1.5** If the DTMPM is unable to obtain a transcript(s) or confirm that a transcript(s) will not be created after attempting to obtain the transcript as described in Sections 5.1.2 through 5.1.4, the DTMPM will notify OGC to allow OGC the opportunity to obtain the transcript(s). The date of the contact and name of the OGC personnel contacted will be recorded in the Testimony Tracker.

**5.1.6** If a transcript is received by personnel outside of the Forensic Analysis Support Unit (FASU), the personnel will notify the DTMPM of the date of the receipt of the transcript, and the transcript will be forwarded to the DTMPM for retention after reviews are complete.

### **5.2 Transcript Retention**

**5.2.1** Transcripts will be retained electronically by the DTMPM for four years from the date the testimony was provided. After the four years, transcripts will be deleted.

**5.2.2** Before deleting a transcript, the DTMPM will contact the appropriate Unit Chief to determine if a redacted copy will be retained for training purposes. The DTMPM will redact all identifying information prior to providing the transcript.

**5.2.3** Transcripts that are found to have substantive violations, as described in Section 5.3.5.1, will be retained permanently by the DTMPM and provided upon discovery request when prior transcripts are requested.

**5.2.4** Transcripts will not be retained by the FBI Laboratory in any manner other than those described above.

### **5.3 Testimony Monitoring**

#### **5.3.1 Testimony Evaluators**

Personnel will not conduct a testimony evaluation of their own testimony. Technical Leaders are authorized to conduct testimony evaluations in their discipline/category of testing. Additionally, a Technical Leader and the appropriate Unit Chief may authorize other personnel to conduct testimony evaluations. Authorized personnel must have been previously competency tested in the discipline/category of testing they are evaluating. This authorization will be recorded in Sentinel.

#### **5.3.2 Transcript Review and Evaluation**

**5.3.2.1** All transcripts received will be reviewed and evaluated using the *Evaluation of Testimony* (7-256) (Appendix B). Video and audio recordings, if the voices are readily distinguishable, will be treated as transcripts.

**5.3.2.2** All testimony reviews and evaluation and the related meeting(s) must be completed within 30 calendar days of the receipt of the transcript in the FBI Laboratory or the direct observation of the testimony.

**5.3.2.3** The witness will review the transcript of their testimony prior to evaluation by an authorized testimony evaluator. The review provides an opportunity for witness input prior to the evaluation. After reviewing the transcript, the witness will complete Section A of the *Evaluation of Testimony*. The witness will also ensure the date their review is completed is entered into the Testimony Tracker.

**5.3.2.4** The authorized testimony evaluator will review the transcript after the witness has completed their review. The testimony evaluator may review a copy of the *Laboratory Report* (7-1, 7-1 LIMS, 7-273, 7-273 LIMS), the FBI Laboratory file, and/or any other material supporting the testimony to assist in their evaluation.

**5.3.2.5** The evaluation will determine if the testimony met the requirements listed in Section 4.1.

**5.3.2.6** After evaluating the transcript, the testimony evaluator will complete Section B of the *Evaluation of Testimony*. The testimony evaluator will ensure the date their evaluation is completed is entered into the Testimony Tracker.

### **5.3.3 Direct Observation, Review and Evaluation**

**5.3.3.1** An authorized testimony evaluator may directly observe a witness testify as an option for testimony monitoring.

**5.3.3.2** After testifying, the witness will complete Section A of the *Evaluation of Testimony* prior to completion of the form by an authorized testimony evaluator. The review provides an opportunity for witness input prior to the evaluation. The witness will ensure the date their review is completed is entered into the Testimony Tracker.

**5.3.3.3** After the witness has completed Section A of the *Evaluation of Testimony* and after observing the testimony, the testimony evaluator will complete Section B of the *Evaluation of Testimony*. The testimony evaluator will ensure the date their evaluation is completed is entered into the Testimony Tracker.

**5.3.3.4** A transcript of the testimony will still be requested and retained as described in sections 5.1 and 5.2. Subsequent review and evaluation of the transcript upon receipt is not required.

### **5.3.4 Evaluation of Testimony Meeting**

The testimony evaluator will meet with the witness to discuss the completed *Evaluation of Testimony*. This meeting will be recorded by each party in Section C of the *Evaluation of Testimony*. The witness' manager must also attend this meeting if a substantive violation is detected or at the testimony evaluator's request. The manager will mark the box on the *Evaluation of Testimony* indicating attendance, if he/she attended the meeting. If the witness' manager does not attend the meeting with the witness, the manager will sign the *Evaluation of Testimony* acknowledging the content of the evaluation.

### **5.3.5 Overall Evaluations**

**5.3.5.1** If a "Y" response is marked for any of the questions in Section B of the *Evaluation of Testimony*, the testimony is deemed to have a substantive violation and will be considered unsatisfactory. If "N" responses are marked for all of the questions in Section B of the *Evaluation of Testimony*, the testimony is considered satisfactory. A testimony can be deemed satisfactory (i.e., "N" responses for all questions in Section B) and still have recommendations for improvement.

**5.3.5.2** If a substantive violation in a testimony occurred (i.e., any "Y" responses in Section B of the *Evaluation of Testimony*), the testimony evaluator will notify the witness' manager in writing at the time this is determined.



**5.3.5.3** The testimony evaluator will prepare a detailed explanation of the reason(s) for determining the substantive violation(s) and recommendations for improvement. This will be attached to the *Evaluation of Testimony* and signed and dated by the witness, the testimony evaluator, and the witness' manager.

**5.3.5.4** The witness' manager will consult an OGC attorney regarding the notification of the attorney who sponsored the witness, so a legal determination can be made regarding further notifications to any appropriate court official(s). OGC will communicate with the sponsoring attorney. The witness' manager will ensure the date(s) the OGC and sponsoring attorney(s) are notified will be recorded on the spaces provided on the *Evaluation of Testimony*.

**5.3.5.5** When practicable, the witness' next testimony will be directly observed.

**5.3.5.6** Additionally, for substantive violations, a *Corrective Action Request* (7-254) will be initiated and the appropriate personnel notified, to include the Quality Manager, according to the Laboratory Operations Manual (LOM) - Practices for Addressing a Nonconformity.

## **6 Practices for Testimony Related Activities by Personnel No Longer in Position/Discipline/Category of Testing**

FBI Laboratory personnel, who are no longer working in the same position/discipline/category of testing in which the testimony will occur, will discuss their anticipated testimony with the appropriate Technical Leader and notify OGC. The witness will review the relevant ASSTR(s) prior to their testimony, when applicable. All associated meetings and reviews will be recorded as a comment on the appropriate entry in the Testimony Tracker.

## **7 Practices for Testimony Related Activities when Examiner Has Not Testified**

**7.1** Examiners that are expected to testify as part of their current FBI job duties may not have the opportunity to do so every calendar year. Each Unit Chief who manages examiners whose current duties include providing testimony will ensure that the potential need for refresher testimony exercises (i.e., not testify at least once in a five year time period) is monitored in their unit.

### **7.2 Refresher Testimony Exercises for Examiners**

**7.2.1** An examiner, who is expected to testify as part of their current FBI job duties and does not provide expert testimony at least once in a five year time period, will participate in a refresher testimony exercise. The refresher testimony exercise will occur no more than 60 calendar days after the end of the five year time period (i.e., date of last moot court exercise, date of last refresher testimony exercise, date of last testimony). The examiner's Unit Chief and applicable Technical Leader will define the requirements of the refresher testimony exercise and provide them to the examiner in writing 30 days prior to the exercise.

**7.2.2** The refresher testimony exercise will be viewed by the examiner's Unit Chief and the applicable Technical Leader. Additional personnel may attend.

**7.2.3** The examiner's Unit Chief and applicable Technical Leader will provide feedback to the examiner at the conclusion of the refresher testimony exercise. Feedback may be provided verbally. If the exercise is successfully completed, no further records are required, except as provided in section 7.2.4 below.

**7.2.4** The Unit Chief will ensure the refresher testimony exercise is entered into the Testimony Tracker. A comment will be added to the corresponding Testimony Tracker record indicating who was present at the exercise. Any fields not applicable to the refresher testimony exercise will be marked as such in the Testimony Tracker. Results and other written records created during the exercise will be retained in the examiner's unit.

**7.2.5** If the examiner's Unit Chief and/or applicable Technical Leader determine that the exercise was not successfully completed, the Unit Chief will ensure a *Corrective Action Request* is initiated. The *Corrective Action Request* will include an appropriate remediation plan.

## **8 Records**

The following records will be generated and/or retained through one accreditation cycle, unless otherwise noted:

- Records associated with the authorization to conduct testimony evaluation will be retained permanently in Sentinel.
- Discovery request entries will be retained permanently in the Discovery Request site, located on BUNET.
- Testimony Tracker entries will be retained permanently in Testimony Tracker, located on BUNET.
- *Evaluation of Testimony* forms and any supplemental records, if applicable, will be retained in the unit.
- Transcripts will be retained by the DTMPM for 4 years from the date each testimony occurred.
- Transcripts that include substantive violations will be retained permanently by the DTMPM.
- Records associated with refresher moot court exercises will be retained in Testimony Tracker, located on BUNET, and in the examiner's unit.

## 9 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, *International* Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
11	01/11/19	Entire document updated to include compliance with DOJ requirements.
12	06/03/19	In section 2, added that these practices apply only to expert witness testimony. Added section 3.1.3.1 to require removal of a CV for personnel no longer with the FBI Laboratory. In section 3.2.2, changed requirement so that subpoenas are attached to Testimony Tracker entries, rather than Discovery Request entries. In section 5.3.1, added that personnel will not evaluate their own testimony and that authorized personnel must have been competency tested. In section 7.2.1, clarified that personnel who provide expert testimony are subject to refresher testimony exercise requirements. Ensured the term "testimony evaluator" used throughout. Updated list of references in section 9.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

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## **FBI Laboratory**

# **Practices for Customer Satisfaction Assessments of FBI Laboratory Services**

### **1 Purpose**

These practices establish the requirements for assessing the services of the FBI Laboratory to conform to the requirements of the FBI Laboratory Quality Assurance Manual (QAM) and the requirements of the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who facilitate, record, and/or review customer satisfaction assessments of examinations performed by the FBI Laboratory.

### **3 Practices**

An evaluation of the services provided by the FBI Laboratory will be solicited from the contributors who have submitted evidence. This will be accomplished through the use of the *Customer Satisfaction Assessment* (FD-1000) (Appendix A). The *Customer Satisfaction Assessment* will assist in determining the areas in which the FBI Laboratory can improve its services.

**3.1** The *Customer Satisfaction Assessment* will be made available electronically or sent, to the contributor for each *Laboratory Report* (7-1, 7-1 LIMS, 7-273, 7-273 LIMS) except for the following circumstances:

- An amended, supplemental, or superseding *Laboratory Report*.
- Film, disposable cameras, slides, or negatives that are processed, or for post-mortem imaging.
- A discontinued or canceled examination *Laboratory Report*.
- Cases sent to an external laboratory.

**3.1.1** For major cases, as designated by a field office, or for Laboratory Director and Quality Manager approved initiatives and/or alternate reporting, the Unit Chief(s) will develop the appropriate frequency to assess customer satisfaction using the *Customer Satisfaction Assessment*.

**3.2** An examiner will ensure the top portion of the *Customer Satisfaction Assessment* (i.e., Laboratory number, Case ID, Performed by, Discipline, and Customer Information) is complete, when appropriate. The *Customer Satisfaction Assessment* may be made available electronically for contributors, or sent to contributors via email or via the U.S. Postal Service.

**3.3** If the contributor returns the *Customer Satisfaction Assessment* to a unit other than



the Forensic Analysis Support Unit (FASU), the *Customer Satisfaction Assessment* will be forwarded to FASU.

**3.4** Upon receipt of the *Customer Satisfaction Assessment*, a member of FASU will initial and date the receipt of each *Customer Satisfaction Assessment*. The results will be entered, typically on a monthly basis, into the Customer Satisfaction Assessment Database and the date of entry will be recorded on each form. The *Customer Satisfaction Assessment* forms will be forwarded, typically on a monthly basis, to the appropriate Unit Chiefs for review.

**3.5** A summary of the results will be reported by the Quality Manager at the annual management review.

**3.6** The Unit Chief will ensure that his/her unit is providing appropriate customer service by reviewing *Customer Satisfaction Assessment* results. The Unit Chief will also ensure that the contributor is contacted for any “No” or “Unsatisfactory” response(s), and the results of the communication are recorded. The Unit Chief may also contact the contributor if otherwise deemed necessary.

**3.6.1** If the communication results in a complaint from the contributor, the Unit Chief will ensure the section regarding complaints in the QAM is followed.

## **4 Records**

The following records will be generated and/or retained through one accreditation cycle or five years, whichever is longer, unless specified otherwise as a result of these practices:

- Customer Satisfaction Assessment Database.
- Record of communication with a contributor for any *Customer Satisfaction Assessment* that has a rating of “No” or “Unsatisfactory” will be maintained by the Unit Chief.
- Record of communication with the contributor if otherwise deemed necessary will be maintained by the Unit Chief.

## **5 References**

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
8	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section, added the ability to make the form available electronically, and modified the form to include TEDAC email addresses.
9	06/03/19	Revised terminology in section 3.1 to refer to an external laboratory. In section 3.3, generalized to allow anyone to forward a <i>Customer Satisfaction Assessment</i> to FASU. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

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## **FBI Laboratory Practices for Blind Verification**

### **1 Purpose**

Blind verification (BV) is an examination of an item(s) of evidence by another examiner qualified and authorized in the same category of testing, who does not know the conclusion of the original examiner. BV tests the reproducibility of conclusions in an environment that minimizes bias.

### **2 Scope**

These practices apply to all FBI Laboratory personnel who are involved in conducting examinations in the following categories of testing:

- Hair
- Firearms
- Toolmarks
- Document Examination
- Impression Evidence (footwear/tires)
- Latent Print Comparisons

### **3 Practices**

**3.1** Each unit, discipline, and/or category of testing that conducts the examinations in the categories of testing specified in Section 2 will have procedures for BV in a level 2 document. A BV procedure will:

- Define what examination types are subject to BV.
- Ensure that any examiner(s) who is consulted by the original examiner during the examination process does not perform the BV.
- Require a record of the BV and any resulting consultations.
- Ensure a representative number of associations and non-associations are blind verified annually.
- Direct examiners to the Laboratory Operations Manual (LOM) - Practices for Resolution of Scientific or Technical Disagreement if consultation does not resolve differences of opinion on a BV.

**3.2** A Unit Chief will ensure a record of the BVs performed is maintained. A Unit Chief will additionally ensure the number of BVs is evaluated and recorded on an annual basis to ascertain that a representative number of associations and non-associations are conducted in the applicable examination types.

**3.3** A BV will be assigned and completed in a timely manner.

## 4 Records

The following records will be generated as a result of these practices and retained through one accreditation cycle or five years, whichever is longer, , unless otherwise specified:

- Record of a BV and any resulting consultations and/or resolution of any disagreement, as examination records in the FBI Laboratory file.
- Record of the number of BVs performed, including the FBI Laboratory number, the category of testing, the type of BV (association or non-association) and any noted differences of opinions between the original examiner and the blind verifier.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
5	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section, expanded language in the purpose section to better describe the intent of BVs, clarified that minimum number of examiners needed to qualify for BV spans both facilities, added requirement that level 2 documents define what types of examinations require BV, added that BVs will be assigned and completed in a timely manner.
6	06/03/19	Removed the term “independent” from section 1 to allow for consultations. In section 2, removed statement that these practices do not apply to a category of testing with fewer than three examiners, as all categories listed meet the criterion. Updated section 4 so that records of BVs are by category of testing. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

## **FBI Laboratory Practices for Oral Board Exercises**

### **1 Purpose**

These practices establish the requirements and procedures for Oral Board exercises. These exercises test a trainee's ability to demonstrate their knowledge in areas such as scientific theories; limitations of the science, discipline, and/or category(ies) of testing; standard operating procedures; examination processes and analyses; and resulting opinions/interpretations, as applicable to a trainee's job duties.

### **2 Scope**

These practices apply to FBI Laboratory personnel who are training to become forensic examiners; personnel who facilitate, record, and/or review training; and other personnel who are directed by Unit Chiefs and/or Executive Management to participate in an Oral Board exercise(s). If a training program requires an Oral Board exercise for personnel other than forensic examiners, these practices may be followed or a level 2 document will define the requirements and procedures for the oral board.

### **3 Practices**

#### **3.1 Establishing Oral Board Exercises**

The trainee must successfully complete the appropriate number of Oral Board exercises that cover the expertise in each discipline/category(ies) of testing as required by the trainee's training plan. See the LOM - Practices for the Forensic Examiner Training Program for information regarding the process for establishing and modifying the required number of oral board exercises in the trainee's training plan.

**3.1.1** Knowledge of administrative practices and job duties can be covered in conjunction with a subject-matter Oral Board exercise.

**3.1.2** The Training Program Manager (TPM) and Technical Leader will determine the applicable discipline/category(ies) of testing to be covered in each exercise.

**3.1.3** A written summary of expectations will be provided to the trainee by the TPM a minimum of 30 calendar days prior to each exercise. The summary of expectations must include:

- Objectives of the Oral Board exercise.
- Topic areas that will be covered.
- Suggested preparation for the Oral Board exercise.

- An evaluation plan outlining trainee proficiency and rating requirements to successfully complete the exercise.

**3.1.4** The TPM will ensure that preparation for each Oral Board exercise includes a practice session that uses the scoring guide provided in the *Oral Board Exercise - Evaluator Score Sheet* (7-266) (Appendix A). Participants in the practice session will ensure feedback and suggestions for improvement are provided. This session may be audio recorded and available for review by the trainee. Any audio recordings of practice sessions are not required to be retained within the trainee's training record.

**3.1.4.1** Additional practice oral board sessions may be added at any time during the training program to assist the trainee with oral board preparation.

## **3.2 Coordinating Oral Board Exercises**

**3.2.1** Prior to the Oral Board exercise, the *Oral Board Exercise - Evaluator Score Sheet* will be prepared. The *Oral Board Exercise - Evaluator Score Sheet* must contain the oral board questions, summary answers, an area for notes on answers given, an area to capture follow-up questions asked of the trainee, and identification of any critical points of failure. The *Oral Board Exercise - Evaluator Score Sheet* may be designed to fit the needs of the exercise, to include the use of supplemental pages.

**3.2.2** The TPM will ensure the coordination of each Oral Board exercise. The coordination of the exercise will encompass identifying, reserving, and arranging an appropriate space for the oral board and, for oral boards for forensic examiner trainees, notifying the Forensic Examiner Training Program Manager (FETPM) of the exercise date. Additionally, the TPM must ensure that the exercise will be audio recorded.

## **3.3 Evaluating Oral Board Exercises**

Each Oral Board exercise will be evaluated by a Subject Matter Expert (SME) panel selected by the trainee's TPM, Unit Chief, and/or Technical Leader. The panel will consist of three SMEs, when practicable. The TPM may request the assistance of non-FBI Laboratory SMEs.

**3.3.1** Each SME panel member will complete an *Oral Board Exercise - Evaluator Score Sheet* in its entirety immediately after the completion of the exercise.

**3.3.2** Each SME panel member will provide their *Oral Board Exercise - Evaluator Score Sheet* to the TPM or designee. The TPM or designee will use the *Oral Board Exercise - Evaluator Score Tally Form* (7-286) (Appendix B) to record the ratings and overall calculated result of the exercise. Successful completion of the exercise will be determined in accordance with the defined evaluation plan with a grade of 80% or higher achieved in the exercise.



### 3.4 Post-Exercise Requirements

**3.4.1** The TPM will ensure the *Oral Board Evaluator Score Sheets* are reviewed with the trainee. The trainee will sign the *Oral Board Exercise - Evaluator Score Tally Form* to record the review.

**3.4.2** The TPM will ensure all audio recordings of Oral Board exercises are maintained within the trainee's training record.

**3.4.2.1** Upon a trainee's request, a copy of the audio recording of the Oral Board exercise will be provided for the trainee's review.

**3.4.2.2** If the trainee discontinues the training program or is removed from the training program, the audio recording will be maintained within the trainee's training record.

**3.4.3** If the trainee successfully completes the Oral Board exercise, the TPM will ensure this is recorded in the trainee's training record.

**3.4.4** If the trainee fails to successfully complete an Oral Board exercise, the Forensic Examiner Training Program Manager (FETPM) will notify the Quality Manager in writing within one calendar day. If the FETPM is not present, the TPM will notify the Quality Manager in writing within one calendar day.

**3.4.5** The FETPM will coordinate and serve on the Root Cause Panel.

**3.4.5.1** All members from the SME panel, and other training personnel as requested by the FETPM, will serve on the Root Cause Panel.

**3.4.5.2** The Quality Manager will ensure a facilitator is selected to serve on the Root Cause Panel.

**3.4.6** The Root Cause Panel will meet within seven calendar days to determine the root cause(s) of the trainee's failure of the Oral Board exercise.

**3.4.7** The Root Cause Panel will interview the trainee and discuss the *Oral Board Exercise - Evaluator Score Sheets* to assist in determining the root cause(s) of the failure.

**3.4.8** After determining the root cause(s), the Root Cause Panel will propose a remediation plan to the trainee's Unit Chief, trainee, TPM, and Technical Leader. The facilitator will record the root cause(s) and remediation plan in a *Corrective Action Request (7-254)* according to the LOM - Practices for Addressing a Nonconformity.

### 3.5 Establishing Repeat Oral Board Exercises

**3.5.1** The trainee will have a second opportunity to successfully complete the same Oral Board exercise. The *Corrective Action Request* must be closed prior to the second attempt at the

Oral Board exercise. The repeated Oral Board exercise will be conducted in the same discipline(s)/category(ies) of testing although different questions may be asked.

**3.5.2** If the trainee fails to successfully complete a second attempt at the same Oral Board exercise, the trainee will be removed from the training program.

## 4 Records

The following records are generated and permanently retained in the trainee's training record as a result of these practices:

- Summary of expectations for each Oral Board exercise.
- *Oral Board Exercise- Evaluator Score Tally Form.*
- Audio recording of each Oral Board exercise.
- If applicable, a copy of any *Corrective Action Request* and corresponding records.

The *Oral Board Exercise - Evaluator Score Sheets* will be retained electronically in the Laboratory Division training portal.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
8	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: clarified Sections 1 and 2, removed the Responsibilities section, added a requirement for an evaluation plan, added a requirement for a practice session, added requirement to complete the 7-266 immediately after the completion of the exercise, removed requirement for QA Specialist on root cause panel, and changed from business to calendar days.
9	06/03/19	Revised evaluation form and renamed to <i>Oral Board Exercise - Evaluator Score Sheet</i> in Appendix A. Added <i>Oral Board Exercise - Evaluator Score Tally Form</i> in Appendix B. In section 3.1.4, clarified that each oral board exercise includes a practice session and added a requirement to use the scoring guidelines. Added section 3.2.1 describing preparation of the <i>Oral Board Exercise - Evaluator Score Sheet</i> . In section 3.2.2, added requirement to notify the FETPM of oral boards for FETs. Added requirement for a minimum 80% grade in section 3.3.2. In section 3.4.1, added requirement for trainee to sign the tally form to record the review of evaluations. Modified section 3.4.5.2 so that Quality Manager ensures selection of facilitator. Updated records in section 4 to reflect revision of forms. Updated list of references in section 5.

### **Approval**

**Redacted - Signatures on File**

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019

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## **FBI Laboratory Practices for Moot Court and Admissibility Hearing Exercises**

### **1 Purpose**

These practices establish the requirements and procedures for Moot Court and Admissibility Hearing exercises. These exercises will test a trainee's ability to accurately and clearly articulate qualifications as an expert and explain scientific theories, as well as the limitations of the science, discipline, and/or category(ies) of testing within the scope of the applicable Department of Justice Uniform Language and Reports document(s) and/or the applicable FBI Approved Standards for Scientific Testimony and Report Language document(s). In addition, these exercises will test a trainee's ability to accurately and clearly explain an examination process and analysis using lay terms, as well as their resulting opinions/interpretations, within a mock courtroom setting. The ability of the trainee to appropriately defend challenges presented to both expert qualifications and scientific testimony will also be tested.

### **2 Scope**

These practices apply to FBI Laboratory personnel who are training to become forensic examiners and as part of their job duties will be providing testimony regarding the results of their examinations; personnel who facilitate, record, and/or review training; and other personnel who are directed by Unit Chiefs and/or Executive Management to participate in a Moot Court/Admissibility Hearing exercise(s).

### **3 Practices**

#### **3.1 Establishing Moot Court/Admissibility Hearing Exercises**

A minimum of three Moot Court exercises, to include one Admissibility Hearing exercise, are required to be successfully completed by the trainee. Training manuals may require more than three exercises to cover the expertise in a discipline/category(ies) of testing. See the LOM - Practices for the Forensic Examiner Training Program for information regarding the process for establishing and modifying the required number of moot exercises in the trainee's training plan.

The trainee must successfully complete all of the Moot Court/Admissibility Hearing exercises indicated in their training plan for a specific discipline/category(ies) of testing to be eligible to become a qualified and authorized examiner in that discipline/category(ies) of testing.

**3.1.1** The Training Program Manager (TPM) and Technical Leader will determine the applicable discipline/category(ies) of testing to be covered in each exercise.

**3.1.2** A written summary of expectations will be provided to the trainee by the TPM a minimum of 30 calendar days prior to each exercise. The summary of expectations must include:

- Objectives of the Moot Court/Admissibility Hearing exercise.
- Case requirements, when appropriate.
- Admissibility requirements, when appropriate.
- Focus of the direct examination.
- Focus of the cross examination.
- Performance-based assessment rubric - *Forensic Examiner Training Program Moot Court Exercise Rubric - Admissibility* (7-277) (Appendix A) or *Forensic Examiner Training Program Moot Court Exercise Rubric - Case Presentation* (7-278) (Appendix B), as appropriate
- An evaluation plan utilizing the performance-based rubric that outlines trainee proficiency and rating requirements to successfully complete the exercise.
- Suggested preparation for the Moot Court/Admissibility Hearing exercise.

**3.1.3** The TPM will ensure that preparation for the first Moot Court/Admissibility Hearing exercise includes a practice session that uses the performance-based assessment rubric in which feedback and suggestions for improvement are provided. This session may be video recorded and available for review by the trainee. The assessment rubric and any video recordings of practice sessions are not required to be retained within the trainee's training record.

**3.1.3.1** Additional practice Moot Court/Admissibility Hearing exercise(s) may be added at any time during the training program to assist the trainee with testimony preparation.

## **3.2 Coordinating Moot Court/Admissibility Hearing Exercises**

**3.2.1** The TPM will ensure the coordination of each Moot Court/Admissibility Hearing exercise and notify the Forensic Examiner Training Program Manager (FETPM) of the anticipated exercise date. The coordination of the exercise will encompass identifying, reserving, and arranging an appropriate space to provide a mock courtroom setting. Additionally, the TPM must ensure that the exercise will be video recorded.

**3.2.2** A licensed attorney will participate in Moot Court/Admissibility Hearing exercises. Any Moot Court/Admissibility Hearing exercise leading up to the final moot court will have, at minimum, one licensed attorney present within one of the three roles: judge, prosecutor, or defense attorney. For the final Moot Court exercise, licensed attorneys will participate in all attorney roles (i.e., judge, prosecutor, and defense). The FETPM will coordinate with personnel from Office of the General Counsel (OGC) to select licensed attorneys with appropriate experience.

**3.2.3** The trainee will initiate and participate in a pretrial conference with the prosecuting attorney that is assigned to the mock case. This may be conducted in-person or over the phone, however an in-person conference is recommended.

**3.2.4** Subject Matter Experts (SMEs) in the discipline(s)/category(ies) of testing will assist the participating attorneys, as needed, with preparing for the Moot Court/Admissibility Hearing exercise as well as during the exercise.

**3.2.5** To ensure the timely coordination of the Moot Court/Admissibility Hearing process among all the participants, the FETPM will provide OGC with regular trainee status reports which will indicate when a Moot Court/Admissibility Hearing is approaching within at least a six-week timeframe.

**3.2.6** The confirmation of the selected Moot Court/Admissibility Hearing date, the identification of the licensed attorney(s), and the initiation of the discovery request must occur at least 30 calendar days prior to the exercise. It is recognized that extenuating circumstances can occur and impact these dates. In these instances, communication between the TPM, FETPM, and OGC must establish an appropriate alternative timeframe.

**3.2.7** The trainee will be responsible for preparing and distributing the discovery packet for distribution to the participants of the Moot Court/Admissibility Hearing.

### **3.3 Evaluating Moot Court/Admissibility Hearing Exercises**

Each Moot Court/Admissibility Hearing exercise will be evaluated by a Moot Court panel consisting of three evaluators, all of whom have FBI expert testimony experience. Two evaluators will be SMEs selected by the trainee's TPM, Unit Chief, and/or Technical Leader. The third evaluator will be from another unit in the FBI Laboratory and selected by the FETPM. The TPM will ensure that each evaluator receives a copy of the summary of expectations (see section 3.1.2).

**3.3.1** Each Moot Court panel member will complete the *Moot Court Exercise - Admissibility Evaluation Form* (7-279) (Appendix C) or the *Moot Court Exercise - Case Presentation Evaluation Form* (7-280) (Appendix D), as appropriate, in accordance with the established proficiency and rating level defined for that exercise. Each Moot Court panel member will complete the appropriate Evaluation Form in its entirety immediately after the conclusion of the exercise.

**3.3.1.1** Notes supporting the evaluation will be recorded on or attached to the *Moot Court Exercise - Admissibility Evaluation Form* or the *Moot Court Exercise - Case Presentation Evaluation Form* and must be retained as official training records. A recorded evaluation rating of "Basic" or less must contain supporting examples or feedback.

**3.3.1.2** Each Moot Court panel member will provide their Evaluation Form to the TPM or designee. The TPM or designee will use the *Moot Court Exercise - Admissibility Evaluator Score Tally Form* (7-281) (Appendix E) or the *Moot Court Exercise - Case Presentation Evaluator Score Tally Form* (7-282) (Appendix F), as appropriate, to record the ratings and result of the exercise.



**3.3.2** The FETPM and/or the TPM will request that the participating attorneys and those serving in a juror role, as applicable, provide feedback on the trainee's performance, as well as the Moot Court process. This feedback will be recorded on the *Forensic Examiner Training Program Moot Court Exercise - Attorney Worksheet* (7- 283) (Appendix G) or the *Forensic Examiner Training Program Moot Court Exercise - Juror Worksheet* (7-284) (Appendix H), as appropriate, reviewed with the trainee, and retained by the FETPM. A copy of completed forms will be provided to the trainee upon request.

### **3.4 Post-Exercise Requirements**

**3.4.1** The TPM will ensure the *Moot Court Exercise - Admissibility Evaluation Form* or the *Moot Court Exercise - Case Presentation Evaluation Form*, as appropriate, and the *Moot Court Exercise - Admissibility Evaluator Score Tally Form* or the *Moot Court Exercise - Case Presentation Evaluator Score Tally Form*, as appropriate are reviewed with the trainee and that these reviews are recorded.

**3.4.1.1** The FETPM will ensure the *Forensic Examiner Training Program Moot Court Exercise - Attorney Worksheet* and the *Forensic Examiner Training Program Moot Court Exercise - Juror Worksheet*, are reviewed with the trainee.

**3.4.2** The TPM will ensure the video recording of Moot Court/Admissibility Hearing exercise is maintained with the trainee's training record.

**3.4.2.1** Upon a trainee's request, a copy of the video recording of the Moot Court/Admissibility Hearing exercise will be provided for the trainee's review.

**3.4.2.2** If the trainee discontinues the training program or is removed from the training program, the video recording will be maintained within the trainee's training record.

**3.4.3** If the trainee successfully completes the Moot Court/Admissibility Hearing exercise, the TPM will ensure this is recorded in the trainee's training record.

**3.4.4** If the trainee fails to successfully complete a Moot Court/Admissibility Hearing exercise, the FETPM will notify the Quality Manager in writing within one calendar day. If the FETPM is not present, the TPM will notify the Quality Manager in writing within one calendar day.

**3.4.5** The FETPM will coordinate and serve on the Root Cause Panel.

**3.4.5.1** All members from the Moot Court panel, and other training personnel as requested by the FETPM, will serve on the Root Cause panel.

**3.4.5.2** The Quality Manager will ensure a facilitator is selected to serve on the Root Cause Panel.

**3.4.6** The Root Cause Panel will meet within seven calendar days to determine the root cause(s) of the trainee's failure of the Moot Court/Admissibility Hearing exercise.

**3.4.7** The Root Cause Panel will interview the trainee and discuss the *Moot Court Exercise - Admissibility Evaluation Form* or the *Moot Court Exercise - Case Presentation Evaluation Form*, as appropriate, and the *Moot Court Exercise - Admissibility Evaluator Score Tally Form* or the *Moot Court Exercise - Case Presentation Evaluator Score Tally Form*, as appropriate to assist in determining the root cause(s) of the failure.

**3.4.8** After determining the root cause(s), the Root Cause Panel will propose a remediation plan to the trainee's Unit Chief, trainee, TPM, and Technical Leader. The facilitator will record the root cause(s) and remediation plan in a *Corrective Action Request* (7-254) according to the LOM - Practices for Addressing a Nonconformity.

### **3.5 Establishing Repeat Moot Court/Admissibility Hearing Exercises**

**3.5.1** The trainee will have a second opportunity to successfully complete the same Moot Court/ Admissibility Hearing exercise. The *Corrective Action Request* must be closed prior to the second attempt at the Moot Court/ Admissibility Hearing exercise. The repeated Moot Court/Admissibility Hearing exercise will have the same case scenario although different questions may be asked.

**3.5.2** If the trainee fails to successfully complete a second attempt at the same Moot Court/Admissibility Hearing exercise, the trainee will be removed from the Forensic Examiner training program.

## **4 Records**

The following records are generated and permanently retained in the trainee's training record as a result of these practices, except as noted:

- Summary of expectations for each Moot Court/ Admissibility Hearing exercise (see section 3.1.2).
- *Forensic Examiner Training Program Moot Court Exercise Rubric - Admissibility*
- *Forensic Examiner Training Program Moot Court Exercise Rubric - Case Presentation*
- *Moot Court Exercise - Admissibility Evaluation Form* and any supporting notes not included on the form
- *Moot Court Exercise - Case Presentation Evaluation Form* and any supporting notes not included on the form
- *Moot Court Exercise - Admissibility Evaluator Score Tally Form*
- *Moot Court Exercise - Case Presentation Evaluator Score Tally Form*
- *Forensic Examiner Training Program Moot Court Exercise - Attorney Worksheet* (retained by the FETPM)

- *Forensic Examiner Training Program Moot Court Exercise - Juror Worksheet* (retained by the FETPM)
- Video recording of each Moot Court/Admissibility Hearing exercise.
- If applicable, a copy of any *Corrective Action Request* and corresponding records.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
8	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: clarified Sections 1 and 2, removed the Responsibilities section, added requirements regarding coordination, evaluation, and post-exercise requirements to include performance-based rubrics, a defined evaluation plan, a practice session, eight new forms, and the TPM will ensure that each evaluator receives a copy of the summary of expectations. Removed the requirement for QA Specialist on root cause panel and changed from working to calendar days. Discontinued use of the 7-265 and added new appendices A-H (forms 7-277, 278, 279, 280, 281, 282, 283, 284).
9	06/03/19	Added DOJ ULTR documents to section 1. Modified requirement in section 3.1.3 to require a practice session prior to the first moot court exercise. In section 3.2.1, added requirement to notify the FETPM of the exercise date. Changed requirement to 30 calendar days in section 3.2.6. Added section 3.3.1.1 requiring notes supporting the evaluation to be recorded and retained. Modified section 3.3.2 to request attorney and juror feedback. Revised section 3.4.5.2 to provide flexibility in selection of a facilitator. Updated list of records in section 4 to include supporting notes. Updated list of references in section 5. Revised evaluation and tally forms in Appendices C-F.

### **Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019









































## **FBI Laboratory Practices for Validating Chemical Procedures**

### **1 Purpose**

These practices provide direction for validating chemical procedures prior to the procedures being introduced into casework in the FBI Laboratory. Validation is the acquisition of test data using the proposed methods and procedures to demonstrate that the expected outcome is reproducible and reliable results are achieved. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and Laboratory Operations Manual (LOM), as well as the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are authorized to validate technical procedures used for chemical analyses. These practices supplement the requirements in the LOM - Practices for Developing Methods and Validating Technical Procedures. For categories of testing that have validation requirements specified by other authoritative bodies, those requirements may supersede these practices.

### **3 Practices**

#### **3.1 Validation**

The following will be conducted and recorded when validating chemical procedures in the FBI Laboratory.

##### **3.1.1 Define the Scope of Validating the Chemical Procedure**

The scope of the chemical procedure will be recorded. The scope will declare the targeted matrices and analyte(s), analytical technique(s), specific equipment, intended application of the chemical procedure, and acceptable limits, when possible. The application of a chemical procedure will generally fall into the following categories:

- Screening for the presence or absence of a specified analyte or class of analytes
- Qualitative identification of a specified analyte or class of analytes
- Quantitation of a specified analyte or class of analytes

##### **3.1.2 Identify the Performance Characteristics of the Chemical Procedure**

The performance characteristics will vary depending on the scope of the procedure. This decision requires professional judgment. For example, some performance characteristics are not

relevant to particular sample types, but in most instances, the following performance characteristics must be considered.

#### **3.1.2.1 Performance Characteristics for the Screening of an Analyte or Class of Analytes**

- Limit of Detection
- Processed Sample Stability
- Interferences

#### **3.1.2.2 Performance Characteristics for the Qualitative Identification of an Analyte or Class of Analytes**

- Limit of Detection
- Processed Sample Stability
- Interferences

#### **3.1.2.3 Performance Characteristics for the Quantitation of a Specified Analyte or Class of Analytes**

- Accuracy
- Calibration Model
- Carryover
- Ionization Suppression/Enhancement
- Limit of Detection
- Limit of Quantitation
- Precision
- Processed Sample Stability
- Interferences

### **3.1.3 Establishing a Validation Plan**

Based on the scope, a validation plan will be recorded and technically reviewed prior to initiating the validation study. The validation plan will be generated, reviewed, and approved according to the LOM - Practices for Developing Methods and Validating Technical Procedures. The plan will include the analytical method(s), specific equipment, and sample preparation techniques(s) to be used for the chemical procedure. Further, it will record the validation requirements of the procedure, as well as the limits of the method that will allow it to be fit for use. The validation plan will provide direction for the experiments that will be performed and acceptance criteria for each performance characteristic. The validation study will include the minimum requirements as described in the LOM - Practices for Developing Methods and Validating Technical Procedures.

### **3.1.4 Conduct Validation Experiments**

The following requirements are the minimum for assessing the listed performance characteristics. In certain instances, it may be beneficial to use more samples than indicated to achieve more statistically meaningful results. The experiments are listed alphabetically and not necessarily in procedural order.



### 3.1.4.1 Accuracy

Accuracy is the closeness of a measured value to the known, or “true” value and is typically reported as a percent difference. The accuracy of an analytical method can be estimated by measuring materials of known composition (e.g., reference materials) and comparing the result(s) with the true value(s). Matrix-matched reference materials are preferred for estimating accuracy. When practical, these samples are obtained from an independent source rather than produced by the same person(s) performing the validation. The samples should be evaluated near the extremes of the calibration range, but may also include a sample near the middle of the calibration curve.

At a minimum, five data sets consisting of two different concentrations or amounts analyzed in triplicate are collected over multiple days or in successive runs using a new calibration curve with each set. The accuracy is calculated as the percent difference of the grand mean at each concentration level from the respective known value as follows:

$$\text{Accuracy at Concentration}_x = \left[ \frac{\text{Grand Mean of Calculated Concentration}_x - \text{Known Concentration}_x}{\text{Known Concentration}_x} \right] \times 100$$

In most instances, the preferred accuracy is  $\pm 15\%$  or better but higher values may be unavoidable, especially near the limit of quantitation (Section 3.1.4.6). The acceptable range will depend on the matrix analyzed (e.g., biological, water, solid mixture) and the equipment employed. In any situation, the percent difference must fall within  $\pm 30\%$ .

### 3.1.4.2 Calibration Model

The calibration model must be determined for quantitative methods. This is accomplished by first determining the range of analyte concentrations over which the method may be used. Within this range, there will be a relationship between the signal response and the analyte concentration in the sample. The calibration model is the mathematical model used to describe this relationship. The choice of an appropriate model is necessary for accurate and reliable quantitative results.

To establish the calibration model, analysis of matrix-matched, spiked calibrator samples is carried out. The calibrator samples should span the range of concentrations expected. At least five different non-zero concentration levels must be used to establish the calibration model. The concentration levels should be evenly spaced over the calibration range. A minimum of three replicates per concentration level must be analyzed and the combined data used to establish the calibration model.

The most often used calibration model is the least squares model for linear regression, although it should be noted that this model is only applicable when there is constant variance over the whole concentration range. When there is a significant difference between variances at the lowest and highest concentration levels, a weighted least squares model should be applied. Ultimately, the simplest calibration model that adequately describes the concentration-response relationship

should be used.

A calibration model can be visually evaluated using residual plots. These allow one to check for outliers that should be eliminated if found to be statistically significant. Residual plots also allow one to determine if the variances appear equal across the calibration range (similar degree of scatter at each level). Finally, they give an indication if the chosen model adequately fits the data (random distribution of individual points). It is emphasized that a calibration model cannot be evaluated simply via its coefficient of correlation. More appropriate alternatives are the Analysis of Variance (ANOVA) lack-of-fit test for unweighted models or checking for significance of the second order term in quadratic (second order polynomial) models.

Once the calibration model has been established, fewer calibration levels and replicates may be used for routine analysis and additional validation experiments, provided the lowest and highest calibration samples continue to be used. For example, if nine calibration samples (e.g., 1, 5, 10, 15, 20, 25, 30, 50, 75 ppm) are used to establish the calibration model, it is acceptable to use less calibration samples (e.g., 1, 10, 20, 50, 75 ppm) for routine use of the method.

#### **3.1.4.3 Carryover**

Carryover is the appearance of an analyte signal in blank samples after the analysis of a positive sample. Carryover will be evaluated during method development and its source investigated. This can be accomplished by running matrix blank samples immediately after a high concentration sample or calibration standard. If possible, the analytical procedure will be modified to remove any carryover. In cases when it is not possible to eliminate the carryover, the SOP must address how carryover will be managed (e.g., the signal in case sample must be ten times greater than the signal in a blank sample immediately preceding the case sample).

#### **3.1.4.4 Ionization Suppression/Ionization Enhancement**

The enhancement or suppression of analyte ionization resulting from the presence of co-eluting matrix components is a phenomenon commonly encountered in liquid chromatography/mass spectrometry (LC/MS). Ionization suppression/enhancement experiments may be performed during the method development phase to ensure that extraction technique and instrumental conditions are properly optimized. It can be further evaluated during the validation phase using either of the following approaches:

##### **3.1.4.4.1 Post-Column Infusion to Assess Ionization Suppression/Enhancement**

The post-column infusion approach provides information on retention times where ionization suppression/enhancement occurs. A solution of the analyte is constantly infused with a syringe pump into the mobile phase from the column via a post-column tee-connection and a constant, baseline signal for the analyte of interest is collected in the mass spectrometer using the method parameters. A minimum of five different extracted matrix blanks are injected into the LC/MS. If there is any considerable suppression or enhancement of the infused analyte signal at the retention time of the analyte, then modification of the chromatographic system or the sample preparation may be required to minimize the effect of ionization suppression or enhancement.

#### **3.1.4.4.2 Post-Extraction Addition Approach to Assess Ionization Suppression/Enhancement**

The post-extraction addition approach yields a quantitative estimation of ionization suppression/enhancement. Two different sets of samples are prepared and the analyte peak areas are compared between sets to evaluate the ionization suppression/enhancement effects. The first set consists of the neat standards at both low and high concentrations run a minimum of two times each. Set two is made of a minimum of five samples extracted from different matrix sources fortified with the analyte(s) of interest after extraction (at both low and high concentrations). The average area of each set ( $\bar{X}$ ) is used to estimate the suppression/enhancement effect at each concentration as follows:

$$\text{Ionization Suppression/Enhancement (\%)} = [ \bar{X} \text{ Area Set 2} / \bar{X} \text{ Area Set 1} ] * 100$$

Again, the effect of ionization suppression or enhancement should be minimized during the method development phase. In instances when it is not possible to eliminate the enhancement or suppression, the SOP must address how it will be managed.

#### **3.1.4.5 Limit of Detection**

The limit of detection (LOD) is an estimate of the lowest concentration or smallest amount of an analyte that can be reliably differentiated from the analyte-free matrix or the background noise. For methods that incorporate identification criteria (e.g., mass spectral comparison criteria), these criteria should be met in order for the sample(s) to be considered reliably differentiated. In some instances, it may not be necessary to establish the absolute LOD, provided it is shown to be less than the lowest concentration required by the method. Because a procedure's LOD incorporates the instrumental performance, as well as the sample matrix and inherent procedural limitations, it may be important to assess LOD over multiple days.

The LOD may be determined by one or more of the following approaches:

##### **3.1.4.5.1 Estimating LOD for Screening Methods**

Matrix-matched samples at decreasing concentrations are analyzed in duplicate to estimate the LOD for methods that screen for the presence or absence of a specified analyte or class of analytes (e.g., chemical color tests).

##### **3.1.4.5.2 Estimating LOD Using Background Noise**

The following approaches may be used for determining the LOD of methods that demonstrate equipment-related background noise.

###### **3.1.4.5.2.1 Estimating LOD Using Reference Materials**

For estimating the LOD using reference materials, two or more replicates of matrix-matched reference materials at known concentrations are analyzed. The LOD is defined as the smallest

amount (or concentration) of an analyte that reproducibly yields a reliable signal greater than or equal to three times the noise level of the background signal.

#### **3.1.4.5.2.2 Estimating LOD Using Statistics**

The LOD may also be determined by statistically comparing results obtained from blank matrix samples and matrix-matched reference materials at known concentrations. At least three blank or negative samples are analyzed. The average signal ( $\bar{X}$ ) and its standard deviation ( $\sigma$  or SD) for these blank samples are calculated. Likewise, matrix-matched reference materials at decreasing concentrations are analyzed in triplicate, however the triplicate signals are evaluated independently and not averaged. The LOD is considered as the lowest concentration of a reference material that consistently yields a signal greater than the average signal of the negative samples plus 3.3 times the standard deviation of the concentrations as:

$$\text{LOD} = \bar{X} + 3.3(\sigma)$$

#### **3.1.4.5.3 Estimating LOD Using Calibration Curves**

The use of the lowest non-zero calibrator or a linear calibration curve are appropriate approaches for quantitative procedures.

##### **3.1.4.5.3.1 Estimating LOD Using Concentration of Lowest Non-Zero Calibrator**

In some instances, it may be sufficient to define the detection limit as the value of the lowest acceptable non-zero calibrator (Section 3.1.4.2). A minimum of three replicates of the lowest calibrator will be analyzed. It is acceptable to use the replicates generated to establish the calibration model.

##### **3.1.4.5.3.2 Estimating LOD Using a Linear Calibration Curve**

A linear calibration model is useful for estimating the LOD for quantitative procedures. A minimum of three calibration curves are constructed (Section 3.1.4.2). The LOD can be estimated from the standard deviation of the y intercept ( $\sigma_y$ ) and the average slope ( $m_{\text{avg}}$ ) as:

$$\text{LOD} = (3.3 \sigma_y)/m_{\text{avg}}$$

#### **3.1.4.6 Limit of Quantitation**

The limit of quantitation (LOQ) is an estimate of the lowest concentration or smallest amount of an analyte that can be reliably differentiated and quantitated from analyte-free matrix. For methods that incorporate identification and/or quantitation criteria (e.g., mass spectral comparison criteria), these criteria should be met in order for the sample(s) to be considered reliably differentiated and/or quantitated. In some instances, it may not be necessary to establish the absolute LOQ, provided it is shown to be at least that of the lowest non-zero calibrator. Because a procedure's LOQ incorporates the instrumental performance, as well as the sample

matrix and inherent procedural limitations it may be important to assess LOQ over multiple days.

The LOQ may be estimated by one or more of the following approaches:

#### **3.1.4.6.1 Estimating LOQ Using Concentration of Lowest Non-Zero Calibrator**

In some instances, it may be sufficient to define the quantitation limit as the value of the lowest acceptable non-zero calibrator (Section 3.1.4.2). A minimum of three replicates of the lowest calibrator will be analyzed. It is acceptable to use the replicates generated to establish the calibration model.

#### **3.1.4.6.2 Estimating LOQ Using Reference Materials**

Triplicates of matrix-matched reference materials are analyzed and the concentrations calculated from a calibration curve constructed over the entire working range. The lowest concentration that is capable of achieving an acceptable accuracy (Section 3.1.4.1) and precision (Section 3.1.4.7) in all three measurements is considered the LOQ.

#### **3.1.4.7 Precision**

Precision is a measure of the repeatability of a series of measurements of the same sample. It is expressed as the coefficient of variation (%CV) and two different types of precision studies will be assessed during method validation: within-run precision and intermediate precision.

Matrix-matched reference materials are preferred for estimating precision. When practical, these samples are obtained from an independent source rather than produced by the same person(s) performing the validation. At a minimum, for a quantitative assay, precision will be assessed by using triplicate determinations per concentration, at two different concentrations in the expected range (low and high) over five different days or runs.

Acceptable %CV values may range from 0% to 30%. The acceptable range will depend on the matrix analyzed and the equipment employed. For most methods, 20% or better is preferred, although  $\leq 30\%$  is acceptable near the LOQ.

##### **3.1.4.7.1 Within-Run Precision Calculations**

Within-run precisions may be calculated using the data from the first triplicate analyses of the sample sets as:

$$\text{Within-run CV(\%)} = \frac{\text{SD of day 1 samples}}{\text{mean calculated value of day 1 samples}} \times 100$$

##### **3.1.4.7.2 Intermediate Precision Calculations**

Intermediate precisions may be calculated using the combined data from the multiple analyses as:

$$\text{Intermediate CV}(\%) = \frac{\text{SD of combined means for each level}}{\text{grand mean for each level}} \times 100$$

### 3.1.4.7.3 One-way ANOVA Approach to Calculating Within-Run and Intermediate Precision

Both within-run and intermediate precisions may be calculated using the one-way ANOVA approach with the varied factor (run number) as the grouping variable. Using this approach, within-run precisions are calculated as:

$$\text{Within - run CV}(\%) = \left[ \frac{\sqrt{MS_{wg}}}{\text{grand mean for each level}} \right] \times 100$$

where  $MS_{wg}$  is the mean square within groups obtained from the ANOVA table.

Likewise, intermediate precisions are calculated as:

$$\text{Intermediate CV} = \left[ \frac{\sqrt{\frac{MS_{bg} + (n-1) \cdot MS_{wg}}{n}}}{\text{grand mean for each level}} \right] \times 100$$

where  $MS_{bg}$  is the mean square between groups obtained from the ANOVA table and  $n$  is the number of observations in each group (e.g.,  $n=3$  when doing triplicate analyses). An example can be found in Appendix A.

### 3.1.4.8 Processed Sample Stability

Circumstances may arise in which samples that have undergone routine preparation cannot be immediately analyzed. It may be necessary to run the sample the following day or later. In these instances, it is important to evaluate the length of time a prepared sample can be maintained before it undergoes unacceptable changes, preventing reliable detection or quantitation.

Reference materials at low and high concentrations in appropriate matrices are processed and used for stability determinations. It is important to ensure that sufficient quantity is prepared to complete this evaluation, keeping in mind that it may be necessary to split the sample into multiple portions.

The first portion of these samples will be immediately analyzed in triplicate. The remaining portions are analyzed in triplicate at different time intervals and responses are compared. For example, samples in different autosampler vials may be analyzed every 8 hours up to 72 hours. The average responses for analytes of interest and any internal standards are used to evaluate significant changes over the duration of the study. The analyte or internal standard will be considered as stable until average signal decreases to 80% or increases above 120% of the original average response.

### **3.1.4.9 Interference Studies**

Interference studies are used to assess the selectivity of a method. Selectivity is the extent to which an analytical procedure is free from interferences arising from non-analytes, including matrix components which may be expected to be present. Selectivity can often be improved by modifying instrumental parameters (e.g., using a different column in chromatography or monitoring an alternate emission line in emission spectroscopy).

The use of an alternate analytical procedure for verification of analytical findings is an additional assessment of selectivity. Whenever possible, orthogonal analytical techniques will be employed to respond to different properties of a particular analyte. For example, Fourier Transform Infrared Spectroscopy (FTIR) and mass spectrometry are orthogonal to each other, while FTIR and Raman spectroscopy are complementary, but non-orthogonal.

#### **3.1.4.9.1 Matrix Interferences**

Matrix interferences are usually sample specific and will be addressed on a matrix-by-matrix basis. When applicable, analyze a minimum of 10 matrix blanks from different sources to demonstrate the absence of interferences in the matrix.

#### **3.1.4.9.2 Other Interferences**

In certain instances, it is necessary to check for possible interferences from other analytes which may be expected to be present in authentic samples. For example, a method for analyzing blood samples for cocaine must be evaluated for interferences caused by the blood matrix, but also evaluated for common drugs of abuse (e.g., opiates, cannabinoids, amphetamines). This is accomplished by analyzing a negative matrix spiked with the potential interference(s) at appropriate concentration(s). Alternatively, neat injection standards of potentially interfering compounds can also be injected for this evaluation.

#### **3.1.4.9.3 Stable-Isotope Internal Standard Interferences**

In methods using stable isotope-labeled analogs, the isotopically-labeled compounds may contain the non-labeled compound as an impurity. Additionally, the mass spectra of the labeled analogs may contain fragment ions with the same mass-to-charge ratios as the significant ions of the target analyte. In both instances, the peak area of the analyte peak would be overestimated, thus compromising quantitation.

Internal standard interferences are assessed by analyzing a blank sample spiked with the internal standard and monitoring the signal of the analyte(s) of interest. Likewise, a blank sample spiked with the analyte(s) at the upper limit of the calibration range is analyzed without internal standard, to evaluate if the unlabeled analyte ions appear as isotopically-labeled compound fragments.

### 3.2 Modification of Previously Validated Procedures

Modifications to a validated method require verification that the changes do not have an adverse effect on the method's performance. The decision regarding which performance characteristics require additional validation will be based on logical consideration of the specific parameters likely to be affected by the change(s). These changes may include, but are not limited to:

- Analytical conditions
- Equipment
- Sample processing
- Data software

For example, changes of extraction solvent or a buffer may affect linearity, selectivity, LOQ, precision, and accuracy. A change of the analytical column or mobile phase may affect linearity and selectivity. Further, consideration should be given to conducting parallel studies with known samples utilizing both a previously validated procedure and the modified procedure in order to evaluate the effects of the changes. The goal is to demonstrate the changes do not negatively impact the performance of the previously validated procedure. Any modifications to validated chemical procedures will follow the requirements of the LOM – Practices for Developing Methods and Validating Technical Procedures.

### 3.3 Technical Review of Validation Records

The technical review and approval of all validation records will be conducted in accordance with the LOM - Practices for Developing Methods and Validating Technical Procedures. The technical review(s) will be recorded on the *Validation of Chemical Procedures Review Form* (7-267) (Appendix B).

### 3.4 Efficiency with Validation

It is recognized that method validation is a time-consuming endeavor. Personnel should keep in mind that some validation experiments may be conducted concurrently. Appendices C, D, and E present examples to assist in streamlining validation experiments.

## 4 Records

The data generated during method validation studies must be recorded and available for audits, reviews, or inspections. These records must be easily retrievable. Further, the records must refer to the appropriate SOP(s).

Validation records must include a summary of the studies conducted and their results. The records will include the following:

- Scope
- Validation plan
  - Description of all the performance characteristics that have been



evaluated. If any of the above required performance characteristics have not been evaluated, then the reason must be stated or justified.

- Sample preparation steps to include concentrations and matrices
- Raw data or reference to where the raw data may be found
- Results and calculations
- Conclusions
- References
- *Validation of Chemical Procedures Review Form*

It is important that the validation records contain specific details regarding the studies conducted, including:

- Personnel involved in the validation
- Specific equipment
- Dates

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Rev. #	Issue Date	History
4	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: removed the Responsibilities section and clarified that these practices are supplemental to the Practices for the Development of Methods and Validation of Technical Procedures.
5	06/03/19	Updated scope in section 2 to specify that personnel must be authorized to perform validations. Modified section 3.1.3 for consistency with LOM - Practices for Developing Methods and Validating Technical Procedures. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019













## **FBI Laboratory Practices for the Forensic Examiner Training Program**

### **1 Purpose**

These practices provide the structure, training requirements, and feedback mechanisms for Forensic Examiner Trainees (FETs) and the Forensic Examiner (FE) training programs (FETP). Following these practices will result in a common understanding of training expectations and training progress. Feedback will be solicited from the FETs and personnel who facilitate, record, and/or review training (e.g., trainers, mentors) that can be used to strengthen the overall training program.

### **2 Scope**

These practices apply to FBI Laboratory FETs and personnel who facilitate, record, and/or review training.

### **3 Practices**

An FET is required to complete all training as detailed in their training plan.

#### **3.1 Initiation of the Forensic Examiner Training Program**

##### **3.1.1 Trainee Assessment and Development of Training Plan**

Prior to the initiation of the FE training program, the Technical Leader will conduct an assessment (e.g., review of previous experience, written/verbal evaluation) of an FET's level of knowledge and skills regarding the specific discipline and/or category(ies) of testing the FET will be trained in. The purpose of the assessment is to determine if the FE training program should be modified.

Based on the assessment conducted by the Technical Leader, the Training Program Manager (TPM) will ensure a training plan is developed and provided to an FET within 45 calendar days of initiating the training program. This plan will contain a list of training exercises and projected completion dates. The projected completion dates in the training plan are subject to change. This change does not need to be recorded.

##### **3.1.1.1 Training Program Modifications**

If it is determined that fewer than the unit, discipline and/or category(ies) of testing training program's required number of exercises are needed due to the trainee's prior experience, the training plan will reflect the modification to the training program. All training plans must be

approved by the Technical Leader and the trainee's Unit Chief.

### **3.1.1.2 Laboratory Division Training Requirement Modifications**

Any requests for the training plan to deviate from completing the Laboratory Division requirements for the FETP Common Core Training (CCT) course, the public speaking exercises as described in these practices, and/or the LOM - Practices for Oral Board Exercises and/or the LOM - Practices for Moot Court and Admissibility Exercises, requires approval from the Forensic Examiner Training Program Manager (FETPM) prior to implementing such changes. These changes and approval(s) will be recorded in the training plan.

**3.1.2** If an FET's progress within the training program indicates a need for a modification to their training plan, the TPM will prepare the modified training plan.

**3.1.3** A copy of the training plan(s) and any approved departures/modifications from the minimum requirements (i.e., unit, discipline and/or category(ies) of testing training program, Laboratory Division) will be maintained in the FET's training record.

**3.1.4** The TPM will ensure the FET reviews their training plan and applicable training manual for a general understanding of expectations, structure, and topics that will be covered throughout training. The TPM or appropriate training personnel will discuss the training plan and the applicable training manual with the FET. The review and discussion will be recorded within the FET's training record.

**3.2** The TPM will ensure that appropriate training resources are available to an FET.

**3.3** The Unit Chief(s) will ensure that personnel are available to provide guidance to an FET throughout their training program.

**3.4** The Technical Leader will ensure that an FET receives the necessary training to become qualified to perform their assigned work.

### **3.5 Training Requirements**

The following course and exercises must be successfully completed to be eligible to become a qualified and authorized forensic examiner in a discipline(s)/category(ies) of testing. These will be incorporated into the approved FE training plan, unless otherwise noted within the approved training plan and/or modified training plan, as appropriate:

- FETP Common Core Training (CCT) course
- Public Speaking Exercises
- Competency Test(s) as described in QAM - Section 6.2.3.1
- Supervised Casework and/or Simulated Casework Exercises
- Oral Board Exercises
- Moot Court/Admissibility Hearing Exercises

A training manual may require other exercises in addition to those listed above.

**3.5.1** An FET is required to enroll in the FETP CCT course via Virtual Academy. The FETP CCT is an online course administered by FBI Laboratory personnel. The FET must begin the course within the first six months of starting their FE position in the FBI Laboratory. Successful completion will be recorded in Virtual Academy and within the FET's training record.

**3.5.1.1** If an FET does not successfully complete the FETP CCT course, they will be given one additional opportunity to retake the course at its next offering. Two unsuccessful attempts at completing the FETP CCT course will result in the removal of the FET from the FETP.

**3.5.2** An FET is required to successfully complete a minimum of two public speaking exercises during their training. The requirements for the public speaking exercises will be listed in each appropriate training manual. The *Public Speaking Exercise Evaluation* (7-271) (Appendix A) will be used to record the evaluation of the presentations. *Public Speaking Exercise Evaluation* forms will be maintained in the FET's training record.

**3.5.3** An FET is required to complete supervised casework and/or simulated casework exercises. Each appropriate training manual will define the minimum number of supervised casework and/or simulated casework exercises to be completed. The TPM will ensure a written evaluation of the defined number of supervised casework and/or simulated casework exercises is provided to the FET. These records will be maintained in the FET's training record.

**3.5.4** An FET is required to successfully complete Oral Board exercises as required by their training plan and in accordance with the LOM - Practices for Oral Board Exercises.

**3.5.5** An FET is required to successfully complete Moot Court/Admissibility Hearing exercises as required by their training plan and in accordance with the LOM - Practices for Moot Court and Admissibility Hearing Exercises.

### **3.6 Evaluation of an FET's Training Progress**

The evaluation of an FET's training progress will be conducted through the following mechanisms:

- Monthly review of FET's training activity logs
- Quarterly evaluation of FET's training progress
- Quarterly assessment of the FET Program

**3.6.1** The FET will maintain a log of all training activities. The TPM or appropriate training personnel will review the FET's training log on a monthly basis and a record of the review will be maintained in the FET's training record.

**3.6.2** The TPM or designee will provide feedback to the FET, at a minimum on a quarterly basis, on the FET's training progress. The review of the FET's training activities, and discussion of their overall training progress and performance will be recorded in the FET's training record using

the *Forensic Examiner Trainee Evaluation* (7-270) (Appendix B).

**3.6.2.1** The FET may request, in writing, interim feedback (i.e., more frequent than quarterly), from the TPM and/or appropriate training personnel. The additional feedback on the FET's training progress and additional review of their training activities, and discussion of overall training progress and performance will be recorded in the FET's training record using the *Forensic Examiner Trainee Evaluation*.

**3.6.3** Training program assessments will be provided electronically to an FET on a quarterly basis throughout the duration of their training. The FET's feedback will be used to assess the effectiveness of the FET training program. Changes to the FET training program will be implemented when appropriate. The FETPM will ensure the review of this quarterly assessment data for all disciplines/categories of testing and the generation of the appropriate quarterly reports for dissemination.

**3.6.4** Timely written feedback (e.g., memo, email, training record sign-offs) will be given to an FET upon completion of any analytical exercise and/or scored tests/quiz.

### **3.7 Concluding the FETP**

When an FET has successfully completed their training program to the satisfaction of the Technical Leader, an Electronic Communication (EC) (FD-1057) will be prepared and approved according to QAM - Section 6.2.6 to record the FET's qualification and authorization(s).

### **3.8 Remediation within the FETP**

A written remediation plan will be generated to address an FET's failure of the FETP CCT course or a public speaking exercise and retained in the FET's training record. Unsuccessful completion of an Oral Board or Moot Court/Admissibility Hearing exercise will be handled in accordance with the LOM - Practices for Oral Board Exercises or the LOM - Practices for Moot Court and Admissibility Hearing Exercises, as appropriate. A level 2 document(s) will define requirements to address the failure of any other exercise in the FET's training plan.

### **3.9 Removal from the FETP**

An FET will be removed from the FETP in accordance with this document, the LOM - Practices for Oral Board Exercises or the LOM - Practices for Moot Court and Admissibility Hearing Exercises, as appropriate, when the second attempt at the same exercise is unsuccessful. An FET may also be removed from the FETP when they are unsuccessful at completing other aspects of the training program. The Unit Chief will be responsible for overseeing the administrative process of removing an FET from the FETP.

### **3.10 FETP Evaluation and Recommendations**

**3.10.1** The FETPM will provide written recommendations, as needed, based on data collected through quarterly training program assessments, to applicable Unit Chiefs, TPMs and

Technical Leaders regarding the FETP. The FETPM will also ensure the FBI Laboratory-wide training trends are reviewed with TPMs and when appropriate, implement changes to the FETP.

**3.10.2** The effectiveness of the FETP be evaluated through the use of electronic FETP assessments. These FETP assessments will be provided to newly qualified FEs at designated intervals after their completion of the FETP. The FETPM will ensure the FBI Laboratory-wide training trends are reviewed with the TPMs and when appropriate, implement changes to the FETP.

## 4 Training Records

The TPM will ensure that the following records are generated and retained permanently in the FET's training record, except as noted below, as a result of these practices:

- Training plan with projected dates for training exercises.
- Modified training plans, if generated.
- Log of training activities, reflecting the monthly TPM or appropriate training personnel review.
- *Forensic Examiner Trainee Evaluation* forms.
- Virtual Academy record reflecting FETP CCT course completion.
- Quarterly training program assessments reports will be retained by the Forensic Analysis Support Unit.
- Record of feedback provided for any analytical exercise and/or scored tests/quiz.
- Written evaluation of supervised casework and/or simulated casework exercises.
- Record of demonstration of competence.
- *Public Speaking Evaluation* forms.
- Copy of FE qualification and authorization EC.
- Remediation plans, if generated.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
4	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Substantive changes include: clarified Purpose section, removed the Responsibilities section, added an initial assessment of knowledge by the Technical Leader, changed from business days to calendar days, clarified roles and responsibilities, reorganized information, updated training evaluation process, updated remediation and removal processes, and updated training records requirements. Moved <i>Public Speaking Exercise Evaluation</i> to Appendix A. Renamed and updated <i>Forensic Examiner Trainee Monthly Evaluation</i> (7-270) to <i>Forensic Examiner Trainee Evaluation</i> (Appendix B). Removed <i>Forensic Examiner Trainee Quarterly Interview Form</i> (7-268) and <i>Forensic Examiner Trainee Close-Out Interview</i> (7-269).
5	06/03/19	Added section titles and reworded for clarity throughout document. In section 3.1.1.1, clarified requirements for training plan modification if need fewer than unit, discipline and/or category(ies) of testing training program's number of exercises. Added FETP CCT course in sections 3.1.1.2, 3.5, 3.5.1, 3.5.1.1, 3.8, and 4. Updated list of references in section 5. Replaced images of forms in Appendices A and B to reflect electronically fillable forms.

### **Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019









## **FBI Laboratory Practices for Processing a Submission and Evidence Breakdown**

### **1 Purpose**

These practices establish requirements for processing a submission and evidence breakdown to conform to the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in processing a submission and evidence breakdown for multi-unit submissions. For Laboratory Director and Quality Manager approved initiatives, a level 2 document will contain procedures for processing a submission and evidence breakdown for initiatives when necessary.

### **3 Practices**

Each submission (i.e., request for examination and the accompanying evidence) or request for other FBI Laboratory services deemed appropriate will be entered into Forensic Advantage (FA).

The information associated with Office of Professional Responsibility (OPR) investigations or prohibited cases will be limited to as few personnel as possible. Case information will be omitted with a notation of where the information is recorded. Evidence handling and examinations will be conducted outside of FA after generating a laboratory number. Evidence handling and examinations will still be conducted within Sample Tracking and Control System (STACS), but the information entered will be limited according to DNA discipline procedures. Personnel managing submissions outside of FA will follow this practice, where practicable, and will release all relevant records as instructed by the contributor.

#### **3.1 General Requirements for Handling Evidence**

**3.1.1** Appropriately trained personnel will ensure all evidence received in the FBI Laboratory is x-rayed and an "X-RAYED" sticker is placed on each package. Refer to the FBI policy regarding x-ray screening.

**3.1.2** Evidence Management Unit (EMU) personnel accepting packages will immediately notify the EMU Chief or their supervisor of any suspicious packages received. At the Quantico facility, EMU will contact the Health and Safety Officer, the Chief Security Officer, the Evidence Response Team Unit, and/or the Explosives Unit, as appropriate. At the Huntsville facility, EMU will contact health and safety personnel, security personnel, Explosives Unit, or a Special Agent Bomb Technician (SABT), as appropriate. Refer to the FBI policy regarding

general mailing for requirements regarding suspicious packages.

**3.1.3** EMU personnel receiving a package that was not intended for the FBI Laboratory or was submitted by a private citizen will not initiate a Chain-of-Custody Log and will not assign it a Laboratory number. The package will be stored appropriately until its disposition is arranged.

**3.1.4** If evidence packages are not immediately opened, the appropriately trained person accepting the evidence will ensure that it is under proper seal, or if the evidence cannot be placed under proper seal, that it is securely stored.

**3.1.5** If evidence is unusually heavy, too large to store in the evidence receiving area, or unsafe to store in the evidence receiving area (e.g., a package with an unusual odor), the appropriate unit will be contacted and arrangements for transferring the evidence should be made.

**3.1.6** A request for examination needs to be associated with evidence submitted to the FBI Laboratory. A request for examination may come in the following ways: Laboratory Examination Request (LER) (FD-1121), Request for Laboratory Examination (RFLE), Electronic Communication (EC) (FD-1057), lead report, Terrorist Explosive Device Analytical Center (TEDAC) *TEDAC Item Submission Form* (7-275) (Appendix A), *TEDAC Bulk Submission Form* (7-276) (Appendix B), or letter on agency letterhead.

**3.1.6.1** Each submission of TEDAC evidence will be associated with a *TEDAC Item Submission Form* or a *TEDAC Bulk Submission Form*. The *TEDAC Item Submission Form* or a *TEDAC Bulk Submission Form* will be provided to TEDAC contributors for completion when submitting evidence to TEDAC. The *TEDAC Item Submission Form* can be used when only one case is submitted to TEDAC. The *TEDAC Bulk Submission Form* can be completed when more than one case is submitted to TEDAC. Should the contributor not provide the appropriate submission form, EMU personnel will complete the *TEDAC Item Submission Form* or a *TEDAC Bulk Submission Form*, as applicable, to include in the TEDAC Case File.

**3.1.6.1.1** If the *TEDAC Item Submission Form* and/or *TEDAC Bulk Submission Form* is revised, TEDAC will notify appropriate contributors in writing and provide a copy of the revised form.

**3.1.6.2** For all other FBI contributors, if a request for examination does not accompany the evidence, appropriately trained personnel will check the pre-log in FA to determine if a request exists. If a pre-log request does not exist, personnel will verify that a request for examination is not available in Sentinel. If the request for examination is not located, the contributor will be contacted up to three times within 30 days to provide the request as soon as possible. If the contributor does not provide the request for examination in any form after three requests within 30 days, the evidence will be returned.

**3.1.6.3** For external contributors (non-TEDAC evidence), if a request for examination does not accompany the evidence, appropriately trained personnel will check the pre-log in FA to determine if a request exists. If the request for examination is not located, the contributor will be

contacted up to three times within 30 days to provide the request as soon as possible. If the contributor does not provide the request for examination in any form after three requests within 30 days, the evidence will be returned.

**3.1.7** Requests for examination submitted by FBI contributors (non-TEDAC evidence) should have a Case ID and serial number/lead number already assigned. If no serial number/lead number is listed on the LER, EC, or lead report, EMU personnel will locate the serial number/lead number.

**3.1.8** At the Quantico facility, FBI Laboratory Case File Office personnel will assign a Case ID and/or serial number for all non-FBI submissions. The Case ID number will be recorded on the request for examination. At the Huntsville facility, EMU personnel will assign a Case ID, as appropriate.

**3.1.9** If case-related information is verbally received, the person receiving the information will record that information on the Case Communication Log in FA or on the *Activity and Communication Log* (7-245), as appropriate.

**3.1.10** Laboratory personnel will ensure evidence is properly stored in order to preserve the integrity of each item and/or ensure the safety of FBI Laboratory personnel.

## **3.2 Routes for Receiving Evidence**

### **3.2.1 Evidence Received via Mail or Carrier**

**3.2.1.1** Submissions are usually received from the U.S. Postal Service or commercial carriers such as FedEx or UPS.

**3.2.1.2** Appropriately trained personnel will sign for the receipt of evidence.

**3.2.1.3** When containers not known to contain evidence are transferred to a person in a case working unit and that person is not appropriately trained to receive evidence, he/she will bring the evidence to an appropriately trained person for processing.

**3.2.1.3.1** The appropriately trained person will initiate a submission in FA.

**3.2.1.3.2** If a person who is not appropriately trained to receive evidence opened the container, that person will record the evidence transfer. If the person does not have an FA account, the electronic signature pad will be utilized to record the signature of the person that opened the container. If the person did not open the container, the appropriately trained person will record the transfer as the person first identifying the container as housing evidence.

**3.2.1.4** Chain-of-Custody forms included in a package will either be mailed back to the contributor upon discovery or at the completion of laboratory examinations when the evidence is returned. TEDAC personnel may retain the Chain-of-Custody in the 1A(s)/1C(s) rather than returning the form to the contributor. Chain-of-Custody forms included in a package will not be

signed by FBI personnel.

### **3.2.2 Evidence Received via Personal Delivery**

**3.2.2.1** Evidence personally delivered by the contributor, will be received by appropriately trained personnel.

**3.2.2.2** At the Quantico facility, personal deliveries will be received at the Evidence Delivery entrance. At the Huntsville facility, personal deliveries will be coordinated with the EMU. Contributors will not be granted access to a facility beyond the evidence receiving area. If access is required, the Laboratory Security Group will be contacted for assistance.

**3.2.2.3** The person accepting custody of evidence will initiate a submission in FA and ensure that the contributor signs the electronic signature pad for the submission in FA. A copy of the transfer receipt will be retained in the FBI Laboratory file.

**3.2.2.4** If an external contributor personally delivering evidence requests his/her Chain-of-Custody to be signed, the person will sign for receiving the sealed package(s) only and not separate items as the evidence is not broken down at this point.

### **3.2.3 Receipt of Evidence from an External Laboratory**

**3.2.3.1** Evidence returned to the Laboratory from an external laboratory will not receive a new Laboratory number. The returned evidence will be transferred to the unit that sent the evidence to the external laboratory and the receipt will be recorded within the original submission in FA as appropriate.

### **3.2.4 Receipt of Evidence Submitted Electronically**

**3.2.4.1** When evidence submitted electronically (e.g., email attachments, evidence serialized in Sentinel by FBI contributors and retrieved by Laboratory personnel for examination) is received by FBI Laboratory personnel who are not appropriately trained to receive evidence, an appropriately trained person will be contacted to initiate a Submission in FA.

**3.2.4.2** The examiner assigned to the case will handle the case according to the Laboratory Operations Manual (LOM) – Practices for Processing a Single Unit Submission.

**3.2.4.3** If evidence that has been submitted electronically is subsequently submitted to the Laboratory in physical form, EMU personnel will determine if the submission is handled as a single unit submission or a multi-unit submissions.

### **3.3 Assessing the Shipping Container(s) and/or Outermost Evidence Package(s)**

**3.3.1** When an appropriately trained person initially identifies a container as housing evidence, the person will open the container to retrieve the incoming request for examination. If the request is not received with the evidence, the person will follow the requirements in sections

3.1.6.2 or 3.1.6.3.

**3.3.2** If damage is observed prior to opening the container, the person will photograph the damage and upload the photo to the FA Case Object Repository.

**3.3.3** The person who retrieved the incoming communication will ensure the shipping container is properly sealed prior to storage.

**3.3.4** When evidence is received without a packaging layer, unsealed, or sealed without tamper-evident tape, personnel will place a proper seal on the packaging.

**3.3.4.1** When an evidence package is received sealed with tape, but without the initials of the sealer, personnel will place a piece of tape across the existing seal. This new tape seal will be placed in a generally perpendicular manner such that it overlaps the initial seal. This person will also initial that tape onto the packaging, where practicable.

**3.3.4.2** When the shipping container is used as the evidence package, the person assessing the seal will reseal the shipping container with a proper seal.

**3.3.4.3** When properly sealing evidence packages housing paper or potential evidence for questioned documents, the person sealing the package will initial the tape prior to placing it on the package if the package is not rigid.

### **3.3.5 Biohazard Labeling**

**3.3.5.1** The person who initially receives the container will verify that the outer container is appropriately labeled with a biohazard label to identify any potentially infectious items contained within.

**3.3.5.2** If a container housing biohazardous material is not appropriately labeled, it will be labeled by the person who opens the container prior to transfer.

## **3.4 Multiple Cases in One Package Submitted Under One Request for Examination**

If evidence for multiple cases is received in one package with one request for examination, it may be returned to the contributor prior to inventory and examination, for the contributor to provide the separate requests for examination. Alternatively, EMU personnel may proceed with initiating the submission.

### **3.4.1 Proceeding with a Multiple Case Submission**

EMU personnel will initiate a submission for each request and ensure an appropriate request for examination is associated with each case.

### **3.4.1.1 External Submissions**

For submissions received via the FBI Laboratory Contributor Portal, the contributor will be contacted and instructed to complete a separate RFLE through the FBI Laboratory Contributor Portal for each submission. Alternatively, EMU personnel will manually enter the additional submissions into FA, ensuring that the same agency and contributor is used as in the original pre-log request. The RFLE will be utilized for each case submitted in the evidence package.

For submissions not received via the FBI Laboratory Contributor Portal and where the included request for examination is applicable to all cases, a copy of the request for examination will be utilized for each case submitted in the evidence package.

### **3.4.1.2 Internal Submissions with Multiple Case IDs**

For internal submission with multiple Case IDs, the EMU personnel will verify that the request for examination (e.g., LER, EC) has been serialized in each Case ID. If not, the contributor will be contacted and instructed to serialize the request in each Case ID. If evidence is included in the package, and the associated Case ID(s) is not referenced on the original request, the contributor will be contacted and instructed to serialize an additional request referencing the appropriate Case ID(s). Three attempts will be made and the contributor will have 30 days to submit the additional request or the evidence will be returned.

## **3.5 Multiple Cases in One Package Submitted Under Separate Requests for Examination**

Evidence for multiple cases may be received in one package submitted under separate requests for examination. When a package containing evidence from more than one case is submitted with more than one request for examination, EMU personnel will initiate a submission for each request, ensure a Case ID is assigned, and ensure each request for examination is serialized.

## **3.6 Laboratory Work Sheet for OPR and Prohibited Cases**

### **3.6.1 Preparation of the *Laboratory Work Sheet***

A *Laboratory Work Sheet* (7-2) (Appendix C) will be generated to record case-related administrative information and the items received for OPR and prohibited cases. If evidence from two or more cases will be examined, a *Laboratory Work Sheet* will be prepared for each Case ID.

### **3.6.2 Dissemination of the *Laboratory Work Sheet***

EMU personnel will, when appropriate, ensure that an electronic copy of the *Laboratory Work Sheet* is provided to each examiner assigned to that submission.

### **3.6.3 Changes to the *Laboratory Work Sheet***

Assigned EMU personnel are responsible for making all changes to the *Laboratory Work Sheet*.



If an examiner identifies a change that needs to be made to the *Laboratory Work Sheet*, he/she will notify the assigned EMU personnel at the time the change is identified. The EMU personnel will ensure a revised *Laboratory Work Sheet* is available to all affected examiners.

### **3.7 Initiating a Submission**

**3.7.1** Classified cases and cases containing Foreign Intelligence Surveillance Act (FISA)-acquired evidence will be entered in FA but classified and FISA information will be omitted with a notation of where the information is recorded. If the submission contains classified information or unclassified information with dissemination controls, an appropriately trained person will complete the *Classification Control Worksheet* (7-285) (Appendix D).

**3.7.2** An appropriately trained person will ensure that adequate searches are performed in order to determine if a new Laboratory number is needed or if it will be handled as a subsequent submission.

**3.7.3** An appropriately trained person will initiate a submission in FA for the request for examination.

**3.7.3.1** For OPR and prohibited cases, the Reserve function in FA will be used to generate a Laboratory number. Evidence handling and examinations will be recorded outside of FA for these cases.

**3.7.3.2** With the approval of the contributor, associated information can be entered into FA for OPR and prohibited cases. This approval will be recorded in the Case Communication Log. The submission must be marked as sensitive in FA by contacting the eLAB Help Desk in order to restrict access to approved personnel.

**3.7.4** If the request for examination or other information indicates a Weapons of Mass Destruction classification or chemical, biological, radiological, or nuclear (CBRN) threat, the Scientific Response and Analysis Unit (SRAU) will review the communication and any enclosed laboratory reports and provide guidance on how to proceed. If the submission has already been assessed by SRAU, then the submission will be assigned to EMU personnel and an *Examination Plan* (7-262) or *TEDAC Examination Plan* (7-274) will be created according to LOM - Practices for Assigning Cases and Conducting Examinations.

**3.7.5** Laboratory numbers will not be routinely assigned without a request for examination. Laboratory numbers may be issued without a request for examination on major cases, disasters, or for field examinations, as appropriate.

**3.7.6** The person receiving the evidence will ensure that a barcode label with the FBI Laboratory number is placed on the shipping container(s), if that container is retained. For OPR and prohibited cases the Laboratory number will be placed on the shipping container(s) as no barcode label will be available.

### 3.8 Subsequent Submissions

**3.8.1** If a submission was received but not all of the evidence from the request was received and a record (e.g., check-in notes) has not been completed, then the evidence in this subsequent submission will be added to the existing submission. If a record (e.g., check-in notes) has been completed the contributor will be contacted up to three times within 30 days to request the remaining evidence. If the contributor provides the evidence after 30 days, a subsequent submission will be initiated referencing the initial request

**3.8.2** When a subsequent submission is received under the same Case ID number or TEDAC Contributor number, a new submission will be created in FA under the associated FBI Laboratory number. For a subsequent submission to a legacy case, a new FA Laboratory number will be generated.

**3.8.3** When a subsequent request is submitted under the same Case ID number without evidence, the assigned EMU personnel or an appropriately trained person will determine whether a new submission will be created in FA.

**3.8.4** When a subsequent verbal request is received, and the assigned EMU personnel determine that a new submission will be created in FA, a written request for examination will be obtained from the contributor. The contributor will be contacted up to three times within 30 days to obtain a request for examination. If the contributor does not provide the written request for examination after three requests within 30 days, the subsequent verbal request will not be addressed.

**3.8.5** A *TEDAC Item Submission Form* or a *TEDAC Bulk Submission Form* will be completed for each TEDAC submission and will be completed by TEDAC personnel if not completed by the contributor.

**3.8.6** When a subsequent verbal request is received, and EMU personnel determine that a new submission will not be created in FA, the request will be recorded on the Case Communication Log.

### 3.9 Submission Assignment

EMU personnel will review all incoming submissions to determine if the evidence will be managed by a single unit, EMU personnel, or the Explosives Unit (EU). The LOM - Practices for Processing a Single Unit Submission will specify practices for evidence items that will be examined by a single unit.

#### 3.9.1 Explosives Unit Submission Assignment

For submissions containing evidence that will be analyzed by the EU, an EU Examiner will serve as the person managing the case, with the following exceptions:

- If a submission contains fire debris evidence and has additional evidence that will be examined by other caseworking units, it will be handled as a multiple unit

- submission and assigned to EMU personnel.
- The EU will conduct examinations on hoax devices on a case-by-case basis as determined by EU. If the EU will not conduct examinations on a hoax device, the submission will be handled as a multiple unit submission and assigned to EMU personnel.

### **3.10 Evidence Breakdown**

The person breaking down the evidence will record in FA any observations, what was performed during the initial opening of the container(s), and/or take photographs of the evidence and packaging. Any observations that are recorded regarding the condition in which the items were submitted will be considered case records.

**3.10.1** The person breaking down the evidence will ensure that the items of evidence submitted with a request for examination are inventoried.

**3.10.2** The person breaking down the evidence will determine if the evidence has been compromised. If so, the contributor will be contacted to advise how the evidence package should have been submitted. This communication will be recorded on the Case Communication Log. For TEDAC evidence, examinations may proceed without contacting the contributor.

**3.10.3** The person breaking down the evidence will ensure that a biohazard label is on each package(s) that houses potentially infectious items such as bloodborne pathogens.

**3.10.3.1** Within units that employ universal precautions on a routine basis, a biohazard label is not required on every package housing potentially infectious items.

**3.10.3.2** When transferring evidence from a unit that employs universal precautions on a routine basis to a unit that does not, those evidence packages housing potentially infectious items will be labeled with a biohazard label.

**3.10.3.3** A member of the Health and Safety Group will be contacted if questions arise as to whether biohazardous material was appropriately packaged.

**3.10.4** The person breaking down the evidence will verify the evidence received against what is listed in the request for examination, when there is a listing offering such detail. If there is a discrepancy between what is received and what is listed on the request for examination, the contributor will be contacted to advise of the discrepancy. This communication will be recorded on the Case Communication Log.

### **3.10.5 Identifying Evidence**

The person breaking down the evidence will enter the item descriptions in FA. There may be times that an item of evidence needs to be further broken down to facilitate examinations.

**3.10.5.1** The person describing the item(s) should make every effort to properly describe each

item for the examiner(s) who will conduct the examination(s). The best characterization of each item, which may include a serial number or other information to differentiate like items, should be the basis for the description. Refer to the FBI Laboratory General Description of Evidence for guidance.

**3.10.5.2** The contributor's item identifier(s), if provided, will be recorded.

**3.10.5.3** Non-evidentiary items will also be identified, transferred appropriately, and accounted for upon return to the contributor.

**3.10.5.4** If items need to be subdivided, refer to LOM - Practices for Assigning Cases and Conducting Examinations.

**3.10.6** Each proximal container/packaging, when practicable, and each transfer package, when practicable, will be labeled with an FA generated label containing the item identifier(s) and FBI Laboratory number.

**3.10.7** Appropriate barcode or submission labels with the FBI Laboratory number will be placed on all evidence packaging. For hand-labeled OPR and prohibited cases, a non-rigid evidence container housing paper or potential evidence for questioned documents with the evidence inside will not be directly labeled as this could potentially damage the evidence.

**3.10.8** When possible, the evidence container(s)/package(s) will be preserved when case-related information such as a 1B number, contributor barcode, or a contributor case number are on the container(s)/package(s). If not possible the appropriate labels or barcodes will be removed and maintained with the new package. Separated packaging will be identified as "Packaging Only" and handled according to LOM - Practices for Transferring and Storing Evidence.

**3.10.9** Any evidence container/package received bearing a *Drug Evidence* label (FD-723) or a *Valuable Evidence* label (FD-723a), or an external contributor's label denoting such, will be handled according to the LOM - Practices for Handling Drug and Valuable Evidence, LOM - Practices for Transferring and Storing Evidence and LOM - Practices for Shipping and Returning Evidence.

**3.10.10** A record (e.g., check-in notes) of what was received and the condition (e.g., proper seal) will be generated and retained in the Case Object Repository.

### **3.11 Receipt of Damaged Evidence**

**3.11.1** If the evidence was received damaged, EMU personnel will, if necessary, contact the appropriate caseworking unit to decide if the integrity of the evidence has been compromised and what, if any, forensic examinations can or will be conducted.

**3.11.2** The caseworking unit or EMU personnel will inform the contributor that the evidence was received damaged and advise what, if any, examinations will be conducted. This

communication will be recorded on the Case Communication Log.

**3.11.3** If the integrity of the evidence has been compromised and no examinations will be conducted, an examiner will be assigned and prepare a *Laboratory Report* according to LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) that states the reasons for not conducting the examinations.

### **3.12 Evidence Not Broken Down**

If a request for examination is received, but canceled by the contributor prior to the evidence being broken down, the assigned person managing the case will prepare a *Laboratory Report* according to LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), explaining that no examinations were conducted and the evidence was not broken down.

### **3.13 Resubmitted Evidence**

**3.13.1** If an item is resubmitted under the same Case ID number or TEDAC Contributor number, a new barcode label will be affixed to the evidence packaging and the original barcode, if present, will be struck through and initialed.

**3.13.2** If an item is resubmitted under a new Case ID number, such as items from one investigation used to support another investigation, the person generating the new submission in FA will identify the items as being resubmitted from a different Case ID number and the associated FBI Laboratory number.

### **3.14 Evidence Storage**

If the evidence is not immediately being transferred, the person who breaks down the evidence will properly store the evidence to preserve the integrity of each item and/or ensure the safety of FBI Laboratory personnel.

## **4 Records**

The following records will be generated and/or retained in the FBI Laboratory file as a result of these practices:

- Request for examination (e.g., LER, RFLE, *TEDAC Item Submission Form*)
- FA Chain-of-Custody Log or *Chain-of-Custody-Log* (7-243)
- *Laboratory Work Sheet*
- FA Case Communication Log or *Activity and Communication Log*
- *Examination Plan* or *TEDAC Examination Plan*
- *Laboratory Report*
- Record of the condition in which the evidence was received (e.g., check-in notes).

## 5 References

FBI Laboratory General Description of Evidence, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 20017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
3	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL. Merged Practices for Inventorying and Identifying Evidence for Legacy Cases into this document. Substantive changes include: removed the Responsibilities section, generalization of RC and EA to evidence management personnel, updated requirements regarding OPR and prohibited cases, added requirements for handling suspicious packages and multiple case submissions, added section on submission assignment, moved content regarding acknowledgement of evidence receipt from this practice to the Practices for Assigning Cases and Conducting Examinations, and added TEDAC evidence processing and breakdown.
4	06/03/19	Changed evidence management personnel to Evidence Management Unit throughout. Revised section 3.1.2 following realignment of Laboratory personnel. Revised terminology in section 3.2.3 and 3.2.3.1 to refer to an external laboratory. Moved requirement regarding classified and FISA cases to section 3.7.1 and added requirement for <i>Classification Control Worksheet</i> in Appendix D. Updated section 3.10.5.1 to reflect a single General Description of Evidence document. Updated list of references in section 5. Updated images of <i>TEDAC Item Submission Form</i> and <i>TEDAC Bulk Submission Form</i> in Appendices A and B to reflect previously revised forms.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019



















## **FBI Laboratory Practices for Assigning Cases and Conducting Examinations**

### **1 Purpose**

These practices establish the requirements for assigning cases and conducting examinations to conform to the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who are involved in case assignment and conducting examinations of evidence. For Laboratory Director and Quality Manager approved initiatives, a level 2 document will contain procedures for case assignment and conducting examinations of evidence when necessary. The LOM - Practices for Processing a Single Unit Submission will specify practices for evidence items that will be examined by a single unit.

### **3 Practices**

Submissions received by the FBI Laboratory will be initiated and have records contained in Forensic Advantage (FA), unless the case must be handled outside of FA (i.e., Office of Professional Responsibility, prohibited cases). Non-Terrorist Explosive Device Analytical Center (TEDAC) legacy cases refer to any submission initiated prior to January 7, 2014. TEDAC legacy cases refer to any submission initiated prior to October 1, 2015. The generation of additional records for legacy cases may be continued in non-FA formats (e.g., *Activity and Communication Log* (7-245) (Appendix A), *Chain-of-Custody Log* (7-243, 7-243a), in Explosive Reference Tool (EXPeRT)). If a subsequent submission to a legacy case is received, a new FA Laboratory number will be generated and records will be maintained in FA.

#### **3.1 Case Assignment**

**3.1.1** Evidence Management Unit (EMU) personnel will contact the contributor, at or near the time of case assignment, to acknowledge that the contributor's package was received. This acknowledgement will be sent as an acknowledgment email (Appendix B), when practicable. If an email address cannot be obtained, voicemail and/or mail can be used to acknowledge receipt. The alternate format and the reason for its use will be recorded in the appropriate communication log (e.g., *Activity and Communication Log*, Case Communication Log).

**3.1.1.1** An acknowledgement email does not need to be sent for evidence received via personal delivery. The copy of the transfer receipt that is retained in the FBI Laboratory file will serve as the record that the contributor is aware that their items were received at the FBI Laboratory.



**3.1.1.2** The acknowledgement email will contain the following:

- FBI Laboratory number
- Contributor/TEDAC number
- Information regarding the receipt of evidence and further communication
- FBI Laboratory contact information

Additionally, the Case ID will be included in the acknowledgment email for internal contributors. The Case ID may be excluded from the acknowledgment email for external contributors. EMU personnel generating an acknowledgment email to an external contributor may include the Case ID to facilitate recordkeeping.

**3.1.1.3** For non-TEDAC submissions that have not yet been broken down, the acknowledgment (e.g., email, voicemail) will indicate that the receipt of evidence does not imply that the FBI Laboratory has verified the items submitted against those listed in the request for examination or transferred in Sentinel. The acknowledgement will also indicate that if there are discrepancies upon breakdown, the contributor will be contacted to resolve any inconsistencies. For non-TEDAC submissions in which evidence has been verified against the request for examination or those transferred in Sentinel, the acknowledgement does not need to indicate that that step has not yet occurred.

**3.1.1.4** The acknowledgement may also contain other pertinent information (e.g., units assigned if known, where to access a *Laboratory Report* upon completion).

**3.1.2** EMU personnel will thoroughly read all relevant case information.

**3.1.3** EMU personnel will review all Submission Details data and update the information, if needed.

**3.1.4** EMU personnel will ensure the appropriate selection is made in the Primary Unit field and the name of the person managing the case is entered in the Request Coordinator field in FA.

**3.1.5** EMU personnel will ensure a date, if available, is entered in the Document Date field for the Request for Examination.

**3.1.6** EMU personnel will ensure the relevant contributor information is entered into FA.

**3.1.7** The EMU person managing the case will prepare an *Examination Plan* (7-262) (Appendix C) or for TEDAC evidence, a *TEDAC Examination Plan* (7-274) (Appendix D). The *Examination Plan* or *TEDAC Examination Plan* maps the sequence in which each item will be examined throughout the FBI Laboratory and records that the request for examination has been reviewed. The *Examination Plan* or *TEDAC Examination Plan* will be retained in the Case Object Repository in FA or as a physical record or in EXPeRT, as appropriate, for legacy cases. For legacy cases, the EMU person managing the case will ensure that a copy of the *Examination Plan* or *TEDAC Examination Plan* is forwarded to each assigned examiner. Copies of the *Examination Plan* or *TEDAC Examination Plan* do not need to be retained.

**3.1.7.1** If EMU personnel identify an additional examination(s) not requested that may be probative, they will contact the affected unit(s) to determine if there is value in conducting the examination(s). If so, the EMU person managing the case will contact the contributor to determine if he/she would like this examination(s) conducted. These communications will occur prior to laboratory examinations commencing. For examinations generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis & Racketeering Records Unit evidence), the contributor will not be contacted, but the *Examination Plan* or *TEDAC Examination Plan* will be updated.

**3.1.7.2** If the contributor agrees to the additional examination(s), the information will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*), the affected examiner(s) will be notified, and the addition will be made to the *Examination Plan*. If the additional examination(s) is not wanted by the contributor, the information will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*). EMU personnel managing the case will ensure that only the examination(s) requested by the contributor is included on the *Examination Plan*.

**3.1.8** The EMU person managing the case will, if necessary, contact the contributor to reconcile any unanswered issues, recording the communication on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*). This may include notifying the contributor that requested examinations are not appropriate to conduct.

**3.1.9** The EMU person managing the case will initiate the necessary Case Records in FA to address the examination(s) requested for each item of evidence.

**3.1.10** A Unit Chief will ensure a Case Record is assigned in FA to appropriate personnel in his/her unit. For legacy cases, the Unit Chief will ensure appropriate personnel are assigned.

**3.1.11** Any changes to the *Examination Plan* after work has commenced will be communicated to all affected examiners by the EMU person managing the case and will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*).

### **3.1.12 On-Site Case Assignment**

In some instances, FBI Laboratory personnel will conduct an on-site breakdown of evidence, for example, at a crime scene.

**3.1.12.1** Whenever possible, the submission will be assigned to EMU personnel prior to commencing the evidence breakdown process. The assigned EMU personnel will use the Reserve function in FA to generate a Laboratory number if the case does not already exist in FA.

**3.1.12.2** A request for examination (e.g., Laboratory Examination Request (LER), Request for Laboratory Examination (RFLE), Electronic Communication (EC), *TEDAC Item Submission Form* (7-275)) will be serialized in Sentinel at the time of the evidence breakdown or upon return to the FBI Laboratory. The Case Record(s) for the examination units will be generated in FA.

## 3.2 Examination Process

**3.2.1** If examinations do not begin within 60 calendar days of receipt of evidence in the unit and creation of the associated Case Record in FA, a person from the unit, such as the examiner assigned the case or a technician, will contact the contributor prior to beginning any examinations. The purpose of the contact(s) will be to discuss case investigative needs; time constraints, such as trial dates; provide clarification on what is forensically feasible and probative; whether additional evidence, such as known samples or reference samples, is required; prioritization of the items to be analyzed; a reasonable estimate of the completion date for the examinations by that discipline/category of testing; and whether the examination(s) is still needed. This communication will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*). This communication is not required for TEDAC cases.

**3.2.1.1** If an examiner or technician identifies an additional examination(s) that may be probative, the examiner will ensure the affected unit(s) is contacted to determine if there is value in conducting the examination(s). If so, the assigned EMU personnel will be notified and the examiner or the evidence personnel will contact the contributor to determine if he/she would like this examination(s) conducted. For examinations generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis & Racketeering Records Unit evidence) the contributor will not be contacted, but the *Examination Plan* or *TEDAC Examination Plan*, as appropriate, will be updated.

If the contributor agrees to the additional examination(s), the information will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*). The affected examiner(s) will be notified, the *Examination Plan* will be updated, and a Case Record will be created in FA, if applicable. If the additional examination(s) is not wanted by the contributor, the information will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*).

**3.2.2** Assigned EMU personnel will promptly communicate any pertinent case-related activity to the examiner(s) and record that information on the appropriate communication log (e.g., *Activity and Communication Log*, *Case Communication Log*).

**3.2.3** If an examiner or technician identifies a change that needs to be made to the FA Submission Details, the assigned EMU personnel will be notified and the examiner or the EMU personnel will make the change, and record the change on the Case Communication Log in FA. For legacy cases, if an examiner or technician identifies a change that needs to be made to the *Laboratory Work Sheet (7-2)* or *TEDAC Laboratory Work Sheet* he/she will notify the assigned EMU personnel to update the *Laboratory Work Sheet* or *TEDAC Laboratory Work Sheet*.

**3.2.4** The examiner will ensure that the appropriate examination(s) is conducted. FBI Laboratory personnel will preserve the integrity of the evidence and maintain effective separation between incompatible activities to prevent cross-contamination.

**3.2.5** Results of examinations, including expedited results when necessary, will be

communicated according to LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) or LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases.

**3.2.6** If an examiner is instructed to discontinue examinations after they have been initiated, the affected examiner will determine the appropriate stopping point in the examination process. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when. All results will be furnished to the contributor according to LOM – Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage or LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases.

**3.2.7** If instructions are received from the contributor to cancel a request for examination and no examinations have been initiated at the time the request was received, the EMU person managing the case will issue a *Laboratory Report* that includes a listing and description of the evidence. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when.

**3.2.8** All cancellation instructions and the name of the person who canceled the request for examination will be recorded on the appropriate communication log (e.g., *Activity and Communication Log*, Case Communication Log). If the cancellation instruction is provided via email, the email(s) will be retained in Sentinel (e.g., in the 1A(s)/1C(s), as a record email).

### **3.3 Itemizing Evidence, Subdivided Evidence, and Secondary Evidence**

Evidence will be accurately described and itemized using the guidance in the FBI Laboratory General Description of Evidence issued by the EMU.

#### **3.3.1 Subdivided Evidence**

There may be times during the examination process that an item of evidence needs to be subdivided. Subdividing an item occurs when an item not initially designated during the evidence breakdown process needs to be uniquely identified. Personnel may subdivide an item as necessary.

**3.3.1.1** For FA cases, the subdivided item and description will be entered into FA using the New Evidence Created in Lab function. The format used to uniquely identify that item will be the item identifier from which the subdivided item came, followed by a dash and a new sequential number.

Item 1	Jeans
Item 1-1	Note removed from Item 1 front pocket

**Figure 1:** Example of identifying a subdivided item of evidence for FA cases

**3.3.1.2** For legacy cases, when an item that needs to be subdivided is identified, the format

used to uniquely identify that item is to assign the item identifier from which the subdivided item came, followed by a decimal point and a new sequential number.

Q1	Jeans
Q1.1	Note removed from Q1 front pocket

**Figure 2:** Example of identifying a subdivided item of evidence for legacy cases

**3.3.1.3** If personnel need to identify different components of one item and subdividing is not appropriate, personnel may identify those components as necessary.

### 3.3.2 Secondary Evidence

Secondary evidence is a material derived from an examination process on an item of evidence. It is not an individual item submitted by a contributor and could not have been assigned an item identifier through the evidence breakdown process.

**3.3.2.1** If a discipline or category of testing will produce secondary evidence, a level 2 document will contain defined means of identifying secondary evidence and generating a secondary evidence log.

**3.3.2.2** The secondary evidence log will be retained in the FBI Laboratory file. For non-TEDAC evidence, the log will be uploaded into the Case Object Repository in FA. For TEDAC evidence, the log will be uploaded into the Case Record Object Repository in FA. For non-TEDAC legacy cases, a copy of the log will be provided to the evidence management person managing the case. For TEDAC legacy cases, the secondary evidence log will be maintained in the examiner's 1A/1C. A copy will be provided to EMU personnel if required (e.g., to ship back secondary evidence to contributor, secondary evidence will be maintained in repository).

**3.3.2.3** For FA cases, secondary evidence, will be added as a separate item using the New Evidence Created in Lab function. The secondary evidence item description will include the name of the discipline or category of testing and the number and type of secondary evidence. For legacy cases, when secondary evidence is added to the listing of what is being transferred, it will be added to the "Item(s)" block on the *Chain-of-Custody Log*. Any *Chain-of-Custody Log* referencing secondary evidence will have a copy of the secondary evidence log attached.

**3.3.2.4** Secondary evidence that is separated from other secondary evidence for transfer will be uniquely identified.

**3.3.2.5** Secondary evidence will be returned to the contributor, unless it is destroyed according to existing regulations or is retained by the FBI Laboratory. Secondary evidence packaging will be labeled with the unit name or acronym, and "secondary evidence". For FA cases, the packaging will also be labeled with an FA generated barcode.

### **3.4 Initialing and Labeling Evidence**

**3.4.1** This section does not apply to evidence submitted electronically (e.g., email attachments, evidence serialized in Sentinel by FBI contributors and retrieved by Laboratory personnel for examination). If evidence submitted electronically is printed and will be retained, a level 2 document will define how the printed item will be handled.

**3.4.2** For FA cases, a container, packaging, or item barcode label will be generated for each item of evidence, printed, and, where practicable, affixed to the proximal evidence container/packaging.

**3.4.3** Each item, where practicable, will be labeled with the:

- Item identifier (e.g., Item 1).
- FBI Laboratory number or a derivative thereof. If a derivative is used, the proximal container/packaging will bear the full FBI Laboratory number.
- Initials of the person labeling the item.

**3.4.4** Personnel directly examining and/or processing an item(s) of evidence will place their initials directly on the evidence, where practicable, or its proximal container/packaging. It is not necessary for personnel whose role is limited to drawing conclusions based on data derived from examination procedures to initial the item(s) of evidence from which the data was derived.

**3.4.5** When initialing or labeling, care should be taken not to mark the item of evidence in such a manner as to affect another examination. Therefore, if the item does not lend itself to marking, the proximal evidence container/packaging or identifying tag will be initialed.

**3.4.6** Personnel who perform documentary or other non-examination processes on evidence such as photography or photocopying do not need to initial the evidence or its proximal container.

**3.4.7** Item descriptions will not be changed to reflect examination results (e.g., item described as “tape” will not be changed to “3/4 inch black electrical tape” after examination).

**3.4.8** For FA cases, personnel will update item descriptions if an item is incorrectly described (e.g., item described as “shirt” during evidence breakdown but identified as “pants” during examination). Personnel will note the change in the Case Communication Log in FA. If it is necessary to update the description in Sentinel, personnel will notify the assigned EMU personnel. For legacy cases, personnel will notify the assigned EMU personnel to update the *Laboratory Work Sheet* or *TEDAC Laboratory Work Sheet*.

### **3.5 Case Records**

**3.5.1** All case-related work will be recorded and retained in the FBI Laboratory file.

**3.5.2** In the event a request for examination is canceled, all case-related records completed up to that point will be retained in the FBI Laboratory file. For legacy cases, personnel will

retain the *Laboratory Work Sheet* or *TEDAC Laboratory Work Sheet* as an administrative record in the FBI Laboratory file.

**3.5.3** Personnel will prepare handwritten administrative and examination records in ink, not pencil. Pencil is only appropriate for making diagrams, tracings or when environmental or other conditions dictate. Computer generated records are acceptable.

**3.5.3.1** Computer generated records may be created in FA. If they are created outside of FA, the computer generated records may be uploaded into the Case Record Object Repository in FA.

**3.5.4** Personnel will generate examination records that are understandable to another examiner in that discipline/category of testing. Case notes will include observations, data, and calculations, where appropriate. These notes will be recorded contemporaneously with, and will be identifiable to, the specific examination performed.

**3.5.5** Abbreviations and notations are acceptable if they are readily comprehensible and/or are clearly recorded. A defined list of specific abbreviations will be maintained in a level 2 document.

**3.5.6** The FBI Laboratory number will be on each page of administrative records or on at least the first page of bound administrative records. For electronic administrative records, the FBI Laboratory number can be applied electronically. The FBI Laboratory number will be on each page of the examination records. Examination records reflect, at a minimum, the starting and ending date(s) of the examinations.

**3.5.7** The examiner's initials will be on each page of the examination records. An examiner's initials will acknowledge his/her agreement with the content of the examination records.

**3.5.7.1** If examination records are maintained only in FA, the examiner will record agreement with the content in FA. If examination records are maintained elsewhere, a level 2 document will contain procedures identifying where the examiner will record his/her agreement with the content of the records.

**3.5.8** When examination records are prepared by a technician(s) or another examiner(s), that person's initials will be on the page(s) of the records representing his/her work. If examination records are maintained only in FA, personnel preparing the examination records will record agreement with the content in FA. The reporting examiner will record his/her review of another person's examination records in FA. If examination records are maintained elsewhere, a level 2 document will contain procedures identifying where the examiner will record his/her agreement with the content of the records.

**3.5.9** The FBI Laboratory number should be the beginning portion of the file name of administrative and examination records uploaded into FA.

**3.5.10** The FBI Laboratory number for each case for which data was generated will be

appropriately recorded on the printout when data from multiple cases is recorded on a single printout.

**3.5.11** When information is recorded on the front and back of a physical examination record, each side will be identified as an individual page, signed or initialed, and labeled with the FBI Laboratory number.

**3.5.12** Changes to physical case records or DNA databasing records are made with an initialed single strike-out, date of the change, and the change entered alongside. Nothing in the case records or DNA databasing records is erased or otherwise made illegible.

For electronic case records or DNA databasing records, sufficient information to determine what was changed, the date of the change, and who made the change is maintained (e.g., track changes, maintaining both the original and amended data and files). For electronic records, measures are taken to avoid loss or change of original data.

Contemporaneous changes (i.e., those made before reaching a decision point) are not considered amendments.

**3.5.12.1** Any modification to a physical *Chain-of-Custody Log* will be initialed and dated and a comment will be entered in the Remarks block indicating why the change occurred.

**3.5.13** Physical attachments that have been affixed to an administrative or examination record will be labeled with the FBI Laboratory number.

**3.5.14** Physical administrative and examination records, together or separately, will be accounted for in their totality and that totality will be recorded. A level 2 document will contain a defined method(s) to account for and record the total number of administrative and examination pages. If FA is used to generate an electronic 1A, the totality does not need to be recorded.

**3.5.15** When standards, controls, or reagents that utilize a unique identifier are specified in a procedure, the examination records will reflect the unique identifier (e.g., lot number, batch number) of the standard, control, or reagent used.

**3.5.16** A level 2 document will contain a defined list of which records are considered administrative records and which are considered examination records.

**3.5.17** Administrative and examination records will be maintained according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) or LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases.



## 4 Records

The following records will be generated and/or retained in the FBI Laboratory file as a result of these practices:

- *Examination Plan* or *TEDAC Examination Plan*
- The appropriate Communication log.
- The appropriate Chain-of-Custody Log.
- Examination records.
- Administrative records.

## 5 References

FBI Laboratory General Description of Evidence, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
4	06/08/18	Revised requirements in sections 3.1.1 through 3.1.1.4 related to acknowledging receipt of evidence. Added that acknowledgement will be via email, when practicable, but can be acknowledged via other methods. Clarified that acknowledgment is not needed for personal deliveries. Modified requirement so that Case ID does not need to be communicated for external contributors. Added that if evidence has broken down, the acknowledgement can omit a statement regarding verification of evidence received. Updated example language in Appendix B to reflect that evidence management is no longer in FASU. Revised TEDAC Examination Plan (7-274) in Appendix D.
5	06/03/19	Changed evidence management personnel to Evidence Management Unit throughout. Broadened language in section 3.1.1.3 and 3.1.1.4 to accommodate acknowledgement in various formats. Added requirement to section 3.1.7.1 that communications regarding additional examination will occur prior to the commencement of the exams. Added section 3.1.11 describing the requirements related to changes to the <i>Examination Plan</i> . Modified sections 3.2.6 through 3.2.8 regarding cancellation of examinations. Updated section 3.3 to reflect a single General Description of Evidence document. In section 3.3.2.2, added requirement to describe handling of secondary evidence logs for TEDAC legacy cases. Generalized language to refer to computer generated records in sections 3.5.3 and 3.5.3.1. Removed exception for evidence management program from section 3.5.5. Added mechanism for electronic administrative records in section 3.5.6. In section 3.5.7.1, broadened requirement for recording agreement with content in FA. In section 3.5.9, removed names of specific object repositories. In section 3.5.12, updated requirements regarding changes to records. Updated list of references in section 5.

### **Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019











## **FBI Laboratory Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA)**

### **1 Purpose**

These practices specify the requirements for performing verifications, preparing, reviewing, and issuing a *Laboratory Report* (7-1 LIMS, 7-273 LIMS), and retaining case-related records using Forensic Advantage (FA) to conform to the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

### **2 Scope**

These practices apply to FBI Laboratory personnel who prepare or issue *Laboratory Reports* and/or generate case-related records in FA. These practices also apply to FBI Laboratory personnel who perform verifications of identifications and associations, conduct technical reviews, and conduct administrative reviews in FA. Appropriate level 2 documents will contain procedures for performing verifications; conducting technical and administrative reviews; preparing and/or issuing *Laboratory Reports*; and/or generating case-related records. When necessary, a level 2 document will also contain procedures for initiatives and/or the use of alternate reporting approved by the Laboratory Director and Quality Manager. See Laboratory Operations Manual (LOM) - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases for requirements regarding Office of Personnel Responsibility (OPR) or prohibited cases.

### **3 Practices**

Every *Laboratory Report* (Appendix A, Appendix B) must be associated with a Case Record. Any information required by ISO/IEC 17025 or AR 3125 not covered in a *Laboratory Report* or alternate reported results will be maintained in the FBI Laboratory. [QAM -Sections 7.8.1.3 and 7.8.1.3.1]

#### **3.1 Formatting a *Laboratory Report***

Each *Laboratory Report* will contain administrative information about the request for examination; a listing and description of evidence; a Results of Examinations section when forensic examinations have been conducted; a Remarks section; and a name block; and will be digitally signed in Sentinel by the person issuing the *Laboratory Report*.

Appropriate fields in the *Laboratory Report* will be populated by FA. The text entered for each *Laboratory Report* will be Times New Roman font. Typically, the font size used in the body of the *Laboratory Report* is 12-point; however, different font sizes may be used in charts. The



bold, italic, or underline functions may be used, and charts and/or images, may be included as necessary.

### **3.1.1 Administrative Information**

The Agency Reference(s), Subject(s), and Victim(s) fields are optional and may be empty or deleted if the contributor did not provide that information in the request for examination or if the information is classified.

If an examiner has any concerns regarding the administrative information, he/she will contact the Evidence Management Unit (EMU) person managing the case to verify that information is accurate.

### **3.1.2 Listing and Description of Evidence**

The Listing and Description of Evidence section contains a listing and description of the item(s) from FA which were submitted to, or examined in, a particular unit, discipline, and/or category of testing. Headings, for example, distinguishing items from the victim and the subject, may be used. The person issuing the *Laboratory Report* will include a statement identifying the discipline/category of testing/examination/evidence management being reported. This statement will follow the listing and description of evidence. If there are items in the FBI Laboratory that are not addressed in the *Laboratory Report*, the *Laboratory Report* will have a statement that items not included in the listing and description of evidence were not examined as part of this report. Alternatively, the results of examination section may provide this information.

### **3.1.3 Results of Examinations**

The Results of Examinations section contains methods, results, opinions, limitations, interpretations, and/or conclusions of forensic examinations conducted by a particular examiner. This information may be under a separate heading(s) as specified in level 2 documents. Additionally, the requirements in QAM - Section 7.8 will be followed.

**3.1.3.1** The wording used to convey the results of examinations is left to the discretion of the examiner, in accordance with the applicable Department of Justice Uniform Language and Reports (ULTR) document(s), the applicable FBI Approved Standards for Scientific Testimony and Report Language (ASSTR), any applicable level 2 documents regarding reporting, and is acceptable to the technical reviewer.

**3.1.3.1.1** The significance of an association will be included in the *Laboratory Report* in a statistic or a qualitative statement.

**3.1.3.1.2** When comparative examinations result in the elimination of a person or object, the *Laboratory Report* will clearly communicate the elimination.

**3.1.3.1.3** When an inconclusive result is reported, the reason(s) will be clearly stated in the *Laboratory Report*.

**3.1.3.1.4** A *Laboratory Report* will include additional information, when it is necessary for the interpretation of the examination results, such as:

- information regarding specific examination conditions;
- a statement of conformity with requirements or specifications, as described in QAM- Section 7.8.6;
- additional information that may be required by specific methods, authorities, or contributors.

**3.1.3.1.5** Measurement uncertainty will be included in the *Laboratory Report*, or as an enclosure, when it is relevant to the validity or application of the examination results; a contributor's instructions require it; it affects conformity to a specification limit; or when the measurement impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement. .

**3.1.3.1.6** The measurement uncertainty will:

- include the measured quantity value,  $y$ , along with the associated expanded uncertainty,  $U$ , and the coverage of probability;
- be in the format of  $y \pm U$ ;
- be limited to at most two significant digits, unless there is a recorded rationale for reporting additional significant digits;
- be reported to the same level of significance as the measurement result.
- where applicable, be presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent).

**3.1.3.2** If evidence is received and the request for examination is to compare the submitted evidence with another item(s) from a closed request(s), the previous FBI Laboratory number(s) will be referenced in the Results of Examinations section. If the item(s) was submitted from a different Case ID number(s), the previous Case ID number(s), and the FBI Laboratory number(s) will be referenced in the Results of Examinations section. This does not constitute a combined report.

### **3.1.4 Individual Characteristic Database (ICD) Searches**

**3.1.4.1** If a forensic sample (e.g., latent print, test fire, DNA profile) is searched as a one-time event, then a *Laboratory Report* must be generated clearly stating the results of the ICD search. A one-time event means that the sample will not be retained in the database and automatically searched against the database on some routine basis.

**3.1.4.2** If a forensic sample is, or will be, entered into a database(s) and is repeatedly searched with negative results, a *Laboratory Report* is not required for each search. However, the first time the sample is entered into the database, written notification (e.g., email, letter of notification, *Laboratory Report*) must be generated which clearly informs the contributor that the sample was, or will be, entered into the database. Any time a positive association is made, written notification (e.g., email, letter of notification, *Laboratory Report*), must be generated. A record of the notification will be maintained.

### **3.1.5 Remarks**

The Remarks section will contain, at a minimum, the disposition of the evidence contained in the *Laboratory Report*, contact information for the examiner, contact information for submission status inquiries, the facility(ies) and/or site(s) where work was conducted, as well as a statement regarding the location of the supporting records. This section may also contain information pertinent to the request, evidence not inventoried, examination cancellations, examinations not conducted, and special evidence handling and storage instructions. Any additional information for this section will be specified in appropriate level 2 documents.

#### **3.1.5.1 Disposition of Evidence**

Each *Laboratory Report* will contain a statement that will address the disposition of the items of evidence and secondary evidence, as applicable. The disposition statement may state that the items:

- Are enclosed with the *Laboratory Report*.
- Will be returned to the contributor under separate cover from the *Laboratory Report*.
- Will be retained.
- Have been consumed during the examination process.

#### **3.1.5.2 Contact Information**

**3.1.5.2.1** Each *Laboratory Report* will contain a statement providing contact information, including the title, name, and telephone number of the person issuing the *Laboratory Report*, should the contributor have questions about the content of the report.

**3.1.5.2.2** Each *Laboratory Report* will include a telephone number and/or email address of the person and/or unit to contact regarding the status of the submission.

#### **3.1.5.3 Facility Statement**

Each *Laboratory Report* will contain a statement which identifies the facility(ies) and/or site(s) where any work (e.g., examination, processing, verification) was performed. The location where each task was performed does not need to be specified.

#### **3.1.5.4 Opinions/Interpretations and Supporting Records Statement**

Each *Laboratory Report* that contains conclusions will contain a statement referencing the applicable Department of Justice Uniform Language and Reports document(s). Additionally, a *Laboratory Report* that contains opinions and interpretations will have a statement indicating that the report contains the opinions and interpretations of the issuing examiner(s) and is supported by records retained in the FBI Laboratory file. A *Laboratory Report* that contains opinions and interpretations will also contain language advising contributors of the time required for discovery requests to be processed.

### **3.1.5.5 Information Pertinent to the Request**

This information may include investigative assistance information or sample collection instructions.

### **3.1.5.6 Evidence Not Broken Down**

If the evidence is being returned prior to the container(s) being opened and/or the content broken down, the EMU person managing the case will issue a *Laboratory Report* explaining that no examinations were conducted and the evidence was not broken down.

### **3.1.5.7 Examination Cancellations**

If instructions are received from the contributor to cancel a request for examination, all cancellation instructions and the name of the person who canceled the request for examination will be recorded in the Case Communication Log in FA. If the cancellation instruction is provided via email, the email(s) will be retained in the 1A(s)/1C(s).

#### **3.1.5.7.1 Cancellation Prior to Any Examinations**

If instructions are received from the contributor to cancel a request for examination and no examinations have been initiated by the FBI Laboratory at the time the request was received, the EMU person managing the case will issue a *Laboratory Report* that includes a listing and description of the evidence. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when.

#### **3.1.5.7.2 Cancellation After Examination Initiation**

If an examiner is instructed to discontinue examinations after they have been initiated, the affected examiner will determine the appropriate stopping point in the examination process. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when. All results of any completed examinations will be included in the Results of Examinations section in a *Laboratory Report*.

Additionally, if there are any remaining examinations that have not been initiated, the person who received the instruction to discontinue examinations will contact the EMU person managing the case. The EMU person managing the case will issue a *Laboratory Report* that includes a listing and description of the evidence. The *Laboratory Report* must include a statement in the Remarks section indicating that the examinations were canceled, by whom, and when.

### **3.1.5.8 Examinations Not Conducted**

**3.1.5.8.1** When a request for a type of examination that is not conducted in the FBI Laboratory is received, the EMU person managing the case will issue a *Laboratory Report* and include a detailed explanation in the Remarks section that describes why the requested examination was not conducted.

**3.1.5.8.2** When a request for a type of examination that is conducted in the FBI Laboratory is received, but will not be conducted, the appropriate examiner will issue a *Laboratory Report* and include a detailed explanation that describes why the requested examination was not conducted. If there are results included in the *Laboratory Report* for another type of examination, then the detailed explanation may be under separate heading(s) as specified in a level 2 document.

**3.1.5.8.3** When evidence is received damaged and the integrity of the evidence has been compromised to the extent that no examinations will be conducted, the appropriate examiner will issue a *Laboratory Report* and include a detailed explanation that describes why the requested examination(s) was not conducted.

### **3.1.5.9 Special Evidence Handling/Storage Instructions**

Instructions to the contributor may be included in the *Laboratory Report* addressing evidence handling and storage (e.g., to freeze, refrigerate the returned evidence).

### **3.1.6 Name Block**

The name and unit of the examiner(s) responsible for the content of the *Laboratory Report* will immediately follow the Remarks section.

### **3.1.7 Enclosures**

**3.1.7.1** Enclosures may be attached to the *Laboratory Report* and serialized in Sentinel or physically mailed to the contributor. If the *Laboratory Report* is being serialized in Sentinel and the enclosure is being mailed, at a minimum, the first page of the report must be printed and attached to the enclosure. For external contributors, the *Laboratory Report* and enclosures will be mailed together.

All enclosures must be accounted for on the first page of the *Laboratory Report*. The enclosure count will be placed on the bottom left margin of the first page of the *Laboratory Report*, above the page number.

### **3.1.8 Major Cases and Other Cases with Multiple Examiner *Laboratory Reports***

**3.1.8.1** Multiple examiners from a caseworking unit(s) may prepare one *Laboratory Report* for a major case or other cases as deemed appropriate by a Unit Chief(s). If applicable, contributing examiners will terminate their Case Record(s) in FA and record in the Case Communication Log that his/her results have been included in the issuing examiner's report.

**3.1.8.2** When a *Laboratory Report* contains the results of multiple examiners, the report will identify each examiner's results (e.g., each examiner's initials or name in parentheses at the end of each paragraph or section, or where appropriate in tables and charts). The initials or name do not need to be electronically secure on the *Laboratory Report*. Each examiner will have his/her own name block in the *Laboratory Report*. Additionally, each contributing examiner will be a co-author or approver in Sentinel, acknowledging agreement with his/her results as reported.

**3.1.8.3** When an Explosives and Hazardous Devices *Laboratory Report* is being issued and results from another examiner(s) must be included, the Explosives and Hazardous Devices examiner will identify each examiner's results (e.g., each examiner's initials or name in parentheses at the end of each paragraph or section, or where appropriate in tables and charts). The initials or name do not need to be electronically secure on the *Laboratory Report*. The Explosives and Hazardous Devices examiner will also include a statement that includes the FBI Laboratory number and Case Record number of the other examiner's report, the examiner's name, and the date of his/her report. Each contributing examiner will be a co-author or approver in Sentinel, acknowledging agreement with his/her results as reported.

### **3.1.9 Combined *Laboratory Report***

An examiner may prepare a *Laboratory Report* combining the information from various open Case Records submitted by the same contributor under the same Case ID number.

#### **3.1.9.1 Different Contributors and Same Case ID Number**

The examiner preparing a combined *Laboratory Report* for evidence submitted by different contributors under the same Case ID number will ensure that the Case ID numbers are the same. If they are not, the *Laboratory Report* will be handled as described below. Each listing of items received under one request will be preceded by an administrative sentence that identifies the contributor and the date of the request. The *Laboratory Report* will be addressed to the FBI office of origin, even if it was not the office contributing the evidence.

#### **3.1.9.2 Comparison of Evidence Submitted Under Different Case ID Numbers**

The examiner preparing a combined *Laboratory Report* for evidence submitted under different Case ID numbers will terminate all but one of the associated Case Records in FA. An entry will be made in each terminated Case Record and include the Laboratory number where the *Laboratory Report* will be generated. An entry will be made in the non-terminated Case Record and include the Laboratory number(s) of the terminated Case Record(s). The examiner will ensure that a *Laboratory Report* is serialized in Sentinel to each applicable Case ID when addressing a request to compare items submitted under different Case ID numbers. Each listing of items received will be preceded by an administrative sentence that identifies the Case ID and the date of each request.

#### **3.1.9.3 Examination of Evidence Received Under Both Legacy and Forensic Advantage Submissions**

A combined *Laboratory Report* can be prepared for reporting results for a case where legacy evidence is already in the FBI Laboratory or has been examined by a unit and new evidence is received and examined in FA. The examiner preparing this type of report will ensure that each listing of items received under one request is preceded by an administrative sentence that identifies the appropriate FBI Laboratory number and the date of the request.

### **3.1.10 Follow Up *Laboratory Reports***

Follow Up *Laboratory Reports* will be prepared when necessary to modify a previously issued *Laboratory Report*.

#### **3.1.10.1 Supplemental *Laboratory Report***

A supplemental *Laboratory Report* will be prepared to provide additional information pertaining to a completed request for examination. When generating a supplemental *Laboratory Report*, the examiner will create a new Case Record using the Follow Up Case Record type with the appropriate evidence assigned to the Case Record.

**3.1.10.1.1** The examiner who prepares a supplemental *Laboratory Report* to provide additional information pertaining to a request for examination will reference the date of the previous *Report(s) of Examination/Laboratory Report(s)* in an introductory sentence. The introductory sentence will precede the Results of Examinations section.

**3.1.10.1.2** The examiner who prepares a supplemental *Laboratory Report* will ensure that a listing and description of items in the previous *Report(s) of Examination/Laboratory Report(s)* that are affected by the supplemental *Laboratory Report* are included.

**3.1.10.1.3** The supplemental *Laboratory Report* will clearly state what additional information is being provided. The supplemental report will be administratively and, when applicable, technically reviewed.

#### **3.1.10.2 Amended *Laboratory Report***

An amended *Laboratory Report* will be prepared if a change must be made to the content of a previous *Report(s) of Examination/Laboratory Report(s)*. When generating an amended *Laboratory Report*, the examiner will create a new Case Record using the Follow Up Case Record type with the appropriate evidence assigned to the Case Record.

**3.1.10.2.1** The examiner who prepares an amended *Laboratory Report* will reference the date of the initial *Report of Examination/Laboratory Report* in an introductory sentence. The introductory sentence will precede the Results of Examinations section.

**3.1.10.2.2** The examiner who prepares an amended *Laboratory Report* will ensure that a listing and description of items in the initial *Report of Examination/Laboratory Report* that are affected by the amended *Laboratory Report* are included.

**3.1.10.2.3** The examiner who prepares an amended *Laboratory Report* will ensure that the amended *Laboratory Report* clearly describes the information from the *Report of Examination/Laboratory Report* being amended and how that information is being changed.

**3.1.10.2.4** The amended *Laboratory Report* will be administratively and when applicable, technically reviewed.

### **3.1.10.3 Superseding *Laboratory Report***

**3.1.10.3.1** When a previously issued report requires a change or addition and an amended or supplemental report could be confusing to the contributor, the examiner may issue a superseding *Laboratory Report*. A superseding *Laboratory Report* will only be prepared with the approval of the Unit Chief. When generating a superseding *Laboratory Report* the examiner will create a new Case Record using the Follow Up Case Record type with the appropriate evidence assigned to the Case Record. If the superseding *Laboratory Report* is being issued because a *Laboratory Report* must be removed due to a spillage event, Unit Chief approval is not required.

**3.1.10.3.2** The *Laboratory Report* will clearly state the Laboratory number(s) affected, the date(s) of the previous *Report of Examination/Laboratory Report*, a complete listing of the item(s) of evidence received in the unit, and, if applicable, that re-examinations were conducted. The *Laboratory Report* does not need to specify the wording that is changing; however, the report will state that all information in the previous *Report(s) of Examination/Laboratory Report(s)* is superseded by the current *Laboratory Report*.

**3.1.10.3.3** The superseded *Laboratory Report* will be administratively and when applicable, technically reviewed.

### **3.1.11 *Laboratory Report* with Results Obtained from Outside Experts**

When a *Laboratory Report* contains results of tests performed by an expert outside the FBI Laboratory, those results will be clearly identified. If the examination results are not included in the *Laboratory Report*, the Unit Chief will ensure that the contributor receives a copy of the outside expert's report.

### **3.1.12 *Laboratory Report* for an Examiner Not Available to Testify**

A court official or contributor may request a new *Laboratory Report* for trial purposes because the examiner who issued the original *Report of Examination/Laboratory Report* is not available to testify (e.g., no longer works for the FBI, on extended leave). The court official and/or contributor will submit a request in writing, according to the LOM - Practices for Processing a Submission and Evidence Breakdown. If the FBI Laboratory agrees to provide a new *Laboratory Report*, EMU personnel will assign a new Laboratory number for legacy cases, or the assigned examiner will create a new Case Record in FA for an existing FA case. The assigned examiner will generate a new *Laboratory Report* in accordance with these practices after re-examining the evidence or reviewing the previous examiner's records, as appropriate.

## **3.2 Reviewing a *Laboratory Report***

### **3.2.1 General Requirements**

**3.2.1.1** Each identification or association rendered as a result of a comparison will be verified. This will occur prior to or concurrently with the technical review.



**3.2.1.2** When a *Laboratory Report* contains examination results, it will be technically reviewed prior to or concurrently with the administrative review.

**3.2.1.3** Each *Laboratory Report* will be administratively reviewed.

**3.2.1.4** FBI Laboratory personnel cannot verify, technically review, or administratively review their own work.

**3.2.1.5** The verification, technical review, and/or administrative review may be conducted by the same person and may be conducted concurrently.

**3.2.1.6** Technical and administrative reviews will be recorded in FA. If the *Laboratory Report* is classified, then the technical and administrative reviewers must be approvers in Sentinel.

### **3.2.2 Expedited Results**

**3.2.2.1** Prior to a *Laboratory Report* being issued to the contributor and a complete technical review being conducted, an examiner may disseminate expedited results or partial results of an examination(s). The appropriate level 2 document may contain requirements that specify results that do not require verification by another examiner prior to dissemination (such as negative results or presumptive results). If a unit, discipline, or category of testing chooses not to define requirements for which results do not require verification prior to dissemination, all results must be verified in accordance with these practices prior to dissemination. The verification will be recorded in the FBI Laboratory file.

**3.2.2.2** When providing expedited results, the examiner will communicate the following dissemination comments to the contributor. This communication will be recorded in the Case Communication Log.

- The examinations performed on pertinent items and the results.
- The results are subject to change.
- Final results will be provided in a *Laboratory Report* that will undergo review prior to issuance.

**3.2.2.3** If the examiner provides the contributor with the final results after a technical review has been conducted but prior to an administrative review, the examiner will record that communication in the Case Communication Log.

### **3.2.3 Verification of Identification or Association**

**3.2.3.1** A verification of identification or association will be conducted by a verifier who did not perform the initial examination.

**3.2.3.1.1** If there is a qualified and authorized person within the FBI Laboratory to verify an identification or association for the discipline/category of testing being reviewed, but that person is unavailable (e.g., deployment, on leave) to conduct the verification, an attempt will be made to

obtain an expert outside the FBI Laboratory to serve as the verifier. If an expert outside the FBI Laboratory can perform the verification, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow the outside expert to verify the identification or association. If an expert outside the FBI Laboratory cannot perform the verification, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow a verification of the identification or association to not occur.

**3.2.3.1.2** If there is not another qualified and authorized person within the FBI Laboratory to verify an identification or association for the discipline/category of testing being reviewed, the appropriate Technical Leader will evaluate the qualifications of an expert outside the FBI Laboratory to serve as a verifier for a specified time. The affected unit(s) will maintain a list of approved external verifiers.

**3.2.3.2** A verification will be performed on the following as it applies to the particular examination:

- Best relevant evidence.
- Derivative information or evidence.
- Data.
- Charts.
- Images.
- Analogous information from which the first examiner based the conclusion.

**3.2.3.3** A level 2 document, will contain a definition of an identification or association and the procedures used to perform the verification.

**3.2.3.4** Upon completion of the verification, the verifier will record his/her agreement with the examiner's results in the FBI Laboratory file or in FA. Records include the date of the verification and either the verifier's signature or name and initials.

## **3.2.4 Technical Review**

**3.2.4.1** A technical review will be conducted by a person who is authorized to conduct technical reviews in the category of testing being reviewed. The technical reviewer will have been competency tested in the task(s) that the review is encompassing. Additionally, the technical reviewer will have knowledge of the technical procedures used in that category of testing.

**3.2.4.1.1** If there is an authorized person within the FBI Laboratory for the category of testing being reviewed, but that person is unavailable (e.g., deployment, on leave) to conduct the technical review, an attempt will be made to obtain an expert outside the FBI Laboratory to serve as the technical reviewer. If an expert outside the FBI Laboratory can perform the technical review, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow the outside expert to conduct the technical review. If an expert outside the FBI Laboratory cannot conduct the technical review, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations to allow a technical review to not occur.

**3.2.4.1.2** If there is not another authorized person within the FBI Laboratory for the category of testing being reviewed, the appropriate Technical Leader will evaluate the qualifications of an expert outside the FBI Laboratory to serve as a technical reviewer. The affected unit(s) will maintain a list of approved external technical reviewers.

**3.2.4.2** Technical reviews will not be conducted by the examiner(s) who authored the examination records or the *Laboratory Report* under review.

**3.2.4.3** A technical review will be performed on all *Laboratory Reports* that contain examination results and the supporting case records. This review will determine if:

- The examinations and supporting case records conform with appropriate technical procedures and applicable portions of the QAM, LOM, appropriate level 2 documents, and technical procedures;
- The appropriate examinations have been performed;
- The examiner's conclusions are consistent with the data records, are within the limitations of the discipline/category of testing, and are supported by the applicable ULTR and/or ASSTR;
- The *Laboratory Report* is accurate and there are sufficient supporting records for the results and/or conclusions of the *Laboratory Report*;
- A verification of identification or association has been completed and properly recorded, when such a conclusion has been reached;
- Associations are put into the appropriate context in the *Laboratory Report*;
- The *Laboratory Report* contains all the required information.

**3.2.4.4** A level 2 document will contain procedures used to select a reviewer and conduct a technical review, to include field examination review, when applicable.

**3.2.4.5** The technical reviewer will record his/her agreement with the examination process and the completion of the technical review in FA.

### **3.2.5 Administrative Review**

**3.2.5.1** An administrative review will not be conducted by the person(s) authoring the report being reviewed. A level 2 document may further define requirements for an administrative reviewer.

**3.2.5.2** An administrative review includes at a minimum:

- Spelling and grammatical accuracy of the *Laboratory Report*;
- The final version of the *Laboratory Report* was checked into FA by the examiner assigned to the Case Record.
- Administrative and examination records are uniquely identified according to the LOM - Practices for Assigning Cases and Conducting Examinations;
- Key information is present in the *Laboratory Report*.
- Proper classification markings have been applied.
- The administrative and examination records conform to QAM - Section 7.5 and LOM - Practices for Assigning Cases and Conducting Examinations. If

the records are retained in FA and will have required elements automatically applied (e.g., FBI Laboratory number, page counts) the administrative review does not need to account for this information.

- The *Laboratory Report* conforms to these practices.
- A technical review has been completed, when applicable, and properly recorded in FA.

**3.2.5.3** A level 2 document will contain procedures used to select a reviewer, conduct an administrative review, and a list of what is considered administrative records and examination records.

**3.2.5.4** The administrative reviewer will record his/her completion of the administrative review in FA. This record signifies approval for serializing the *Laboratory Report* to Sentinel.

### **3.2.6 Resolution of Scientific or Technical Disagreement**

Personnel will follow LOM - Practices for Resolution of Scientific or Technical Disagreement to resolve any disagreement resulting from a verification, blind verification, technical review, and/or administrative review.

## **3.3 Issuing a *Laboratory Report***

A *Laboratory Report* is primarily issued to a contributor. In some instances, it may be issued to a person other than the contributor such as a prosecutor or a lead investigator. The *Laboratory Report* will be issued only after it has been reviewed and serialized in Sentinel.

A *Laboratory Report* will be issued to an FBI contributor in an electronic file serialized in Sentinel. For an external submission received through the FBI Laboratory Contributor Portal, a *Laboratory Report* will be issued in an electronic file through the portal. For other external submissions, a *Laboratory Report* will be emailed or physically mailed to the contributor. For TEDAC submissions, a *Laboratory Report* will be available in an electronic file in the Explosives Reference Tool (EXPeRT). A *Laboratory Report* in EXPeRT may be viewed by all partners, not just a single contributor.

**3.3.1** Multiple examiners may issue one *Laboratory Report* for a major case or other cases with multiple examiners according to these practices.

**3.3.2** A *Laboratory Report* that references more than one Case ID number will list the additional Case ID number(s) in the Additional Case field in Sentinel.

**3.3.3** The *Laboratory Report* will be addressed to the FBI office of origin, even if it was not the office contributing the evidence.

**3.3.4** The *Laboratory Report* will be serialized in Sentinel. When someone other than the person issuing the *Laboratory Report* serves as the author of the *Laboratory Report* in Sentinel, the person issuing the *Laboratory Report* will serve as an approver in Sentinel.

**3.3.4.1** If the person(s) issuing the *Laboratory Report* is not available and the *Laboratory Report* must be issued immediately, a deviation will be requested as described below.

**3.3.4.1.1** If a single case requires immediate issuance of a *Laboratory Report* in the issuing person's absence (i.e., an examiner that is responsible for the examination(s)), a minor deviation will be requested according to the LOM – Practices for Authorizing Deviations to allow another person to issue the *Laboratory Report* on behalf of the issuing person (i.e., will have the issuing person's name). The minor deviation will state why the *Laboratory Report* needs to be issued immediately and why the issuing person is unavailable to be an approver in Sentinel (e.g., deployment, leave). The minor deviation will be authorized and recorded in the Case Record Communication Log. The issuing person will be listed for distribution in Sentinel and will acknowledge review of the issued report in the Case Record Communication Log upon his/her return.

**3.3.4.1.2** If multiple cases require immediate issuance of *Laboratory Reports* in the issuing person's absence (e.g., the examiner that is responsible for the examination(s)), a major deviation will be requested according to the LOM – Practices for Authorizing Deviations to allow another person(s) to issue the *Laboratory Reports* on behalf of the issuing person (i.e., will have the issuing person's name). The major deviation will state why the *Laboratory Reports* need to be issued immediately and why the issuing person is unavailable to be an approver in Sentinel (e.g., extended deployment, extended leave). A copy of the authorized major deviation will be included in the FBI Laboratory file and referenced in the Case Communication Log. The issuing person will be listed for distribution in Sentinel and will acknowledge review of the issued report in the Case Record Communication Log upon his/her return.

### **3.3.5 Requests for a Previously Issued *Report of Examination/Laboratory Report***

**3.3.5.1** If an FBI contributor requests a previously issued *Report of Examination/Laboratory Report*, the FBI contributor will be directed to retrieve the *Report of Examination/Laboratory Report* from Sentinel.

**3.3.5.2** If an external contributor requests a previously issued *Report of Examination/Laboratory Report*, the *Report of Examination/Laboratory Report* will be retrieved from Sentinel and may be sent to an external contributor, the contributing agency, and/or the prosecutor for that specific case. If the *Laboratory Report* was issued via the FBI Laboratory Contributor Portal, the *Laboratory Report* may be regenerated from the original Case Record and released to the external contributor via the FBI Laboratory Contributor Portal.

**3.3.5.3** For DNA cases involving a missing person, where a comparison is conducted with either a sample from another laboratory or a sample from a CODIS index, a copy of the *Report of Examination/Laboratory Report* may be issued to the laboratory who contributed the compared sample without authorization from the contributor.

**3.3.5.4** A Follow-Up Case Record will not be generated when a previously issued *Report of Examination/Laboratory Report* is provided.

### 3.4 Retaining Case-Related Records

Requests for examinations, administrative records, examination records, and *Laboratory Reports* are routinely received or generated by FBI Laboratory personnel. At a minimum the person managing the case will retain the Case Report, Chain-of-Custody Log, *Examination Plan* (7-262) or *TEDAC Examination Plan* (7-274), records in the Case Object Repository, records in the Case Communication Log Object Repository, and the Case Communication Log from FA. At a minimum, the examiner will retain his/her Case Record Report, records in the Case Record Object Repository, examination records, and if applicable, the Case Record Communication Log from FA and records in the Case Record Communication Log Object Repository.

#### 3.4.1 Request for Examination

The person managing the case will ensure that the request for examination is retained in Sentinel.

#### 3.4.2 Evidence Acknowledgment

An *Acknowledgement Letter* (7-3 LIMS) or an acknowledgment email to the contributor, will be retained in Sentinel. If voicemail and/or mail was used to acknowledge receipt, the appropriate communication log (e.g., *Activity and Communication Log*, Case Communication Log) will serve as the evidence acknowledgment.

#### 3.4.3 Laboratory Report

The person issuing the *Laboratory Report* will ensure it is serialized in Sentinel.

#### 3.4.4 Supporting Records

Each person who issues a *Laboratory Report* will prepare a 1A(s)/1C(s) containing supporting records for serializing in Sentinel. A new 1A(s)/1C(s) will be prepared for amended, supplemental, and superseding reports to ensure associated records support the new *Laboratory Report*. When necessary, records may be placed in the original 1A(s)/1C(s) (e.g., use of a physical record originating from the original 1A(s)/1C(s)).

**3.4.4.1** Physical supporting records will be placed in a *Supporting Documentation Envelope(s)* (7-251) and serialized as a physical attachment 1A in Sentinel. Supporting records that are too bulky to fit in a physical 1A(s) may be placed in a bulky 1C(s). Physical supporting records will be delivered to the file room. A summary of the enclosures in the 1A(s) and/or 1C(s) will be noted in Sentinel.

**3.4.4.2** The person managing the case will import supporting electronic records to the Case Object Repository or Case Communication Log Object Repository as appropriate. Personnel will import supporting electronic records to the appropriate Object Repository. Each electronic page should not exceed the largest allowed attachment size for FA. Files uploaded to FA should have the Laboratory number as the beginning portion of the file name (e.g., 2017-00002 Check-in Notes.pdf).

**3.4.4.3** Physical 1A(s) and 1C(s) generated in FA will be serialized in Sentinel,. If the file is larger than the largest allowed attachment size for Sentinel, personnel will save the files to electronic media and retain the media in the physical 1A(s) or 1C(s).

**3.4.4.4** Communication(s) will be recorded in the Case Communication Log. Substantive email communication(s) will be referenced in the Case Communication Log and the email(s) will be retained in the 1A(s)/1C(s).

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### **3.4.7 Retention of an FBI Laboratory File**

Long-term retention and disposition of files will be coordinated by the Information Management Division.

## **4 Records**

The following records will be generated and/or retained in the FBI Laboratory file and/or in Sentinel when completed as a result of these practices:

- Request for examination.
- FA Chain-of-Custody Log.
- Acknowledgement email or *Acknowledgement Letter*.
- *Examination Plan* or *TEDAC Examination Plan*.
- FA Case Communication Log.
- FA Case Record Communication Log(s), if populated.
- Record(s) of verification of an identification or association.
- *Laboratory Report*.
- 1A(s) and/or 1C(s), containing administrative and examination records.
- FA Case Object Repository, if populated.
- FA Case Record Object Repository(ies), if populated.
- FA Case Communication Log Object Repository, if populated.
- FA Case Record Communication Log Object Repository, if populated.
- Record(s) of a technical review.

- Record(s) of an administrative review.
- Additional request records, when necessary.
- FA Case Record Report(s).
- FA Case Report.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Forensic Advantage User Guide, Forensic Advantage® Systems, a division of The Computer Solution Company, Inc., latest revision.

FBI Corporate Policy Directive 0423D, Preservation and Disclosure of Electronic Communications in Federal Criminal Cases, Federal Bureau of Investigation, latest revision.



Rev. #	Issue Date	History
3	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL and to address the intelligence driven mission of the TEDAC Section of the Laboratory. Substantive changes include: removed the Responsibilities section, changed from unit based structure to a mixture of unit/discipline/category of testing based structure, referenced level 2 documents, added ability to use alternate reporting formats, generalization of RC and EA to evidence management personnel, added information about ICD Search reporting, added information about Follow Up reports and added the superseding report, updated requirements for technical and administrative reviews, added direction for issuance of a report in the absence of the issuing examiner, and updated section regarding requests for a previously issued report.
4	06/03/19	Changed evidence management personnel to Evidence Management Unit throughout document. In section 3 added a statement that any information required by accreditation requirements which is not in a <i>Laboratory Report</i> or alternate reported results will be maintained in the FBI Laboratory. Modified section 3.1 to move details about listing and description of evidence section to section 3.1.2. Removed list of examples from section 3.1.1. In section 3.1.2, added requirement for <i>Laboratory Report</i> to include a statement regarding items not examined. Added reference to DOJ ULTR documents in sections 3.1.3.1 and 3.2.4.3. Modified and added requirements in sections 3.1.3.1 through 3.1.3.1.6 to reflect revised accreditation requirements. In sections 3.1.5 and 3.1.5.3, added requirement to also provide sites where work was conducted. Added requirement for <i>Laboratory Report</i> to reference DOJ ULTR documents and discovery requirements in section 3.1.5.4. Clarified requirements regarding exam cancellations in sections 3.1.5.7 through 3.1.5.7.2. In section 3.1.8.3, allowed contributing examiners to alternatively be co-authors in Sentinel. Clarified that supplemental <i>Laboratory Report</i> pertain to completed requests in section 3.1.10.1. Relocated requirement regarding verification to section 3.2.2.1. Revised requirements for technical reviews in section 3.2.4.1 through 3.2.4.1.2 to remove requirements for person to be qualified and have casework experience, and to add requirement to have been competency tested. In section 3.3 broadened requirements to allow emailing <i>Laboratory Report</i> . Added communication log object repositories in sections 3.4 and 3.4.4.2. Revised section 3.4.2 to accommodate acknowledgement in various formats. Generalized serialization requirements in section 3.4.4.3. Updated list of records in section 4. In section 3.4.7, updated division name. Updated list of references in section 5.

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019





## FBI Laboratory Practices for Processing a Single Unit Submission (SUS)

### 1 Purpose

These practices establish the requirements for receiving evidence, processing a request for examination, and returning evidence for submissions in which examinations are to be conducted by a single unit.

### 2 Scope

These practices apply to FBI Laboratory personnel that receive, examine, and return evidence submitted to the FBI Laboratory for examination by a single unit. Single Unit Submissions (SUS) will be designated based on the type of evidence submitted.

The following items will be handled as SUS by the designated units:

Unit	Evidence Items
Chemistry Unit	Fire debris/ignitable liquid items Paint Toxicological samples including blood, hair, urine, and bodily fluid samples Metallurgical materials
DNA Casework Unit or Scientific and Biometric Analysis Unit - DNA	Swabs Known samples and toothbrushes submitted as alternate knowns Tissue samples from remains
Explosives Unit - Huntsville	Soil samples Explosives swabs and samples
Explosives Unit - Quantico	Fire debris/ignitable liquid items Explosives-related chemistry items
Firearms/Toolmarks Unit	Expendable bullets and cartridge cases
Latent Print Operations Unit	Drug packaging Known fingerprint cards Lifts
Operational Projects Unit	Film Disposable cameras Photographs Slides Negatives
Questioned Documents Unit	Shoeprint or tire casts/lifts Known samples Shredded documents

Scientific and Biometric Analysis Unit - Latents	Known fingerprint cards Lifts
Scientific and Biometric Analysis Unit – Toolmarks	Casts
Trace Evidence Unit	Geological samples Known hair and fiber samples

In addition to the above items, Compact Discs, DVDs, nonoriginal evidence, and evidence received electronically, and request only submissions will be assigned to the appropriate unit as a SUS.

Any submissions containing materials defined as hazardous by the Department of Transportation must be returned by personnel who have been trained to ship packages containing hazardous materials by a certified Department of Transportation (DOT) or International Air Transport Association-approved school. DOT defines hazardous materials as materials that in shipment pose risk to health, safety, and property. The materials are classified as being explosive, toxic, flammable, oxidizing, radioactive, or corrosive. Examples of hazardous materials include ammunition, lighters, lithium batteries, pressurized containers, matches, and chlorine.

### 3 Practices

The assigned examiner will function as the person managing the case for his/her submission/Case Record. The person managing the case and unit will be assigned at the submission level in Forensic Advantage (FA).

If the evidence receipt has not been acknowledged, the person managing the case will send an acknowledgement email as described in FBI Laboratory Operations Manual (LOM) - Practices for Assigning Cases and Conducting Examinations.

#### 3.1 Initial Receipt of Evidence

**3.1.1** Evidence Management Unit (EMU) personnel may determine if submitted evidence, that is not listed in Section 2, will be handled as a SUS based on the criteria that only one unit has and/or will examine the evidence.

**3.1.1.1** The submitted evidence will be handled as a SUS as described in this document from the time that it is designated as a SUS.

**3.1.2** EMU personnel will create a submission in FA as described in the LOM - Practices for Processing a Submission and Evidence Breakdown. Physical evidence may be stored temporarily in evidence receiving areas until the assignment occurs.

**3.1.3** EMU personnel will create a Case Record in FA for the assigned unit. In lieu of an *Examination Plan (7-262)* or *TEDAC Examination Plan (7-274)*, the assignment of the Case Record will record the review of examinations.

**3.1.4** The Unit Chief of the assigned unit will ensure the SUS is assigned to the unit and an examiner, and the Case Record is assigned to the examiner.

**3.1.5** If a lead was created in Sentinel by an FBI contributor, it will be forwarded to the assigned unit by EMU personnel.

### **3.2 Request Only Submissions and Submissions of Evidence Received Electronically**

**3.2.1** When evidence is received electronically (e.g., email attachments, evidence serialized in Sentinel by FBI contributors and retrieved by Laboratory personnel for examination) or a request only submission is received by a person who is not appropriately trained to receive evidence, he/she will contact an appropriately trained person to initiate a submission in FA.

**3.2.2** Request only submissions will be created in FA using the Request evidence type.

**3.2.3** Evidence submissions received electronically will be created in FA using the Item Evidence type.

**3.2.4** Request only submissions and evidence received electronically will be directly forwarded to the appropriate unit. The evidence will be received on the FA New Submissions grid prior to starting examinations.

**3.2.5** If multiple types of evidence are submitted electronically for separate units under a single request, a Case Record will be assigned to each of the requested units. Each examiner will function as the person managing the case for his/her assigned Case Record.

### **3.3 Evidence Breakdown**

**3.3.1** A person in the assigned unit will breakdown the evidence as described in the LOM - Practices for Processing a Submission and Evidence Breakdown. Personnel breaking down the evidence will record what evidence was received and the condition in which it was received (e.g., check-in notes).

**3.3.1.1** If a firearm is assigned as a SUS and there are no indications the item has been rendered safe (e.g., green zip tie affixed to a visible part of the weapon), the person breaking down the evidence will consult with an appropriately trained person to render the firearm safe before handling.

**3.3.1.2** If the person breaking down the evidence determines that the submission should be handled as a Multiple Unit Submission (MUS), the person will determine a logical stopping point and will consult with EMU personnel for possible reassignment.

### **3.4 Examination Process**

**3.4.1** An examiner will review the information for each case and determine the necessary examinations. An *Examination Plan* or *TEDAC Examination Plan* is not required.

**3.4.2** Examinations will be conducted as described in the LOM - Practices for Assigning Cases and Conducting Examinations.

### **3.5 Laboratory Report**

**3.5.1** The *Laboratory Report* (7-1 LIMS, 7-273 LIMS) will be formatted as described in the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). The examiner does not need to additionally state that they may be contacted regarding the status of the submission.

**3.5.2** The Description of Evidence section will include a full list of all evidence submitted within the submission.

### **3.6 Change of Request From a SUS to a MUS**

**3.6.1** If it is determined that the evidence submitted does not meet the definition of a SUS as listed in section 2, the change of request will be recorded in the Case Communication Log in FA and the submission will be reassigned to EMU personnel to manage the submission.

**3.6.2** The EMU person managing the case will create an *Examination Plan* or *TEDAC Examination Plan* and follow the LOM - Practices for Assigning Cases and Conducting Examinations to process the request.

### **3.7 Change of Request From a MUS to a SUS**

**3.7.1** When evidence has been sent to a unit as a MUS and unit personnel would like to request that the status be changed to a SUS, the person managing the case will contact EMU personnel to request the change.

**3.7.1.1** The decision to change the status of submitted evidence from MUS to SUS may occur at any time as long as only one unit has and/or will examine the evidence (e.g., contributor decides he/she only wants one examination).

**3.7.2** EMU personnel will determine if the status of the submission should be changed. If so, the change in status and any information that supports the change (e.g., communication with the contributor, EMU personnel) will be recorded in the Case Communication Log in FA.

### **3.8 Evidence Disposition**

**3.8.1** Evidence will be packaged and returned as described in the LOM - Practices for Shipping and Returning Evidence.



**3.8.2** If evidence will be archived (i.e., TEDAC Evidence Repository), the examiner will ensure that all evidence is properly sealed and accounted for on the Chain-of-Custody Log.

### **3.9 Retaining Case Records**

**3.9.1** After evidence has been returned, the examiner will ensure that the Chain-of-Custody Log and other records are complete for the submission.

**3.9.1.1** If this is the only submission within the case, or if all other Case Records are closed, the examiner will ensure that the Case and Case Record 1A(s)/1C(s) are generated and retained.

**3.9.1.2** If other submissions in the case are still open, the examiner will ensure that the Case Record 1A(s)/1C(s) is generated and retained.

**3.9.2** The appropriate records from FA will be serialized in Sentinel and the *Laboratory Report* will be issued.

**3.9.3** A person from the assigned unit will ensure the lead is covered in Sentinel, if applicable, for evidence submitted by an FBI contributor.

## **4 Records**

The following records may be generated and/or retained in the FBI Laboratory file or Sentinel as a result of these procedures:

- Record of verification of an identification or association.
- Record of a technical review.
- Record of an administrative review.
- *Laboratory Report*.
- Request for examination.
- Authorization or request documentation, when necessary.
- Record of the change in status and any information that supports that change between a MUS and a SUS.
- FA Chain of Custody Log.
- Record of the condition in which the evidence was received (e.g., check-in notes).
- FA Case Communication Log, if populated.
- FA Case Record Communication Log, if populated.
- FA Case Object Repository, if populated.
- FA Case Record Object Repository, if populated.
- FA Case Communication Log Object Repository, if populated.
- FA Case Record Communication Log Object Repository, if populated.
- FA Case Record Report.
- FA Case Report.
- FA Secondary Evidence Log.
- 1A(s)/1C(s), containing administrative and examination records.

## 5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
2	10/02/17	Document revised to include updated requirements due to the addition of the satellite facility in Huntsville, AL and to address the intelligence driven mission of the TEDAC Section of the Laboratory. Substantive changes include: removed the Responsibilities section, added TEDAC Section units' defined single unit submissions, added requirements for ensuring firearms are rendered safe, generalization of RC and EA to evidence management personnel, updated requirements for breakdown when a SUS becomes a MUS, removed requirement for communication with contributor within 10 days of evidence receipt in a unit, updated personnel authorized to change a submission's status from a MUS to a SUS.
3	06/03/19	Changed evidence management personnel to Evidence Management Unit throughout. Revised table in Section 2 to reflect realignment of Laboratory personnel and removed footnote. In sections 3.1.1, 3.6.2, and 3.7.2 removed requirement for authorization. In section 3.1.1 removed requirement for unit agreement for evidence to be handled as a SUS. Added reference to green zip tie in section 3.3.1.1. Updated title of section 3.8 and added section 3.8.2 to cover archived evidence. Added communication log object repositories to list of records in section 4. Updated list of references in section 5.

### **Approval**

Redacted - Signatures on File

Laboratory Director

Date: 06/03/2019

Quality Manager

Date: 06/03/2019