Quality Assurance Manual

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Quality Assurance Manual

1 GENERAL

1.1 Laboratory Activities and Services

Laboratory activities are performed by FBI Laboratory personnel to support FBI and other federal, state, local, and foreign investigations as well as intelligence matters. Additionally, FBI Laboratory personnel provide DNA databasing services, participate in ongoing field investigations by assisting with crime scene searches, and provide other scientific and/or technical services as necessary. FBI Laboratory personnel also provide testimony. The Handbook of Forensic Services contains a general listing of forensic services offered by the FBI Laboratory.

1.2 Quality System

A. The FBI Laboratory provides quality forensic services to its customers and is committed to the continued development and improvement of its quality system. The FBI Laboratory quality system ensures functions are performed as intended and conform to the requirements of applicable accrediting body(ies). FBI Laboratory personnel are responsible for ensuring they understand and apply the quality system to their daily activities. [ISO 17020 8.2.1] [ISO 17025 8.2.1] [ISO 17025 8.2.3]

B. The FBI Laboratory quality system provides a mechanism for identifying and/or implementing the policies and procedures that support consistent, accurate and reliable forensic products and services. Additionally, the quality system addresses the competence and impartiality of FBI Laboratory personnel. The LAB-100 document is comprised of quality-supporting requirements such as document control, performance monitoring, and calibration. The LAB-200 document covers the FBI Laboratory evidence/forensic service cycle and is comprised of requirements such as evidence handling, examinations, and reporting. In LAB-100 and Lab-200, a 'NOTE:' provides clarification, and is not a requirement. Unit, discipline, and subdiscipline documents (Level 2) supplement the LAB-100 and LAB-200 documents (Level 1) and provide specificity for laboratory activities. [ISO 17020 8.2.1] [A2LA R318 7.1 FI1.1] [ISO 17025 8.2.1] [ISO 17025 8.2.2]

C. The FBI Laboratory quality system applies to FBI Laboratory personnel, both FBI employees and contractors.

D. The FBI Laboratory quality system demonstrates the consistent achievement of the requirements of its accrediting bodies, ISO/IEC 17020:2012 (ISO 17020), ISO/IEC 17025:2017 (ISO 17025), American Association for Laboratory Accreditation (A2LA) R318, ANSI National Accreditation Board (ANAB) AR 3125, FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, FBI Quality Assurance Standards for DNA Databasing Laboratories, and assures the quality of laboratory results. The FBI Laboratory operates its quality system in accordance with Option A of ISO 17025 and ISO 17020 and addresses all the required elements. [ISO 17020 8.1] [ISO 17020

8.1.1] [ISO 17020 8.1.2] [ISO 17020 8.2.1] [ISO 17025 8.1, 8.1.1] [ISO 17025 8.1.2] [ISO 17025 8.2.1]

E. Disciplines that are accredited are listed on the FBI Laboratory ANAB Scope of Accreditation. This also lists the component/parameters, items, and key equipment/technology that are accredited.
    - Subdisciplines defined by the FBI Laboratory under the Materials (Trace) discipline on the ANAB Scope of Accreditation are:
        - Hairs and Fibers
        - General Chemistry
        - Geology
        - Metallurgy
        - Paints and Polymers
    - Subdisciplines defined by the FBI Laboratory under the Fire Debris and Explosives discipline on the ANAB Scope of Accreditation are:
        - Explosives and Hazardous Devices
        - Explosives Chemistry
        - Fire Debris
F. Cryptology and Illicit Business Records are FBI Laboratory defined disciplines.
G. Chemical/Biological/Radiological/Nuclear (CBRN) material and related evidence is listed on the FBI Laboratory A2LA Scope of Accreditation. The direction and coordination of examinations, to include traditional forensic analysis, are accredited.
H. FBI Laboratory management is committed to the development, implementation, and continuous improvement of the quality system. This is communicated via policies, the quality system, other written communication such as emails, and meetings with FBI Laboratory personnel. Additionally, regular meetings and the annual management review provide for discussions between Executive Management and the Quality Manager regarding the continual improvement of the quality system. With the support of the FBI Laboratory's management and input from personnel, policies and procedures are developed, revised, and implemented as necessary. [ISO 17020 8.2.2] [ISO 17025 8.2.3]
I. All components related to the fulfillment of the accrediting bodies' requirements are included, referenced, or linked to the quality system. [ISO 17020 8.2.4] [ISO 17025 8.2.4]
J. FBI Laboratory personnel have access to the quality system documents and related information necessary for their responsibilities. [ISO 17020 8.2.5] [ISO 17025 8.2.5]

1.3 Quality System Objectives

The FBI Laboratory quality system objectives are as follows: [ISO 17025 8.2.1, 8.2.2]

- To ensure services and results provided to FBI Laboratory customers are reliable and scientifically sound.
- To formally establish methods of quality assurance within the FBI Laboratory through the implementation of recognized standards.

- To ensure procedures are valid, dependable, reproducible, and adequate for the intended purpose.
- To ensure the routine operational performance of units, disciplines, and subdisciplines within the FBI Laboratory are monitored.
- To ensure all areas of the quality system are periodically audited to demonstrate that policies and procedures are being followed.
- To maintain quality, impartiality, 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.

1.4 Terms and Definitions

1.4.1 Addressing in Writing

The following words (to include forms of the same word) used in accrediting bodies' requirements or in this document require addressing in writing: agreed, authorize, define, instructions, method, plan (noun only), procedure, program, record, schedule, specify. The use of i.e., means 'in other words' and the use of e.g., is 'for example'. [ANAB AR 3125 8.2.1.1]

1.4.2 List of Terms and Definitions

- **1A** - Compilation of records that are serialized in Sentinel. Physical records related to a submission are placed in a *Supporting Documentation Envelope* (7-251).
- **1C** - Records of the same nature as 1A material but are physically too large to be filed in the 1A.
- **Analytical/Interpretive Error** - A technical error identified in casework, DNA databasing, or performance monitoring (see section 10.2.6).
- **Archived Storage** - A digital or physical location for long-term storage of evidence.
- **Association** - A determination that a relationship exists between individuals and/or objects. [ANAB AR 3125 3.10]
- **Audit** - Process for obtaining records, statements of fact, or other relevant information about the quality system and evaluating it objectively to determine the extent to which specified requirements are fulfilled. [ANAB AR 3125 3.11]
- **Authorized** – A document or record providing a role or individual permission to a perform a task.
- **Blind Verification** - An independent examination of an item(s) of evidence by another authorized examiner who is unaware of the original examiner's conclusion.
- **Calibration** - The adjusting or standardizing of equipment to ensure agreement of a measurement with a reference standard.
- **Case ID** - A unique alphanumeric identification number assigned by the FBI to an investigation.
- **Case Notes** - The record of controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other records generated by laboratory personnel to support conclusions.

- **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. [ANAB AR 3125 3.12]
- **Chain-of-Custody Log (7-243, 7-243a or equivalent in a Laboratory Information Management System (LIMS))** - A chronological record of the handling and storage of items related to a request over which the FBI Laboratory has control.
- **Check-In Notes** - A mechanism to record the items received, including evidentiary and non-evidentiary items, the container/packaging, and the condition of these items.
- **Communication Log (7-245 or equivalent in a LIMS)** - A record of activity or communication related to a case.
- **Competency Test** - The evaluation of a person's knowledge, skills, and/or ability to perform work. Required for individuals who perform laboratory activities. [ANAB AR 3125 3.13]
- **Continuing Education** - The mechanism through which a person increases or updates their knowledge, skills, or abilities, reinforces their knowledge, or learns of the latest research, developments, or technology related to their duties.
- **Control** - A measure that maintains and/or modifies risk.
- **Controlled Document** - A document that is issued and distributed in a trackable manner (see Document).
- **Corrective Action Plan (CAP) -** A plan to eliminate the cause of a detected nonconformity deemed major or other undesirable situation adverse to quality and to prevent recurrence. This may include the effect or impact on the quality of work, the integrity of evidence, or the quality of the testimony (see section 5).
- **Corrective Maintenance** - Actions taken on equipment to restore it to proper operation.
- **Customer** - A person or organization that submits evidence to and/or requests the services of the FBI Laboratory. Equivalent to 'client' as used in ISO 17020 and A2LA R318 or 'customer' as used in ISO 17025 and ANAB AR 3125.
- **Decision Rule** - A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. [ISO 17025 3.7]
- **Designee** - A person or role designated in writing to perform a task. The designee can be assigned responsibility for that task by the original person or their manager.
- **Deviation** - A planned departure from a requirement(s) (see section 4).
- **Disagreement** - When personnel come to competing or mutually exclusive opinions (or as defined in a Level 2 document(s) for a given discipline and/or subdiscipline).
- **Discipline** - A major area of activity in forensic science which may appear on a scope of accreditation (see section 1.2.E and F). [ANAB AR 3125 3.17]
- **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 17025, and ANAB AR 3125.

- **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 Level 0, Level 1, Level 2, Level 3, and Level 4 documents (see section 2).
- **Electronic Communication (EC) (FD-1057)** - A standardized form typically used to record information in Sentinel as an FBI official record.
- **Ensure** - To make certain that something will or has occurred. This does not require a written confirmation. A task may be completed by someone other than the person required to ensure the task is completed.
- **Environmental Conditions** - Any characteristic of the FBI Laboratory facilities that could reasonably be expected to affect or impact the quality of work.
- **Evaluation Elements** - Specific measures that are assessed during a training evaluation.
- **Evidence** - An item submitted for examination(s). Equivalent to 'item' as used in ISO 17025, ISO 17020, ANAB AR 3125, and A2LA R318. (see Secondary Evidence).
- **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.
- **FBI Laboratory** - In this manual, this term refers to the entity that includes personnel who are responsible for receiving, checking in/inventorying, handling, and/or examining evidence; DNA databasing; reviewing and providing results; providing instrument operations support; developing, modifying, verifying, and validating methods/procedures; providing opinions and/or testimony; and maintaining the quality system (see Roles and Responsibilities of FBI Laboratory Personnel (LAB-401) and Summary of Requirements for FBI Laboratory Personnel (LAB-402)).
- **FBI Laboratory File** - Records generated and/or maintained by the FBI Laboratory for a submission (see Operations Manual (LAB-200) section 7).
- **Follow Up Report** - A *Laboratory Report* or i3 product generated if a change or addition must be made to the content of a previously issued *Laboratory Report* or i3 product and/or to provide additional information pertaining to a completed request for examination.
- **Hazardous Material Evidence** - Any item or agent (biological, chemical, physical, radioactive) 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 in shipment that pose risk to health, safety, and property. The materials are classified as being explosive, toxic, flammable, oxidizing, radioactive, or corrosive (see FBI Laboratory Safety Manual).
- **i3 Product** - Report intended for intelligence, information, and/or investigative leads only and not intended for adjudication purposes (see Operations Manual (LAB-200) section 4).

- **i3 Service** - Service provided for intelligence, information, and/or investigative leads only (see Operations Manual (LAB-200) section 4).
- **Individual Characteristic Database (ICD)** - A computerized, searchable collection of features generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images). [ANAB AR 3125 3.18]
- **Intelligence** - Information gathered to support 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.
- **Interlaboratory Comparison** - Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. [ISO 17025 3.3]
- **Internal Audit** - An audit conducted by FBI Laboratory personnel to compare the various aspects of the FBI Laboratory's performance with a standard for that performance.
- **Internal Auditor** - A person who conducts Forensic Analysis Support Unit (FASU) directed audits. In the FBI Laboratory, auditors performing internal audits must successfully complete an approved course.
- **Intralaboratory Comparison** - Organization, performance, and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions. [ISO 17025 3.4]
- **LabApps (formerly Explosive Reference Tool (EXPeRT))** - A LIMS in which TEDAC shares information with the Counter-Improvised Explosive Device (C-IED) community. It is also used for case management of TEDAC Legacy submissions.
- **Laboratory Activities** -Testing and sampling performed or directed by FBI Laboratory personnel.
- **Laboratory Core Training (also known as Common Core)** - Training topics developed and executed in a consistent manner for FBI Laboratory personnel, as applicable.
- **Laboratory Examination Request (LER) (FD-1121)** - A Sentinel-based form that may be used to request forensic examinations from the FBI Laboratory (see Request for Examination).
- **Laboratory Number** - The FBI Laboratory's identifier that is assigned to each case for examination.
- **Laboratory Report (7-1, 7-1 LIMS)** - An official FBI Laboratory report that presents case-related information to a customer regarding FBI Laboratory work.
- **Legacy Case** - Evidence or a request for examination submitted to the FBI Laboratory prior to the implementation of the Forensic Advantage (FA) LIMS.
- **Management** – Laboratory Director, Section Chiefs and technical management.
- **Materially Inaccurate Statement in Testimony** - Statement which tends to make any fact at issue before the court more or less likely and may include one that impacts the strength of a person's conclusion.
- **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 the value of a quantity.
- **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** - Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. Also known as uncertainty of measurement.
- **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.
- **Nonconformity** - A nonfulfillment of a requirement. A nonconformity can result in nonconforming work, therefore throughout this document, the term nonconformity will encompass nonconforming work (see section 5).
- **Performance Check** - A check carried out at appropriate intervals to verify equipment is working as expected, or to maintain confidence in the calibration status of equipment. Analysis of a control may be used as a performance check.
- **Performance Monitoring** - Processes used to evaluate the ongoing ability of a person and/or the FBI Laboratory to carry out duties reliably.
- **Practicable** - Available and capable of being done after taking into consideration cost, existing technology, and logistics considering overall purpose.
- **Preventive Action** - Action intended to eliminate the cause of a potential nonconformity or other undesirable potential situation.
- **Preventive Maintenance** - Actions taken to ensure instruments and equipment continue to operate properly.
- **Procedure** - A specified way to carry out an activity or a process.
- **Proficiency Testing** - Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. In the FBI Laboratory, these tests are purchased from accredited external providers. [ISO 17025 3.5]
- **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 completed their assigned training program, demonstrated competence, and participate in performance monitoring, when applicable.
- **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 17025 and ISO 17020 and ANAB AR 3125.
- **Quantity Value** - Property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference.

- **Reagent** - A substance used because of its known chemical or biological activity. [ANAB AR 3125 3.19]
- **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 (e.g., mass spectra, motor vehicle paints, firearms, ammunition). [ANAB AR 3125 3.20]
- **Reference Material** - Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. [ANAB AR 3125 3.21]
- **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. [ANAB AR 3125 3.23]
- **Remediation -** The process used to correct a deficiency of demonstrated competence in an evaluated activity.
- **Request for Examination** - A customer's request for FBI Laboratory services; may be submitted via a Laboratory Examination Request (LER) (FD-1121), Electronic Communication (EC) (FD-1057), Lead, *Terrorist Explosive Device Analytical Center (TEDAC) Item Submission Form* (7-275), *TEDAC Bulk Submission Form* (7-276), or a letter on agency letterhead. This term may be used when requesting a service that is not considered an examination and does not cover requests for DNA databasing.
- **Request Only** - A request for FBI Laboratory services that does not require the submission of evidence.
- **Resource Manager** - A module in a LIMS for tracking FBI Laboratory equipment and calibration and specified maintenance records. Other recordkeeping software (e.g., Laserfiche, STACS) may be used to perform equivalent functions.
- **Root Cause(s)** - The fundamental reason(s) a nonconformity occurred.
- **Sample Tracking and Control Software (STACS)** - The LIMS that may be used by DNA personnel in lieu of or in addition to the FBI Laboratory's main LIMS.
- **Sampling** - Selection and/or collection of material/data. [ANAB AR 3125 3.25]
- **Scientific Review Board** - Personnel selected to assist in the resolution of a disagreement of a scientific or technical nature within the FBI Laboratory.
- **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 customer and could not have been assigned an item identifier through the evidence breakdown process.
- **Secondary Evidence Log** - A listing of secondary evidence. Level 2 forms may vary slightly in naming of this log.
- **Sentinel** - The FBI's official recordkeeping, information, and case management system.
- **Should** - A word used when an element of the quality system is recommended but not required.
- **Sponsoring Attorney** - Attorney who subpoenaed the witness.

- **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 (SDO) such as ASTM International (formerly known as the American Society for Testing and Materials).
- **Subdiscipline** - A subcategory of activity in a forensic science discipline and designated as such in the FBI Laboratory.
- **Subject Matter Expert (SME)** - A person having specific skills and/or knowledge of a particular topic derived from training and/or experience.
- **Submission** - Single instance of providing evidence and/or a request for service to the FBI Laboratory.
- **Substantive Violation in Testimony** - Meaningful or significant violation of any requirement related to testimony monitoring (i.e., testimony in conflict with Department of Justice (DOJ) Uniform Language for Testimony and Reports (ULTR) or the Approved Standards for Scientific Testimony and Reporting (ASSTR)).
- **Technical Management** - Includes the Quality Manager, the caseworking/DNA databasing/evidence management Unit Chiefs and Supervisors, and Technical Leaders (see section 1.7).
- **Technical Procedure** - A Level 2 document that specifies the way to carry out an activity or a process (e.g., steps, methods, equipment). Technical procedures are written to provide instruction and standardization for conducting laboratory activities and those processes that influence laboratory activities (e.g., photography).
- **Technical Records** - Accumulations of data and information that support laboratory activities and that indicate whether specified quality or process parameters are achieved. These are non-transitory records as defined by FBI policy that may include forms, worksheets, case notes, calibration and maintenance records, reagent records, and calibration certificates. Some records may be retained independent of the FBI Laboratory file. All issued *Laboratory Reports* and i3 products are retained as technical records.
- **Technical Review** - Evaluation of case notes, data, and other records that are the basis for the scientific results and conclusions contained in the *Laboratory Report* and/or i3 product. This review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the recorded data, and the conclusions are within the scope of the discipline and/or subdiscipline. This term may also be used to describe other reviews (e.g., document preparation).
- **Technical Reviewer** - A competency tested person who is authorized to conduct technical reviews of examination, i3, and/or DNA databasing records in that discipline and/or subdiscipline. For other types of reviews involving technical matters (e.g., documents, validations), a person must have adequate subject matter expertise.
- **TEDAC (Terrorist Explosive Device Analytical Center)** - A section within the FBI Laboratory that performs forensic examinations on IEDs and related material.

- **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 customers 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 customers or FBI personnel to request TEDAC examinations when more than one case is submitted to TEDAC (see Request for Examination).
- **TEDAC Repository** - The location for the long-term retention of TEDAC materials. Items may be eligible for lending to TEDAC partners.
- **Trainee -** Personnel engaged in required training as described in this document and/or a unit, discipline, or subdiscipline training manual prior to performing tasks independently (see section 6.2.3.A Note).
- **Training Manual –** A document that provides an organized description and details to describe expected knowledge, skills, and abilities for each job, process, or task.
- **Training Plan** - An outline of topics, evaluations, and anticipated date range of training required for a trainee to achieve specific learning within a training program (see section 6.2.3).
- **Training Program** - A structured and organized set of activities designed to develop or enhance a trainee's knowledge, skills, and abilities in a specific area.
- **Training Records** - A collection of records related to a person's training, qualification, and authorization to perform work.
- **Unexpected Results/Observation** - A discrepancy identified during performance monitoring.
- **Validation** - The process for determining whether specified requirements are adequate for an intended use.
- **Verification** - Provision of objective evidence that a given item fulfills specified requirements (e.g., confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person).
- **Verification of Effectiveness** - Confirmation that action steps associated with a CAP were effective.
- **Verifier** - A competency tested person who is authorized to conduct verifications.
- **Will** - A word used when an element of the quality system is required.
- **Working Standard** - Measurement standard routinely used to verify measuring instruments or measuring systems.

1.5 Impartiality

A. The FBI Laboratory performs and manages its laboratory activities in a structured manner to safeguard impartiality. [ISO 17020 4.1.1] [ISO 17025 4.1.1]

B. FBI Laboratory management is committed to impartiality. All personnel are expected to remain objective and impartial when performing laboratory activities, including when testifying in court. [ISO 17020 4.1.5] [ISO 17025 4.1.2]

C. The FBI Laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial, or other pressures to compromise its impartiality. [ISO 17020 4.1.2] [ISO 17020 6.1.11] [ISO 17025 4.1.3]
D. FBI Laboratory personnel are committed to good, ethical professional practice as described in the Department of Justice Code of Professional Responsibility for the Practice of Forensic Science. [ISO 17020 6.1.12] [ANAB AR 3125 4.1.3.1.a]
E. FBI Laboratory management ensure the Department of Justice Code of Professional Responsibility for the Practice of Forensic Science is reviewed each fiscal year by FBI Laboratory personnel via the FBI Virtual Academy Forensic Ethics Training Course. A record of the review is retained in Virtual Academy. Appropriate actions will be taken when necessary. [ANAB AR 3125 4.1.3.1.b] [ANAB AR 3125 4.1.3.1.c] [ANAB AR 3125 6.2.2.2.c]
F. The FBI Laboratory identifies risks to its impartiality on an on-going basis. This includes risks that arise from its activities, from its relationships, or from the relationships of its personnel. Such relationships do not necessarily present a risk to impartiality. [ISO 17020 4.1.3] [ISO 17025 4.1.4]
    1. If a risk to impartiality is identified, FBI Laboratory personnel eliminate or minimize the risk to include requirements described in this document and/or according to FBI policy. [ISO 17020 4.1.4] [ISO 17025 4.1.5]

1.6 Confidentiality

A. The FBI Laboratory is responsible for the management of all information it obtains or creates during the performance of laboratory activities and maintains confidentiality with its customers. The FBI Laboratory does not place customer requested/specific information pertaining to laboratory activities in the public domain. If this becomes necessary, the customer will be informed in advance. [ISO 17020 4.2.1] [ISO 17025 4.2.1]
B. Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on behalf of the FBI Laboratory, keep all information obtained or created during the performance of laboratory activities confidential, except as required by law. [ISO 17020 6.1.13] [ISO 17025 4.2.4]
C. Information is only released to customers who have a need to know (e.g., customers who submit evidence, case agents, intelligence partners, law enforcement partners, prosecutors) or as required by law (e.g., discovery, Freedom of Information & Privacy Acts). Customers are not notified of information provided unless the release of confidential information is required beyond the requests typical of a public forensic service provider. [ISO 17020 4.2.2] [A2LA R318 7.4 FI1.5] [ISO 17025 4.2.2]
D. Information received about a customer from sources (e.g., complainant, regulator) other than the customer will be kept confidential by the FBI Laboratory. The FBI Laboratory also keeps the source of the information confidential, and will not share it with the customer, unless agreed to by the source. [ISO 17020 4.2.3] [17025 4.2.3]
E. FBI *Laboratory Reports* and/or i3 products will contain the applicable warning statements regarding personally identifiable information (PII) and/or information

related to juveniles and/or protected identities as described in LAB-200. [FBI Laboratory Executive Management (EM) Directive HQ-A1487699-LAB, Serial 104]

1.7 FBI Laboratory Structure

The FBI is the principal investigative arm of the United States Department of Justice. The FBI Laboratory is a forensic service provider in the FBI. [ISO 17020 5.1.1] [ISO 17025 5.1]

A. The Laboratory Director has overall responsibility and authority for the FBI Laboratory. Section Chiefs are responsible for managing their section and Unit Chiefs and have authority to suspend or stop technical operations in their section. Unit Chiefs are responsible for managing their unit and unit personnel and have authority to suspend technical operations in their unit. The Quality Manager has final technical authority for quality and accreditation matters relating to laboratory operations. The Quality Manager also has authority to suspend operations based on a breach of the quality standards. Technical Leaders are responsible for technical matters within their discipline and/or subdiscipline and have authority to initiate, suspend and resume laboratory activities in their discipline and/or subdiscipline. [ISO 17025 5.2] [ISO 17025 5.5.b]
B. The Laboratory Director's duties are defined in the FBI Assistant Director job description. [ANAB AR 3125 5.2.1]
C. The FBI Laboratory provides a range of forensic services as specified in its ANAB Scope of Accreditation and its A2LA Scope of Accreditation. The accredited disciplines listed on the ANAB Scope of Accreditation conform to the ISO 17025 requirements. Forensic inspections listed on the A2LA Scope of Accreditation conform to the ISO 17020 requirements. FBI Laboratory defined disciplines, cryptology and illicit business records, as well as i3 services and products conform to applicable FBI Laboratory quality system requirements. [ISO 17020 5.1.3] [ISO 17025 5.3]
D. The FBI Laboratory provides forensic services based on a customer's request, a submission of evidence, a request to search biometric databases, and/or to confirm a biometric database match. These laboratory activities are conducted in such a way as to conform to the requirements of applicable regulatory authorities and organizations providing recognition (e.g., accrediting bodies). This includes laboratory activities performed at permanent facilities and at other facilities or sites where FBI Laboratory personnel perform forensic services. [ISO 17025 5.4]
E. Personnel performing DNA analysis comply with the National DNA Index System (NDIS) Operational Procedures Manual, the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, and/or the FBI Quality Assurance Standards for DNA Databasing Laboratories, as appropriate. [ANAB AR 3125 Note 5.4]
F. The FBI Laboratory conforms to the requirements in the ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. [ANAB AR 3125 5.4.1]
G. The FBI Laboratory will disclose any event or nonconformity that could substantially affect the integrity of laboratory activities and is related to an accreditation

requirement or the requirements of the regulatory authorities. FBI Laboratory personnel must notify the Quality Manager of any event or nonconformity that they identify or comes to their attention meeting these requirements. The Quality Manager will disclose any event or nonconformity to ANAB in accordance with ANAB MA 3033. [ANAB AR 3125 5.4.2] [ANAB MA 3033 4.6]

1. ANAB will be notified within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence, ANAB will be notified immediately.
2. If a CAP is initiated, the Quality Manager will determine when a CAP meets these requirements.

H. The FBI Laboratory organizational chart shows the structure and the relationships between Executive Management, the Quality Manager, technical operations (i.e., caseworking units, DNA databasing units), and support services. The FBI Laboratory's position in the FBI is shown in the FBI organizational chart. Technical Leaders are designated for each discipline or subdiscipline (see section 1.2.E, F, and G) except for DNA and Friction Ridge where they are positions. Each Technical Leader is on a list maintained by FASU. [ISO 17020 5.1.2] [ISO 17020 5.2.1] [ISO 17020 5.2.4] [ISO 17025 5.5.a]

I. The FBI Laboratory defines the responsibility, authority, and interrelationship of all its personnel who manage, perform, or verify work affecting the results of laboratory activities in the FBI Laboratory organizational chart, unit organizational charts, appropriate quality system documents, and authorization records. [ISO 17020 5.2.2] [ISO 17020 5.2.3] [ISO 17025 5.5.b]

J. The FBI Laboratory has procedures to ensure the consistent application of its laboratory activities and the validity of results. [ISO 17025 5.5.c]

K. The FBI Laboratory provides its personnel the authority and resources needed to carry out their duties including: [ISO 17025 5.6]

1. Implementation, maintenance, and improvement of the quality system; [ISO 17025 5.6.a]
2. Identification of deviations from the quality system or from the procedures for performing laboratory activities; [ISO 17025 5.6.b]
3. Initiation of actions to prevent or minimize such deviations; [ISO 17025 5.6.c]
4. Reporting to laboratory management on the performance of the quality system and any need for improvement; [ISO 17025 5.6.d]
5. Ensuring the effectiveness of laboratory activities. [ISO 17025 5.6.e]

L. FBI Laboratory management ensures that:

1. Communication occurs via email, meetings, or other means regarding the effectiveness of the quality system and the importance of meeting customers' and other requirements. [ISO 17025 5.7.a]
2. The integrity of the quality system is maintained when changes to the quality system are planned and implemented. [ISO 17025 5.7.b]

M. The FBI Laboratory has the personnel, facilities, equipment, and support systems necessary to manage and perform its laboratory activities. [ISO 17020 6.1.2] [ISO 17025 6.1]

1.8 Facilities and Environmental Conditions

A. FBI Laboratory permanent facilities are in Quantico, Virginia, and Huntsville, Alabama. Laboratory activities may also be performed by FBI Laboratory personnel at sites away from the permanent facilities, in associated temporary or mobile facilities, or at a customer's facility.

B. Units, disciplines, and/or subdisciplines ensure facilities and environmental conditions are suitable for laboratory activities and do not adversely affect the validity of the results. [ISO 17020 6.2.1] [ISO 17025 6.3.1]
    1. Environmental or facility conditions necessary for the performance of laboratory activities are documented in the appropriate technical procedure. [ISO 17020 6.2.3] [ISO 17025 6.3.2]
    2. If environmental conditions influence the validity of results of laboratory activities, then units, disciplines, and/or subdisciplines will monitor, control, and record those conditions as required in a Level 2 procedure. [ISO 17025 6.3.3]

C. Measures to control the FBI Laboratory facilities are implemented, monitored, and periodically reviewed to include:
    1. Access to and use of areas affecting laboratory activities; [ISO 17025 6.3.4.a]
    2. Prevention of contamination, interference, or adverse influences on laboratory activities; [ISO 17020 7.2.4] [ISO 17025 6.3.4.b] and
    3. Effective separation between areas with incompatible laboratory activities. [ISO 17025 6.3.4.c]

D. When laboratory activities are undertaken at sites or facilities other than the permanent FBI Laboratory facilities, personnel will ensure requirements related to facilities and environmental conditions are met. [ISO 17025 6.3.5]

E. Policies and procedures for security and access to areas where laboratory activities occur are documented in LAB-200 and FBI policy. [ISO 17020 6.2.2] [A2LA R318 6.2 FI1.1] [ANAB AR 3125 6.3.4.1]

F. All personnel, evidence, DNA database samples, and FBI Laboratory files are secure while in FBI Laboratory facilities. [ANAB AR 3125 6.3.4.1]

G. Due to security, classification issues, and the sensitivity of cases, the FBI Laboratory Director restricts access to the FBI Laboratory facilities to only FBI Laboratory personnel, authorized non-FBI Laboratory personnel, and others when escorted by FBI Laboratory personnel. Access to the FBI Laboratory for the purpose of viewing laboratory activities is prohibited. [ISO 17020 6.2.2] [ANAB AR 3125 6.3.4.1]

H. The FBI Laboratory is committed to a safe and healthful work environment and provides policies and procedures regarding health and safety to laboratory personnel in the FBI Laboratory Safety Manual. [ISO 17020 7.1.9]

1.9 Externally Provided Products and Services

The FBI Laboratory ensures the suitability of externally provided products and services that affect laboratory activities. These include when such products and services are intended for incorporation into FBI Laboratory activities; are provided, in part or in full, directly to the

customer by the FBI Laboratory, as received from the external provider; and/or are used to support the operation of the FBI Laboratory (see Operations Manual (LAB-200) sections 2.3.A.5.iii and 3.1.8.4). [ISO 17025 6.6.1.a] [ISO 17025 6.6.1.b] [ISO 17025 6.6.1.c]

Table 1: Examples of Externally Provided Products and Services

Products	Services
Consumable materials	Assessment/Accreditation
Equipment	Calibration
Reference materials	Equipment maintenance
Reference standards	Method development and validation
	Proficiency tests
	Technical reviews
	Testing/Results
	Verification of results

1.9.1 Requirements for Externally Provided Products and Services

A. FBI Laboratory units, disciplines, and/or subdisciplines communicate their requirements to external providers by ensuring purchase orders, contracts, and/or for no cost products or services, Memorandums of Understanding/Agreements (MOUs/MOAs), contain adequate information to describe, as applicable:
   - the products and services to be provided,
   - the acceptance criteria,
   - the competence, including any required qualification of personnel, and
   - activities that FBI Laboratory, or a customer, intends to perform at the external provider's premises, when applicable. [ISO 17025 6.6.3.a] [ISO 17025 6.6.3.b] [ISO 17025 6.6.3.c] [ISO 17025 6.6.3.d]

B. The purchase of externally provided products and services must adhere to the Federal and FBI Procurement Policies and Regulations and the additional requirements in this document. The FBI Laboratory Financial and Property Management Unit (FPMU) ensures compliance with all Federal, FBI, and divisional budget/accounting policies. When no cost products or services are obtained, applicable FBI policies that describe the procedures for defining, reviewing, and approving agreements will be followed.

C. Whether products or services are purchased or obtained at no cost, the purchase requester and/or manager(s) approving the order, contract, and/or MOU/MOA is responsible for ensuring the request meets the necessary quality criteria. [ISO 17020 6.2.11.a] [ISO 17025 6.6.2.a] [ISO 17025 6.6.3.a] [ISO 17025 6.6.3.b] [ISO 17025 6.6.3.c]

1.9.2 Evaluation and Selection of External Providers

A. For products and services that affect laboratory activities, the FBI Laboratory evaluates and selects external providers based on one or more applicable criteria: [ISO 17020 6.2.11.a] [ISO 17025 6.6.2.b] [ISO 17025 6.6.3.a] [ISO 17025 6.6.3.b] [ISO 17025 6.6.3.c]
   - Products or services are not anticipated to negatively impact the quality of forensic examinations.
   - Products or services meet characteristics specified in technical procedures (e.g., 95% ethanol).
   - Services are provided by technically competent personnel (see additional requirements for verification of a result and technical review).
   - Products or services have met requirements based on historical performance.
   - Availability, timeliness, and/or cost-effectiveness of the product or service.
   - Recommendations/evaluations from other laboratories/organizations.
   - Meets requirements specified in this document (see sections 9.2 and Monitoring).
   - Is a signatory of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) multilateral recognition arrangements, demonstrating ISO/IEC 17011 compliance.
   - External provider's accreditation (see additional requirements below).

1.9.2.1 Additional External Products and Services Requirements When Accredited Provider Must be Searched

A. Additional requirements include centralized recordkeeping for assessment/accreditation, calibration, certified reference materials, method development and validation, proficiency tests, and testing/results products and/or services. A search for an accredited provider with an applicable scope of accreditation for the product/service needed must be included in the evaluation.
   1. If a provider is selected based on their accreditation, the initial evaluation and approval of the external provider will be recorded via the Centralized External Providers: Evaluation and Approval. Additionally, their accreditation certificate/scope of accreditation must also be uploaded.
   2. If an accredited external provider is not available, does not meet the need, or their scope of accreditation does not include the product/service needed, the initial evaluation and approval of an external provider will be recorded via the Centralized External Providers: Evaluation and Approval to include evaluation reasoning for selecting a non-accredited external provider.

B. If an existing provider for assessment/accreditation, calibration, certified reference materials, method development and validation, proficiency tests, and testing/results services, will continue to be used, the provider must be re-evaluated.
   1. If the provider is accredited, they need to be re-evaluated and approved at or near the time their accreditation certificate expires. If the provider is selected again based on their accreditation, the re-evaluation, approval, and

updated accreditation certificate/scope of accreditation of the external provider will be recorded via the Centralized External Providers: Evaluation and Approval.

2. If they are not accredited, the re-evaluation and approval of the provider will occur at least every 4 years. If a non-accredited provider will continue to be used, then evaluation reasoning must be recorded on the Centralized External Providers: Evaluation and Approval.

1.9.2.2 Additional External Technical Reviewer and Verifier Requirements

A. If an individual(s) external to the FBI Laboratory will conduct technical reviews and/or verifications of result(s) on work performed by FBI Laboratory personnel, the individual's competence must be evaluated (e.g., review of training, competency test(s), performance monitoring test(s), qualification/authorization records). This evaluation will be performed by an FBI Laboratory individual who is qualified and authorized in the same discipline and/or subdiscipline to ensure the external individual meets the requirements in the Operations Manual (LAB-200) section 3.2 for a technical reviewer and/or a verifier of a result. This evaluation(s) and associated records described below will be recorded via the Centralized External Providers: Evaluation and Approval.

   1. For an external technical reviewer, the external individual will be provided an FBI Laboratory technical review competency test to demonstrate their competence in performing a technical review according to the Operations Manual (LAB-200) section 3.2.3.1. An FBI Laboratory issued proficiency test or performance monitoring test can be used where the individual performs the technical review to cover the technical review competency test. The external technical reviewer's authorization will be recorded in the associated external provider records.
   2. For an external verifier, they must be qualified to perform the testing. Performance monitoring records from their laboratory can be provided as demonstration of on-going monitoring of competence for performing verifications. The external verifier's authorization will be recorded in the associated external provider records.

1.9.2.3 Re-Evaluation of External Providers

The criteria in these sections are also used to monitor and re-evaluate the performance of external providers. Actions are taken and recorded, when necessary, due to evaluations, performance monitoring, and re-evaluations. [ISO 17025 6.6.2.b] [ISO 17025 6.6.2.d]

1.9.3 Ensuring Conformance of Externally Provided Products and Services

Units, disciplines, and/or subdisciplines ensure externally provided products and services conform with specifications defined in the criteria above, the technical procedure, when applicable, and the purchase request prior to their use. Units, disciplines, and/or subdisciplines retain records of demonstrated conformance. Validation records can serve as demonstrated conformance for software and equipment. [ISO 17020 6.2.11.b] [ISO 17025 6.6.2.c].

1.10 Control of Data and Information Management

A. The FBI Laboratory has access to the data and information needed to perform laboratory activities. [ISO 17025 7.11.1]
B. Each FBI Laboratory LIMS used for the collection, processing, recording, reporting, storage, or retrieval of data is validated for functionality, including the proper functioning of interfaces within the LIMS, before introduction. Whenever there are any changes, including software configuration or modifications to commercial off-the-shelf software, they are authorized, documented, and validated before implementation. [ISO 17020 6.2.13.a] [ISO 17025 7.11.2]
C. Units, disciplines, and/or subdisciplines will have a plan for the validation of computer software developed in-house and retain records of the validation. [ANAB AR 3125 7.11.2.1]
D. Each LIMS
    1. Is protected from unauthorized access; [ISO 17025 7.11.3.a]
    2. Is safeguarded against tampering and loss; [ISO 17025 7.11.3.b]
    3. Is operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; [ISO 17020 6.2.13.c] [ISO 17025 7.11.3.c]
    4. Is maintained in a manner that ensures the integrity of the data and information; and [ISO 17020 6.2.13.b] [ISO 17025 7.11.3.d]
    5. Includes the recording of system failures and appropriate immediate and corrective actions. [ISO 17025 7.11.3.e]
E. The FBI Laboratory ensures that external providers or operators managing and maintaining a LIMS comply with all applicable requirements of the quality system. [ISO 17025 7.11.4]
F. The FBI Laboratory ensures instructions, manuals, and reference data relevant to the LIMS are readily available to personnel. [ISO 17020 7.1.4] [ISO 17025 7.11.5]
G. Units, disciplines, and/or subdisciplines will ensure calculations and data transfers are checked in an appropriate and systematic manner unless the calculation or data transfer is secure and not subject to human error. [ISO 17020 7.1.8] [ISO 17025 7.11.6] [ANAB AR 3125 7.11.6 Note]
    1. When applicable, technical records will indicate that the check of calculations and data transfers was conducted and who conducted the check. When possible, the check will be conducted by individuals other than the personnel who performed the calculations or data transfers. This check may be part of a technical review. [ANAB AR 3125 7.11.6.1]

1.11 Risk/Opportunity/Improvement

A. The FBI Laboratory considers risks and opportunities associated with laboratory activities by: [ISO 17025 8.5.1]
    1. Assessing the quality system to ensure it achieves its intended results (see section 10.6); [ISO 17025 8.5.1.a]

2. Enhancing opportunities to achieve FBI Laboratory objectives and fulfill its purpose (see section 10.6); [ISO 17025 8.5.1.b]
3. Preventing, or reducing, undesired impacts and potential failures in laboratory activities (see section 5); [ISO 17025 8.5.1.c] and
4. Achieving improvement. [ISO 17025 8.5.1.d]

B. FBI Laboratory personnel identify risks and opportunities for improvement and implement any necessary actions to include: [ISO 17025 8.5.2.a] [ISO 17025 8.5.2.b] [ISO 17025 8.6.1]:
1. Reviewing quality system documents and technical procedures,
2. Performing method development and validations,
3. Identifying and addressing nonconformities,
4. Assessing results from internal audits and external assessments,
5. Considering requested deviations,
6. Implementing preventive actions,
7. Assessing personnel training programs,
8. Analyzing data,
9. Performing technical, administrative, and transcript reviews,
10. Participating in and reviewing results of performance monitoring (e.g., proficiency testing, interlaboratory and intralaboratory comparisons),
11. Conducting verifications and blind verifications,
12. Addressing suggestions and complaints from personnel and customers, and
13. Evaluating the quality system and FBI Laboratory objectives through the annual management review.

C. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results. [ISO 17025 8.5.3]

D. Risks and opportunities related to health and safety are addressed by the Health, Safety and Security Unit (HSSU). [ANAB AR 3125 8.5.1.1]

2 DOCUMENT CONTROL

The documents that comprise the FBI Laboratory quality system are controlled. [ISO 17020 8.3.1] [ISO 17025 8.3.1]

2.1 Document Structure

A. The FBI Laboratory Quality Assurance Manual (LAB-100) and the FBI Laboratory Operations Manual (LAB-200) are the foundational documents of the quality system.

B. Cross-referencing is used within and between documents when possible so that requirements are only stated once.

C. The Laboratory Division document hierarchy includes Level 0, Level 1, Level 2, Level 3, and Level 4 documents.

2.1.1 Level 0 Documents (Accreditation, FBI, DOJ, and External Standards/Requirements)

A. ISO 17020, ISO 17025, accrediting body requirements, FBI Laboratory Safety Manual, Handbook of Forensic Services, FBI Policies, and standards/requirements adopted in

full (e.g., DNA Quality Assurance Standards (QAS), applicable Organization of Scientific Area Committees for Forensic Science (OSAC), ASTM, DOJ ULTR) are considered Level 0.

B. Level 0 documents are referenced by their existing name and do not have separate FBI Laboratory document identifiers.
C. Level 0 documents' approvals are completed external to the FBI Laboratory document control process. The approvals for adequacy are performed and documents are issued by the authoritative body.

2.1.2 Level 1 Requirements Documents (Laboratory Wide)

A. Laboratory wide requirements are specified in Level 1 documents that apply to FBI Laboratory personnel.
B. LAB-100 contains requirements related to administrative and quality assurance processes.
C. LAB-200 contains requirements related to laboratory activities including the evidence lifecycle/forensic services.

2.1.3 Level 2 Requirements Documents (Unit, Discipline, Subdiscipline)

A. Unit, discipline, subdiscipline and task specific requirements are contained in Level 2 documents and apply to personnel as specified in each document.
B. Level 2 documents are discipline and/or subdiscipline based, when practicable, and include technical procedures, administrative and quality assurance procedures, and training manuals.

2.1.4 Level 3 Externally Produced Documents (Equipment Manuals)

A. Externally produced equipment manuals are Level 3 documents.
B. Level 3 documents are controlled when personnel must follow a procedure within an external document as directed by a Level 2 document. [ISO 17020 8.3.2.f]
C. Level 3 documents are referenced by their existing name and do not have separate FBI Laboratory document identifiers. [ISO 17020 8.3.2.f]

2.1.5 Level 4 Guidance Documents (Laboratory Wide/Unit/Discipline/Subdiscipline Checklists, Quick Reference Guides, Style Guides, and Work Instructions)

A. Level 4 documents are for guidance and do not contain requirements.
B. Laboratory wide, unit, discipline, and/or subdiscipline checklists, quick reference guides, style guides, and work instructions are Level 4 documents.
C. Laboratory wide 400 series documents are Level 4 documents and are controlled by FASU as outlined in sections 2.2-2.4.
D. Other Level 4 documents are controlled by a unit, discipline, and/or subdiscipline as outlined in sections 2.2-2.4.

2.1.6 Forms

A. Forms capture variable information and, upon completion, are considered records. Checklists used as guides to denote completion of stepwise processes where the information does not vary are not considered forms or records.
B. Laboratory wide forms are Level 1 forms controlled by FASU as outlined in sections 2.2-2.4. Unit, discipline, and/or subdiscipline forms are Level 2 forms controlled as outlined in sections 2.2-2.4.
C. Automated workflows can be used in lieu of forms. Automated workflow records and system generated records are not considered forms.
D. The use of forms is described in documents. Cross-references to forms can be hyperlinked to the appropriate forms page.

2.1.7 References

References are optional in documents and should only be included when all or part of their content is necessary for the understanding of the document.

2.2 Controlled Document Requirements

A. Level 1, Level 2, Level 3, and Level 4 documents and forms are approved for adequacy prior to issuance by authorized personnel as described in section 2.3. [ISO 17020 8.3.2.a] [ISO 17025 8.3.2.a]
B. Documents are periodically reviewed and updated as necessary as described in section 2.7. [ISO 17020 8.3.2.b] [ISO 17025 8.3.2.b]
C. Changes and the current revision status or version of documents are identified as described in section 2.5.1. [ISO 17020 8.3.2.c] [ISO 17025 8.3.2.c]
D. Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled as described in section 2.4. [ISO 17020 7.1.4, 8.3.2.d] [ISO 17025 7.2.1.2] [ISO 17025 7.2.1.3] [ISO 17025 8.3.2.d]
E. Documents are uniquely identified. Level 1 and Level 2 documents are identified according to section 2.2.1. [ISO 17020 8.3.2.e] [ISO 17025 8.3.2.e]
F. The unintended use of obsolete documents is prevented through restrictive electronic version control or by marking obsolete documents accordingly if they are retained for any purpose. [ISO 17020 8.3.2.g] [ISO 17025 8.3.2.f]

2.2.1 Level 1 and Level 2 Documents and Forms Identifier Conventions

A. Titles are brief and contain only the procedure name. Document identifiers are only required for Level 1 and Level 2 documents.
B. Documents are identified according to three components.
    1. The first part indicates the source of the document (e.g., LAB, FRD, EXPL).
    2. The middle numeric portion represents the document type (e.g., 200 is a technical procedure)
    3. The last portion of the document identifier is the revision number. As an example, LAB-101-01 is the first revision of a laboratory wide document, and FD-200-02 is a second revision of a fire debris subdiscipline document.

4. Level 1 forms are identified by the division number and form number (e.g., 7-262) and date of issuance. The FD-1000 is also considered a Level 1 form.
5. Level 2 forms are identified by the title and/or a form number and date of issuance.
6. Forms do not require a revision number.

C. Guidance for document identifiers can be found in the Document Control Guide (LAB-407).

2.2.2 Level 1 Templates for Level 2 Documents

A. The Procedure Template (LAB-103) is required for administrative, quality assurance, and technical procedures.
B. The Training Manual Template (LAB-105) is required for training manuals.
NOTE: This template provides structure and format for consistency and ease of use. The required content is described in section 6.2.

2.3 Approval and Authorization for Documents

Table 2: Document Approval/Authorization

Documents and Forms	Applies to	Approved for Adequacy by	Authorized to Issue by
Level 0	Laboratory wide requirements	Not applicable as approvals for adequacy are performed by the authoritative body	Not applicable as documents are issued by the authoritative body
Level 1 - LAB-100, LAB-200, LAB-103, and LAB-105	Laboratory wide requirements	Quality Manager	Laboratory Director
Level 4 - LAB-400 Series	Laboratory wide guidance	SME	Quality Manager
Level 2	Unit, discipline and/or subdiscipline requirements	Representative(s) from every affected unit and applicable Technical Leader(s) for technical documents	Laboratory Director
Level 3	Unit, discipline and/or subdiscipline	Representative(s) from every affected unit	Not applicable as externally produced
Level 4	Unit, discipline and/or subdiscipline guidance	SME	Applicable Unit Chief(s)

Approvals will be recorded.

2.3.1 Record Retention

A. Level 1 and Level 2 document approval records are maintained by FASU.
B. Level 3 and Level 4 document approval records are maintained by the applicable unit(s) or applicable support unit.

2.3.2 Routine Prepublication

Routine revisions of Level 1 documents are prepublished prior to issuance for a minimum of five business days for familiarization and review for non-substantive (e.g., typos) corrections.

2.4 Issuance (Internal Distribution)

A. At a minimum, Level 0, Level 1, Level 2, and Laboratory wide Level 4 - 400 series documents are posted on the FBI Laboratory's quality system page as the official, controlled documents. Any copies that are not posted on the quality system page are considered uncontrolled (e.g., posted on internet, provided for legal purposes).
    1. If units, disciplines, or subdisciplines choose to maintain additional controlled copies of Level 0, Level 1, or Level 2 documents and forms, a Level 2 document will describe their document control requirements.
B. Level 3 and Level 4 documents are available in a location(s) determined by the unit, discipline, and/or subdiscipline controlling a document.

2.4.1 Stakeholder Notification (e.g., briefing, email)

A. Stakeholders of Level 1, Level 2, Level 3, and Level 4 documents are notified in writing prior to or within one business day of the issuance date of all new or revised documents.
B. Significant changes requiring staff to perform new or updated tasks (e.g., changes in instrument parameters, record new or additional information in record) will be described in the notification and/or via a unit, discipline, and/or subdiscipline meeting.

2.5 Revisions and Archives

A master document library is maintained on the quality system page for Level 1 and Level 2 documents.

2.5.1 Revision History

A. Revision histories to include the revision number are required for Level 1 and Level 2 documents and should only contain high level, substantive changes.
B. The history can be linked to the section of the document that changed.
C. Forms and Level 4 documents are version controlled (e.g., issue date), but revision histories and revision number are not required.
D. Level 0 and Level 3 documents may not have revision histories.

2.5.2 Archived or Discontinued

A. Level 1 and Level 2 archived documents are clearly marked with the effective dates and a watermark.
B. Controlled Level 3 documents as described in section 2.1.4 will be archived. Level 4 documents do not need to be archived.
C. Stakeholders will be notified prior to or within one business day when Level 1, Level 2, Level 3, or Level 4 documents are discontinued.

2.6 External Publication

A. Publicly available documents and applicable validation summaries are posted at https://fbilabqsd.fbi.gov. [Memorandum for Head of Department Components, 2016, justice.gov]
B. Documents requiring redactions for posting on https://fbilabqsd.fbi.gov are indicated as such when they are submitted.
C. FASU personnel send documents approximately twice a year to the unit, discipline, and/or subdiscipline for marking areas that need to be redacted.

2.7 Annual Document Review

A. The Quality Manager (for Level 0, Level 1, and Laboratory wide Level 4 documents) and applicable Unit Chiefs (for Level 2, Level 3, and Level 4 documents) will ensure that each controlled document is reviewed annually and revised when necessary.
    1. This annual review will include checking for conformity to applicable Level 0 documents. FASU will ensure the current versions of Level 0 documents are posted during its annual review.
    2. The Technical Leader will be a reviewer of their discipline's/subdiscipline's technical procedures.
B. A detailed record (i.e., who, when, and what) of the annual review is maintained.
    1. For Level 0, Level 1, and Laboratory wide Level 4 documents, FASU maintains the review record(s).
    2. For Level 2, Level 3, and Level 4 documents, the unit, discipline, and/or subdiscipline maintains the annual review record(s).
    3. A document revision can serve as the annual document review for a document. That revision must be recorded as such on the annual review.

2.7.1 Topics to Review

A reviewer(s), as applicable:

- Evaluates Level 1 documents to ensure conformance with Level 0 documents.
- Evaluates Level 2 documents to ensure conformance with Level 0 and Level 1 documents.
- Evaluates relevant OSAC registry standards and determines whether they should be incorporated into Level 2 documents.
- Evaluates Level 2 technical procedures for accuracy.

- Reviews deviation and nonconformity records to incorporate requirements/changes as necessary.
- Reviews Level 3 documents for relevance.
- Evaluates Level 4 documents for accuracy.

3 WRITING LEVEL 2 DOCUMENTS

3.1 Procedures and Training Manuals

Required procedure sections are described below and the Procedure Template (LAB-103)must be used.

3.1.1 Administrative and Quality Assurance Procedures

A Title and Revision History section headings are required for administrative and quality assurance procedures.

3.1.2 Technical Procedures

Section headings for technical procedures are listed below. Any sections not listed as required are optional depending on their applicability to the technical procedure. Other sections not listed may be used if necessary. The Procedure section can be broken up into multiple sections for clarity (e.g., Sample Preparation Procedure, Sample Analysis Procedure).

- Title (Required)
- Introduction (Required)
- Scope (Required)
- Equipment
- Standards and Controls
- Sampling
- Procedure (Required)
- Calculations
- Acceptance Criteria
- Measurement Uncertainty
- Limitations (Required)
- Safety
- References
- Revision History (Required)

3.1.3 Training Manuals

Required Training Manual information and sections are described in section 6 and the Training Manual Template (LAB-105)

3.2 Exceptions to Level 1 Requirements

A. In certain circumstances, exceptions to a Level 1 requirement(s) may be approved. An exception is an intentional difference needed to meet the specific needs of a

particular discipline and/or subdiscipline procedure or case type. They are requested as specified below, and then reviewed and approved by the Quality Manager and the Laboratory Director. Once approved, a Level 2 document will describe the exception in addition to referencing the Level 1 requirement(s).

B. Exception requests will include:
    1. Level 1 Document(s) (document title, revision number, and issue date)
    2. Requirement(s) (clause number and/or the requirement text)
    3. Exception requested
    4. Merits/Risk (pros/cons of why needed)
    5. Scope (who/what the exception applies to)
    6. Requester
    7. Approver(s)
    8. Date(s) of Approval

4 DEVIATIONS

Deviations to requirements within the quality system will occur only if the deviation has been recorded, technically justified (if appropriate), and approved *prior* to departing from the specific requirement(s). By submitting items to the FBI Laboratory, the customer accepts deviations deemed necessary by FBI Laboratory personnel. [ISO 17025 7.2.1.7]

4.1 Evaluation and Selection of Deviation Type

A. Laboratory personnel authorized to perform laboratory activities will evaluate the significance of deviations to determine the appropriate action. [ISO 17020 6.1.3] [ISO 17025 6.2.3]
    1. A minor deviation will be recorded and approved prior to a departure from a requirement that is not expected to significantly impact the quality system and applies to a single or finite number of instances at the time requested.
    2. A major deviation will be recorded and approved prior to a departure from a requirement that has the potential to significantly impact the quality system and/or is expected to affect multiple instances or be applicable for an extended period.

B. Major and minor deviations must be requested and approved prior to departing from the specified requirement(s).

C. An approved deviation does not eliminate the requirement for validating modifications to existing technical procedures. The Technical Leader will determine if the modification requires validating and will indicate when it does on the deviation.

D. Minor deviations will not be used if a document is identified as no longer being fit for purpose.

4.2 Authorized Approvers for Deviations

Each approver will consider the impact on the quality system and the merits and risks of a deviation before approving (see section 4.1).

Table 3: Deviation Approvers

Deviation Type	Approvers - Administrative Nature	Approvers - Technical Nature
Minor	Unit Manager or Technical Leader	Technical Leader*+
Major	Unit Chief(s) and Quality Manager	Technical Leader(s), Unit Chief(s), and Quality Manager

* If the Technical Leader requests a minor deviation of a technical nature, another person qualified and authorized in the same discipline or subdiscipline will serve as the approver.

\+ Unit Manager (e.g., supervisor, Unit Chief) if the work is not in a discipline or subdiscipline.

4.3 Deviation Requests, Approvals, and Records

4.3.1 Major Deviations

A. A major deviation will be recorded via a workflow on a Major Deviation Request form (7-258) and will include:
   1. Document(s) (document title or Document ID combined with revision number or issue date)
   2. Requirement(s) (clause number and/or the requirement text)
   3. Deviation requested
   4. Reference to additional validation, if required
   5. Instances/Duration (when the deviation would be applied/how long)
   6. Merits/Risk (pros/cons of why needed)
   7. Scope (who/what the deviation applies to)
   8. Requester
   9. Approver(s)
   10. Date(s) of Approval

B. Major deviation requests and approvals will be recorded and maintained by FASU.

C. A major deviation can be inactivated prior to the expiration date if it is no longer needed, renewed once for up to 6 months, or be inactivated on the expiration date.

D. Major deviations are posted on the FBI Laboratory's quality system page.

4.3.2 Minor Deviations

A. Minor deviation requests will include:
   1. Document(s) (document title or Document ID combined with revision number or issue date)
   2. Requirement(s) (clause number and/or the requirement text)
   3. Deviation requested
   4. Reference to additional validation, if required
   5. Requester
   6. Approver(s)
   7. Date(s) of Approval

B. Minor deviations will be recorded and maintained in a centralized location by a unit, discipline, or subdiscipline to identify trends (see section 4.6).

4.4 Deviation Notifications

A. When a major deviation is approved, renewed, or becomes inactive, the requester and the Laboratory Director will be notified.
B. If the major deviation is applicable to all FBI Laboratory personnel, all personnel will be notified.
C. For minor deviations and major deviations that are not applicable to all FBI Laboratory personnel, the requester will ensure affected personnel are notified.

4.5 Deviation Disclosures

A. When a major deviation directly impacts laboratory activities or the reporting process, a copy of the approved major deviation will be included in the FBI Laboratory file for each applicable case (e.g., attach to a communication log entry, retained in the LIMS, copy in the 1A).
B. When a minor deviation directly impacts laboratory activities or the reporting process, the approved deviation will be included in the FBI Laboratory file.

4.6 Annual Review of Minor Deviation Records

Unit Chiefs will ensure centralized minor deviation records are reviewed annually, at a minimum, to determine if any trends are occurring. The review will evaluate any repeat minor deviations and/or if any actions such as document revisions, and/or discussions would be beneficial. The review of centralized minor deviation records will be recorded and will include the name of the reviewer, the date of the review, the evaluation, and any actions.

5 NONCONFORMITIES

A nonconformity is the nonfulfillment of a requirement. Nonconforming work occurs when any aspect of laboratory activities or a result(s) of laboratory activities do not conform to procedures. A nonconformity can result in nonconforming work, therefore throughout this document, the term nonconformity will encompass nonconforming work.

5.1 Identification

FBI Laboratory personnel, internal or external customers, and/or external auditors/assessors may identify a situation or condition in which a nonconformity may have occurred. The individual will notify a member of technical management and/or unit quality representative to assess whether the situation or condition is a nonconformity.

NOTE: Internal auditors/external assessors determine nonconformities from audits/assessments. [ISO 17020 8.7.4.a] [ISO 17025 7.7.3] [ISO 17025 7.10.1.a]

5.2 Initial Assessment/Containment of a Nonconformity

When a nonconformity occurs, the individual involved in and/or who identified a nonconformity will assess the nonconformity in consultation with technical management and/or the unit quality assurance representative to determine if any immediate containment action(s) is necessary. Immediate containment action(s) may include halting work, halting

issuance of results and/or reports, and/or repeating of work (see section 1.7.A). Technical Leaders have the authority to resume work when it is halted. [ISO 17020 8.7.3] [ISO 17020 8.7.4.d] [ISO 17020 8.7.4.e] [ISO 17025 7.10.1.b] [ISO 17025 7.10.1.f] [ISO 17025 7.10.2] [ISO 17025 8.7.1.a]

5.3 Categorization of the Nonconformity

Following the initial assessment and any immediate containment action(s), the nonconformity will be evaluated and categorized as minor or major in consultation with technical management and/or the unit quality assurance representative. The categorization of the nonconformity will be determined based on the Nonconformity Matrix (Table 4).

Table 4: Nonconformity Matrix

		Risk of Repeatability		
Significance/ Impact to Previous Results/ Acceptability of Work/ Adverse to Quality		**Low likelihood recurrence/ High likelihood detection**	**Med likelihood recurrence/ Med likelihood detection**	**High likelihood recurrence/ Low likelihood detection**
	Negligible/ Acceptable	**Minor**	**Minor**	**Minor**
	Moderate/ Acceptable	**Minor**	**Minor**	**Major**
	Severe/ Unacceptable	**Major**	**Major**	**Major**

5.4 Nonconformity Records

All identified nonconformities will be recorded in a centralized location within a unit, discipline and/or subdiscipline. The records will contain: [ISO 17025 7.10.2] [ISO 17025 8.7.3.a] [ISO 17025 8.7.3.b]

- the person who identified the nonconformity,
- when it was identified,
- a description of the nonconformity,
- the requirement that was not fulfilled (i.e., Doc ID or title of document with revision number, section),
- categorization of the nonconformity (i.e., minor, or major),
- evaluation of the significance of the nonconforming work including an impact analysis on previous results, as applicable, [ISO 17025 7.10.1.c]
- decision on the acceptability of the nonconforming work, [ISO 17025 7.10.1.d]
- actions taken (e.g., correction, acceptance/acknowledgement, initiation of CAP if deemed major). [ISO 17020 8.7.4.c] [ISO 17025 7.10.1.b] [ISO 17025 7.10.1.e]

5.4.1 Nonconformity Disclosures

In addition to the disclosure requirements in section 1.7.G, when a nonconformity directly impacts laboratory activities, a description of the nonconformity, will be recorded in the FBI

Laboratory file for each applicable case (e.g., referenced in a communication log entry, retained in the LIMS, copy in the 1A).

5.5 Addressing a Major Nonconformity

A nonconformity determined to be major will be managed via a CAP (7-254). The affected Unit Chief(s), Technical Leader(s) (when technical in nature), and the Quality Manager will be notified in writing when the nonconformity is determined to be major. When a nonconformity is major, an individual from the unit, discipline and/or subdiscipline will manage the CAP (i.e., CAP manager). [ISO 17020 8.7.3] [ISO 17025 7.10.1.a] [ISO 17025 7.10.1.b] [[ISO 17025 7.10.1.c] [ISO 17025 7.10.3] [ISO 17025 8.7.1.a]

5.6 Corrective Action Plan - Development

A. When a CAP is initiated for a major nonconformity, it will include reviewing and analyzing the nonconformity; determining the cause(s) of the nonconformity; assessing if similar nonconformities exist or could potentially occur; and developing action steps that include preventing recurrence. [ISO 17020 8.7.2] [ISO 17020 8.7.4.a] [ISO 17020 8.7.4.b] [ISO 17020 8.7.4.d] [ISO 17020 8.7.4.e] [ISO 17025 8.7.1.b] [ISO 17025 8.7.1.c]
B. Development and approval of a CAP will occur within 45 calendar days of the determination of the nonconformity as major, when practicable. Completion of CAP action steps should not exceed 4 months. [ANAB AR 3125 8.7.1.g]
C. The CAP form will include: [ISO 17020 8.7.1] [ISO 17025 7.10.3]
    1. Description of the nonconformity(ies)
    2. Frequency of the nonconformity(ies)
    3. Impact to results
    4. Document(s) and requirement(s) that were not adhered to
    5. Any immediate containment action(s) taken
    6. Cause(s) analysis
    7. Action steps, corrective and/or preventive, which are specific, measurable, achievable, relevant, and time bound. A reasonable timeframe for completion is required for each action step. Action steps will also be proportional to the effects of the nonconformity. [ISO 17020 8.7.4.e] [ISO 17020 8.7.4.f] [ISO 17025 8.7.1.c] [ISO 17025 8.7.2] [ANAB AR 3125 8.7.1.g]
        i. If the steps are needed to address an analytical/interpretive error that resulted in the development of a CAP, the CAP will include, at a minimum, the following action steps:
            - Deauthorization, at least temporarily, in writing, from performing associated laboratory activities and/or reporting of results.
            - Review of the person's records of laboratory activities that were completed since the last satisfactory performance monitoring activity in that discipline and/or subdiscipline and that are relevant to the error.

- Customer notification and/or recalling the work.
- Appropriate remedial training.
- Administration of a competency test (i.e., for requalification) (see section 6.3.4) in the discipline and/or subdiscipline in which the unexpected results/information occurred.
- Reauthorization, in writing, to allow the person to resume performing laboratory activities in the discipline and/or subdiscipline in which the analytical/interpretive error occurred.

8. A plan for the verification of effectiveness of corrective action will be recorded. The verification of effectiveness will specify the timeframe following the completion of all action steps and the compliance objectives. [ISO 17020 8.7.4.g] [ISO 17025 8.7.1.d]

D. The applicable Unit Chief(s), and Technical Leader(s) (when technical in nature), and the Quality Manager, will approve a CAP for implementation.
   1. Any changes to the content of an approved CAP must be requested in writing and agreed to by the applicable Unit Chief(s), and Technical Leader(s) (when technical in nature), and the Quality Manager.

5.7 Corrective Action Plan – Implementation of Action Steps

The CAP manager will ensure each action step is implemented by the expected completion date or request an extension through FASU. The CAP manager will also ensure that objective evidence in support of the completion of each action step is generated and included in the CAP records. [ISO 17020 8.7.4.e] [ISO 17025 8.7.1.c]

5.8 Corrective Action Plan - Review of Effectiveness and Closing Out Corrective Action

A. The CAP manager will review the effectiveness of corrective action taken according to the verification plan and include that objective evidence in the CAP records.
B. FASU personnel will evaluate the objective evidence provided for each action step and the effectiveness of a CAP according to the verification plan. [ISO 17020 8.7.4.g] [ISO 17025 8.7.1.d]
   1. If the verification plan is not met, the Quality Manager will be notified. Additional action steps and a new verification plan will be developed by the CAP manager and approved by the applicable Unit Chief(s), Technical Leader(s) (when technical in nature), and Quality Manager. [ISO 17025 8.7.1.e]
   2. If the verification plan is met, the CAP can be closed.
C. Once all action steps and verification of effectiveness are complete, and objective evidence has been generated and reviewed, the applicable Unit Chief(s), Technical Leader(s) (when technical in nature), and Quality Manager will approve the closure of a CAP.
D. FASU will retain CAPs and their associated records. [ISO 17020 8.7.4.f] [ISO 17025 7.10.2] [ISO 17025 8.7.3.a] [ISO 17025 8.7.3.b]

5.9 Preventive Action

A. A preventive action is an action to eliminate the cause of a potential nonconformity. FBI Laboratory personnel may identify a potential nonconformity where a preventive action would be helpful. [ISO 17020 8.8.1] [ISO 17020 8.8.3.a]
B. Preventive actions can be initiated independent of the nonconformity process. [ISO 17020 8.8.3.b] [ISO 17020 8.8.3.c]
C. Preventive actions will be appropriate to the probable impact of the potential problems. [ISO 17020 8.8.2]
D. Records related to preventive actions independent of the nonconformity process will be maintained by the unit including the review of the effectiveness of the preventive actions taken. [ISO 17020 8.8.3.d] [ISO 17020 8.8.3.e]

5.10 Centralized Nonconformity Records Risk/Opportunity Review

A. Unit Chiefs will ensure centralized unit, discipline, and/or subdiscipline nonconformity records are reviewed at least quarterly (i.e., every 3 months) to determine if any trends are occurring. The review will evaluate any repeat nonconformities and/or if any additional follow-up/action such as training, document revisions, and/or discussions would be beneficial.
B. Nonconformities will be reviewed to consider the risks and opportunities associated with the nonconformities to prevent, or reduce, undesired impacts and potential failures in the laboratory activities. [ISO 17025 8.5.c]
    1. When an opportunity or risk is identified, mitigation measures may be performed. Mitigation measures will be recorded. [ISO 17025 8.6.1]
    2. When a risk identifies the need for further action to eliminate the cause(s) of a nonconformity(ies), a CAP will be initiated. [ISO 17025 8.7.1.b]
C. The review of centralized nonconformity records will be recorded and will include the name of the reviewer, the date of the review, the evaluation, and any actions. [ISO 17025 7.10.2] [ISO 17025 8.6.1] [ISO 17025 8.7.1.f] [ISO 17025 8.7.3.a] [ISO 17025 8.7.3.b]

6 PERSONNEL

A. FBI Laboratory personnel, including contract personnel, act impartially, are competent, and work in accordance with the FBI Laboratory quality system. The FBI identifies core competencies for each FBI employee and job-related competencies that are applicable to each FBI job. FBI Laboratory management communicates to personnel their duties, responsibilities, and authorities. [ISO 17020 6.1.4] [ISO 17020 6.1.12] [ISO 17025 6.2.1] [ISO 17025 6.2.4]
B. Position requirements (e.g., education, qualification for position, work experience, knowledge, skills, abilities (KSAs)) for hiring personnel are recorded in each FBI position description (FD-243). Selection of personnel follows Human Resources Division guidance. Records for FBI Laboratory personnel unit/position assignments are maintained by the Laboratory Division Administrative Unit (AU). [ISO 17020 5.2.7] [ISO 17020 6.1.5] [ISO 17025 6.2.5.b]

C. Personnel are hired based on their education, qualification for position, and knowledge, skills, and abilities (as related to specific job series). Upon entering employment with the FBI Laboratory, personnel are trained and evaluated to competently perform their job tasks in accordance with their specified unit, discipline, and/or subdiscipline Level 2 training manuals. [ISO 17020 6.1.3] [ISO 17025 6.2.3] [ISO 17025 6.2.5.a] [ISO 17025 6.2.5.b]
D. For personnel who authorize results and/or express opinions and/or interpretations in the following disciplines/subdisciplines, they must meet the minimum education requirements: [ISO 17020 6.1.1] [A2LA R318 6.1 FI1.1] [ISO 17025 6.2.2] [ANAB AR 3125 6.2.2.1]

Table 5: Minimum Education Requirements

Discipline/Subdiscipline	Minimum Education Requirements
Fire Debris and Explosives; Materials (Trace); Seized Drugs	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 or forensic science. If performing DNA analysis and where applicable, meet the educational requirements of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories or FBI Quality Assurance Standards for DNA Databasing Laboratories, as appropriate.

6.1 Competency Requirements to Perform Job Tasks

In addition to position and education requirements stated in section 6 (above), competency requirements for FBI Laboratory personnel include the analysis of necessary KSAs needed to perform job tasks. SMEs in consultation with the applicable Technical Leader(s)[1] determine necessary KSAs. Each unit, discipline, and/or subdiscipline training program includes activities designed to develop and/or enhance the KSAs of trainees in a specific area(s). A training manual articulates the necessary training to ensure a trainee can demonstrate competency to perform their job tasks. [ISO 17020 6.1.1] [ISO 17020 6.1.5] [ISO 17025 6.2.2] [ISO 17025 6.2.5.a]

6.2 Training Programs, Manuals, and Plans

For additional information, refer to Guidance for Administering Training in a Unit, Discipline, and/or Subdiscipline (LAB-414).

6.2.1 Training Programs

A. Unit, discipline, and subdiscipline training programs have been created for FBI Laboratory personnel.

[1] Any reference to a Technical Leader in Section 6 will be the Supervisor if the trainee is not working in a discipline or subdiscipline.

B. Laboratory Core Training provides foundational training and is assigned as follows:
    1. All FBI Laboratory personnel - Topics 1-3 (Health & Safety, Forensic Ethics, Foundational Information)
    2. FBI Laboratory personnel who handle/test evidence - Topic 4 (Evidence)
    3. FBI Laboratory personnel who utilize FA in any capacity - Topic 5 (LIMS)
    4. FBI Laboratory personnel who provide discovery and/or testimony - Topics 6 - 8 (Forensic Challenges, Foundational Legal Systems, Legal Testimony)

    NOTE: Topic numbers are different than module numbers listed in the actual Laboratory Core Training.

C. Discipline and/or subdiscipline training should cover the applicable topics for the position and/or task(s): [ISO 17020 6.1.5] [ISO 17025 6.2.5.c] [ANAB AR 3125 6.2.2.2]
    1. History and basic theory of the discipline and/or subdiscipline
    2. Knowledge of related fields (e.g., biological processes related to friction ridge development, physics for shooting reconstruction),
    3. Relevant literature,
    4. Nature and properties of examined evidence types and forms in which they may be submitted,
    5. Methodologies and validation studies,
    6. Associated equipment/instrumentation,
    7. Statistics and probability (including uncertainty, sampling population characteristic inferences, etc.),
    8. Results analysis and/or results review,
    9. Verification of results,
    10. Reporting,
    11. Technical review,
    12. Opinions and interpretation, and
    13. Testimony.

D. The maintenance of skills and expertise of FBI Laboratory personnel are addressed through continuing education (see section 6.7) and monitoring (see section 10), as applicable to the position and/or tasks. [ANAB AR 3125 6.2.2.2.f]

6.2.2 Training Manuals

Each unit, discipline, and/or subdiscipline training manual will follow the content and format detailed in the Training Manual Template (LAB-105) and section 6.1. Training topics will contain specific learning objectives that tie directly to job competencies and tasks. [ISO 17020 6.1.1] [ISO 17020 6.1.6.b] [ISO 17025 6.2.5.c] [ISO 17025 6.2.5.d] [A2LA R318 6.1 FI1.2] [ANAB AR 3125 6.2.2.2.a] [ANAB AR 3125 6.2.2.2.b] [ANAB AR 3125 6.2.2.2.c] [ANAB AR 3125 6.2.2.2.d] [ANAB AR 3125 6.2.2.2.e] [ANAB AR 3125 6.2.2.2.f] [ANAB AR 3125 6.2.2.2.g] [ANAB AR 3125 6.2.3.1]

6.2.3 Individualized Training Plans and Previous Work Experience

A. Each trainee will receive an individualized training plan that includes:
    - Trainee's name,

- Position title,
- Discipline and/or subdiscipline,
- Reference to applicable training manual (i.e., title or DOC ID, revision number) and assigned training topics, and
- Anticipated date range of training (e.g., Topic 10 - 3 weeks).

NOTE: Trainee can also be a person that has been previously qualified and authorized in a position and/or tasks and is adding a new qualification and/or authorization. Being in this 'trainee status', does not affect an individual's current qualification or position, however, they are expected to adhere to training requirements in this document and applicable training manual. An individualized training plan is not needed when individuals are being trained and competency tested on a newly validated procedure.

B. Prior to preparing an individualized training plan, the Technical Leader may consider a trainee's previous work experience and/or training to be substituted for portions of a training program. If warranted, a record must be generated describing how (e.g., knowledge check) the KSAs of any portion of the training program were demonstrated by the trainee. [ISO 17020 6.1.7] [ANAB AR 3125 6.2.2.2 Note 1]
C. Once an individualized training plan has been initiated/provided to a trainee, the Technical Leader will be consulted if changes to an individualized training plan such as the addition/removal of training topics are appropriate.
   NOTE: Ongoing information such as actual completion dates and/or time spent in training may be recorded in an initiated training plan to cover tracking necessary for the Forensic Examiner Training Continued Service Agreement Policy Directive (1323D), FBI LD Service Vision, etc.
D. Records will be retained in trainee's training records and will include:
   1. Technical Leader review and description of how KSAs were demonstrated by the trainee if previous work experience/training substituted for any portion of the training plan.
   2. Individualized training plan for trainee.
   3. Notes of a consultation with Technical Leader if individualized training plan needs to be modified after it is initiated.

6.3 Evaluation of FBI Laboratory Trainees

FBI Laboratory trainees must be evaluated on the KSAs for the assigned training topics in their training plan and the training manual.

6.3.1 Evaluation Methods

The following are evaluation methods, and the associated requirements used to evaluate trainees:

A. Completion of Task
   1. Minimum of one evaluator
   2. Evaluate training topics as complete/incomplete

3. Record of 'complete/incomplete' status and date. Retain record in trainee's training records.

B. Accuracy Determination
   1. Minimum of one evaluator
   2. Evaluate accuracy using unit, discipline, and/or subdiscipline pre-defined criteria to meet a score threshold for acceptable performance.
   3. Record of score and date with correlation to outcome (e.g., pass). Retain record in trainee's training records.

C. Rubric for Performance
   1. Minimum of three evaluators for oral board exercise, testimony-style exercise, and moot court exercise.
   2. Minimum of one evaluator for a public speaking, competency test, and unit, discipline, and subdiscipline critical thinking exercise other than testimony-style exercise.
   3. Evaluate performance of multiple evaluation elements and determination of performance level using *General Rubric Structures Form* (7-289) (see Training Rubrics Guide (LAB-406)) with defined criteria for each of the levels.
   4. Rubric performance levels:
      - Non-Performance: 'minimally...'
      - Needs Improvement: 'partially...'
      - Satisfactory: 'sufficiently...'
      - Distinguished: 'extensively...'
   5. Record of the completed *General Rubric Structures Form*. Retain record in trainee's training records. Also, when trainee is rated at 'Non-Performance' OR 'Needs Improvement' level, the trainee and the trainee's supervisor will acknowledge this in writing.

6.3.2 Overall Training Evaluation Exercises

The following exercises are used for the evaluation of an individual's KSAs. Training evaluation exercise options and associated abbreviations are listed below, with requirements for communication exercises in section 6.3.3 and competency tests in section 6.3.4. Further guidance for other types of training evaluation exercises can be found in Guidance for Administering Training in a Unit, Discipline and/or Subdiscipline (LAB-414). [ANAB AR 3125 6.2.2.2.a]

- Knowledge Check (K)
- Public Speaking Exercise (PS)
- Oral Board Exercise (OB)
- Testimony- Style Exercise (TSE)
- Unit, Discipline, and/or Subdiscipline Designed Critical Thinking Exercise (no defined symbol)
- Moot Court Exercise (MC)
- Competency Test (CT)
- Simulated Laboratory Activities (SIM)

- Supervised Laboratory Activities (SLA)
- Written Test or Quiz (T)

6.3.3 Training Evaluation Communication Exercises for Personnel Who Perform Laboratory Activities

Personnel who perform laboratory activities, in accordance with their position, assigned role and job tasks, will complete a minimum of one communication exercise per category as listed below in Table 6.

Table 6: Communication Training Milestones for Personnel Who Perform Laboratory Activities

Personnel	Public Speaking	Critical Thinking	Moot Court
Forensic Examiner (FE)	x	x	x*
Analyst**	x	x	

* FEs (e.g., Federal DNA Database Unit (FDDU)) that are not expected to testify are not required to participate in moot court exercises based on their job tasks.

** Analyst encompasses the following non-examiner roles: chemist, biologist, electronics engineer, physical scientist, document analyst.

6.3.3.1 Public Speaking Exercises

A. Public speaking exercises support job tasks related to providing briefings, tours, and presentations and are an opportunity for trainees to demonstrate that skill. Public speaking exercises can include a unit, discipline, and/or subdiscipline capability briefing, a discipline or subdiscipline-defined briefing, or a technical lecture.
B. A minimum of one public speaking exercise is required. Completion of Task or Rubric for Performance will be the evaluation method. Completion of FBI Presentation Skills Course or Basic Instructor Course may be substituted with Technical Leader approval.
C. Prior to the exercise, the trainee and evaluator(s) will be provided with a summary of expectations[2], in writing. Also, the unit, discipline and/or subdiscipline Training Program Manager (TPM) will ensure that the evaluation method is reviewed with the trainee and the evaluator(s), as appropriate.
D. When the designated evaluation method is Rubric for Performance, at least one practice session opportunity will be offered to the trainee. This will include performance feedback based on the use of the *General Rubric Structures Form*. This form from the practice session will be retained in the person's training records. If the trainee does not accept a practice session, it will be recorded in their training records. A practice session may count as an officially evaluated exercise if it follows

[2]A summary of expectations will contain details such as objectives, topics covered, and associated timeframes. The designated evaluation method will be listed on the summary of expectations. If this information is detailed in the training manual, the trainee and evaluator(s) can be provided the reference to the applicable portion(s) of the training manual in lieu of a summary of expectations.

all the evaluation requirements, including use of the required form and retention of applicable records.

E. If a trainee fails a public speaking exercise based on the designated evaluation method, the trainee's Unit Chief and the Quality Manager will be notified, in writing. A remediation plan will be developed for the trainee (see section 6.3.6). A second attempt of the same public speaking exercise will be conducted after the remediation plan is completed by the trainee.
F. Records will include actual completion dates, as applicable, and be retained in a trainee's training records (see section 6.3.1):
    1. Completion of FBI Presentation Skills Course or Basic Instructor Course with Technical Leader approval,
    2. Summary of expectations.
    3. Practice session if Rubric for Performance or note that trainee did not accept.
    4. Record of the Completion of Task or Rubric for Performance.
    5. Remediation plan, as applicable.

6.3.3.2 Critical Thinking Exercises

A. Critical thinking exercises support job tasks related to communicating technical and scientific concepts to a variety of audiences and are an opportunity for trainees to demonstrate their knowledge. Critical thinking exercises include at a minimum, oral boards and testimony-style exercises (i.e., exercise that focuses on technical topics often covered in testimony).
B. Forensic examiner trainees are required to participate in a minimum of one critical thinking exercise identified as an oral board and evaluated via Rubric for Performance evaluation method.
C. Analyst trainees are required to participate in a minimum of one critical thinking exercise that aligns with their specified job tasks and evaluated via Rubric for Performance.
D. For each critical thinking exercise, the trainee and evaluator(s) will be provided a summary of expectations, in writing, prior to the exercises.
E. Rubric for Performance will be used for oral boards and testimony-style exercises. Accuracy Determination or Rubric for Performance will be the evaluation method for any other critical thinking exercise. Oral boards must be audio recorded.
    - When the evaluation method is Rubric for Performance, three evaluators are required. The *General Rubric Structures Form* must be used.
    - The three evaluators for an oral board or a testimony-style exercise will be SMEs in the discipline and/or subdiscipline, where practicable.
    - When the designated evaluation method is Accuracy Determination, only one evaluator is required.
F. Prior to a critical thinking exercise, the TPM will ensure that the evaluation method is reviewed with the trainee and the evaluator(s), as appropriate.
G. When the designated evaluation method is Rubric for Performance, at least one practice session opportunity will be offered to the trainee. This will include performance feedback based on the use of the *General Rubric Structures Form*. This

form from the practice session will be retained in the person's training records. If the trainee does not accept a practice session, it will be recorded in the person's training records. A practice session may count as an officially evaluated exercise if it follows all the evaluation requirements, including use of the required form, exercise audio recorded, and applicable records are retained.

H. If the trainee fails a critical thinking exercise based on the designated evaluation method, the trainee's Unit Chief and the Quality Manager will be notified, in writing. A remediation plan will be developed for the trainee (see section 6.3.6). A second attempt of the same critical thinking exercise will be conducted after the remediation plan is completed by the trainee.

I. Records will include actual completion dates, as applicable, and be retained in the trainee's training record (see section 6.3.1):
    1. Summary of expectations.
    2. Practice session if Rubric for Performance or note that trainee did not accept.
    3. Record of the Accuracy Determination or Rubric for Performance.
    4. Remediation plan, as applicable.
    5. For an oral board, the audio recording.

6.3.3.3 Moot Court Exercise

A. A moot court exercise supports job tasks related to providing expert testimony in a legal setting and is an opportunity for forensic examiner trainees to demonstrate their abilities.

B. Forensic examiner trainees are required to participate in at least one moot court exercise. Rubric for Performance will be used for the moot court. The moot court exercise will cover the discipline(s) and/or subdiscipline(s), and/or component/parameters, as applicable, recorded on their training plan. This can occur in a single, comprehensive moot court exercise, or in multiple, individual discipline and/or subdiscipline moot court exercises. [A2LA R318 6.1 FI1.3] [ANAB AR 3125 6.2.2.2.d]
    1. Moot court exercise(s) must include licensed attorneys in all three roles: judge, prosecuting attorney, and defense attorney.
    2. The scheduling of a moot court exercise(s) will be coordinated by the TPM, the Forensic Science Training Program Manager (FSTPM), and the Forensic Science Law Unit (FSLU).
    3. Forensic examiner trainees must prepare and distribute discovery packets to the attorneys and evaluators in accordance with the timeframe requested. Forensic examiner trainees will utilize eDiscovery to enter their discovery information.

C. For each moot court exercise, the trainee and evaluators will be provided a summary of expectations, in writing, prior to the exercise.

D. Rubric for Performance will be used for the evaluation method. Moot courts must be video recorded.
    1. The *General Rubric Structures Form* must be used.

2. Three evaluators are required. Two evaluators must be SMEs in the applicable discipline or subdiscipline and one evaluator will be from another FBI Laboratory unit. All evaluators must have testimony experience.

E. Prior to the moot court exercise, the TPM will ensure that the rubric evaluation method is reviewed with the trainee and the evaluators, as appropriate.

F. At least one practice session opportunity will be offered to the trainee for a moot court exercise. This will include performance feedback based on the use of the *General Rubric Structures Form.* This form from the practice session will be retained in the person's training records. If the trainee does not accept a practice session, it will be recorded in the person's training records.
NOTE: A practice session cannot count as an officially evaluated exercise as licensed attorneys are not present.

G. If the trainee fails a moot court exercise based on the designated Rubric for Performance evaluation method, the trainee's Unit Chief and the Quality Manager will be notified, in writing. A remediation plan will be developed for the trainee (see section 6.3.6). A second attempt of the same moot court exercise will be conducted after the remediation plan is completed by the trainee.

H. Records will include actual completion dates, as applicable, and be retained in trainee's training records (see section 6.3.1):
1. Summary of expectations.
2. Practice session Rubric for Performance or note that trainee did not accept.
3. Record of Rubric for Performance.
4. Remediation plan, as applicable.
5. For a moot court, the video recording. [A2LA R318 6.1 FI1.3]

I. A trainee's moot court (or last moot court if there are multiple) will be recorded in eDiscovery according to section 10.7.6.

6.3.4 Competency Testing Process for Personnel Who Perform Laboratory Activities

A. Personnel performing laboratory activities must be competency tested. The trainee/participant will achieve the competency test(s) intended results prior to working on evidence/DNA databasing items. [ISO 17025 6.2.3] [ANAB AR 3125 6.2.3.1] [A2LA R318 6.1 Fl1.4]
1. Competency testing will include practical examination(s) that cover the spectrum of anticipated tasks related to the test. [ANAB AR 3125 6.2.3.1]
2. Personnel conducting technical reviews or evaluating testimony must also meet competency testing requirements in the testing tasks they will review. [ANAB AR 3125 6.2.3.2] [A2LA R318 7.3 FI1.6.b]

NOTE: Participant refers to an instance when a person enters a status that requires competency testing to return to performing laboratory activities.

B. Accuracy Determination or Rubric for Performance will be used for the evaluation method. Only one evaluator is required for either designated evaluation method.

C. Development of competency tests requires SME planning and the generation of records to reflect the design, intended outcome, and criteria for acceptable

performance. *Competency Test Forms* (7-288a, b, c) must be used for all competency tests and completed in their entirety.

D. A trainee's/participant's competency test results must meet predefined expected results and evaluation criteria described on *Competency Test - Design* (7-288a) before performing laboratory activities. [ANAB 3125 6.2.3.1]
    1. 7-288a *Competency Test -Design*: Completed by test preparer. Approval by Technical Leader indicated by their signature and date.
    2. 7-288b *Competency Test - Reported Results*: Completed by the trainee/participant to include their reported results. Trainee's/Participant's signature and date are also recorded.
    3. 7-288c *Competency Test - Evaluation*: Completed by a SME. Evaluation of trainee/participant's results in accordance with the test's specified evaluation process based on the information recorded on the 7-288a. Trainee's/Participant's signature and date are also recorded.

E. If the trainee/participant fails a competency test, the trainee/participant's Unit Chief and the Quality Manager will be notified, in writing. A remediation plan will be developed for the trainee/participant (see section 6.3.6). A second attempt of the same competency test will be conducted after the remediation plan is completed by the trainee/participant.

F. Records will include actual completion dates, and the Competency Test forms (7-288a, b, c) completed in their entirety.
    1. *Competency Test - Design* (7-288a) is maintained by the unit, discipline, and/or subdiscipline.
    2. *Competency Test – Reported Results* (7-288b) Trainee's/Participant's Results and *Competency Test - Evaluation* (7-288c) are maintained in the trainee's/participant's training records.
    3. If an issue regarding the test design and/or preparation is identified during the evaluation of the trainee's/participant's results, the test will be reviewed and adjudicated by the Technical Leader. This will occur before providing the evaluation to the trainee/participant.

6.3.5 Successful Completion of Training

A trainee must successfully complete the topic evaluations listed in their individualized training plan to be qualified to perform specific work for the FBI Laboratory. 'Successful completion' is meeting the criteria for acceptable performance for the evaluation method selected per topic, exercise, and/or task. Training records will capture the actual training completion dates (see section 6.2.3).

6.3.5.1 Summary of Specific Criteria for Successful Completion

A. Laboratory Core Training Topics
    - Criteria: Trainee must meet the 'successful completion' criteria listed for the lessons/modules.

B. Laboratory-Required Training Topics

- Criteria for Public Speaking: Achieve 'complete' for Completion of Task designated evaluation method or performance level of 'Satisfactory' or 'Distinguished' for Rubric for Performance designated evaluation method.
- Criteria for Oral Board Exercise, Testimony-Style Exercise, Moot Court Exercise, and Competency Testing: Achieve performance level of 'Satisfactory' or 'Distinguished' for Rubric for Performance designated evaluation method.
- Criteria for any other Critical Thinking Exercise and Competency Testing with designated evaluation method of Accuracy Determination: Achieve the pre-determined passing score threshold (e.g., 85%, at least 13 of 15 elements correct).

C. Unit, Discipline, and/or Subdiscipline Training Topics
   - Criteria: Detailed in respective training manuals, specifying acceptable performance based on designated evaluation methods (see section 6.3.1).

6.3.6 Remediation Plans

A. A remediation plan will be developed to address areas identified as needing improvement when a trainee does not meet the criteria for acceptable performance. [ANAB AR 3125 6.2.2.2.e]
B. Remediation plan needed when:
   - Trainee did not achieve successful completion after a communication exercise milestone.
   - Trainee does not meet expected results and evaluation criteria on a competency test.
   - Other situations defined in unit, discipline, and/or subdiscipline training manual.
C. Records will include remediation plans and records demonstrating completion of the plan. These will be retained in the trainee's training records.

6.3.7 Removal from Training

A. A trainee will be removed from training when they fail to meet the successful completion criteria, for any of these elements required as part of their training plan, for the following:
   - Two attempts of the same Laboratory-required communication training milestone exercises per category (i.e., public speaking, critical thinking, moot court).
   - Two attempts of the same competency tests.
   - Two attempts of the same unit, discipline, and/or subdiscipline evaluation exercise as defined in unit, discipline, and/or subdiscipline training manual (see section 6.3.2).
   - Simulated and/or supervised laboratory activities as defined in unit, discipline, and/or subdiscipline training manual.

B. Records will include evaluation method records associated with the failures and a formal notification to the trainee of their removal. These records will be retained at a minimum in the trainee's training records.

6.4 Qualification and Authorization for Supervised and Independent Performance of Laboratory Activities or Tasks, and Changes in Authorization

6.4.1 Supervised Laboratory Activities Authorization

A. After completion of applicable training and competency testing, personnel who will perform laboratory activities on evidence/test items under the supervision of a qualified and authorized individual (i.e., not performing independent laboratory activities), must be authorized prior to and with the limitation to performing supervised laboratory activities.
B. A serialized authorization EC will be generated in Sentinel for the individual to perform supervised laboratory activities. The FSTPM, applicable Unit Chief(s), and Technical Leader(s) are required approvers if they are not already the author of the EC. The trainee will be on the distribution list, when practicable.

6.4.2 Independent Laboratory Activities and Evidence Handling Qualification and Authorization

A. If a person will be performing any of the following laboratory tasks independently, they must be authorized: [ISO 17020 6.1.5] [ISO 17025 6.2.5.e]
    - Testing, all aspects including, as applicable, the use of equipment; [ISO 17025 6.2.6] [ANAB AR 3125 6.2.6 Note]
    - Development, modification, verification, and validation of methods and procedures; [ISO 17025 6.2.6.a]
    - Analysis of results; [ISO 17025 6.2.6.b]
    - Review and authorization of results; [ISO 17025 6.2.6.c]
    - Verification of results;
    - Performing technical reviews;
    - Expressing opinions or interpretations; [ISO 17025 7.8.7.1]
    - Reporting results; [ISO 17025 6.2.6.c]
    - Issuing *Laboratory Reports* and/or i3 products; and [ISO 17025 6.2.6.c]
    - Evaluation of testimony.
B. Authorization is also required for personnel who handle evidence (e.g., evidence management personnel, forensic photographers). [ISO 17020 6.1.5] [ISO 17025 6.2.5.e]
C. Qualification and authorization records for FBI Laboratory personnel will be generated and serialized as an EC in Sentinel. The FSTPM, applicable Unit Chief, and Technical Leader are required approvers if they are not already the author of the EC. The trainee will be on the distribution list, when practicable (see Qualification and Authorization EC Guide(LAB-410)). [ISO 17020 6.1.10] [ISO 17025 6.2.5.e]
NOTE: Previous authorizations may be retained in locations outside of Sentinel.

6.4.3 Changes in Authorization

A. Permanent changes in authorization will be generated and serialized as an EC in Sentinel. Permanent changes in authorization may include addition of new technique, addition of new component/parameter or equipment, removal of all authorizations, or removal of a specific authorization (e.g., specific procedure, specific task).
    1. For deauthorization, the applicable Unit Chief, and Technical Leader are required approvers if they are not already the author of the EC. The FSTPM will be on the distribution.
B. Temporary changes in authorization (e.g., removal related to nonconforming work being addressed in a CAP and reauthorization after remediation) will be recorded in writing and retained by the unit and/or when part of a CAP, retained by FASU.

6.5 Training Records

A. Training records associated with applicable requirements in this document and the applicable training manual as well as authorization records will be retained for each trainee as described in each section in section 6.
B. The following summary of records will be generated for each trainee:
    - Individualized training plan to include reference to training manual (i.e., title or DOC ID, revision number).
    - Training Manual that may include records of completion of training topics
    - Actual training completion dates
    - Time spent on training (as applicable per FETSA policy 1063D). [Examiners only]
    - Overall evaluation outcomes (per training topic)
    - Virtual Academy (VA) transcripts reflecting training topic completion(s), as applicable
    - Written feedback
    - Qualification and authorization records (see Qualification and Authorization EC Guide (LAB-410)

6.6 Supervising and Monitoring Competence

A. FBI Laboratory personnel are supervised according to the organizational charts and in accordance with FBI policy. [ISO 17025 6.2.5.d]
B. Continued monitoring of competence of personnel who perform laboratory activities and/or handle evidence will be conducted as described in Monitoring (see section 10.2). [ISO 17020 6.1.5] [ISO 17025 6.2.5.f]

6.7 Continuing Education for FBI Laboratory Personnel

A. FBI Laboratory personnel will complete a minimum of eight hours of continuing education each fiscal year. Management and/or each unit will establish objectives for the continuing education of personnel to meet the present and anticipated needs of the FBI Laboratory. [ISO 17020 6.1.6.c] [ANAB AR 3125 6.2.2.2.f]

B. Continuing education will be recorded on a person's FBI Virtual Academy transcript. [A2LA R318 6.1 FI1.7]

7 MEASUREMENT UNCERTAINTY EVALUATION

A. Units, disciplines, and/or subdisciplines will identify the contributions to measurement uncertainty. These contributions are recorded in each appropriate technical procedure, or the appropriate technical procedure will reference the location of the record(s) of the identified contributions if the record(s) is retained elsewhere. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, will be considered using the appropriate methods of analysis. [ISO 17025 7.6.1]

B. Technical procedures, when applicable, will include considerations for estimating the measurement uncertainty. The method of analysis for evaluation of measurement uncertainty: [ANAB AR 3125 7.6.1.1]
    1. 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; [ANAB AR 3125 7.6.1.1.a]
    2. Includes the process of rounding the expanded uncertainty; [ANAB AR 3125 7.6.1.1.b]
    3. Requires the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and [ANAB AR 3125 7.6.1.1.c]
    4. Specifies the schedule to review and/or recalculate the measurement uncertainty. [ANAB AR 3125 7.6.1.1.d]

C. 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. [ISO 17025 7.6.3]
    1. Units, disciplines, and/or subdisciplines will evaluate or estimate measurement uncertainty when applicable, for all reported quantitative results. [ANAB AR 3125 7.6.3.1]

D. Unit, disciplines and/or subdisciplines will retain the following records for each evaluation and estimation of measurement uncertainty: [ANAB AR 3125 7.6.4]
    1. Statement defining the measurand; [ANAB AR 3125 7.6.4.a]
    2. Statement of how traceability is established for the measurement; [ANAB AR 3125 7.6.4.b]
    3. The equipment (e.g., measuring device(s) or instrument[s]) used; [ANAB AR 3125 7.6.4.c]
    4. All uncertainty components considered; [ANAB AR 3125 7.6.4.d]
    5. All uncertainty components of significance and how they were evaluated; [ANAB AR 3125 7.6.4.e]
    6. Data used to estimate repeatability, intermediate precision, and/or reproducibility; [ANAB AR 3125 7.6.4.f]

7. All calculations performed; and [ANAB AR 3125 7.6.4.g]
8. The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty. [ANAB AR 3125 7.6.4.h]

8 SELECTION, VERIFICATION, AND VALIDATION OF METHODS

A. The FBI Laboratory uses appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. The FBI Laboratory also uses appropriate methods and procedures for all associated data analysis and interpretation. [ISO 17025 7.2.1.1] [ANAB AR 3125 7.2.1.1.1]
B. If a technical procedure involves the comparison of an unknown to a known for the purpose of source association, 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). [ANAB AR 3125 7.2.1.1.2]
    1. This requirement is not focused on the process of assessing an unknown to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known prior to the assessment of the unknown.
C. FBI Laboratory personnel select appropriate methods and procedures to meet the needs of the customer while considering the nature of the evidence, the request for examination, and any pertinent case information received. The methods are published either in international, regional, or national standards; by reputable technical organizations; in relevant scientific texts or journals; as specified by the manufacturer of the equipment; or are developed or modified by the FBI Laboratory. Any references for technical procedures are maintained with the validation records. [ISO 17020 7.1.1] [ISO 17025 7.1.1.d] [ISO 17025 7.2.1.4]
D. FBI Laboratory personnel verify (e.g., performance check) that they can properly perform methods before introducing them by ensuring they 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. [ISO 17025 7.2.1.5] [A2LA R318 7.1 FI1.3]

8.1 Method Development

A. Method development involves the acquisition and evaluation of test data for the determination and optimization of conditions of a method to achieve consistent results. A method development plan will be prepared prior to developing a new method. [ISO 17025 7.2.1.6]
B. The method development plan will be reviewed and approved by the applicable Technical Leader. As method development proceeds, periodic review is carried out to confirm the needs of the customer(s) are still being fulfilled. Any modifications to the development plan are reviewed and authorized by the Technical Leader. If the

Technical Leader is the preparer, a SME will approve the plan/changes to the plan. [ISO 17025 7.2.1.6]

8.2 Method Validation

A. Method validation is the process of determining whether pre-defined performance requirements are met to declare the method fit-for-purpose. Standard methods, non-standard methods, and FBI Laboratory-developed methods must be validated prior to use in the FBI Laboratory. [ISO 17020 7.1.3] [A2LA R318 7.1 FI1.4] [ISO 17025 7.2.1.5] [ISO 17025 7.2.2.1]
    1. If a significant modification (determined by applicable Technical Leader) needs to be made to an existing method/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. [ISO 17025 7.2.2.2]

B. A validation plan will be prepared prior to validating a method. The validation plan will be reviewed and approved by the Technical Leader. If the Technical Leader is the preparer, a SME will approve the plan.
    1. When modifications to an existing method/previously validated procedure are expected to affect the original validation as determined by the Technical Leader, or when a previously validated procedure will be used in a new facility, a validation plan is also required.
    2. When a previously validated FBI Laboratory procedure will be used in a new FBI Laboratory facility, a simplified validation (e.g., verification, performance check) can be performed to ensure technically sound results can be produced. [ISO 17025 7.2.1.5] [ISO 17025 7.2.2.1]
    3. In developing the validation plan, the performance characteristics, as assessed for the intended use, will take into consideration the customers' needs and be consistent with specified requirements. [ISO 17025 7.2.2.3]

C. Validations will:
    1. Be as extensive as is necessary to meet the needs of the given application or field of application. [ISO 17025 7.2.2.1]
    2. Be conducted according to the validation plan. [ANAB AR 3125 7.2.2.1.1.a]
    3. Include the associated data analysis and interpretation steps. [ANAB AR 3125 7.2.2.1.1.b]
    4. Establish the data and acceptance criteria required to report a result, opinion, interpretation, or statement of conformity. [ANAB AR 3125 7.2.2.1.1.c]
    5. Identify limitations of the method. [ANAB AR 3125 7.2.2.1.1.c]
    6. Include the conditions under which reliable results can be obtained.
    7. Include the use of known samples.

D. Appropriate Level 2 documents will define and/or reference the minimum requirements for a validation study within a unit, discipline, and/or subdiscipline.

E. Units, disciplines, and/or subdisciplines will retain records for a validation including:
    1. The validation procedure used; [ISO 17025 7.2.2.4.a]

2. Specification of the requirements; [ISO 17025 7.2.2.4.b]
3. Determination of the performance characteristics of the method; [ISO 17025 7.2.2.4.c]
4. The results obtained; [ISO 17025 7.2.2.4.d]
5. Statement on the validity of the method, detailing its fitness for intended use; [ISO 17025 7.2.2.4.e]
6. References for technical procedures.

8.3 Software Acceptance/Validation

A. Software validation is the process of establishing that performance requirements are met to declare the software fit-for-purpose and function appropriately in laboratory activities. Software applications that are not part of the testing process (e.g., Microsoft Office Suite) do not fall under this section.
B. New software to include commercial software and those developed by the FBI Laboratory will be validated. If this is an update to existing software, a performance check can be performed.
C. A software validation plan will be developed and will be approved by the appropriate SME. The version of the software validated will be tracked.
D. User acceptance testing (UAT) will be performed to verify that the application performs as expected prior to use.
NOTE: Data generated through user acceptance testing of software may be used as part of a validation if it fulfills the requirements of a validation plan.

8.4 Validation Summaries

Validation summaries will be prepared for public posting with the associated technical procedure. [Memorandum For Heads Of Department Components - 2016 (justice.gov)]

8.5 Competency Tests for New Procedures

A. Competency tests will be created with expected results and evaluation criteria and administered to each examiner and/or analyst who will apply a new procedure to laboratory activities (see section 6.3.4).
B. The Unit Chief and the Technical Leader may approve a validation to serve as demonstration of competency for personnel involved in that validation.

8.6 Method Development and Validation Records

A. Records of method selection, development, and validation (see section 8.2.E), to include software validations, will be retained by the applicable unit, discipline and/or subdiscipline.
B. Approvals of method development plans and validation plans will also be retained. [ISO 17025 7.2.1.5] [ANAB AR 3125 7.11.2.1] [A2LA R318 7.1 FI1.4]

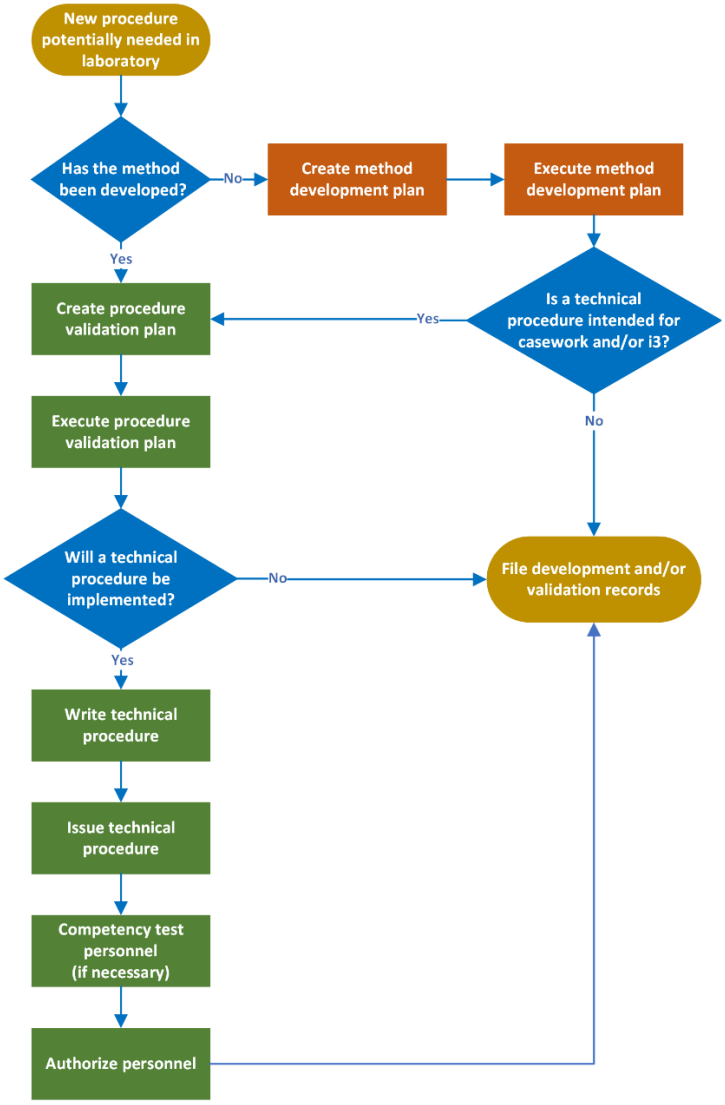

Figure 1: Method Development, Validation, and Implementation Flowchart

9 EQUIPMENT CALIBRATION/MAINTENANCE

9.1 Equipment

A. The FBI Laboratory is furnished with, or has access to, equipment needed for the correct performance of laboratory activities and that can influence the results. [ISO 17020 6.2.1, 6.2.2] [ISO 17025 6.4.1]

B. Equipment may include measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus as well as any other applicable equipment defined in Level 2 documents. [ISO 17025 6.4.1]

9.1.1 Equipment Identified in Resource Manager

A. Each piece of equipment entered in Resource Manager will receive a unique identifier and label that will, when practicable, be placed on the equipment. The Resource Manager fields will be populated. [ISO 17020 6.2.4] [ISO 17020 6.2.15] [ISO 17025 6.4.13.a] [ISO 17025 6.4.13.b] [ISO 17025 6.4.13.d]
B. Equipment used for laboratory activities that requires calibration will be identified in Resource Manager or STACS, as appropriate. [ISO 17020 6.2.4] [ISO 17020 6.2.15] [ISO 17025 6.4.13]

9.1.2 Equipment Outside of Permanent Control

When units, disciplines, and/or subdisciplines use equipment outside of their permanent control, they will ensure that the applicable requirements are met. [ISO 17025 6.4.2]

9.1.3 Equipment Handling, Transport, Storage and Use

Units, disciplines, and/or subdisciplines have Level 2 procedures for handling, transport, storage, and use of equipment to ensure proper functioning and to prevent contamination or deterioration. [ISO 17020 6.2.5] [ISO 17025 6.4.3]

9.1.4 Reference Collections

Units, disciplines, and/or subdisciplines 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. [ANAB AR 3125 6.4.3.2]

9.1.5 Reagents

A. Units, disciplines, and/or subdisciplines have procedures for checking the reliability of reagents. [ISO 17025 6.4.3] [ANAB AR 3125 6.4.3.1] [A2LA R318 6.2 FI1.2]
B. Reagents prepared in the FBI Laboratory are labeled with the identity of the reagent and the date of preparation or lot number. [ISO 17025 6.4.3] [ANAB AR 3125 6.4.3.1]
C. Records are retained by the units, disciplines, and/or subdisciplines identifying who made the reagent and the components used in preparation. [A2LA R318 6.2 FI1.3] [A2LA R318 6.2 FI1.4] [ISO 17025 6.4.3] [ANAB AR 3125 6.4.3.1]

9.1.6 Refrigerators and Freezers

Refrigerators and freezers that store evidence and/or items that have a direct effect on the validity of laboratory activities will have their temperatures monitored and maintained as needed. [ISO 17020 6.2.11.c] [ISO 17025 6.4.1]

9.1.7 Software and Firmware

Records of software and firmware version that can influence laboratory activities will be maintained by units, disciplines, and/or subdisciplines. Version and effective dates are acceptable records. [ISO 17025 6.4.13.a]

9.1.8 Equipment Placed or Returned into Service

Equipment used for laboratory activities must meet the requirements of the relevant technical procedure or applicable specifications. Before being placed into or returned to service, equipment that has a direct effect on the quality of laboratory activities is calibrated and/or performance checked by the applicable unit, discipline, and/or subdiscipline to verify it meets the specifications. Records will be maintained. [ISO 17020 6.2.6] [ISO 17025 6.4.4] [ISO 17025 6.4.13.c]

9.1.9 Equipment Measurement Accuracy and/or Measurement Uncertainty

Units, disciplines, and/or subdisciplines ensure the equipment used for measurement can achieve the measurement accuracy and/or measurement uncertainty required to provide a valid result. [ISO 17025 6.4.5]

9.1.10 Equipment Overloading/Mishandling/Power Interruption

A. 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. [ISO 17020 6.2.14] [ISO 17025 6.4.9]
    1. The equipment will be isolated to prevent use and/or clearly labeled or marked as being out of service until it has been returned into service. [ISO 17020 6.2.14] [ISO 17025 6.4.9]
B. Units, disciplines, and/or subdisciplines will determine and record the effect of the defect or departure from specified requirements and implement nonconforming work procedures. [ISO 17020 6.2.14] [ISO 17025 6.4.9]
C. If an instrument can be affected by a power interruption, units, disciplines, and/or subdisciplines will check the instrument operation after a shutdown, whether deliberate or otherwise.

9.1.11 Equipment Unintended Adjustments

Units, disciplines, and/or subdisciplines will take practicable measures to prevent unintended adjustments of equipment from invalidating test results. [ISO 17025 6.4.12]

9.1.12 Equipment Performance Checks

A. When performance checks are necessary to maintain confidence in the performance of equipment, units, disciplines, and/or subdisciplines will carry out these checks according to Level 2 procedures. [ISO 17020 6.2.9] [ISO 17025 6.4.10]
    1. Performance check procedures will be included in the appropriate technical procedure 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.
B. 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: [ISO 17025 6.4.13]

1. Type or name of equipment. [ISO 17025 6.4.13.a]
2. Equipment serial number or another unique identifier. [ISO 17025 6.4.13.b]
3. Date of the performance check.
4. Results of the performance check. [ISO 17025 6.4.13.c]
5. Material used for the performance check, including unique identifying information, if applicable.
6. Acceptance criteria, if applicable. [ISO 17025 6.4.13.f]
7. Identity of person performing the performance check.

9.2 Traceability

A. Units, disciplines, and/or subdisciplines will establish and maintain metrological traceability of their applicable measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. [ISO 17020 6.2.7] [ISO 17025 6.5.1]

B. Units, disciplines, and/or subdisciplines will ensure measurement results are traceable to the International System of Units (SI) through: [ISO 17025 6.5.2]
   1. Calibration provided by a competent laboratory (see section 9.2.1)[ISO 17025 6.5.2.a]; or
   2. Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI [ISO 17020 6.2.10] [ISO 17025 6.5.2.b]; or
   3. Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. [ISO 17025 6.5.2.c]

C. When metrological traceability of measurements to SI units is not technically possible, units, disciplines, and/or subdisciplines will demonstrate metrological traceability to an appropriate reference, for example: [ISO 17025 6.5.3]
   1. Certified values of certified reference materials provided by a competent producer; [ISO 17025 6.5.3.a]
   2. 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. [ISO 17025 6.5.3.b]

9.2.1 Calibration Service Providers

A. When measuring equipment and/or certified reference materials that are used to establish or maintain traceability are calibrated, the external supplier of the calibration service will be one of the following (if available): [ANAB AR 3125 6.5.1.1]
   1. 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 [ANAB AR 3125 6.5.1.1.a]

2. A service supplier accredited to ISO 17025 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) MRA, with the calibration of measuring equipment to be purchased listed in a scope of accreditation; or [ANAB AR 3125 6.5.1.1.b]
3. An accredited reference material producer that is accredited to ISO/IEC 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. [ANAB AR 3125 6.5.1.1.c]

B. In situations where a supplier that meets the above specifications 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 units, disciplines, and/or subdisciplines using that supplier. Objective evidence of the confirmation will be maintained by the units, disciplines, and/or subdisciplines. [ANAB AR 3125 6.5.1.2]
C. The FBI Laboratory does not perform calibrations or issue calibration certificates as part of its scope of accredited activities. [ISO 17025 7.6.2] [ISO 17025 7.8.4] [ISO 17025 7.8.4.1] [ANAB AR 3125 6.5.1.3] [ANAB AR 3125 7.2.1.1.3] [ANAB AR 3125 7.5.1.6] [ANAB AR 3125 7.7.5.e] [ANAB AR 3125 7.8.1.2.3]

9.3 Calibration

A. Equipment that meets one or both of the following criteria will be calibrated. [ISO 17025 6.4.6]
    1. The measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
    2. Calibration of the equipment is required to establish the metrological traceability of the reported results.
B. Units, disciplines, and/or subdisciplines will ensure calibration was completed and ensure the calibration certificate provided by a vendor is reviewed for accuracy and checked for conformance with applicable requirements for their needs. A record of this review will be maintained. [ISO 17025 6.4.13.e]
C. Units, disciplines, and/or subdisciplines will ensure Resource Manager or STACS, as appropriate, is updated to record the calibration information in a timely manner. [ISO 17025 6.4.13.e]
D. Calibration records, including calibration certificates, for all equipment will be maintained by the unit coordinating the calibration. These records will be maintained on the Equipment Calibration and Service site and/or in a unit specified location(s).
E. Equipment that requires calibration will not be used for laboratory activities if satisfactory calibration cannot be achieved. If the calibration has expired, personnel

will verify the calibration status is satisfactory prior to using the equipment (see section 9.1.12).

9.3.1 Calibration Program

A. Units, disciplines, and/or subdisciplines have a calibration program described in a Level 2 document, which they review and adjust as necessary to maintain confidence in the status of the calibration(s). [ISO 17020 6.2.6] [ISO 17025 6.4.7]
B. Each calibration program includes: [ANAB AR 3125 6.4.7.1.a] [ANAB AR 3125 6.4.7.1.b] [ANAB AR 3125 6.4.7.1.c] [ANAB AR 3125 6.4.7.1.d]
    1. A list of the equipment requiring calibration;
    2. Specifications for the calibration service provider(s);
    3. Specified requirements for the calibration; and
    4. The interval of calibration.

9.3.2 Calibration Interval

A. Units, disciplines, and/or subdisciplines will ensure that equipment requiring calibration is calibrated within the required intervals as specified in Level 2 documents.
B. 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 (see section 9.1.12).

9.3.3 Labeling

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. [ISO 17025 6.4.8]

9.3.4 Reference Values or Correction Factors

When calibration and reference material data will include reference values or correction factors, units, disciplines, and/or subdisciplines will ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. [ISO 17025 6.4.11]

9.4 Maintenance

A. Maintenance is performed on equipment to ensure reproducible and uninterrupted operation; maintenance may also be corrective. Maintenance performed on a regular, predetermined schedule is based on manufacturer's recommendations (as available and relevant), historical observations of issues, operating experience, and/or how often the equipment is used. The interval for any equipment requiring preventive maintenance will be specified in a Level 2 document. [ISO 17020 6.2.3]

B. Units, disciplines, and/or subdisciplines will have maintenance procedures, including planned maintenance, for equipment that has a direct effect on the quality of laboratory activities to ensure proper functioning, and to prevent contamination or deterioration. [ISO 17020 6.2.5] [ISO 17025 6.4.3]
C. Maintenance will be performed on equipment:
    1. According to a regular, predetermined schedule (e.g., microscope maintenance performed annually);
    2. Based on routine monitoring of performance;
    3. Following adjustment of common parameters (e.g., head pressure, solvent degas); and/or
    4. When a piece of equipment cannot be properly calibrated, fails a performance check, fails to meet the performance characteristics established for the procedure(s), or otherwise produces unacceptable results (i.e., corrective maintenance).
        i. Equipment will be isolated to prevent use and/or clearly labeled or marked as being out of service until it has been returned into service. [ISO 17025 6.4.9]
D. Maintenance records will include information on the maintenance performed, when relevant to the performance of the equipment, and provide details of any damage, malfunction, modification to, or repair of, the equipment. 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. These records will be maintained by the units, disciplines, and/or subdisciplines. [ISO 17020 6.2.15] [ISO 17025 6.4.13.a] [ISO 17025 6.4.13.b] [ISO 17025 6.4.13.g] [ISO 17025 6.4.13.h]
E. Unit Chiefs will ensure maintenance records provided by a vendor are reviewed for accuracy and checked for conformance with applicable requirements. A record of this review will be maintained.

10 MONITORING

A. The FBI Laboratory monitors its performance, including the performance of personnel. [ISO 17025 7.7.2] [ANAB AR 3125 7.7.4]
B. Proficiency testing, interlaboratory comparisons, intralaboratory comparisons, and/or observation-based performance monitoring, technical reviews, and testimony evaluations are used for monitoring the performance of the laboratory and its personnel. Auditing, customer feedback, complaints, and the annual management review of the quality system are also types of monitoring in the FBI Laboratory to ensure the validity of results. [ISO 17025 7.7.2.a] [ISO 17025 7.7.2.b] [ANAB AR 3125 7.7.4]

10.1 Validity of Results Monitoring

A. Units, disciplines, and/or subdisciplines define applicable quality control procedures for monitoring the validity of results in Level 2 documents and maintain applicable records. [ISO 17025 7.7.1] [A2LA R318 7.1 FI1.2]

B. The resulting data is recorded in such a way that trends are detectable and, when practicable, statistical techniques are applied to the review of the results. [ISO 17025 7.7.1]
C. Monitoring the validity of results is planned and reviewed and includes the following, where appropriate:
    1. Use of reference materials or quality control materials; [ISO 17025 7.7.1.a]
    2. Use of alternative instrumentation that has been calibrated to provide traceable results; [ISO 17025 7.7.1.b]
    3. Performance check(s) of measuring and testing equipment; [ISO 17025 7.7.1.c] [ISO 17025 7.7.1.e]
    4. Use of check or working standards with control charts, where applicable; [ISO 17025 7.7.1.d]
    5. Replication of tests using the same or different procedures; [ISO 17025 7.7.1.f]
    6. Retesting of retained items; [ISO 17025 7.7.1.g]
    7. Correlation of results for different characteristics of an item of evidence; [ISO 17025 7.7.1.h]
    8. Review of reported results, technical records, and testimony (see section 10.7.7); [ISO 17025 7.7.1.i] [ANAB AR 3125 7.7.1.l]
    9. Intralaboratory comparisons; [ISO 17025 7.7.1.j]
    10. Testing of blind sample(s). [ISO 17025 7.7.1.k)]
D. Data from monitoring activities is analyzed, used to control and, if applicable, improve the FBI Laboratory's activities. [ISO 17025 7.7.3]
    1. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported. [ISO 17025 7.7.3]

10.2 Performance Monitoring

10.2.1 Performance Monitoring Plan

A. Each Unit Chief will ensure a performance monitoring plan is developed and maintained for their qualified and authorized personnel. This includes:
    - Individuals who perform laboratory activities,
    - Individuals who handle evidence but do not perform laboratory activities, and/or
    - Individuals who are authorized to perform other laboratory tasks that require monitoring of competence as described in ANAB GD 3152 and who do not participate in a proficiency test, interlaboratory comparison or intralaboratory comparison. [ANAB AR 3125 7.7.6.a]

    When an individual is qualified and authorized, the unit will add them to the performance monitoring plan.
B. For personnel performing laboratory activities, the plan must ensure inclusion of a portion of the components/parameters and equipment/technologies within each

discipline on the FBI Laboratory's ANAB Scope of Accreditation or each discipline and/or subdiscipline as defined by the FBI Laboratory. [ANAB AR 3125 7.7.6.b]

C. For personnel who handle evidence (e.g., evidence management personnel, forensic photographers) but do not perform laboratory activities, and personnel who do not participate in a proficiency test, interlaboratory comparison or intralaboratory comparison who are authorized to perform other laboratory tasks that require monitoring of competence as described in ANAB GD 3152, the plan must ensure they are monitored through FBI required performance feedback (e.g., check-in, wrap-up) and once an accreditation cycle through observation.
D. Performance monitoring plans will be maintained to cover at least the current year; however, planning should consider the accreditation cycle.

10.2.2 Performance Monitoring Requirements

A. Results will not be known or readily available to the participant being monitored. [ANAB AR 3125 7.7.5.a]
B. Each participant must use approved methods and participate to the extent they would perform the procedures in testing. [ANAB AR 3125 7.7.5.b]
C. Evaluation criteria for successful performance will be established prior to the monitoring activity (i.e., proficiency test, intralaboratory comparison, interlaboratory comparison, or observation-based performance monitoring) being conducted. [ANAB AR 3125 7.7.5.c]
    1. Participants will be aware of the expectations of the activity prior to beginning the monitoring activity. [ANAB AR 3125 7.7.5.c]
D. A mechanism to ensure the quality of the monitoring activity will be recorded prior to personnel being performance monitored. [ANAB AR 3125 7.7.5.d]
    1. For proficiency tests, this will be as required by the proficiency test provider.
    2. For other performance monitoring (i.e., intralaboratory comparison, interlaboratory comparison, or observation-based performance monitoring), requirements will be described in a Level 2 document.
        i. The test design, participant results, and evaluation will be recorded on the *Performance Monitoring Other Than Proficiency Testing* (7-290a, b, c) forms.
        ii. The test design will be approved by the Technical Leader. If the Technical Leader will be a participant, a SME will approve the test.
E. The date assigned identifies the day on which the participant was assigned the monitoring activity. This date identifies the calendar year for which the performance monitoring activity will be credited.
F. Personnel verifying, reviewing, and/or evaluating the monitoring activity must be SMEs in the task(s) being monitored. Personnel overseeing the administration of the monitoring process do not need to be SMEs. [ISO 17020 6.1.8]
G. Proficiency test, intralaboratory comparison, and interlaboratory comparison identifications or associations will be verified, when appropriate. All proficiency tests, intralaboratory comparisons, and interlaboratory comparisons will be

technically reviewed using the same procedures used for casework and administratively reviewed.

1. If a person who will verify, technically review, and/or administratively review a proficiency test, intralaboratory comparison, or interlaboratory comparison is participating in the same test distribution, they will not conduct any verifications or reviews until their testing is complete.

H. Proficiency test results will be evaluated within 20 calendar days after the individual and/or summary reports are received. Intralaboratory comparison, interlaboratory comparison, or observation-based performance monitoring results will be evaluated within 20 calendar days from the administrative review or recorded completion of the activity, as appropriate.

1. If a nonconformity regarding the test design and/or preparation is identified during the evaluation of the results, the issues concerning the nonconformity will be reviewed and adjudicated by the Technical Leader. This will occur prior to providing the results to the participant.

I. The Unit Chief will ensure the completion of the evaluation for each individual performance monitoring activity, the appropriate evaluation term (i.e., satisfactory, unsatisfactory, or discontinued), and the test participant's feedback date are recorded (see section 10.2.7).

10.2.3 Proficiency Testing

A. For personnel qualified and authorized to perform laboratory activities in a discipline appearing on the FBI Laboratory's ANAB Scope of Accreditation or an FBI Laboratory defined subdiscipline, each person must demonstrate successful performance in at least one proficiency test per calendar year in each accredited discipline and/or subdiscipline in which the person is qualified and authorized to conduct work (see section 10.2.1). [ISO 17025 6.2.5.f] [ANAB AR 3125 7.7.2.1.a] [ANAB AR 3125 7.7.2.1.b] [ANAB AR 3125 7.7.4]

B. Units will use a proficiency test provider who is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement (MRA) and has the applicable proficiency test on its scope of accreditation. [ANAB AR 3125 7.7.7.a]

C. Where proficiency tests are not available or appropriate for the work conducted in an accredited discipline, units will gain approval from ANAB for an alternate means of interlaboratory comparison. [ISO 17025 7.7.2.b] [ANAB AR 3125 7.7.7.d]

D. Units will submit proficiency test results to the proficiency test provider on or before the date determined by the test provider and authorize the provider to release the results to ANAB. [ANAB AR 3125 7.7.7.b] [ANAB AR 3125 7.7.7.c]

E. Proficiency test samples must be retained through the evaluation of a proficiency test and, when applicable, the resolution of any nonconformity(ies) associated with that proficiency test.

10.2.4 Performance Monitoring Other Than Proficiency Testing

A. If a proficiency test is not available or appropriate for an aspect of work performed in an accredited discipline, an intralaboratory comparison or interlaboratory comparison is acceptable. If those options are not available or appropriate, an observation-based performance monitoring is acceptable (see section 10.2.3.C). [ANAB AR 3125 7.7.4]

B. For personnel qualified and authorized to perform laboratory activities in a discipline *not* appearing on the FBI Laboratory's ANAB Scope of Accreditation, each person will participate in an annual performance monitoring activity as defined in a Level 2 procedure. [ISO 17025 6.2.5.f]

C. For personnel qualified and authorized to perform evidence handling who are not qualified and authorized to perform laboratory activities, each person will be monitored annually through performance evaluations and once an accreditation cycle through observation. [ISO 17025 6.2.5.f]

D. For personnel who do not participate in proficiency testing, intralaboratory comparisons, or interlaboratory comparisons who are qualified and authorized to perform other laboratory tasks that require monitoring of competence as described in ANAB GD 3152, each person will be monitored annually through FBI required performance evaluations and once an accreditation cycle through observation. [ISO 17025 6.2.5.f]

10.2.5 Extended Time from Laboratory Activities

When a person who performs laboratory activities does not perform them for an extended time (e.g., on extended leave, on temporary duty (TDY), training on other tasks/duties), the Unit Chief and Technical Leader will discuss the person's maintenance of skills and expertise upon their return. If competency testing (e.g., requalification) is needed, this can occur as described in section 6.3.4 and/or other means as described in a Level 2 document. Extended time away exceeding one half of an annual proficiency test cycle requires monitoring for continued competence. A Technical Leader may require monitoring of a person after a shorter time away from laboratory activities.

10.2.6 *Unexpected Results/Observation and Other Situations in Performance Monitoring*

A. When an expected result is not attained (e.g., unexpected results/observation, non-consensus result) during a monitoring activity, or performance monitoring will not/does not occur as required in sections 10.2.3 or 10.2.4, it will be reported to FASU via the Report a Performance Monitoring Event within 10 calendar days of being identified (e.g., technical review, evaluation, performance monitoring will not/does not occur).

   1. ANAB will be notified within 30 calendar days when the expected result is not attained during any monitoring activity. [ANAB AR 3125 7.7.5.f]

   NOTE: For a consensus-based proficiency test, the consensus result is the expected result.

NOTE: When an identification or exclusion is the expected result, an outcome of inconclusive is considered an unexpected result.

B. Non-technical unexpected results/observations noted during the monitoring process will be recorded and addressed as appropriate (see section 5).
C. Unexpected results/observations identified during the monitoring process that may be technical in nature will be recorded and the Technical Leader notified (see section 5).
D. The Technical Leader will determine if the unexpected result/observation is an analytical/interpretive error and:
    1. Determine the steps needed to address the unexpected result/observation. Their final decision will be recorded.
    2. If the unexpected result/observation was achieved by the Technical Leader, a SME will determine if the unexpected result/observation is an analytical/interpretive error, and the steps needed to address the issue. The final decision will be recorded.
    3. Analytical/interpretive errors identified during verification, technical review and/or administrative review of an external proficiency test can be corrected prior to submission to the provider. Records will be retained, and corrective action may be warranted.
E. Corrective Action
    1. If the steps needed to address the analytical/interpretive error result in the development of a CAP, refer to sections 5.6.

10.2.7 Records of Performance Monitoring

A. The following records will be retained for all performance monitoring:
    1. Tasks that require evidence handling, discipline(s), and/or subdiscipline(s) monitored [ANAB AR 3125 7.7.8.a]
    2. Design of the monitoring activity [ANAB AR 3125 7.7.8.b]
    3. Expected results and evaluation criteria [ANAB AR 3125 7.7.8.c]
    4. Location of FBI Laboratory where monitoring occurred [ANAB AR 3125 7.7.8.d]
    5. Records submitted to and received from a proficiency test provider, if applicable [ANAB AR 3125 7.7.8.e]
    6. Appropriate technical records [ANAB AR 3125 7.7.8.f]
    7. Evaluation of results and action taken for unexpected results [ANAB AR 3125 7.7.8.g]
    8. Feedback on individual performance provided to the participant. [ANAB AR 3125 7.7.8.h]
B. Records for continued monitoring of competence of personnel can be found in a unit's performance monitoring records, testimony evaluation records, and technical and administrative reviews of casework. [ISO 17020 6.1.10]
    1. For individuals qualified and authorized to perform laboratory activities, records related to performance monitoring will be entered into the appropriate LIMS, contemporaneously with the evaluation and feedback. The

feedback date is the date the evaluation was reviewed by the test participant.

2. For individuals qualified and authorized to handle evidence but do not perform laboratory activities, performance monitoring records will be retained by their unit, discipline, or subdiscipline.

10.3 Customer Feedback

A. The FBI Laboratory receives customer feedback through multiple means. Customers may provide unsolicited feedback, or the laboratory may request feedback from a customer.

B. All feedback is considered for continual improvement of the FBI Laboratory. [ISO 17025 8.6.2]

10.3.1 Laboratory Initiated Request for Feedback

A. *Customer Satisfaction Assessments* (FD-1000) will be provided for *Laboratory Reports* for new submissions. A *Customer Satisfaction Assessment* will be provided to the customer, or the customer will be directed to the location of an electronic *Customer Satisfaction Assessment* they can complete.

B. A *Customer Satisfaction Assessment* or other unit generated customer feedback form received with a response that indicates dissatisfaction (e.g., 'No', 'Unsatisfactory') will be considered a complaint and will be addressed as described in section 10.4.1.

C. FBI Laboratory personnel may also solicit feedback through direct communication with a customer.

10.4 Complaints

A. A complaint is the expression of dissatisfaction by any person or organization to the laboratory, relating to the activities or results of the laboratory, where a response is expected. [ISO 17020 3.10] [ISO 17025 3.2]

B. FBI Laboratory employees may contact the Quality Manager regarding concerns with quality-related aspects of the quality system.

C. The FBI Laboratory is responsible for all decisions at all levels of the handling process for complaints and ensures the process for handling complaints is posted to the publicly available website: https://fbilabqsd.fbi.gov. [ISO 17020 7.5.2] [ISO 17020 7.5.4] [ISO 17025 7.9.2]

10.4.1 Process to Receive, Evaluate, and Take Actions on Complaints

A. Complaints will be recorded in a centralized location via the Complaint Intake. The recipient of the complaint will enter the information, or if it is an internal complainant, they can enter the information. FASU and the Quality Manager will be notified of the entry. An appropriate evaluator will be selected to handle the complaint through this process. [ISO 17020 7.5.1] [ISO 17020 7.5.3] [ISO 17020 7.6.1.a, b] [ISO 17025 7.9.1] [ISO 17025 7.9.3.a, b]

1. For a complaint from a customer of activities or results provided by the FBI Laboratory, an FBI Laboratory employee, or an external party (i.e., not a customer or FBI Laboratory employee), the evaluator will be the applicable Technical Leader (when technical in nature) or the Unit Chief. When risks to impartiality are identified they will be mitigated (see section 1.5).

B. The evaluator will then assess whether the complaint relates to laboratory activities the FBI Laboratory is responsible for, and if so, will deal with it. [ISO 17020 7.5.3] [ISO 17025 7.9.2]

C. If the complaint is related to laboratory activities, the evaluator will:
   1. Acknowledge receipt of the complaint, in writing, to the complainant. [ISO 17020 7.6.3] [ISO 17025 7.9.5]
   2. Gather information necessary to validate and investigate the complaint and determine if action is warranted. The evaluator may consult Executive Management, Senior Scientists, Quality Manager, Office of General Counsel, and/or external personnel, as necessary for investigating the complaint. [ISO 17025 4.1.5] [ISO 17020 7.5.1] [ISO 17020 7.5.3] [ISO 17020 7.6.1] [ISO 17020 7.6.2] [ISO 17025 7.9.1] [ISO 17025 7.9.2] [ISO 17025 7.9.3.a] [ISO 17025 7.9.4]

D. If the complaint is related to laboratory activities and there are exceptional circumstances, the evaluator may discuss the complaint with their Section Chief and the Laboratory Director. The Laboratory Director may ask the evaluator to collect preliminary information related to the complaint. The Laboratory Director can determine to handle the complaint through the Quality System complaint process or direct the complainant to another appropriate FBI process (e.g., FOIPA, OPA, INSD) and/or DOJ process. The Laboratory Director's decision and reason(s) will be retained in the centralized Complaint records.

E. If the complaint is determined to be a nonconformity, it will be addressed according to section 5 in conjunction with the complaint process. [ISO 17020 7.6.1.a] [ISO 17025 7.9.3.a]

10.4.2 Progress Reports, Outcome, and Records of Complaints

A. When practicable, progress reports and the outcome(s) to be communicated to the complainant will be made by the evaluator. The outcome(s) to be communicated to the complainant will be reviewed and approved by the evaluator's Section Chief. Individuals involved in the original laboratory activities in question cannot determine or review the outcome(s). [ISO 17025 7.6.3] [ISO 17020 7.6.4] [ISO 17025 7.9.5] [ISO 17025 7.9.6]

B. When practicable, the evaluator will notify the complainant, in writing, of the end of the complaint handling process. This can be communicated at the same time as the outcome if that is the end of the complaint handling process. Individuals involved in the original laboratory activities in question may request a copy of the outcome(s). It may be provided with approval from the evaluator or Laboratory Director, as applicable, depending on the how the complaint was handled. [ISO 17020 7.6.5] [ISO 17025 7.9.7]. [ISO 17020 7.6.5] [ISO 17025 7.9.7]

C. Evaluators will ensure records of all complaints, including, assessment (e.g., whether it is related to laboratory activities), validation and investigations including interviews, actions taken, progress reports, and outcomes to the complainant are retained in the centralized Complaint records. [ISO 17020 7.5.1] [ISO 17020 7.5.3] [ISO 17020 7.6.1.a] [ISO 17020 7.6.1.b] [ISO 17020 7.6.2] [ISO 17020 7.6.3] [ISO 17020 7.6.4] [ISO 17025 7.9.1] [ISO 17025 7.9.2] [ISO 17025 7.9.3.a] [ISO 17025 7.9.3.b] [ISO 17025 7.9.4] [ISO 17025 7.9.6]
D. The Quality Manager will review complaint records to ensure appropriate actions were taken in the complaint process for resolving the complaint. [ISO 17020 7.6.1.c] [ISO 17025 7.9.3.c]

10.5 Internal Quality Assurance Audits

10.5.1 Internal Auditor Training

A. An internal auditor must successfully complete a Quality Manager approved course prior to conducting an audit. [ISO 17020 8.6.5.a] [ISO 17025 8.8.2.a]
B. FASU will maintain a list of approved courses and a list of internal auditors who have completed an approved course.

10.5.2 Audit Planning

A. Internal audits will be conducted at least annually. [ISO 17020 8.6.4] [ISO 17025 8.8.1.a] [ANAB AR 3125 8.8.1.1]
B. A risk evaluation of the laboratory's quality system will be conducted annually by the Quality Manager in collaboration with FASU. A summary of this risk evaluation will be recorded and maintained by FASU. [ISO 17025 8.8.1.a]
C. A plan for internal audits, based on a risk evaluation of laboratory's quality system, including laboratory activities, changes in those activities, and the results of previous audits, will be prepared annually and maintained by FASU. [ISO 17020 8.6.2] [ISO 17020 8.6.3] [ISO 17025 8.8.1.a] [ISO 17025 8.8.1.b] [ISO 17025 8.8.2.a] [ISO 17025 8.8.2.b]
D. The plan will identify the topics and approximate dates of the audits. This plan may be changed at the discretion of the Quality Manager and/or FASU. [ISO 17025 8.8.2.a]
E. The audit plan must include direct observation of a portion of the laboratory activities within each discipline and subdiscipline. [ANAB AR 3125 8.8.2.b.1]

10.5.3 Preparing for the Audit

A. An audit team leader(s) and/or internal auditors will be identified to assist in performing an audit. The audit team leader will coordinate the audit. [ISO 17025 8.8.2.a]
B. Audit checklists will be prepared and will be accessible to the auditee(s) and the internal auditor(s). [ISO 17025 8.8.2.a] [ISO 17025 8.8.2.b]

10.5.4 Conducting the Audit

A. Internal auditor(s) will review records, interview personnel, and/or observe conditions and facilities to collect data on conformance with requirements and effectiveness of quality control measures. An internal auditor will not review their own work. [ISO 17020 8.6.5.b] [ANAB AR 3125 8.8.1.a.1]
B. The audit checklist will be used to record the audit data, and any pertinent questions, observations, and/or comments identified during the audit. Audit checklists will be maintained by FASU. [ISO 17025 8.8.2.e]

10.5.5 Notification and Resolution of the Audit Results

A. The applicable Quality Assurance Representative, Unit Chief, and Technical Leader(s) will be notified of the outcome for each audit including any nonconformities and recommendations. [ISO 17020 8.6.5.c] [ISO 17020 8.6.5.d] [ISO 17020 8.6.5.e] [ISO 17020 8.6.5.f] [ISO 17025 8.8.2.c] [ISO 17025 8.8.2.d] [ISO 17025 8.8.2.e]
B. If an auditee identifies a concern with the audit results, they will contact the audit team lead and/or internal auditor to discuss a resolution.
C. Nonconformities will be addressed according to section 5 and the auditee will record the required information in the checklist. The resolution of audit nonconformities will be implemented in a timely and appropriate manner by the applicable personnel. [ISO 17020 8.6.5.d] [ISO 17025 8.8.2.d]
D. The Quality Manager will conduct a final review of the audit checklists including resolved nonconformities. If the Quality Manager conducts an audit, another QA Specialist will conduct a final review.

10.6 Management Review

FBI Laboratory Executive Management and the Quality Manager evaluate the quality system to ensure its continued suitability, adequacy, and effectiveness, to include the quality requirements and objectives. The management review is conducted annually and is used as the foundation for future development of FBI Laboratory objectives as well as any necessary changes or improvements to the quality system. [ISO 17020 8.5.1.1] [ISO 17020 8.5.1.2] [ISO 17025 8.9.1] [ANAB AR 3125 8.9.1.1]

10.6.1 Management Review Inputs

The inputs to the management review are recorded and include information related to the following [ISO 17020 8.5.2] [ISO 17025 8.9.2]:

A. Changes in internal and external issues 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 17025 and ISO 17020 standards, 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, personnel 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.

10.6.2 Records of Management Reviews

Records of management reviews are serialized in Sentinel and include all decisions and actions related to: [ISO 17020 8.5.1.3, 8.5.3] [ISO 17025 8.9.3]

A. The effectiveness of the quality system and its processes;
B. Improvement of the laboratory activities related to the fulfillment of the accrediting bodies' requirements;
C. Provision of required resources; and
D. Any issues identified and actions taken to address them.

10.7 Testimony Related Activities

A. The requirements for testimony related activities apply to FBI Laboratory personnel who:
    1. Provide expert testimony as part of their current job duties (i.e., testifying personnel).
    2. Manage testifying personnel.
    3. Conduct testimony evaluations.
    4. Support testimony related activities.
B. Fact based testimony will be addressed by a unit, discipline and/or subdiscipline as needed.
C. For FBI Laboratory personnel who are requested to provide testimony for past FBI Laboratory job duties, refer to 10 7.2.D.
D. Additional guidance for use of the eDiscovery application is in the eDiscovery Guide (LAB-411).

10.7.1 Curriculum Vitae (CV)

Testifying personnel will maintain an up-to-date CV that meets the following requirements:

A. Not contain any official seal.
B. Include a listing of testimonies for at least the previous four years, including depositions and grand jury testimonies (unless prohibited).

C. Include the case name (e.g., United States v. John Doe), the year of the testimony, the jurisdiction (e.g., Eastern District of New York) or location (i.e., city and state), and the subject matter of the testimony (e.g., discipline, subdiscipline).
D. Include a listing of all publications authored for at least the previous 10 years.
E. Include affirmation when no testimony has been provided in the last four years or no publications have been authored in the last 10 years. [FBI Laboratory Assistant Director Directive]

10.7.2 Testimony Requests

A. Testifying personnel should notify their management of any request for their testimony.
B. Upon receipt of a subpoena request to testify, testifying personnel will ensure the subpoena is attached to the associated entry in eDiscovery or Testimony Tracker as appropriate.
    1. 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.
C. FBI Laboratory personnel will notify FSLU if they are made aware of a request for testimony or when testimony is provided by former FBI Laboratory personnel. The requirements of section 10.7 will be followed, when practicable.
D. FBI Laboratory personnel, who are no longer working in the same position or discipline and/or subdiscipline which the testimony will occur, will notify their management and OGC, and discuss their anticipated testimony with the appropriate Technical Leader.
    1. The witness will review any applicable Approved Standards for Scientific Testimony and Report Language (ASSTR) and/or any applicable Uniform Language for Testimony and Reports (ULTR) prior to their testimony.
    2. All associated meetings with the Technical Leader and OGC, and reviews of any applicable ASSTR and/or ULTR will be recorded by the testifying individual as a comment on the eDiscovery entry.

10.7.3 Discovery Requests

A. Discovery Requests are coordinated through FSLU.
B. Testifying personnel will:
    1. Ensure that all reports, 1A files, accurate/up-to-date CV, major and minor deviations associated with the case, and applicable Level 2 documents in use at the time of their examinations are provided in discovery.
C. FASU personnel will add applicable Level 1 quality system documents to eDiscovery. All discovery material will be provided to FSLU.
D. Discovery request entries will be retained permanently in eDiscovery.

10.7.4 Giglio Requirements

A. The FBI Laboratory must disclose to a prosecutor all potential Giglio information as early as possible prior to providing a sworn statement or testimony in any criminal investigation or case. [DOJ Policy: Justice Manual, 9-5.100]
B. Giglio information includes all information that could potentially be used by the defense to impeach a witness. This includes information that could be used by the defense to call into question the accuracy and/or strength of an examiner's professional conclusion. This also encompasses personal choices and circumstances which occur outside the context of a criminal investigation and could potentially be used by the defense to attack a witness' credibility or character for truthfulness, or information that could potentially be used to suggest a witness is biased in favor of the prosecution or against a defendant. However, potential impeachment material may be found in a myriad of forms and is not limited to these.
C. The FBI Laboratory will disclose all agency-held information that could potentially be used for impeachment purposes, including:
    1. Errors made during proficiency tests.
    2. Allegations or findings of unsatisfactory and/or inaccurate casework performance.
    3. Substantive violation(s) of the ULTRs or ASSTRs in testimony (see section 10.7.14).
    4. Testimony that does not violate the ULTRs or ASSTRs but contains materially inaccurate statement(s) (see section 10.7.14).
    5. Information required to be disclosed by the 1997 Department of Justice Office of the Inspector General Report or Microscopic Hair Review.
    6. Personnel records reflecting allegations or findings of misconduct that reflect on the candor or possible bias of an employee.
    7. Any additional information that may reasonably be used for impeachment purposes.
D. A testimonial presentation that has been found to contain a substantive violation, or a material inaccuracy (as determined by OGC or the sponsoring prosecutor, or by a court ruling), or has been deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate is considered potential Giglio material and will be disclosed during the established discovery process.
E. Testifying personnel must also contact the prosecutor to schedule a candid conversation to disclose any information they believe could potentially constitute Giglio (impeachment) information.

10.7.5 Requirements When Providing Testimony

All personnel providing expert testimony must provide testimony such that:

A. Testimony is consistent with FBI Laboratory procedures regarding testimony about the forensic analysis and any associated interpretations.

B. Testimonial opinions, conclusions, and statements regarding case-specific facts or data are properly qualified and do not exceed the limitations of any relevant method or discipline and/or subdiscipline. [ISO 17025 7.8.7.1]
C. Conclusions are in conformity with any applicable ASSTR and/or any applicable ULTR.

10.7.6 Tracking Testimony, Moot Court, and Refresher Testimony Exercise Details

FBI Laboratory testifying personnel will ensure their testimony is entered in eDiscovery or Testimony Tracker as appropriate. Additionally, the final moot court exercise and any refresher testimony exercise(s) will be entered into eDiscovery.

10.7.7 Testimony Monitoring

The expert testimony of FBI Laboratory personnel will be monitored through direct observation or through transcript review. [ISO 17025 6.2.5.f] [ANAB AR 3125 7.7.1.l.4] [ANAB AR 3125 7.7.1.l.5] [ANAB AR 3125 7.7.1.l.6] [ANAB AR 3125 7.7.1.l.7] [ANAB AR 3125 7.7.1.l.8] [A2LA R318 6.1 FI1.5] [A2LA R318 6.1 FI1.6] [DOJ Testimony Monitoring Framework]

10.7.7.1 Authorized Evaluators

A. FBI Laboratory personnel will not conduct a testimony evaluation of their own testimony. [ANAB AR 3125 7.7.1.l.2]
B. Technical Leaders are authorized to conduct testimony evaluations in their discipline or subdiscipline.
C. A Technical Leader and the applicable Unit Chief may authorize additional personnel to conduct testimony evaluations.
    1. Authorized personnel must have been previously competency tested in the discipline and/or subdiscipline they are evaluating. [ANAB AR 3125 7.7.1.l.1]
    2. This authorization will be recorded as required in section 6.4.

10.7.8 Transcript Requests

A. A transcript will be requested promptly by FASU personnel for every expert testimony provided and evaluated when received.
B. The initial transcript request, follow up requests, substantive communications regarding the request, and transcript receipt date will be recorded in eDiscovery or Testimony Tracker, as appropriate.

10.7.9 Transcript Review and Evaluation

A. All transcripts received will be reviewed and evaluated using the *Evaluation of Testimony* (7-256). [ANAB AR 3125 7.7.1.l.5]
B. The *Evaluation of Testimony* will be retained by the witness' unit or applicable support unit.
C. Video and audio recordings, if the voices are readily distinguishable, will be treated as transcripts.

D. All testimony reviews, evaluations, and related meetings, if applicable, must be completed within 30 calendar days of the receipt of the transcript in the FBI Laboratory or the direct observation of the testimony. [DOJ Testimony Monitoring Framework]
E. Extensions of the review period with cause (e.g., parental leave, extended deployment) may be approved in writing by the appropriate Unit Chief or Technical Leader.

10.7.10 Witness Review of Transcript

A. The expert witness will review the transcript of their testimony and complete Section A of the *Evaluation of Testimony*. This review provides an opportunity for witness input prior to the evaluation. [ANAB AR 3125 7.7.1.l.5]
B. The witness will ensure the date their review is completed is entered into eDiscovery or Testimony Tracker, as appropriate.
C. If the witness identifies a transcription error that impacts the substance of their testimony, they will notify their manager and OGC in writing. The witness will ensure that any written communication regarding transcription errors is entered into the associated case file(s) in Sentinel and a copy is provided to FASU.
D. FASU personnel will add the written communication as an addendum to the transcript and retain it.

10.7.11 Testimony Evaluator Review of Transcript

A. The authorized testimony evaluator will review the transcript. [ANAB AR 3125 7.7.1.l.5]
B. The evaluator will determine if there are any issues detected in the testimony. Issues can be one of three types: [ANAB AR 3125 7.7.1.l.8]
    1. Substantive violation;
    2. One or more potential materially inaccurate statements; and/or
    3. Other feedback to be given to improve the witness' testimony.
C. After evaluating the transcript, the evaluator will complete Section B of the *Evaluation of Testimony*.
D. 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 (see section 10.7.14).
E. If 'N' responses are marked for all 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 which will be recorded on the *Evaluation of Testimony*.
F. If an evaluator determines there is a statement that is potentially materially inaccurate, they will refer to section 10.7.14.4.
G. The evaluator will ensure the date their evaluation is completed is entered into eDiscovery or Testimony Tracker, as appropriate.

H. The evaluator will notify the witness when the *Evaluation of Testimony* is completed. The evaluator's name and the date the evaluation is provided to the witness will be recorded in Section B of the *Evaluation of Testimony*. [DOJ Testimony Monitoring Framework].

10.7.12 Testimony Evaluation Meeting

A. If there are no concerns and no follow up is needed, the box 'Meeting not needed' will be checked in Section C of the *Evaluation of Testimony*. No other information needs to be completed in Section C.
B. Testimony determined by the evaluator to have an issue(s) or needing follow up requires a meeting with the witness.
    1. The witness' manager must also attend this meeting if testimony is deemed unsatisfactory or at the testimony evaluator's request.
    2. The witness' manager will check the appropriate box on the *Evaluation of Testimony* indicating their attendance.
    3. The evaluator, witness, and the witness' manager (when they attend) will sign Section C of the *Evaluation of Testimony* when a meeting occurs.

10.7.13 Direct Observation, Review, and Evaluation

A. An authorized testimony evaluator may directly observe an expert witness testify as an option for testimony monitoring.
B. After testifying, the expert witness will complete Section A of the *Evaluation of Testimony*. This review provides an opportunity for witness input prior to or in conjunction with the evaluation.
C. The witness will ensure the date their review is completed is entered into eDiscovery or Testimony Tracker, as appropriate.
D. Refer to section 10.7.7.1 for evaluator requirements.
E. A transcript of the testimony will also be requested and retained. Subsequent review and evaluation of the transcript upon receipt is not required.

10.7.14 Substantive Violations and Materially Inaccurate Statements

10.7.14.1 Substantive Violation in Testimony

A. The term 'substantive violation' will be interpreted as a meaningful or significant violation of any requirement listed in section 10.7.5, within the context of the entirety of the expert witness' testimony.
B. A 'substantive violation' is not a trivial misstatement or the inartful phrasing of a testimonial statement.
C. In addition, a misstatement that is later corrected during a testimonial presentation or that constitutes an isolated reference clarified by the balance of an expert witness' testimony would generally not be considered a 'substantive violation' of the listed criteria.

D. A statement made by counsel or the judge at a time when an expert witness is not afforded an opportunity to intercede, such as during opening or closing remarks, would not constitute a 'substantive violation'.

10.7.14.2 Addressing a Substantive Violation in Testimony

A. If the evaluator identifies testimony that is potentially noncompliant with the criteria listed in section 10.7.5, the evaluator will consult with OGC and the sponsoring attorney to determine if a substantive violation has occurred. The date of this consultation will be recorded in Section C of the *Evaluation of Testimony*.
B. The final determination of whether the testimony contained a substantive violation is made by the authorized testimony evaluator after obtaining input from OGC and the sponsoring attorney.
C. If the evaluator concludes the testimony contained a substantive violation (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.
D. The testimony evaluator will prepare a detailed explanation of the reason(s) for determining the testimony was unsatisfactory and recommendations for improvement.
E. The explanation and recommendations will be attached to the *Evaluation of Testimony* and signed and dated by the witness, the testimony evaluator, and the witness' manager.
F. Additionally, for substantive violations, a CAP will be initiated. (see section 5) [A2LA R318 6.1 FI1.6]
G. All testimonies deemed unsatisfactory will be tracked and a copy of the completed *Evaluation of Testimony* retained by FASU.
H. When practicable, the witness' next testimony will be directly observed.

10.7.14.3 Materially Inaccurate Statement in Testimony

A. Testimony may be compliant with the requirements section 10.7.5 (i.e., does not constitute a substantive violation), but still contain one or more materially inaccurate statements.
B. A materially inaccurate statement is one which tends to make any fact at issue before the court more or less likely.
C. A materially inaccurate statement may include one which impacts the strength of a person's conclusion.
NOTE: An example of a materially inaccurate statement may be found where a person provides different answers during direct and/or cross examination, if such differing answers bear on the same fact, which is at issue before the Court.

10.7.14.4 Addressing a Materially Inaccurate Statement in Testimony

A. If an evaluator identifies a potential materially inaccurate statement, the evaluator will notify OGC, in writing, to evaluate the materiality of the inaccurate statement(s) within the context of the court proceeding as a whole, and OGC will determine if formal disclosure of the statement to the sponsoring prosecutor is necessary.

B. A detailed explanation of the findings of the testimony evaluator, the discussion with OGC and other pertinent individuals, and the outcome of the deliberations will be retained with the *Evaluation of Testimony*.
C. The witness's manager will be notified of any such materially inaccurate statements, or any other statements deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate.
D. Regardless of whether the testimony is determined to be materially inaccurate, for any nonconforming testimony that is not determined to be a substantive violation, the manager will ensure the Nonconformities section is followed (see section 5). [A2LA R318 6.1 FI1.6]
E. The witness' manager will notify FASU, in writing, of any testimony that is found to contain a material inaccuracy (as determined by OGC or the sponsoring prosecutor, or by a court ruling), or that has been deemed by OGC to merit a formal disclosure due to the potential for it to be considered materially inaccurate.
F. All such testimonies will be tracked and a copy of the completed *Evaluation of Testimony* and written notification to the sponsoring attorney, as applicable, retained by FASU.

10.7.15 Transcript and Video/Audio Retention

A. FASU personnel will contact the appropriate unit personnel to determine if a redacted copy will be retained for training purposes. Any identifying information will be redacted prior to providing the transcript to the unit.
B. Transcripts will be retained electronically by FASU for at least four years from the date the testimony was provided.
    1. Video and audio recordings will not be retained.
C. Transcripts that are found to have substantive violations, material inaccuracies, or for which disclosure was made by OGC as described in section 10.7.4 will be retained permanently by FASU.
D. Requests for prior transcripts will be handled by OGC separately from the discovery request.
E. Transcripts will not be retained by the FBI Laboratory in any manner other than those described above.

10.8 Refresher Testimony Exercises When a Person Has Not Testified

A. FBI Laboratory personnel who provide testimony as part of their current job duties who have not provided expert testimony at least once in a five-year period will participate in a refresher testimony exercise. [A2LA R318 6.1 FI1.5]
B. Each Unit Chief who manages testifying personnel will ensure that the need for refresher testimony exercises is monitored in their unit (i.e., testifying personnel that do not testify at least once in five years).
C. The Unit Chief and applicable Technical Leader will ensure a refresher testimony exercise occurs no more than 60 calendar days after the end of the five years (i.e.,

date of last moot court exercise, date of last refresher testimony exercise, date of last testimony). [A2LA R318 6.1 FI1.5]

D. A testifying person's Unit Chief and applicable Technical Leader will ensure a summary of expectations for the refresher testimony exercise is provided in writing to the person at least 10 calendar days prior to the exercise.
E. The refresher testimony exercise will be viewed by the person's Unit Chief and the applicable Technical Leader.
F. The person's Unit Chief and applicable Technical Leader will provide feedback (e.g., verbal) to the person at the conclusion of the refresher testimony exercise.
G. If there are no concerns with the exercise, the Unit Chief will ensure the refresher testimony exercise is recorded in eDiscovery.
    1. A comment will be added to the corresponding eDiscovery record indicating who was present at the exercise.
    2. Any fields not applicable to the refresher testimony exercise will be marked as such in eDiscovery.
    3. Written records created during the exercise will be retained in the person's unit. [A2LA R318 6.1 FI1.6]
H. If the person's Unit Chief or applicable Technical Leader determine that there are concerns with the refresher exercise, the Unit Chief will ensure a CAP is initiated as described in section 5. [A2LA R318 6.1 FI1.6]

11 Records Management

Records are retained as stated throughout this document and according to FBI Information Management Division policies. Access to records is consistent with the confidentiality commitments, and records are readily available. [ISO 17020 8.4.1] [ISO 17020 8.4.2] [ISO 17025 8.4.1] [ISO 17025 8.4.2]

12 Revision History

Revision	Issued	Changes
04	05/28/2024	1.2.E, F, and G Edited for clarity. 1.4.1 Added meaning of e.g., and i.e., for clarity. 1.4.2 Updated Competency Test, Corrective Action Plan, i3 Product, Laboratory Report, Nonconformity, Proficiency Testing, and Technical Management, and Technical Records definitions. 1.4.2 Renamed Explosive Reference Tool (EXPeRT)to LabApps and changed FBI Laboratory Number to Laboratory Number. 1.9.1.F Removed as duplicative. 1.9.4.B Edited for clarity. 3.1.2 Added information regarding additional sections can be added or breaking up of Procedures into multiple sections. 4.3.1 Clarified where major deviations posted. 4.6 Edited for clarity and expectations of the annual review of minor deviations.

Revision	Issued	Changes
		5 Updated entire section on nonconformities to include information on nonconforming work, requirements for recording nonconformities, and what quarterly reviews cover. 6 Clarified entire section. 6.1 Edited for clarity regarding competency requirements, including competency test results must meet evaluation criteria as stated on 7-288 form, and use of the 7-288. 6.2.1.C Added section to detail use of training plans. 6.2.3 Edited entire section for clarity. Added Quality Manager must be notified if someone fails a public speaking exercise. Removed requirement for evaluation records from PSC and BIC being maintained. Added UC must be notified if someone fails critical thinking exercise or moot court exercise. Clarified moot court exercise for Forensic Examiners. 6.3 Edited entire section for clarity. 6.3.2 Removed requirement to use the Trainee Evaluation Form (7-270). 6.4.2 Added section for changes in authorization. 6.4.F Specified temporary changes to authorization requirements. 8.2.B Edited for clarity for when validation plan required. 8.5 Clarified competency test must be created with expected results and evaluation criteria. 9.3.D Edited for clarity regarding calibration records. 10.2 Edited entire section for clarity and added requirement for reporting when performance monitoring will not/does not occur as required in 10.2.3 or 10.2.4. Also, in 10.2.5 added information about deauthorization in writing when there is an analytical/interpretive error that results in a CAP, and re-authorizing in writing. In 10.2.6 clarified evaluation criteria also required with expected results. 10.3.1.A Edited for clarity that FD-1000 is provided to customer without specifying how. 10.5.2 Updated that Quality Manager will perform risk evaluation in collaboration with FASU.
05	05/05/2025	Edits for clarity throughout. 1.2.B. Clarified what NOTE: means. 1.4.2 Added definitions for Authorized, Ensure, Management, Trainee, Training Manual, Training Plan, and Training Program. Added ‘opinions’ to FBI Laboratory definition. 1.5 Added all personnel expected to remain objective, impartial. 1.7.A Clarified authorities and added in Quality Manager authorities.

Revision	Issued	Changes
		1.7.C Clarified claim of conformity to ISO standards. 1.9 Clarified requirements for externally provided products and services including when an accredited provider must be included in the search. Additionally, requirements for external individuals that will perform technical reviews and/or verification of a result on FBI Laboratory work added. Records to demonstrate conformance with the requirements will be retained. 2.2.2 Updated name of template for procedures 2.3.2, 2.4.1, 2.5.2 Clarified one business day. 2.7 Clarified Technical Leader will be a reviewer for annual review of technical procedures. 5 Clarified nonconformity requirements. 5.1 Added heading on identification and clarified who assesses situation or condition. Also added a NOTE: about internal auditors/external assessors. 5.2 Clarified who performs initial assessment/containment and that Technical Leaders have authority to resume work. 5.4.1 New section for clarity on nonconformity disclosures. 5.6 Moved from performance monitoring section on what a CAP must include if an analytical/interpretative error occurs. 6 Extensive revisions for clarification of requirements for training of personnel to include determination of competency, training program including suggested topics, training manual, individualized training plan, evaluation methods and overall training evaluation exercises, specifications for communication exercises, competency tests, successful completion criteria, remediation plans, removal of training. 6.4 Clarified qualification and authorization for supervised laboratory activities and independent laboratory activities, approvals, and deauthorization. 6.5 Added section for summary of training records. 8.3 Clarified on software acceptance/validation. 10.B. Added technical reviews. 10.2.1.D Added accreditation cycle should be considered in planning and to add individuals to plan when they are qualified and authorized. 10.2.2.D Specify the mechanism for ensuring quality of monitoring activity is through proficiency tests and as described in a level 2 for other performance monitoring. Also, add that 7-290 must be used for Performance Monitoring.

Revision	Issued	Changes
		10.2.3.D Clarified each person who performs laboratory activities must take one proficiency test per calendar year in each discipline and/or subdiscipline in which they are qualified and authorized. 10.2.4.A Clarified if a proficiency test is not available or appropriate in an accredited discipline, other performance monitoring is acceptable. 10.2.5 Added heading to cover extended time away from performing laboratory activities. 10.2.6.A Clarified 10 calendar days from being identified an unexpected result must be reported. Clarified 30 calendar days for notifying ANAB. 10.2.6.D.1 Clarified Technical Leader's final decision will be recorded when determining if an analytical/interpretive error. 10.4 Updated to streamline and clarify complaint process. 10.5.5 Updated team lead and/or internal auditor will work to resolve concerns from auditee. Also, auditee will enter nonconformity resolution on checklist and Quality Manager will conduct final review including resolved nonconformities. 10.7.11.H Relocated and updated that evaluator notifies witness when the Evaluation of Testimony is completed. Evaluator's name and date the evaluation is provided to the witness recorded in Section B of the Evaluation of Testimony. 10.7.12 Updated documentation requirements when Evaluation Meeting not required. 10.7.15 Added Video/Audio to heading and clarified requests for prior transcripts handled separately by OGC from discovery request. 10.8.D. Clarified summary of expectation must be provided 10 calendar days prior to refresher testimony exercise.