



# Laboratory Services Quality Documents

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## 1. General

Laboratory Services is a division of Forensic Services within the Office of Science and Technology (OST) of the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). ATF is a component of the United States Department of Justice. Services provided include forensic examinations, expert testimony, technical assistance, specialized forensics training, and research.

Laboratory Services consists of three laboratories at two locations.

Forensic Science Laboratory – Atlanta (FSL-A), Atlanta, Georgia  
Forensic Science Laboratory – Washington (FSL-W), Beltsville, Maryland  
Fire Research Laboratory (FRL), Beltsville, Maryland

## 2. Mission

The mission of the ATF Laboratories is issued under the authority of the OST Deputy Assistant Director, Forensic Services. Laboratory management develops and maintains the Laboratory Services operating plan, which outlines the goals, visions, and values.

*The Mission of the ATF Laboratories is to provide the accurate and authoritative scientific information needed by ATF in reducing violent crime and protecting the public.*

### 2.1 Goals

- Develop and maintain scientific excellence and lead in setting national and international standards in ATF's areas of expertise by developing partnerships and employing new technology.
- Ensure that Laboratory Services substantially advances and sustains ATF's Strategic Goals and Programs.
- Provide timely services in ways that can be sustained.

### 2.2 Vision

We envision an organization that:

- is scientifically authoritative and worthy of our customer's trust,
- is dedicated to quality and responsiveness,
- has the financial, physical, and human resources to excel,
- values and respects the individual, and empowers each to creatively challenge the status quo,



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- encourages open communication and teamwork, and
- makes continual improvements in knowledge, technology, services, and professional development enabling our employees to attain their goals.

### 2.3 Values

We are a team of professionals, striving for excellence, and demonstrating:

- commitment to quality and customer satisfaction,
- professional integrity and scientific objectivity,
- concern for an efficient and positive work environment,
- respect for the individual through communication, recognition, and celebration of achievements, and
- pride in the laboratory and ATF.

### 3. Commitment to quality

Laboratory Services is committed to providing accurate and authoritative scientific information in accordance with the management system requirements, forensic science and other professional industry standards, and customer requirements. ATF scientists and engineers work with professional integrity to produce quality results with a particular focus of scientific objectivity through efforts to mitigate bias. The Quality Programs office ensures that the laboratory activities are conducted in accordance with the appropriate internal and external quality standards.

### 4. Scope of accreditation

The ATF Laboratories' accreditation body, the ANSI National Accreditation Board (ANAB), has published the scope of the ATF Laboratory system's accreditation on their website, [anab.ansi.org](http://anab.ansi.org).

The ATF Laboratories are accredited to provide services for the following disciplines:

- Biology
- Document Examination
- Engineering
- Fire Debris and Explosives
- Firearms and Toolmarks
- Friction Ridge
- Impressions
- Materials (Trace)



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Collection activities for safeguarding evidentiary material are performed in all disciplines.

Laboratory Services may provide non-accredited services to meet customer requirements if appropriate expertise and test methods are available.



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1. Laboratory Services shall meet the requirements established by the Department of Justice for forensic laboratories and examiners and the accreditation requirements of the ANSI National Accreditation Board (ANAB), based on the following standards documents.
  - *ISO/IEC17025:2017 General requirements for the competence of testing and calibration laboratories*
  - *AR3125 ANAB Accreditation Requirements for Forensic Testing and Calibration (2023)*
  - *Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories*
2. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document applies.
3. Conclusions shall conform with the relevant Department of Justice policy on Uniform Language for Testimony and Reports available at [www.justice.gov](http://www.justice.gov).
4. Testimony shall be reviewed to ensure proper qualification and appropriate communication of forensic examination results by Laboratory Services examiners.



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## 1. Policies

1.1. The definitions and terminology used by Laboratory Services shall be found in the following references and lists. When different definitions are given in reference documents, the definition in the ATF List of terms and definitions or the most stringent definition shall apply.

- *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*
- *ANAB AR3125 ISO/IEC 17025:2017 Forensic Testing and Calibration Laboratories Accreditation Requirements*
- *The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories*
- *ATF-LS 3.1 List of terms and definitions*
- Laboratory Services technical discipline glossaries, definitions, and abbreviations lists

## 2. Procedures

### 2.1. Terms and definitions

2.1.1. Laboratory Services shall maintain a list of terms and definitions that are used in the quality documents.

### 2.2. Discipline-specific abbreviations

2.2.1. Where necessary, a list of abbreviations used shall be developed and maintained with discipline-specific procedures.



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Audit types	<p><u>External audit:</u> A systematic, independent, documented process that is conducted by personnel other than Laboratory Services personnel. The process involves obtaining records, statements of fact, or other relevant information and assessing them objectively to determine the extent to which accreditation requirements are fulfilled.</p> <p><u>Internal audit:</u> An evaluation of records and documentation of an ATF laboratory, performed by ATF personnel, against various accreditation requirements and management system documents to demonstrate continued conformance.</p>
Authorize	<p><u>Authorize results:</u> Results are authorized when the responsible examiner signs the report or approves the review in FireTOSS.</p> <p><u>Authorize release:</u> (1) Results are authorized for release when the administrative reviewer signs and dates the report. (2) Results are authorized for release to an external proficiency test provider and accrediting body when the Laboratory Chief signs the authorization memo or forwards the electronic results in the CTS Portal to Quality Programs.</p> <p><u>Authorize to work:</u> An employee or contractor is authorized to work when the Laboratory Chief determines that competency has been demonstrated in accordance with <i>ATF-LS-6.2 Personnel standards and training program</i> and documents the authorization.</p>
Case	A mechanism to group together all laboratory work conducted for a specific ATF investigation. Cases are created when the first submission is received by any ATF laboratory for an investigation. Only one case should be created for any single ATF investigation.
Case number	Case numbers are unique identifiers for each case. Case numbers are assigned by StarLIMS and have a standard 13-character format consisting of three types of information separated by hyphens. The first four digits represent the calendar year the case was created, followed by a one-character laboratory code indicating which ATF laboratory created the





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	<p>case. The last six digits represent the count of the cases created during that calendar year at the indicated laboratory. For example, case number 2019-W-000022.</p> <p>Short case number format – A seven-character format is sometimes used for case numbers consisting of a 2-digit year, a one-character laboratory code and a 4-digit number. For example, case number 2020-W-000123 has a short format of 20W0123.</p>
Concession	The determination that a nonconformity had minimal impact, is not likely to recur, and that no action to correct it is necessary.
Correction	An action taken to fix, eliminate, or otherwise address a detected nonconformity. Corrections are appropriate when there is minimal likelihood of the nonconformity recurring.
Customer	The individual(s) listed as the case agent on the Laboratory Exam Request or memo. For FRL’s scene support, including NRTs, the customer is the ATF agent assigned as the lead Certified Fire Investigator
Customer request status	<p>When customers submit requests to the laboratory, the laboratory does not automatically start working on the request. A laboratory manager has to review the request and agree that the laboratory will perform the requested work.</p> <p><u>Received:</u> Before the manager agrees to perform the work, the status of the request is Received.</p> <p><u>Accepted:</u> After the manager agrees to perform the work, the status of the request is Accepted.</p>
Document (noun)	Any controlled policy, process, procedure, work instruction, or form encompassed by Laboratory Services management system documents. Also, accreditation requirement documents.
Document types	<p><u>External document:</u> Documents that are externally generated (not written by ATF laboratory personnel) and are not under the control of Laboratory Services or Quality Programs. Examples include references listed in quality documents,</p>



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	<p>manufacturer user manuals, Federal regulations, ATF Directives, and external standards.</p> <p><u>Technical document:</u> Written material pertaining to the testing of evidence or material including instrumentation and equipment used for testing. Examples include test methods, procedures, work instructions, manufacturer manuals, instrument/equipment logbooks, validation records, records/logbooks for references or standards.</p>
Examination	Act or process of observing, searching, detecting, recording, prioritizing, collecting, analyzing, measuring, comparing, and/or interpreting. Examination includes conducting experiments, tests, and instrumental analyses.
Examiner	A Laboratory Services employee with the responsibility and authority to examine evidence and issue reports.
FACETS	A database program that was used by the ATF laboratories to manage casework projects from the 1990s through September 2019. FACETS only stored information about cases and case assignments. FACETS did not store any file attachments or other electronic records.
FireTOSS	An information system used to collect instrument data, store electronic information, perform standardized analyses, and generate administrative and examiner reports.
Guideline	An uncontrolled document that provides guidance or suggests a process for accomplishing a task. It may include stepwise instructions or a worksheet format.
Investigation Number (IN)	A unique identifier assigned to an ATF criminal investigation provided to the laboratory by the customer.
Laboratory code	Each ATF laboratory has been assigned a one-character code: FSL-Atlanta (A), Fire Research Laboratory (F), FSL-San Francisco (S), and FSL-Washington (W). Prior to October 2019, FSL-Washington was assigned code (N).
Lab-generated evidence	Evidence that is created or produced as a result of the examination of evidence. These would be sub-exhibits that were not with the parent item as originally submitted to the laboratory for analysis. Examples include



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	footwear/tire track test impressions, firearms test fires, test toolmarks, preserved charcoal strips, and casts.
Lab-separated evidence	Evidence that is removed or separated from a parent item of evidence during examination. Examples include DNA swabs/extracts, hairs, and fibers.
Management types	<p><u>Management team:</u> Quality Manager, Section Chiefs, Laboratory Chiefs, and Deputy Assistant Director. May also be referred to as “managers.”</p> <p><u>Key management:</u> Management team and DNA Technical Leader.</p> <p><u>Top management:</u> Laboratory Chiefs, Deputy Assistant Director. May also be referred to as “Top Managers”</p>
Notification	A communication to the customer regarding the creation of sub-items of evidence due to the collection of potential DNA via swabbing or other method. A notification may also contain information from database searches (e.g., AFIS, CODIS) that result in an association. A notification is not a test report for purposes of ANAB requirements; however, it does require a review of the case record prior to its release to the customer.
Personal identity verification (PIV)	A photo identification card issued by ATF or TTB after the completion of a background investigation. It also includes temporary PIV issued to persons detailed to the laboratory.
Personnel	ATF or TTB employees and contractors who are permanently or temporarily assigned to work at the laboratory and who have a PIV. Examples of temporarily assigned personnel include National Firearms Examiner Academy (NFEA) students, interns, visiting scientists, and ATF personnel who require access on a long- term occasional basis.
Project	A mechanism that FireTOSS uses to group work assignments. Projects are assigned to project categories (e.g., casework, research, training given). Projects always include a project leader and can include multiple staff. For casework projects, the project information is automatically entered into FireTOSS from StarLIMS.



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Project number	<p>A unique identifier for each FireTOSS project. Project numbers are assigned by FireTOSS and have a format consisting of a two-digit year, one character laboratory code, an optional project activity code, and a four-digit counter. For example, 19FR0002 refers to the second research (R) project that was opened at the Fire Research Laboratory (F) in 2019. For casework projects, FireTOSS uses a seven-character version of the StarLIMS case number. For example, 19W0022 is the FireTOSS project number for StarLIMS case 2019-W-000022.</p>
Project types	<p><u>Administrative projects:</u> Administrative projects are conducted within laboratory services. For example, an examiner assigned with maintaining records of instrument calibrations for the laboratory would record the time spent on this activity in an Administrative project. This project type is not covered by laboratory accreditation.</p> <p><u>Casework projects:</u> Laboratory Casework projects are conducted in support of official ATF investigations. StarLIMS maintains the official list of casework projects as well as the official records of evidence receipt and handling. FRL stores other casework project records in FireTOSS. This project type is covered by laboratory accreditation.</p> <p><u>Court projects:</u> Court projects are opened to track activity related to judicial actions. Court projects are typically an additional submission for an existing casework project. This project type is covered by laboratory accreditation.</p> <p><u>External projects:</u> Projects conducted for a non-casework purpose for a non-laboratory services customer. For example, testing projects conducted for other government agencies. This project type is not covered by laboratory accreditation.</p> <p><u>Internal projects:</u> Projects conducted for a non-casework purpose for a laboratory or all of forensic services. For example, testing projects conducted to assure the proper operation of an instrument. This project type is not covered by laboratory accreditation.</p> <p><u>Research projects:</u></p>



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	<p>Projects conducted with the approval of the examiner’s supervisor to perform analysis or testing to answer specific questions. This project type is not covered by laboratory accreditation.</p> <p><u>Technical assistance projects:</u>          Technical assistance projects are used when examiners need to store records related to an ATF investigative activity that has not been opened as a casework project. Technical assistance projects cannot produce any formal reports. For example, there are situations where an engineer participates in a fire scene examination, but there is no reason to write a report because there was no engineering analysis or evidence examination. In this situation, the engineer may open a technical assistance project to store notes and to record their activity time. This project type is not covered by laboratory accreditation.</p> <p><u>Technical working group projects (TWG):</u>          TWG projects are used for tracking labor and communications for projects related to scientific working groups and standards development organizations. This project type is not covered by laboratory accreditation.</p> <p><u>Training given projects:</u>          Training given projects are used to maintain records associated with laboratory activities and communications related to training provided by FRL staff. This project type is not covered by laboratory accreditation.</p> <p><u>Training received projects:</u>          Training received projects are used to maintain records of courses taken by laboratory staff including the time required for the class and the costs associated with taking the class. This project type is not covered by laboratory accreditation.</p> <p><u>Other projects:</u>          These are projects that are not included in the other project categories. This project type is not included in laboratory accreditation.</p>
Project type code	FireTOSS project numbers can include a project type code to indicate the category of the work to be performed. The codes are Administrative (A), External Project (E), Internal Project (I), Research (R), SWG-Committee (G), Technical Assistance (TA), Scene Assist (S), Training Given (TG), and Training Received (TR).



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Proper seal	Proper seals may be accomplished in various ways such as heat sealing a package or sealing with tamper evident tape. All lab-generated seals must be initialed by the person sealing the evidence. Tape and heat-sealed packages must have the initials across the seal to be properly sealed.
Qualtrax	A document management system used by Laboratory Services to manage management system documents and selected records.
Record types	<p><u>Administrative record:</u> Administrative records include documentation, whether hardcopy or electronic, related to the receipt, intra-lab handling, and disposition of evidence. Examples include ATF E-Form 7140 Laboratory Exam Request, Fire Research Laboratory Request for Services memorandums, copies of investigative reports and other customer-provided transmittal paperwork, records of case-related communication, and other pertinent non-technical information.</p> <p><u>Case record:</u> A record consisting of administrative and technical records generated or received by Laboratory Services pertaining to a particular case. Electronic records created or scanned and uploaded into FireTOSS or StarLIMS are the equivalent to a physical file folder (case jacket).</p> <p><u>Technical record:</u> Technical records include examination documentation and the laboratory report. Examination documentation, whether hardcopy or electronic, includes documentation of procedures followed, tests conducted, standards and controls used, diagrams, printouts, photocopies, notes, photographs, references, observations, and results of testing and examination.</p>
Report date	The date listed in the header of the report.
Report issue date	The date that the report was authorized for release as signified by the administrative reviewer's dated signature on the report.
Sample selection	A practice of selecting a sample of the whole for testing. The sample is not presumed to be representative, and results cannot be extrapolated to untested items.
Security access card	An electronic card used to access secure areas.



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Signature	<p>The term “signature” is used for handwritten signatures, digital signatures, and electronic signatures as defined in <i>ATF O 7031.1 ATF Electronic and digital signature policy</i>.</p> <p>Note: Files and records that are stored in a secure electronic storage system, like Qualtrax, StarLIMS, and FireTOSS, that have been marked as reviewed or approved in the system, are defined as having the electronic signature of the person that approved or reviewed the file or record. When files are downloaded from these systems, the downloaded files do not have electronic signatures unless the file has a certified digital signature.</p> <p>Files that are not stored in a secure electronic storage system, are considered to have an electronic signature when they have certified digital signatures. PDF files must pass the “validate all signatures” function in Adobe Acrobat to be considered to have an electronic signature.</p>
StarLIMS	A laboratory information management system (LIMS) used by ATF Laboratories to manage casework projects.
Supervisor	A supervisor within laboratory services is a position with subordinate employees, and includes section chiefs, laboratory chiefs and the deputy assistant director.
Technician/Scientist	A Laboratory Services employee or contractor with the responsibility and authority to examine evidence but does not issue reports.
Validation	The process of demonstrating that a method is fit for its intended purpose.
Verification	<p><u>Method verification:</u> The process of confirming that a previously-validated method performs as expected.</p> <p><u>Results verification:</u> The process of confirming an examiner’s results.</p>
Work instruction	Step-by-step instructions usually associated with instruments and equipment.



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Work product	Documents and records normally sent to the customer. The work product always includes the examination report. Work product may also include other information as specified by the Laboratory Chief or the discipline procedures. This is not applicable to laboratory specimens.
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## 1. Policies

- 1.1. Laboratory Services is committed to impartiality and shall ensure appropriate actions are taken when necessary.
- 1.2. The *ATF O 2130.2 Employee Ethics and Responsibilities* describes the standards of ethical conduct required of all ATF personnel, including contracted personnel. This order defines the policies and procedures, including disciplinary actions. It also includes the requirements for outside employment and activities, as well as teaching, writing, speaking engagements, and responding to proffered gifts.
- 1.3. If a risk to impartiality is identified, Laboratory Services shall eliminate or minimize any associated risks in accordance with the ATF orders. Potential impacts on casework shall be evaluated. The actions taken shall be recorded.
- 1.4. Laboratory Services has adopted the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science* as its code of ethics and all managerial and technical staff shall comply with it.
- 1.5. Laboratory Services will ensure that appropriate actions are taken, when necessary, to address issues related to ethics, including potential risks to impartiality.
- 1.6. Refer to Chief Counsel for guidance on ATF O 9410.1 Giglio Policy if necessary.

## 2. Procedure

- 2.1. The following shall be completed in accordance with *ATF O 2130.2 Employee Ethics and Responsibilities*. The training activities shall be documented.
  - 2.1.1. All ATF employees must complete ethics training within 90 days of their reporting date. This training is administered by the Office of Chief Counsel or through the ATF online training application.
  - 2.1.2. All ATF employees shall complete ethics training based upon the *14 General Principles of Ethical Conduct for Federal Employees* on an annual basis.
- 2.2. Laboratory management and technical personnel shall review the *ANAB GD3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* and *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science* as part of their initial training and annually thereafter.



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2.3. Risks to impartiality shall be handled in accordance with the referenced ATF Orders. When potential risks to impartiality are not adequately addressed in ATF Orders, then guidance from Chief Counsel shall be sought.

### 3. Records

3.1. The records required by the ATF orders and this document shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-4.2 Confidentiality	ID: 7020 Revision: 6
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## 1. Policy

- 1.1. Laboratory Services shall maintain as confidential all information that can be associated with a specific case or individual.
- 1.2. Laboratory Services case records, regardless of type or form of media, are considered sensitive but unclassified (SBU) unless otherwise designated.
- 1.3. Requests for Laboratory Services reports, testimony, records, and management system documents will be individually evaluated prior to authorizing any disclosure.
- 1.4. The *Federal Rules of Criminal Procedure*, *Federal Rules of Civil Procedure*, and the *Code of Federal Regulations (CFR)*, Title 28 parts 16.21- 16.29 govern the disclosure of protected DOJ information.
  - 1.4.1. The following ATF documents elaborate on the requirements and processes.
    - *ATF O 1340.5 Records Management Program*
    - *ATF O 1340.4 Preserving and Producing Bureau Records, Documents, and Information Subject to the Legal Process*
    - *ATF O 3270.10 The Disclosure, Documentation and Handling of Investigative Information*
  - 1.4.2. 28 CFR 16.22 prohibits employees and former employees from disclosing ATF records or information, including testimony, in response to any request or demand without express authority.
    - 1.4.2.1. The ATF Director delegates the authority to approve these requests or demands to the Laboratory Chiefs. Refer to *ATF O 3270.10 The Disclosure, Documentation and Handling of Investigative Information*. Authorizations for disclosure shall be documented.
- 1.5. Records may be made available for external audit and quality control purposes. In general, individuals external to ATF who are given access to these records must sign a non-disclosure agreement.

## 2. Handling requests for information

### 2.1. Reports

- 2.1.1. See *ATF-LS-7.8 Reporting of Results* for guidance on routine distribution.



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2.1.2. Laboratory Services reports may be distributed for ATF internal purposes.

2.1.3. Laboratory Services reports may be released to the relevant federal or state prosecuting attorney.

## 2.2. Testimony, records, and management system documents

2.2.1. Laboratory work product shall not be disclosed beyond the customer prior to Laboratory Chief authorization. The authorization shall be stored in Qualtrax.

2.2.2. Requests from state and local prosecutors, defense counsel, civil attorneys, or the private sector must be reviewed by ATF's Office of Chief Counsel.

2.2.3. Requests for testimony, records, and management system documents shall be noted in the case record.

2.2.4. Documentation of the information released shall be noted in the case record.

2.2.5. The customer shall be notified of the release of any case specific information, except when the customer specifically requests a release of information or distribution listed in 1.5, 2.2.2, and 2.2.3.

2.3. Laboratory Services' quality records not normally associated with case records may be provided upon request. Intra-agency requests for this information should be made in writing to the Deputy Assistant Director, Forensic Services through an ATF Special Agent in Charge or ATF Division Chief. The Deputy Assistant Director, Forensic Services or his designee will consider the merits of the request as well as the confidentiality of the material prior to releasing this type of information. The policies and procedures for release of this type of information to non-ATF customers is described in the regulations in *28 CFR 16.21-16.29* and *ATF O 3270.10 The Disclosure, Documentation and Handling of Investigative Information*.

## 3. Information obtained about the customer

3.1. Any information about the customer obtained from sources other than the customer (e.g., complainant, regulators) shall be confidential to the laboratory, and shall not be shared with the customer, unless agreed to by the source.



ATF-LS-4.2.1 Prohibition on external observation of testing	ID: 9993 Revision: 2
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## 1. Policy

- 1.1. Due to the security classifications, the sensitivity of cases, and the integrity of the evidence, it is Laboratory Services' policy that those who are not employees of ATF are prohibited from observing the testing of evidence by Forensic Science Laboratory (FSL) staff.
- 1.2. This policy is in place to ensure that the integrity of evidence remains intact, case confidentiality is maintained, laboratory safety and efficiency are not compromised and that no unnecessary risks to evidence testing are introduced. Access for observers to the working areas of the laboratory is prohibited.

## 2. Background

- 2.1. FSL testing is conducted in accordance with policies and procedures that are available to the defense for cross-examination purposes.
- 2.2. The presence and actions of unauthorized parties during the implementation of these protocols constitute an unacceptable risk to the scientific process.
- 2.3. A defendant retains the ability to challenge the testing procedures by cross examining the examiner or by impeaching the reliability of the methods. Observation of testing is not necessary because it does not materially aid the defendant in challenging the reliability of the test [*North Carolina vs. Byrd, et. al.* (11 CR 51546), *California v. Trombetta* (467 U.S. 479)].

## 3. Exceptions

- 3.1. Persons being trained in forensic testing by Laboratory Services may observe testing when it is a fundamental aspect of the training.
- 3.2. Observations by the accrediting body required as an element of the external audit process will be permitted because it is necessary to maintain accreditation.
- 3.3. When observation is allowed under these exceptions, measures shall be in place to mitigate the associated risks.



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## 1. Policies

- 1.1. All Laboratory Services' personnel are responsible for executing the mission. Our commitment to quality is demonstrated by quality statements, provided by the Deputy Assistant Director, Forensic Services, which address the effectiveness of the management system meeting the requirements of the Department of Justice and maintaining accreditation. Laboratory personnel have the responsibility and authority to address laboratory management and Quality Programs with any concerns.
- 1.2. The activities that support the mission and quality statements are detailed in the management system documents. For additional guidance, refer to *ATF-LS-8.5 Actions to address risks and opportunities*. Laboratory personnel are expected to:
  - participate in the implementation, maintenance, and improvement of the management system.
  - identify deviations from the management system or from the procedures for performing laboratory activities.
  - initiate actions to prevent or minimize such deviations.
  - report to laboratory management on the performance of the management system and any need for improvement.
  - ensure the effectiveness of laboratory activities.

## 2. Services

- 2.1. The range of laboratory activities that meet the requirements of ISO/IEC 17025 and the accreditation body are described in the Scope of Accreditation record maintained by the ANSI National Accreditation Board (ANAB), [anab.ansi.org](http://anab.ansi.org). The scope of accreditation is specific to each laboratory.
- 2.2. The laboratory may provide services outside the scope of accreditation using proper quality controls.

## 3. Management system documentation

- 3.1. The laboratory procedures shall be documented to the extent necessary to ensure the consistent application of activities and validity of results. Refer to *ATF-LS-8.2 Management system documentation*.
- 3.2. The most current version of an externally-controlled or referenced document shall be effective for the laboratory unless a version is specified within a Laboratory Services document.



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#### 4. Management system continuity

- 4.1. The organization charts of Laboratory Services and the individual laboratories shall be maintained.
- 4.2. Laboratory management shall ensure that the integrity of the management system is maintained when changes are planned and implemented.
- 4.3. New documents and procedure changes shall be communicated to relevant personnel according to *ATF-LS-8.2 Management system documentation*; changes should be communicated no less than two weeks before implementation. Published documents remain available to Qualtrax users when revisions are in progress.
- 4.4. Key personnel shall delegate actors when necessary in accordance with *ATF O 1100.168 Delegation Order – Delegation of Authorities within the Bureau of Alcohol, Tobacco, Firearms and Explosives*.
- 4.5. Laboratory Services maintains a continuity of operation plan in accordance with *ATF O 1660.1 Emergency Management Program*.
- 4.6. It may be necessary at times to conduct examinations at locations other than permanent facilities. The Laboratory Services management system requirements apply to laboratory activities performed in all permanent facilities, at sites away from permanent facilities, in associated temporary or mobile facilities, or at a customer's facility.

#### 5. Duties and responsibilities

- 5.1. The Deputy Assistant Director, Forensic Services, manages the Laboratory Services system and is the ultimate authority for the administration of the management system. This individual is responsible for establishing the organization's commitment to the management system, implementing it, and delegating responsibility for its accomplishment.
- 5.2. Laboratory Chiefs manage the individual laboratories with the support of Section Chiefs. They are responsible for ensuring that the organizational commitment to quality is met in the individual laboratories.
- 5.3. The Quality Manager aids top management in monitoring laboratory operations to ensure adherence to the accreditation requirements. The Quality Manager facilitates the interpretation of the management system requirements and the accreditation requirements for all laboratory personnel. The Quality Manager shall serve as the liaison to the accreditation body when representing the Laboratory Services system.



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- 5.4. Laboratory personnel conduct testing and other duties, in accordance with their authorizations to work, to fulfill requests for services.
- 5.5. Technical leaders are designated by the Deputy Assistant Director, Forensic Services, to serve as technical liaisons to Quality Programs and laboratory management. Technical leaders are responsible for establishing and maintaining the technical requirements for discipline-specific testing, examination, and analysis. Technical leaders may share authority on technical requirements where there is discipline overlap.
- 5.5.1. The DNA Technical Leader is responsible for the overall technical operation of the Forensic Biology discipline. The qualifications and responsibilities are as listed in the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.
- 5.6. The safety officer is appointed by the Laboratory Chief and shall maintain the safety program and ensure compliance within the laboratory.
- 5.7. Administrative support are non-technical personnel responsible for administrative support, financial support, and recordkeeping duties as assigned by top management.





ATF-LS-5.1 Forensic Biology contingency policies	ID: 9626 Revision: 3
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## 1. Policies

### 1.1. DNA Technical Leader vacancy contingency

#### 1.1.1. Temporary vacancy

1.1.1.1. In the event that the DNA Technical Leader is temporarily unavailable, a qualified Forensic Biologist will be designated as the Acting DNA Technical Leader in accordance with *ATF O 1100.168 Delegation Order – Delegation of Authorities within the Bureau of Alcohol, Tobacco, Firearms and Explosives*.

1.1.1.2. Forensic Biology casework will proceed as normal throughout the vacancy.

#### 1.1.2. Position vacancy

1.1.2.1. In the event that the DNA Technical Leader position is vacated, the Laboratory Chief will designate a qualified Forensic Biologist as acting DNA Technical Leader using the official acting designation process, which will be disseminated to all Forensic Science Laboratory personnel.

1.1.2.2. The acting designation shall include the following:

- name of the individual designated to act
- statement that the acting designee's qualifications were reviewed and are in conformance with the requirements of the *FBI Quality Assurance Standards for Forensic DNA Testing Laboratories*.
- duration of the acting assignment.

1.1.2.3. In the unlikely event that a qualified replacement is not available, the Laboratory will notify the NDIS Custodian and the State CODIS Administrator within 5 days of the vacancy and submit a contingency plan to the FBI within 14 days of the vacancy. Refer to Appendix B of the QAS audit document.

1.1.2.3.1. Analysis on all new casework will be suspended until the contingency plan is approved by the FBI.

### 1.2. Employment of less than two full-time qualified Forensic Biologists contingency

1.2.1. In the unlikely event that the Laboratory has less than two qualified full-time Forensic Biologists, the Laboratory will notify the NDIS Custodian and the State CODIS Administrator within 5 days and submit a contingency plan to the FBI



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within 14 days of failing to meet standard of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. Refer to Appendix B of the QAS audit document.

- 1.2.1.1. Analysis on all new casework will be suspended until the contingency plan is approved by the FBI.



ATF-LS-6.2 Personnel standards and training programs	ID: 6311 Revision: 6
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## 1. General

1.1. All laboratory personnel, including contractors, that could influence the laboratory's activities shall act impartially, be competent, and work in accordance with the laboratory's management system.

1.2. The following activities demonstrate the laboratory's commitment to ensuring that Laboratory Services personnel are properly qualified and that they participate in continuing professional development activities.

- Qualification
  - evaluation
  - training programs and training activities
  - competency testing
  - authorization
- Professional development
  - continuing education
  - research
  - presentations
  - publications

## 2. Qualification

2.1. The qualification process to perform laboratory casework includes the initial evaluation, training, competency testing, and authorization.

2.1.1. Qualification is required for the performance of tasks related to testing and activities that create or separate items for testing; this applies to technical personnel employed by the laboratory, including contractors.

2.1.2. Section Chiefs are responsible for the completion of the evaluation and training programs. Training activities may be delegated to technical experts.

2.1.3. Laboratory Chiefs are responsible for authorizing personnel to perform tasks.

2.2. The criteria for qualification to perform tasks are established by the position descriptions and training programs.

### 2.3. Evaluation

2.3.1. The evaluation consists of a review of relevant education, training, and experience acquired prior to employment with the laboratory or before beginning cross-training in a new discipline.



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- 2.3.1.1. Records of prior education, training, experience, authorizations, and proficiency testing may be used as part of the evaluation process.
- 2.3.1.2. Personnel who issue or authorize results, opinions, and/or interpretations shall meet the minimum educational requirements for the position and the accreditation requirements for the discipline. Where a position description requires a baccalaureate or an advanced degree a copy of the degree shall be maintained with the training record.
- 2.3.1.3. Past work experience and training in a task may be substituted for training program components when the relevant knowledge, skill, or ability has been demonstrated.

#### 2.4. Training programs and training activities

- 2.4.1. Training shall consist of Laboratory Services training and technical training for examiners and technical support personnel.
  - 2.4.1.1. Laboratory Services training shall include the following.
    - General knowledge of forensic science
    - Application of ethical practices in forensic science
    - Applicable civil law, criminal law, and testimony
    - Quality assurance requirements, including accreditation
  - 2.4.1.2. Technical training programs shall be based on job function, documented, and shall include the following.
    - Knowledge, skills, and abilities necessary for the task(s)
    - Criteria for acceptable performance of the task(s)
    - Responsibility assignments for the Section Chief, trainer, and trainee
  - 2.4.1.3. Technical training programs shall include the following.
    - Literature review
    - Practical exercises
    - Practical, written, and/or oral examinations
- 2.4.2. A schedule should be established to promote completion of the training program in a timely manner. The Section Chief or trainer shall monitor progress and prepare periodic reports as required by the Laboratory Chief.
- 2.4.3. Training records shall be kept current, maintained by the employee, and available for review.



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2.4.4. Training programs shall be used as the basis for retraining when necessary. Retraining does not need to include the entire training program but should focus on addressing the identified deficiencies.

## 2.5. Competency testing

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

2.5.2. The competence requirements for each function influencing the results of laboratory activities shall be documented, including requirements for education qualification, training, technical knowledge, skills, and experience.

2.5.3. All personnel who perform testing on evidence shall be competency tested. Competency shall be demonstrated prior to performing the tasks on evidence.

2.5.3.1. A competency test shall meet the following requirements.

- Simulate typical casework
- Include a practical examination that covers the spectrum of anticipated tasks related to the test
- Include a mock trial regarding reported results

2.5.3.2. For new or additional methods and/or instruments, a mock trial is not required as part of the competency test for examiners currently authorized within the laboratory.

2.5.4. Personnel who perform the following tasks shall meet the competency requirements for the specific area of testing that is to be reviewed.

- Reviews results, opinions, and interpretations
- Performs technical reviews
- Reviews testimony

2.6. The laboratory or parent agency has procedures and retains records for the following.

- Determining competence requirements
- Training of personnel
- Supervision of personnel
- Authorization of personnel
- Monitoring competence of personnel



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## 2.7. Authorization

2.7.1. The Section Chief shall provide the Laboratory Chief with a summary of the evaluation, training, and competency testing upon completion of training and successful testing and their recommendation for authorization.

2.7.1.1. The authorization to perform casework shall be issued by the Laboratory Chief. These records communicate to personnel their duties, responsibilities, and authorities.

2.7.1.2. The authorization records shall correspond with the laboratory scope of services.

2.7.1.3. Competent personnel shall be authorized to perform specific laboratory tasks including the following. The record shall state any limitations or exclusions for the authorized area of testing, as applicable.

- Perform testing, including operation of specific equipment or instruments
- Analyze results
- Issue and authorize test reports containing an opinion or interpretation and/or notifications
- Review technical records and testimony
- Verify results
- Develop, modify, verify, and validate test methods

2.7.1.4. When transfer of personnel occurs within Laboratory Services, the receiving Laboratory Chief may adopt the competency test from the other ATF Laboratory as part of a streamlined authorization.

## 3. Professional development

3.1. Top management supports the professional development of Laboratory Services personnel. Professional development includes the following.

- Attendance at technical and/or professional development courses, conferences, and seminars
- Participation in professional organizations
- Presentation of technical material for informational and educational purposes
- Conducting and publishing research
- Details, cross training, and other developmental assignments

3.2. Additional guidance is available in the following ATF Orders.

- *ATF B 1900.2 Policy and Guidance on Conference and Training Events*



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- *ATF O 2130.2 Employee Ethics and Responsibilities, Gifts of Travel*

### 3.3. Laboratory management shall establish an annual training plan.

3.3.1. The training plan is subject to change depending upon the needs of the laboratory and Laboratory Services.

3.3.2. All Laboratory Services personnel may contribute to the plan via requests to their supervisor.

### 3.4. Research

3.4.1. The Laboratory Services Research Advisory Panel (RAP) shall review scientific analyses and testing that requires the commitment of Laboratory Services resources.

3.4.1.1. This requirement does not apply to scientific analyses and testing conducted for casework and training. Refer to *ATF-LS-7.2 Test method selection, verification and validation* for the development or modification of approved test methods.

#### 3.4.2. The RAP:

- provides advice to managers on the technical aspects of research projects.
- provides a path for field generated research ideas to be pursued.
- reviews research plans and works with researchers to develop project plans.
- monitors project plans.
- organizes a panel of subject matter experts to review publication proposals.

### 3.5. Presentations

3.5.1. Presentations other than routine trainings may generally be reviewed at the Section Chief level.

3.5.1.1. Presentations that will be published or otherwise merit additional review shall be approved by the Laboratory Chief.

### 3.6. Publications

3.6.1. Publications authored by technical personnel shall be subjected to review by subject matter experts familiar with the topic(s).

3.6.2. Manuscripts shall be reviewed and approved prior to submission for publication.



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All laboratories shall have the opportunity to review technical manuscripts.

- 3.6.3. The author(s) shall address the review comments and recommendations.
- 3.6.4. Prior to publication the manuscript must be approved by the Deputy Assistant Director, Forensic Services.
- 3.6.5. An abstract submitted for presentation at scientific meetings shall be approved by the Section Chief and Laboratory Chief.

#### 4. Records

- 4.1. Qualification and professional development records shall be created in accordance with this procedure and maintained in accordance with *ATF-LS-8.4 Control of records*.
- 4.2. When available, certificates of attendance or participation for external training should be maintained.
- 4.3. Records should be sufficiently detailed to demonstrate that technical examiners have been properly trained in the assigned tasks and that their ability to competently perform these tests has been formally evaluated.





ATF-LS-6.3 Facilities and environmental conditions	ID: 7072 Revision: 3
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## 1. General

- 1.1. The facilities and environmental conditions shall be suitable for the Laboratory Services testing operations and shall not adversely affect the validity of results.
- 1.2. The Laboratory Services requirements supplement the following ATF requirements.
  - *ATF O 1600.5 Safety, Health and Environmental Services*
  - *ATF O 1720.1 Physical Security Program*
- 1.3. Access to ATF Laboratories is generally limited to laboratory employees. Exceptions may be made on a case-by-case basis and must be authorized by top management.
- 1.4. When it is necessary to perform testing at sites or facilities outside the control of Laboratory Services, the examiner shall ensure that the environmental conditions will not adversely impact the testing results and are noted where relevant.
  - 1.4.1. Testing outside of the control of Laboratory Services may be necessary when items cannot be physically delivered to the laboratory (e.g., fingerprints on a door frame) and tests are conducted at a scene or other location, such as a temporary laboratory space.
  - 1.4.2. During crime scene investigations by the Fire Research Laboratory, insofar as possible, the environmental conditions shall be noted when they could affect the interpretation of the results.

## 2. Accommodation

- 2.1. Laboratories shall have designated areas for the following activities.
  - Evidence reception
  - Evidence storage
  - Testing
  - Administrative functions
- 2.1.1. Separation of the functional areas of the laboratory serves to:
  - control the environmental conditions for testing.
  - control testing instruments/equipment.
  - ensure the integrity of consumable supplies and reference materials.
  - allow for access control and area-specific security.
  - minimize cross-contamination of evidence.



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2.2. Accommodations shall be made for the different types of evidence that have defined handling requirements established by law or ATF, (e.g., explosives, firearms, etc.) to ensure compliance. Refer to *ATF-LS-7.4 Handling of test items* and the technical procedures for more information.

2.3. Measures shall be taken to prevent cross-contamination of evidence. Refer to *ATF-LS-7.4 Handling of test items*.

2.4. Engineering controls

2.4.1. Chemical fume hoods and safety cabinets are available in laboratories where chemicals are used and stored.

2.4.2. Chemical hood maintenance is addressed in the laboratory safety programs and the manufacturer's user instructions.

3. Environmental conditions

3.1. Laboratory facilities for testing, including ventilation, energy sources, lighting, and environmental conditions, shall be such as to facilitate correct performance of the tests.

3.2. Environmental conditions shall be documented, monitored, controlled, and recorded as required by the technical documents or where they influence the validity of the test results.

3.2.1. Factors that may affect test results may include the following.

- Biological sterility
- Dust
- Electromagnetic disturbances
- Radiation
- Humidity
- Electrical supply
- Temperature
- Sound and vibration levels

3.3. Environmental conditions that jeopardize the validity of test results shall be addressed. Refer to *ATF-LS-8.5 Actions to address risks and opportunities* to select the appropriate course of action.

3.4. Refer to *ATF-LS-7.8 Reporting of results* and the technical documents when the interpretation of the reported results must include information about the environmental conditions at the time of testing.



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#### 4. Security

##### 4.1. Security controls include the following.

- ATF Personal Identification Verification (PIV)
- Electronic pass cards
- Alarm systems
- Security guards

##### 4.2. Entrances to the facility shall be secure.

##### 4.3. Access to the secure areas of the laboratory where testing occurs shall be controlled and limited.

###### 4.3.1. Records shall be maintained that demonstrate an accountability of all keys and electronic pass cards.

###### 4.3.2. Laboratory Chiefs shall authorize access to laboratory areas to ATF personnel whose duties require access to the space.

###### 4.3.2.1. Laboratory Chiefs assign Evidence Control access to as few persons as necessary.

###### 4.3.2.1.1. Evidence Control access assignments shall be reviewed at least annually.

###### 4.3.2.2. Access to the Evidence Control storage (vault) by personnel not assigned access shall be escorted and logged.

###### 4.3.3. Emergency entry by personnel not regularly assigned access to a secure area shall be documented.

###### 4.3.4. Refer to the site-specific security programs for additional information regarding visitor policies.

#### 5. Safety

##### 5.1. Each laboratory shall have a documented safety program.

##### 5.2. The Laboratory Chief shall designate an individual responsible for monitoring the conformance of the laboratory with the safety requirements and maintaining the safety records.



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## 6. Records

6.1. The technical, safety, and security records generated in accordance with this procedure shall be maintained according to *ATF-LS-8.4 Control of records*.



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## 1. Policies

1.1. The laboratory equipment shall be appropriate to the test methods, qualified prior to being placed into service, and maintained in a manner that ensures valid results. Use of equipment for casework is limited to trained and authorized personnel to ensure the acceptable performance of qualified equipment.

1.1.1. The term equipment will be used as a collective term to include the types of equipment listed on the laboratory's equipment inventory. These requirements do not apply to general services equipment (e.g., ovens, hotplates, furnaces, cameras, stirrers), unless otherwise stated in a test method.

1.2. Primary operators are assigned to major equipment. They are responsible for:

- ensuring that proper installation and operation of the equipment.
- aiding users with performance qualifications when needed (i.e., quality control checks).
- documenting the initial testing and assessment of equipment.
- ensuring that the maintenance and repairs of the equipment.
- ensuring that users are properly trained.

1.3. Equipment shall be subject to qualification requirements prior to use in casework to ensure it is fit for its intended purpose. Examples of such testing include quality control checks, verifications, and validations. Equipment that has not passed such qualifications shall be labeled as out of service and may not be used for casework.

### 1.3.1. Installation qualification

1.3.1.1. Installation qualification ensures that the equipment meets the requirements of the purchase agreement prior to acceptance of the equipment by the laboratory. Installation records provided by the vendor shall be retained.

### 1.3.2. Operational qualification

1.3.2.1. Operational qualification ensures that the equipment, as installed, is fit for the purpose of the test method before being placed into service.

1.3.2.1.1. The testing should be adequate to ensure the equipment is capable of achieving the desired performance while experiencing variations that might be expected to occur in normal use. The operation ranges of testing should include a set of conditions encompassing upper and lower operating limits where appropriate. This may be achieved as a



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part of equipment verification and validation. Refer to *ATF-LS 7.2 Test method validation, verification, and selection*.

### 1.3.3. Performance qualification

- 1.3.3.1. A routine performance qualification, (e.g., a quality control check) ensures that the equipment is fit for use prior to analyses of casework. Where necessary, intermediate checks may occur to maintain confidence in the performance of the equipment during testing. The performance qualification criteria and the records required to document these performance qualifications are in the discipline technical documents.
- 1.3.3.2. When provided by the vendor, certificates or other reference documents shall be maintained for primary standards or reference materials used for performance qualifications. These records, generally supplied by the vendor or made available online, establish the traceability for a standard or contain information about the properties or characteristics of the reference material.
- 1.3.3.3. Equipment that fails a performance qualification prior to or during testing may not be used until the performance is corrected to acceptable criteria.
  - 1.3.3.3.1. Data obtained from malfunctioning equipment shall be reviewed from the time of the last successful performance qualification. The effect of the malfunction on the validity of the results shall be evaluated with repeated testing where necessary and if possible.
    - 1.3.3.3.1.1. The data from the initial and repeated testing shall be maintained.
  - 1.3.3.3.2. Repair records shall include the following information.
    - Description of any damage, malfunction, modification, and repair
    - Date the problem was observed and by whom
    - Date of the repair and by whom
- 1.3.3.4. Successful completion of the performance qualification is required prior to returning the equipment to service.

### 1.3.4 Intermediate checks on measuring equipment

- 1.3.4.1. Intermediate checks may occur on measuring equipment that is calibrated or verified by a qualified service provider by periodically checking for continued adherence to quality standards in the laboratory between service dates.



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1.3.4.2. The technical procedures shall define the requirements for intermediate checks.

1.3.4.3. Records provided by the service provider shall be maintained. The measuring equipment should be calibrated or verified according to the schedule established by the service provider.

1.3.4.3.1. The length of time between checks is subject to change, dependent upon the stability of the equipment and the variability of the data over time. Justification for a lengthening of time between service dates shall be documented and must be acceptable to the service provider.

1.3.4.3.2. Measuring equipment may be used past the expiration date provided that the intermediate check is performed prior to each use in casework and the data meets the established criteria.

1.3.4.4. Records of intermediate checks shall be maintained.

#### 1.4. Maintenance

1.4.1. Equipment shall be maintained in a manner that ensures the proper performance of testing. Maintenance programs for equipment and reference materials shall be executed as described in the manufacturer's or supplier's instructions and/or a technical document. The maintenance programs, including calibrations, will include the following information.

- Identification of equipment and/or reference material
- Schedule
- Allowable variance appropriate to the test
- Required records

1.4.2. All equipment and reference materials requiring calibration or which have a defined period of validity shall be labeled, coded, or otherwise identified to allow users to readily identify the status of the calibration or period of validity.

1.4.3. Maintenance records shall include dates of service, results, and any adjustments.

#### 1.5. Inventory

1.5.1. When equipment must be tracked, it shall be uniquely identified and included in the laboratory's equipment inventory.



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- 1.5.1.1. The equipment inventory record must include the following information.
  - Unique identification number or ATF PIN
  - Manufacturer's name, equipment type or model identification, and serial number
  - Location
- 1.5.1.2. Equipment records shall indicate the software and firmware versions.
- 1.5.1.3. The inventory need not be updated for the temporary relocation of critical equipment (less than 6 months).

## 1.6. Handling, transport, and storage

- 1.6.1. All equipment shall be handled in a manner that minimizes the risk of damage.
- 1.6.2. Following transport of non-portable equipment, it shall be inspected for damage and performance checked to demonstrate proper functioning prior to use.
- 1.6.3. If equipment is placed in storage, it shall be properly packaged and stored in a location that mitigates potential for damage.

## 2. Procedures

- 2.1. Manufacturer's user manuals or Laboratory Services technical documents (e.g., test method or work instructions) outlining equipment operating instructions should be available. The technical documents will be controlled to ensure periodic review for upgrades of equipment, applications, and manufacturer information. Refer to *ATF-LS-8.3 Control of management system documents*.
- 2.2. Competency and authorization requirements regarding the use of equipment for testing are defined in *ATF-LS-6.2 Personnel standards and training programs* and the discipline training programs.
- 2.3. The physical security of the laboratory, and the equipment contained therein, is addressed in *ATF-LS-6.3 Facilities and environmental conditions*.
- 2.4. The security of computer applications used for laboratory testing is addressed in *ATF-LS-7.11 Control of data and information management*.
  - 2.4.1. Equipment computers that are not integrated with the ATF network must be password-protected to prevent unauthorized use.





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2.4.2. Application updates shall be tracked. Only authorized, trained personnel may modify testing applications.

2.5. When the investigation of an equipment malfunction determines that the quality of the test results have been affected, refer to *ATF-LS-8.5 Actions to address risks and opportunities*. If a nonconformity is identified, refer to *ATF-LS-7.10 Nonconforming work policy*.

### 3. Records

3.1. Records shall be prepared according to this document and the technical documents maintained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-6.5 Metrological traceability	ID: 7069 Revision: 6
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## 1. Policies

### 1.1. Laboratory Services does not report results that require an uncertainty.

- 1.1.1. Technical procedures shall define any necessary calibration programs, including a plan, schedule, and instructions.
- 1.1.2. Calibrations or performance checks shall be performed prior to the measurement equipment, reference standard, or certified reference material being placed into service, and periodically thereafter according to the established schedule.
- 1.1.3. If the uncertainty contribution from the calibration contributes to no more than the smallest reported increment of measurement of the test result, then these requirements are not applicable.
- 1.1.4. A reported measurement without a stated uncertainty is considered a descriptor of the item, and these requirements are not applicable. Qualifying terms should be used with the measurement (e.g., approximate, estimated).

### 1.2. Calibrations shall be performed by a body that provides the appropriate traceability or by the laboratory, demonstrating that the requirements of ISO/IEC 17025 and this document have been met. Calibrations performed by Laboratory Services are not part of the accredited services.

#### 1.2.1. External calibrations

- 1.2.1.1. Suppliers of external calibration services for measuring equipment, reference standards, and certified reference materials used by Laboratory Services shall be one of the following:
  - National Metrology Institute that is a signatory to the BIPM – CIPS Mutual Recognition Agreement with the calibration of measuring equipment and/or reference standard to be purchased in Appendix C of the BIPM key comparison database (KCDB);
  - service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Agreement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation;
  - an accredited reference material producer that is accredited to ISO 17034 by an accreditation body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC



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Mutual Recognition Arrangement, with a scope of the accreditation covering the certified reference material; or

- an equipment manufacturer that offers calibration services that utilizes National Institute of Standards and Technology (NIST) traceable equipment. A calibration certificate shall be provided showing that the equipment has been calibrated to a NIST traceable standard.

### 1.2.2. Internal calibrations

1.2.2.1. Equipment used for testing within its defined scope may be calibrated within the laboratory if the related requirements in ISO/IEC 17025 and the following are met.

- The calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel
- The calibration method shall be verified prior to use
- Certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties
- The calibration shall be carried out in an appropriate environment
- Technical records of the calibration shall be established and maintained
- The laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts
- A technical review of the technical records, including any data transfers and calculations, shall be completed by an individual other than the person(s) who performed the work

### 1.3. Reference materials for measurements

1.3.1. Refer to technical procedures for the requirements when measurement traceability must be assured for reporting measurement uncertainty.

1.3.2. Reference materials shall, where possible, be traceable to certified reference materials that use SI units. Internal reference materials shall be checked as far as is technically and economically practicable.



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- 1.3.3. Where applicable to measuring equipment, technical procedures shall have a procedure and schedule for the calibration of its reference standards by a body that can provide the appropriate traceability.
- 1.4. In situations where an ISO/IEC 17025 accredited supplier is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be maintained.
- 1.5. If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for the applicability of measurement traceability accreditation requirements.
2. Procedure
  - 2.1. Refer to the calibration programs within the technical documents.
3. Records
  - 3.1. Traceability records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



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## 1. General

- 1.1. Laboratory Services shall ensure that externally provided products and services that could impact laboratory testing are suitable. These requirements only apply to products and services that are critical to testing. These requirements do not apply to products and services that do not impact the laboratory results, e.g., cleaning services and supplies, office supplies, general construction materials, etc.
- 1.2. Subcontracting may occur due to unforeseen reasons, e.g., workload, need for further expertise, or temporary incapacity.
  - 1.2.1. The ATF laboratory is responsible to the customer for the subcontractor's work. The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the acknowledgment of the customer, preferably in writing.
  - 1.2.2. The outsourcing requirements in the *Quality Assurance Standards for Forensic DNA Testing Laboratories* shall apply to DNA subcontracted work.
- 1.3. The provisions in this policy remain in effect when an ATF laboratory provides externally procured products or services directly to a customer.
- 1.4. Laboratory Services' contracted personnel are subject to the requirements of *ATF-LS-6.2 Personnel standards and training programs*. The criteria for these services are included in the contracts.

## 2. Vendor qualification

- 2.1. Qualification of a vendor shall be based on their ability to consistently provide products and services that meet the established criteria. The qualification shall be documented by the Technical Leader or Section Chief.
- 2.2. A record shall be created and maintained for the evaluation of vendors according to the following evaluation criteria. Additional factors may be considered.
  - Third-party registration - Vendor accredited to ISO/IEC 17025 or other appropriate standards.
  - Historical evidence - Evidence that a vendor has consistently and reliably supplied goods or services conforming to the criteria over a period of time.
  - Feasibility - When vendor assessment is not feasible, examiners may purchase from a vendor not on the approved vendor list, with Technical Leader or Section Chief approval. In these instances, an appropriate inspection or testing will be performed and documented to verify the quality of the materials.



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- 2.3. A competent subcontractor is one that complies with comparable accreditation requirements as the ATF laboratory for the work performed.
- 2.4. Each discipline shall maintain a list of qualified vendors as a controlled document in Qualtrax.
  - 2.4.1. The qualified vendor list and the associated vendor qualification records shall be reviewed at least once annually and updated as necessary.
  - 2.4.2. The list shall include the evaluation criteria or include a reference to an ATF procedure that defines the criteria. Some examples of additional evaluation factors include accurate and timely deliveries, quality of goods or services, compliance with contract terms, product and technical support, ability to resolve any problems that are encountered, and history of corrective actions.
  - 2.4.3. Vendors shall remain qualified unless a periodic re-evaluation or specific event(s) demonstrates that the products or services no longer meet the criteria. Justification for disqualification shall be documented.

### 3. Acquisition

- 3.1. Appropriate records shall be produced for the selection, evaluation, and purchase of products and services.
- 3.2. Purchase request records, contracts, and memorandums of understanding shall define the laboratory's expectations of the provider's products or services.
  - 3.2.1. As applicable, a contract or memorandum of understanding shall specify the service criteria, the competence or qualification of the external provider's personnel, and the location(s) where activities shall occur.
- 3.3. The requestor or purchaser shall ensure that the purchase records are completed according to this policy and that the vendors are on the list of qualified vendors. The review shall be documented on the purchase request record.
- 3.4. All purchases require management approval.

### 4. Receipt

- 4.1. The products and services received shall be verified against the purchase request, quote, or invoice.



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- 4.2. When applicable, performance checks of products shall be conducted and documented according to technical procedure requirements. Examiners are responsible for verifying that the required checks were completed prior to using products or serviced equipment in testing activities.
- 4.3. When products or services are received that do not meet expectations, appropriate actions will be taken, such as contacting the vendor.
  - 4.3.1. Rejected products shall not be used for laboratory testing activities.
  - 4.3.2. Actions shall be documented.



ATF-LS-7.1 Review of requests, tenders, and contracts	ID: 6308 Revision: 5
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## 1. General

- 1.1. ATF Laboratories provide services designed to enhance and support the law enforcement initiatives of the Bureau of Alcohol, Tobacco, Firearms and Explosives. When evidence is submitted to an ATF laboratory, examiners will perform one or more types of analyses as determined by the customer and examiners.
- 1.2. The requirements for submitting evidence for laboratory testing are in the following.
  - *ATF Order 7140.3 Completing ATF Form 7140.7 Laboratory Exam Request*
  - *ATF Special Agents' Guide to ATF Laboratory Services*
- 1.3. Non-evidence services are requested in two ways: submission of the FRL request for technical assistance memo, or for scene examination support, by communicating with the Section Chief or the Laboratory Chief.
- 1.4. Where external providers are used to fulfill the request, the requirements of *ATF-LS-6.6 Externally provided products and services* apply. The laboratory must gain the customer's approval in advance.
  - 1.4.1. Use of an external provider may occur when the laboratory does not have the resources or competence to perform the examinations (or tests), or when the laboratory provides the service(s), but for various reasons is temporarily unable to do so.
- 1.5. Records of pertinent discussions relating to a customer's requirements, or the results of the laboratory activities shall be retained. Refer to *ATF-LS-8.4 Control of records, Communication records*.
- 1.6. The extent of database searches (e.g., DNA profiles and friction ridge) shall be communicated to the customers and updated as needed. Refer to *ATF-LS-7.8 Reporting of results, Activity notifications*.
- 1.7. The laboratory shall cooperate with customers in monitoring the laboratory's progress in relation to the work requested.

## 2. Laboratory services

- 2.1. The accredited services are listed in each laboratory's scope of accreditation. Other non-accredited services may be provided.





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2.2. When a requested service is one that is not provided by the laboratory, is inappropriate for the evidence, or is out of date, the customer shall be contacted. Options for meeting the customer's needs may be discussed, when appropriate.

### 3. Case acceptance criteria

3.1. ATF Laboratories only accept cases in which ATF has an open investigation and has an assigned ATF Investigation Number (IN), unless special arrangements have been made in advance.

3.1.1. Evidence submitted directly to the ATF Laboratories from external agencies is generally not accepted.

3.1.2. Cases may be accepted from other agencies when there is a formal memorandum of understanding (MOU) specifying the arrangement.

3.1.3. Exceptions regarding the acceptance of cases will be authorized by the Laboratory Chief or designee.

3.1.4. Records of authorized exceptions will be maintained in the case record, unless it is an MOU, in which case it may be stored with other laboratory records.

3.2. Previously examined evidence will only be accepted for examination under special circumstances.

3.2.1. If the evidence was examined by an ATF laboratory, then re-examination must be authorized in advance by the Deputy Assistant Director, Forensic Services and may be conducted under one of the following circumstances.

3.2.1.1. The Section Chief determines that a re-examination would offer additional information because of available instrumentation or techniques.

3.2.1.2. The re-examination is conducted as part of a quality assurance activity.

3.2.1.3. The original examiner is not available for court and a re-examination is necessary for a second examiner to testify in court.

3.2.2. Evidence examined by a non-ATF laboratory is generally not accepted for re-examination. Any exception to this policy must be authorized in advance by the Deputy Assistant Director, Forensic Services.



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3.2.2.1. This does not apply to evidence submitted to the ATF Fire Research Laboratory.

### 3.2.3. Requests for DNA examination

3.2.3.1. Laboratory Chiefs and DNA Section Chiefs have the authority to make exceptions to the DNA case acceptance policy as needed. Not all ATF cases can be accepted. Requests for DNA examination are subject to the following requirements.

3.2.3.1.1. Cases will be evaluated to determine if the evidence is probative and if the items submitted are likely candidates for successful DNA analysis.

3.2.3.1.2. Cases in which Felon in Possession of a firearm is the only expected charge will not be accepted for DNA analysis.

3.2.3.1.3. DNA analysis may not be conducted on items that have already been linked to an individual by identification of a latent print.

3.2.3.1.4. DNA analysis of sexual assault evidence is not conducted by the ATF Laboratories.

3.2.3.1.5. When requested by a customer or at the discretion of the Section or Laboratory Chief, DNA collection may be performed on cases or items not meeting the above laboratory guidelines for DNA case acceptance. In addition, customers may request that DNA samples collected from submitted items be returned without further analysis. In these instances, the collected DNA samples will not be analyzed and will be returned to the submitting agency.

## 4. Review of request

4.1. A request for testing shall be evaluated by a relevant Section Chief. The review ensures that the laboratory has the capability and resources required and that the appropriate methods will be selected to fulfill the request. The Section Chief shall make the determination as to whether or not to accept the case.

4.2. The evaluation includes a review of the *ATF Form 7140.7 Laboratory Exam Request* or the FRL request for technical assistance, all supporting documentation, *ATF Form 3120.2 ROI*, or other agency reports and investigative information provided by the customer.



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4.3. Laboratory management shall indicate the case acceptance by assigning examiners in the LIMS.

5. Tender

5.1. Evidence Control or a supervisor shall issue a notice of case received to the customer and a copy shall be retained with the contract in the LIMS. Non-evidence case received notices shall be stored with the case communications.

6. Contract

6.1. The *ATF Form 7140.7 Laboratory Exam Request* and the FRL request for technical assistance provide a means for Laboratory Services customers to make a request for service. These documents serve as a contract between Laboratory Services and the customer.

6.1.1. When the request for scene support is received by email, the request email from the customer and the reply email from a supervisor accepting the request serves as the contract between Laboratory Services and the customer.

6.2. The contract shall be acceptable to both the laboratory and the customer. Any changes to the request shall be resolved before laboratory activities commence on that portion.

7. Contract modifications

7.1. The opening inventory, the course of the examination(s), or communications with the customer may result in contract modifications, which includes the addition and cancellation of examinations.

7.2. If a contract is amended after work has commenced, both the customer and the laboratory must agree to the change. An examiner may accept the change on behalf of the laboratory and must document the customer's concurrence. When necessary, the examiner should consult with the relevant Section Chief.

7.3. As appropriate, amendments shall be communicated to other affected examiners working the case.

7.4. The customer shall be informed of any deviation from the contract.

7.5. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.



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7.6. Contract amendments shall be recorded in the case record.



ATF-LS-7.2 Test method validation, verification, and selection	ID: 7006 Revision: 6
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## 1. General

- 1.1. Laboratory Services shall use the appropriate test methods for all examinations.
- 1.2. Test methods for examinations shall include the requirements for data collection, analysis, and interpretation.
- 1.3. Test methods for activities that just involve the collection of items or data will not include data analysis and interpretation requirements.
- 1.4. Technical procedures shall define which test methods produce presumptive results and those that produce confirmatory results.
- 1.5. For all test methods that involve the comparison of an unknown to a known, the characteristics suitable for comparison shall be identified in the unknown item prior to comparison with a known item. This requirement is not applicable to the identification of items by comparison with exemplars.
  - 1.5.1. Initial characterization of the unknown shall occur prior to the comparison. Refer to the technical procedures for specifics.
  - 1.5.2. Preliminary characterization of a known sample prior to the assessment of an unknown is permissible under certain circumstances, e.g., searching debris for relevant trace evidence.

## 2. Validation and Verification

- 2.1. The test methods must be validated, whether internally or externally, prior to use.
  - 2.1.1. In-house validations shall be performed for non-standard methods, laboratory-developed methods, and standard methods used outside their intended scope or otherwise modified.
    - 2.1.1.1. The validation study shall:
      - include data analysis and interpretation,
      - establish the data required to report a result, opinion, or interpretation,
      - identify limitations of the method and the reported results, opinions, or interpretations, and
      - include a statement as to the validity of the method and its fitness for intended use.



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- 2.1.1.2. When appropriate, the validation should include the following performance characteristics.
- Accuracy
  - Precision
  - Reproducibility
  - Sensitivity
  - Stability
  - Specificity
  - Upper and lower operating limits
  - Contamination or matrix interferences
  - Comparison of results to other validated methods
  - Any other relevant factors
- 2.1.1.3. The validation of Forensic Biology test methods shall meet the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.
- 2.1.1.4. When changes are made to a validated method, the influence of such changes shall be determined. Where they are found to affect the original validation, a new method validation shall be performed.
- 2.1.2. If a test method has been externally validated, an internal verification shall be performed. This applies when test methods are substantially based upon international, regional, or national standards, specifications published by reputable technical organizations, or publications in relevant scientific texts and journals. The test method may be supplemented with details specific to Laboratory Services to produce the laboratory test methods.
- 2.1.2.1. The laboratory shall verify that it can achieve the required performance. The parameters are dependent upon the test method being evaluated. The evaluation could include analyzing known samples, contaminated samples, and samples throughout the range of the detection limits.
- 2.1.2.2. The verification must address the scope and limitations of the test method.
- 2.1.2.3. Prior to using a method that has been revised by the issuing body, the method shall be verified to the extent necessary.
- 2.1.3. Commissioning new equipment with established test methods does not require verification. Performance qualifications (i.e., a quality control check) must be conducted according to *ATF-LS-6.4 Equipment*.



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- 2.2. Validations, verifications, and commissioning of new instruments shall be performed by competent personnel.
- 2.3. The proposed test method must be approved by the Technical Leader and is then published in Qualtrax.
- 2.4. At the Laboratory Chief's discretion, the Laboratory Services Research Advisory Panel (RAP) can provide status monitoring, advice, and review for activities related to validation and verification of test methods.

### 3. Selection

- 3.1. The *ATF Form 7140 Laboratory Exam Request* and the FRL request for technical assistance memo provide a means for Laboratory Services customers to make a request for service. These documents serve as a contract between Laboratory Services and the customers.
- 3.2. The laboratory examiner(s) will select the appropriate test method(s) to fulfill the request unless a test method is specified by the customer. The laboratory shall inform the customer when an examination proposed by the customer is considered to be inappropriate.
- 3.3. When an examination outside the expertise or capability of Laboratory Services is requested, the customer may be directed to a reliable source to meet the request.

### 4. Deviation

- 4.1. A deviation from a test method shall be technically justified, documented, and authorized.
- 4.2. The acceptance of a deviation by the customer is inherent in the contract.

### 5. Test method

- 5.1. The Laboratory Services test method shall meet the requirements of *ATF-LS-8.2 Management system documentation*.

### 6. Records

- 6.1. Verification and validation records shall be retained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-7.3 Sample selection	ID: 7022 Revision: 5
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## 1. Policy

- 1.1. Laboratory Services receives items that are generally the best evidence selected by the customer according to the *ATF Special Agents' Guide to Laboratory Services*; these items are not considered representative evidence. Laboratory Services has no control over the evidence collected for submission to the laboratory.
- 1.2. Laboratory Services does not perform statistical sampling. Results of laboratory testing are only applicable to the specific item or sample tested.
- 1.3. There shall be no assumption of homogeneity in an item submitted by the customer. However, homogeneity can be established through examination in the laboratory. Selection of samples for testing by the examiner shall be based on the training, competency, and experience of the examiner, in order to test the best sample possible.
- 1.4. In the rare instance in which a customer employed a statistical sampling plan, it must be communicated to the laboratory in the request for examination. Even in these cases, however, the examiner cannot make inferences about the whole population from which the tested items were chosen.

## 2. Procedures

- 2.1. Where applicable, technical documents shall include guidance for sample selection.
- 2.2. When it is necessary to sub-designate and package a sample separately from a submitted item, refer to *ATF-LS-7.4 Handling of test items*.

## 3. Records

- 3.1. Sample selection information shall be noted in the technical records according to *ATF-LS-7.5 Technical records*.





ATF-LS-7.4 Handling of test items	ID: 6310 Revision: 6
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## 1. General

- 1.1. This procedure contains the requirements for the transportation, receipt, handling, protection, storage, retention, and return of test items.
- 1.2. Access to areas where evidence is stored or examined is limited to personnel authorized by top management. Emergency access to locations where evidence is present shall be documented.
- 1.3. Test items shall be handled in a manner that protects the integrity of the items and protects the interests of the laboratory and its customers.
  - 1.3.1. Any special handling instructions provided by the customer shall be followed.
  - 1.3.2. Refer to *ATF O 3320.7 Explosives Programs and Operations* and *ATF O 3400.1 Property Taken into Bureau Custody* for additional guidance.
- 1.4. Precautions shall be taken to avoid deterioration, contamination, loss, or damage to items while in the custody of the laboratory.
- 1.5. All evidence not in the process of examination shall be stored under proper seal.
- 1.6. Each laboratory shall conduct and document an evidence inventory audit annually and following relevant personnel changes. These audits shall account for all evidence in the custody of the laboratory.

## 2. Transportation

- 2.1. Evidence is transported to the laboratory in accordance with *ATF O 3400.1 Property Taken into Bureau Custody*.

## 3. Receipt

- 3.1. Evidence accepted for examination by Laboratory Services shall receive a laboratory case number, which is auto generated by the Laboratory Information Management System (LIMS). In some cases, evidence that will not be examined may be returned to the customer without a laboratory case number.
  - 3.1.1. The LIMS record shall include the following.
    - Laboratory case number
    - Submission number
    - Investigation number (IN)



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- Customer contact information
- Mode and date of receipt: commercial courier, hand-delivered
- Examiner assignments
- Type(s) of examination; refer to *ATF-LS-7.1 Review of requests, tenders and contracts*

Cases transitioned into the LIMS system may not contain all required records.

3.1.2. When necessary, packages may be placed in a secure area for short term storage before they are logged into the LIMS and assigned a laboratory case number. In these instances, the packages will be marked with the initials or equivalent identifier of the receiver and date before being placed in the secure area. Paperwork submitted with the evidence will be retained with the packages until it can be uploaded into LIMS.

3.1.3. Refer to *ATF-LS-7.1 Review of requests, tenders and contracts* regarding the request review and evidence acceptance criteria.

### 3.2. Chain of custody

3.2.1. A chain-of-custody record shall be established and maintained for all evidence received for examination by the laboratory. The laboratory chain of custody begins upon the receipt of the evidence by the laboratory.

3.2.2. Any damage to the exterior container that may affect the integrity of the evidence shall be documented and a supervisor shall be notified. A supervisor shall conduct a limited inventory and notify the customer if necessary.

3.2.3. When a container is received without the supporting paperwork on its exterior, the Evidence Control Specialist may open the container to retrieve the paperwork then seal the container without necessitating an inventory of its contents. Opening containers for this purpose by Evidence Control shall be documented.

3.2.3.1. If a container must be opened by Evidence Control for reasons other than removing paperwork prior to its initial inventory, a limited inventory shall be conducted by a supervisor. The inventory shall confirm, to the extent possible, that the contents are as expected according to submission paperwork. This limited inventory does not require descriptions of inner packaging or seals. Documentation of the container opening should include the justification for the limited inventory and confirmation of expected contents or customer contact regarding any observed discrepancies.



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- 3.2.3.2. When items of evidence need to be separated prior to examiner assignment (such as placing fire debris evidence in the freezer or separating FRL and FSL evidence), a supervisor shall open the appropriate containers, perform a limited inventory to verify the number of items agree with the submitted paperwork, and document the separation of evidence.
- 3.2.4. The individual initiating a transfer is responsible for ensuring the proper documentation of the event. These records shall include the following.
- Signatures of both individuals involved in the transfer
  - Date of the transfer
  - Laboratory case number
  - Item or container identification information
- 3.2.4.1. A signature should be identifiable to the source, or the printed name shall be proximal to the signature.
- 3.2.4.2. After the initial inventory, the transfer of items shall include a brief description of the items being transferred.
- 3.2.4.3. When a transfer between examiners involves only select items of a submission, those items must be consolidated with the remaining evidence prior to the return to Evidence Control in order to maintain accountability.
- 3.2.5. When items are transferred between laboratories for technical review or verification purposes only, the recipient laboratory shall not assign a new laboratory case number. The recipient laboratory shall document chain of custody while in their possession.
- 3.2.6. An item that is lab-generated or lab-separated shall be designated in a manner that relates it to the original item from which it was derived.
- 3.2.6.1. The chain of custody for a lab-generated or lab-separated item shall begin with its creation or separation. The creation and disposition of sub-designated items will be recorded in the case record as required by discipline methods. To the extent possible, the electronic chain of custody will be initiated contemporaneously. In situations where that cannot be accomplished on the same day, the sub-designated item's description in LIMS shall include the date of generation or separation. The justification for the delayed LIMS entry will be made in the case record.
- 3.2.6.1.1. Example wording for delayed LIMS entry item description.



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- Suspected fiber removed from tape (separated on MM/DD/YYYY), or
- Test fires from Item 1 (generated on MM/DD/YYYY)

3.2.6.2. A lab-generated item that cannot be reproduced will be returned to the customer with the original item. Examples include footwear lifts (e.g., gel lifts, electrostatic dust print lifts), firearms test fires, test cuts and casts, preserved charcoal strips, and ESDA impressions.

3.2.6.2.1. A latent print capture generated in the laboratory is typically not returned with the original item. Latent print captures are handled as evidence with a documented chain of custody and stored in a secure manner. Chain-of-custody documentation for latent print captures may be recorded in a variety of ways (e.g., control cards, logbooks).

3.2.6.3. Refer to the technical procedures for discipline specific disposition of lab-separated items. Some examples of these include DNA swabs and extracts, hairs, fibers, paint chips, and charcoal strips.

#### 4. Handling

##### 4.1. Safeguarding

- 4.1.1. All evidence shall be securely maintained in the laboratory vault under proper seal when not in the process of examination.
- 4.1.2. The evidence shall be packaged and sealed properly or be maintained in a secure, restricted access location when it is not conducive to packaging.
- 4.1.3. The order of examinations and workflow is based upon maximizing the evidentiary value of the item and minimizing the likelihood of loss or damage.
- 4.1.4. The examiner is responsible for safeguarding and securing the items in their custody during an examination, which is generally expected to be less than 90 days. Limited extensions past 90 days must be authorized by a supervisor and documented in the case record.
  - 4.1.4.1. Evidence in the process of examination may be maintained in controlled access laboratory workspaces.



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4.1.5. Each facility that handles explosives shall be equipped with an explosion-proof container, magazine, or bunker for the safe and secure storage of explosives evidence.

4.1.5.1. Access to secured magazines/bunkers is restricted to personnel authorized by the Laboratory Chief.

4.1.6. Currency and controlled substances

4.1.6.1. ATF laboratories do not accept controlled substances.

4.1.6.1.1. When controlled substances are received by the laboratory, the customer shall be contacted, and the item returned.

4.1.6.2. Currency is only accepted by the laboratory under unusual conditions and with prior arrangements.

4.1.6.2.1. When currency is submitted, it shall be inventoried in the presence of a witness. The witness shall confirm the amount of currency in the case record and initial and date the closing seal.

4.1.6.3. If currency or suspected controlled substances are discovered within inventoried items of evidence, it shall be documented.

4.1.6.3.1. If the amount of currency is greater than \$20, then 4.1.6.2.1 applies.

4.2. Hazards and contamination

4.2.1. Measures shall be taken to protect personnel from hazards and minimize cross-contamination while handling items.

4.2.2. Universal precautions shall be used when indicated by the evidence.

4.2.3. When hazard or contamination is a concern, laboratory surfaces and examination tools shall be new or appropriately cleaned between the handling of items.

4.2.4. Access to laboratory examination areas where contamination is a concern is controlled and limited.

4.3. Packaging

4.3.1. Evidence shall be appropriately packaged for the type of evidence.



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4.3.1.1. It shall be documented in the case record if the packaging is unsuitable upon receipt by the laboratory. This may be documented by Evidence Control personnel or an examiner.

4.3.1.2. Refer to the technical procedures for discipline-specific packaging requirements.

4.3.2. Original shipping containers may be combined based upon the circumstances. The containers shall be relabeled appropriately to reflect the consolidation. The change in the number of containers shall be documented in the chain-of-custody record.

4.3.2.1. Container numbering shall indicate when multiple containers exist (e.g., 1 of 2, 2 of 2).

4.3.3. Items should be maintained and returned to the customer in the original packaging. If re-packaging is necessary, the original packaging shall remain with the evidence so that the customer can identify their labels and markings.

#### 4.4. Seals

4.4.1. Containers received by the laboratory which are not under proper seal will be sealed upon receipt. A record of these types of sealing activities shall be documented.

4.4.2. All containers distributed by and returned to Evidence Control shall be properly sealed.

4.4.3. During the examination, packages may be securely closed to prevent evidence loss, deterioration, or damage. Closures are not considered proper seals.

4.4.4. When items are transferred from one examiner to another for immediate examination, it is not necessary to seal the evidence. Sealing of packages is recommended, but evidence may be exchanged between examiners in an opened state.

4.4.5. Evidence that is not conducive to packaging, due to size or risk of evidence damage, shall be safeguarded for its evidentiary value.

#### 4.5. Identification



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4.5.1. Items, including sub-designated items, shall be labeled with their unique identifier, which includes the laboratory case number and the laboratory item number, while under the responsibility of the laboratory. The proximal packaging will be labeled for items that do not lend themselves to labeling.

4.5.2. The designation for lab-generated or lab-separated items shall be unique and include the identification number of the parent item.

4.5.2.1. Sub-designated items shall only be generated by the person who has custody of the parent item.

## 5. Retention

5.1. If lab-generated or lab-separated items are to be retained by the laboratory, such as DNA extracts or latent print captures, the examiner will record the disposition in the chain of custody.

## 6. Return

6.1. Evidence Control Specialists and supervisors are the only individuals authorized to return evidence to the customer or to transfer evidence to another ATF laboratory or entity.

6.1.1. Transfer of evidence to and from National Integrated Ballistic Identification Network (NIBIN) personnel may occur through Evidence Control or an examiner, provided all proper documentation requirements for chain of custody are met.

6.2. The return of evidence to the customer shall be recorded in the chain of custody. Records shall include the date of return and the assigned tracking number for containers that are shipped or the name and signature of the person to whom the evidence is being released. Partial shipments, explosives transfer to bunker, or items for destruction must be clearly documented.

### 6.3. Special handling of explosive materials and ignitable liquids

6.3.1. According to *ATF O 3400.1 Property Taken into Bureau Custody*, ATF Agents will keep duplicate samples of the explosive materials and ignitable liquids submitted to the laboratory. This allows samples sent to the laboratory to be destroyed after analysis.

6.3.1.1. After the analysis is completed by the laboratory, the examiner shall separate the explosive material from its original evidence packaging and



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handle per site-specific procedures in *ATF-LS-7.4.1 FSL-A Explosives handling process* and *ATF-LS-7.4.2 FSL-W Explosives handling process*. The explosives evidence packaging will be returned with the remaining evidence to the customer upon completion of all analyses.

6.3.1.2. Bulk ignitable liquids shall not be shipped back to the customer. Ignitable liquids are typically destroyed with a portion preserved and returned to the customer.

6.3.2. Site-specific procedures for handling and storage of explosives for destruction are detailed in the work instructions.





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## 1. General

- 1.1. Technical procedures shall define the discipline-specific report conclusions and the minimum requirements for the supporting documentation retained in the case record.
- 1.2. Abbreviations, symbols, and terms specific to the laboratory shall be defined in *ATF-LS-3.1 List of terms and definitions* or within the technical procedures. A unique abbreviation, symbol, or term may be utilized within a technical record, provided that it is defined at the point of initial usage.
- 1.3. The examination documentation is considered final when submitted for technical review. A report is not final, and considered a technical record until all signatures have been affixed. Following the administrative and technical review and signing of the report the case record is complete.
- 1.4. Recorded observations and data collected shall be preserved.
- 1.5. An audit trail of current and previous values shall be maintained for changes made to electronically stored case records.
  - 1.5.1. For attached files that are edited, replaced, or deleted, the audit trail shall include a copy of all previous file attachments.
  - 1.5.2. Electronic records that have been changed shall be clearly identifiable to users of the electronic storage system.
  - 1.5.3. The audit trail shall be available as a record that can be printed or saved to a file. Previous versions of file attachments shall be available.

## 2. Technical records

- 2.1. Upon examiner receipt of physical evidence, an inventory of the items shall be conducted.
  - 2.1.1. The inventory shall be compared with the listing of items on the *ATF Form 7140.7 Laboratory Exam Request* or as described in the chain-of-custody transfer record. The closing inventory may occur after the technical review.
  - 2.1.2. Firearm submissions shall be handled and examined as firearms, regardless of relation to the legal definition of a firearm or Final Rule 2021R-05F.
    - 2.1.2.1. When a firearm includes components that are not listed on the *ATF F 7140.7*, they shall be documented in the technical record as part of the firearm.



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- 2.1.2.1.1. Examples of firearms components include pistol brace, scope, adapted or modified grip, tape, suspected conversion device, and laser sights. The appropriate Technical Leader shall be consulted, as necessary.
      - 2.1.2.1.2. When there is more than one magazine in the package with the firearm and it is not accounted for on the *ATF F 7140.7*, that evidence discrepancy shall be documented in the technical record and communicated to the customer.
      - 2.1.2.1.3. When a sub-designated item (e.g., DNA swab, latent print) has been created from a component, that component must be stated in the report.
    - 2.1.3. The inventories shall include descriptions of the packaging and seals and denote when transfers occurred without packaging and/or seals. The closing inventory must also account for any lab-generated or lab-separated items.
    - 2.1.4. Documentation of item packaging and seals as part of an inventory is not required for transfer of lab-separated items when the packaging and sealed condition is inherent in the item's description (e.g., DNA extracts, slide with mounted trace) and readily understood.
  - 2.2. Technical records must be sufficiently detailed and shall provide a clear account of the actions taken during the testing process and include all of the supporting information for the results as required by the technical procedures. Technical records to support a report (including results, opinions, and interpretations) shall be such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the results. Sufficient information to identify any factors affecting the uncertainty of the results shall be included.
  - 2.3. The technical record shall clearly reflect the identity of the person responsible for each laboratory activity and the date for each laboratory activity. Original observations, data, and calculations shall be recorded during or as close to the activity as possible. These may be hand-written, typed, or recorded in electronic media.
  - 2.4. When instrumental analyses are conducted, the operating parameters shall be recorded.
  - 2.5. When an exemplar that is part of an exemplar collection is used in casework, its unique identifier shall be recorded in the technical record.



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2.6. Visual and audio records (e.g., photographs, videos, diagrams) may be included.

2.6.1. Photographic conditions (e.g., magnification, lighting, image-processing applications) shall be recorded to the extent necessary to facilitate interpretation of the photograph's content. Photographs taken solely for descriptive purposes do not require this information. Rulers or objects of a fixed, known size may be used in photographs for size reference.

2.6.2. Technical procedures shall specify any image annotation requirements.

2.7. Technical records may include the following.

- Original observations, including notes, worksheets, forms, and checklists
- Reference to technical procedures selected
- Quality control data, e.g., instrument and equipment functionality data, reagent functionality, control graphs, calibration records, etc.
- Qualification of the significance of associations whether by a statistic or qualitative statement
- Factors affecting uncertainty, such as uncertainty of measurement
- Assumptions
- Calculations, models, and values
- Literature references
- Documentation regarding reference materials and exemplar collections
- Sample selection mechanism or sampling plans
- Internal and external reports

2.7.1. The requirements for documenting sample selection are in *ATF-LS-7.3 Sample selection* and in the technical procedures.

2.7.2. The requirements for documenting measurement traceability are in *ATF-LS-6.5 Metrological traceability* and in the technical procedures.

2.8. If the initial notation has sufficient detail, cross-referencing may be used within technical records to minimize redundancy.

2.9. Controlled worksheets shall be used when required by discipline procedures.

3. Case record reviews and verifications

3.1. When verifications are required, the documentation shall include the result of the verification, who performed the verification, and the date it was performed.

3.1.1. The resolution of any discrepancies shall be recorded in the case record.



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3.2. Technical records shall be reviewed in accordance with *ATF-LS-7.7.1 Review of case records, reports, and notifications*.

3.2.1. All changes made to resolve technical discrepancies shall be recorded in the case record. Technical discrepancies may be uncovered through routine quality control processes, such as verification or technical review.

#### 4. Conditional requirements

##### 4.1. Examination cancellations

4.1.1. A cancellation is an examination request modification. The record requirements are dependent upon when the cancellation occurred.

4.1.1.1. Cancellations prior to case acceptance are addressed in *ATF-LS-7.1 Review of requests, tenders and contracts*.

4.1.1.2. When a cancellation request is made after examiners have been assigned but before examinations have commenced, the cancellation shall be recorded in the case record and the relevant personnel notified.

4.1.1.3. When the examination is cancelled after work has started, test results of the partial examinations shall be reported in accordance with *ATF-LS-7.8 Reporting of results*.

##### 4.2. Deviations

4.2.1. Deviations from technical procedures shall be justified and recorded in the technical record.

4.2.2. Deviations in Forensic Biology shall be authorized by the Technical Leader either before the occurrence or as soon as practical after the testing.

4.2.3. Deviations in other disciplines shall be authorized by the Section Chief, either before the occurrence or as soon as practical after the testing.

##### 4.3. Rejections



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4.3.1. When observations, data, or test results are rejected or removed from consideration, the technical record shall include the reason, the identity of the individual taking the action, and the date. Any such records shall be retained in the case record.



ATF-LS-7.7 Ensuring the validity of results	ID: 7057 Revision: 6
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## 1. General

- 1.1. Laboratory Services uses a wide variety of mechanisms to ensure the validity of test results, including training and competency testing personnel, using validated methods, reviewing test results, conducting proficiency testing, and numerous quality control procedures.
- 1.2. Quality control mechanisms are used to ensure the validity of the laboratory's test results. Monitoring activities shall be planned and reviewed. Data from monitoring activities shall be analyzed and may be used to improve the laboratory's activities.
- 1.3. For quality control data that has a numerical measure the resulting data shall be recorded and evaluated in such a way that trends are detectable. Instruments or methods that are infrequently used may not be amenable to trend analysis.
- 1.4. When results from monitoring activities are found to be outside predefined criteria then appropriate methods shall be consulted to address the cause. The technical procedures shall address quality control mechanisms applicable to the discipline and will include a schedule or plan, the criteria for acceptable performance, and any documentation required.
- 1.5. When the results of a quality control check are outside the predefined criteria, appropriate action shall be taken prior to proceeding with casework.

## 2. Quality control mechanisms

### 2.1. Exemplar collections

- 2.1.1. Exemplars that may be used in identifications and comparisons to determine possible sources shall be preserved and stored in a manner that protects their integrity.
- 2.1.2. Collections of exemplars shall be sufficiently documented such that the materials are traceable to their source when possible. Exemplar information should include the following when available.
  - Unique identifier designated by the laboratory section
  - Name(s) and description
  - Manufacturer's lot number, date of manufacture, and certificates, if available
  - Date of receipt or purchase by the laboratory
  - Expiration date, if applicable



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- 2.2. Reference materials for measurements shall be checked as required by *ATF-LS-6.5 Metrological traceability* and the technical documents.
- 2.3. Functional checks of testing equipment shall be performed as required by *ATF-LS-6.4 Equipment* and the technical documents.
- 2.4. Working standards
  - 2.4.1. The identity or composition of working standards from a supplier shall be specified in the technical procedures. Records certifying the quality of the standard provided by the supplier shall be retained.
    - 2.4.1.1. Expired standards should be replaced but may still be used if it has been demonstrated that the data analyses would not be substantively affected. One way that this may be accomplished is by comparison with historical data.
  - 2.4.2. Preparation of working standards by the laboratory shall be defined in a technical procedure and documented, including who made the standard and the date of preparation.
  - 2.4.3. When control charts are used, periodic reviews of control charts shall be documented.
- 2.5. Intermediate checks on measuring equipment shall be performed as required by *ATF-LS-6.4 Equipment*, and the technical documents.
- 2.6. Casework verifications
  - 2.6.1. The following disciplines may require verifications: Firearms & Toolmarks, Impressions, Friction Ridge, Document Examination, and Materials (Trace). Discipline-specific technical documents will prescribe the examinations that require verifications.
  - 2.6.2. Comparison examinations that result in a source identification are verified unless deemed non-probative (e.g., physical fits within an item or between items from the same location). Discipline-specific technical documents will prescribe the results that require verification.
  - 2.6.3. Verifications shall be conducted by an individual who is currently authorized to perform the testing. An examiner who performs a verification may also be the technical reviewer.



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- 2.6.4. The verification must be conducted to the extent that the verifier could independently defend and testify to the result(s) reached.
- 2.6.5. Verification shall be documented in the technical record. Discipline-specific technical documents will prescribe the format on how documentation occurs (e.g., form, signature). The documentation shall include the following.
- Identification of verifier
  - Date of verification
  - Method of verification (e.g., visual, microscopic, photographic, review of technical records)
  - Results of verification including the verifier's justification (e.g., specific area, class/individual characteristics)
  - Items examined
- 2.6.6. If a discrepancy exists between the conclusions of the primary examiner and verifier that cannot be resolved between the parties, the Section Chief shall attempt to reach a resolution. The Section Chief may consult the Technical Leader or a qualified third party. The Laboratory Chief shall be consulted as appropriate and necessary. Discrepancy resolutions must be documented in the case record.

## 2.7. Other

- 2.7.1. Technical and administrative reviews shall be conducted and documented for all case records, reports, and notifications in accordance with *ATF-LS-7.7.1 Review of technical records, reports, and notifications*.
- 2.7.2. Testimony shall be reviewed in accordance with *ATF-LS-7.7.2 Testimony reviews*.
- 2.7.3. Laboratory Services maintains a proficiency testing program. Refer to *ATF-LS-7.7.3 Proficiency testing*.





ATF-LS-7.7.1 Review of case records, reports, and notifications	ID: 7008 Revision: 9
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## 1. General

1.1. In general, the technical and administrative reviews are done by different individuals. These reviews may be performed by a single individual, but this should be rare.

1.2. The administrative and technical reviews may not be performed by the person who performed the work or authored the report or notification.

## 2. Scope of review

2.1. The scope of the technical review shall ensure the following:

- reported results, opinions, and interpretations are accurate, properly qualified, and supported by the test record;
- test method(s) and applicable policies and procedures are followed;
- test report or notification contains all required information; and
- results are scientifically valid.

2.1.1. The Forensic Biology technical reviews shall include the elements required by the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.

2.2. The scope of the administrative review shall include the following:

- review of the test report or notification for spelling, grammar, and format;
- review of all administrative and examination records to ensure that the records are uniquely identified; and
- review of the test report or notification to ensure that all key information is included.

## 3. Reviewer qualifications

### 3.1. Technical reviewer

3.1.1. A qualified technical reviewer is an individual who has been authorized by the Laboratory Chief to conduct technical reviews in the area being reviewed. The authorization to work for Laboratory Services employees includes the authorization to conduct technical reviews in that area and no separate record is required.

3.1.2. A technical reviewer need not be currently proficiency tested; however, they must have been competency tested in the area being reviewed.



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3.1.3. Qualification records for reviewers external to the system may take a variety of forms. Based on a review of these records, the Laboratory Chief can grant an authorization to conduct technical reviews.

3.1.3.1. Formal competency test records may not exist for external subject matter experts based on their position and the infrastructure and/or quality system of their current organization.

3.1.4. Technical reviewers of Forensic Biology analyses must meet the qualifications of the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.

### 3.2. Administrative reviewer

3.2.1. The administrative reviewer shall be a Section Chief or an employee authorized by the Laboratory Chief.

## 4. Review process

4.1. Results of the reviews shall be documented.

### 4.2. Author review

4.2.1. Prior to submission for technical review, the author of the report or notification shall document their review of the case record and report or notification by signing and dating the case record review form or completing the electronic equivalent.

### 4.3. Technical review

4.3.1. The technical reviewer shall document their review of the case record and report or notification by signing and dating the case record review form or completing the electronic equivalent.

4.3.2. A technical review of all case records and the related test report or notification shall be conducted and documented by a qualified reviewer prior to the distribution of the report or notification. However, if the report is time sensitive and a qualified technical reviewer is unavailable, then the technical review may be conducted and documented as soon as practical after distribution.

4.3.2.1. If a nonconformity or technical error is discovered after a report is issued, then based on the nature of the issue, an appropriate plan of action shall be developed.



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4.3.3. The Section Chief shall attempt to resolve a discrepancy between the report author and the technical reviewer. If needed, they may consult a qualified third party. The Laboratory Chief shall be consulted as appropriate and necessary. Discrepancy resolutions must be documented in the case record.

#### 4.4. Administrative review

4.4.1. An administrative review of each case record and the related test report or notification shall be conducted and documented prior to the distribution of the report or notification.

4.4.2. The administrative reviewer shall document their review of the case record and report or notification by signing and dating the case record review form or completing the electronic equivalent.

### 5. Records

5.1. Records of authorized technical and administrative reviewers shall be maintained.

5.2. The appropriate review form shall be used to document the reviews. Digital case record reviews shall be electronically documented.

5.2.1. Forensic Science Laboratories – General

*ATF-LS-F1-7.7.1 Case Record Review Form*

5.2.2. Forensic Science Laboratories – Forensic Biology

*ATF-LS-F2-7.7.1 DNA Case Record Review Form*

*ATF-LS-F3-7.7.1 DNA Collection Review Form*

*ATF-LS-F5-7.7.1 DNA Ownership Review Form*

5.2.3. Forensic Science Laboratories – Triage

*ATF-LS-F4-7.7.1 Triage Case Record Review Form*

5.2.4. Fire Research Laboratory

*ATF-FRL-F-102 Review Form-Memo to File*

*ATF-FRL-F-103 Review Form-Experiments*

*ATF-FRL-F-122 Review Form-Scene*

*ATF-FRL-F-123 Review Form-Engineering Analysis*



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*ATF-FRL-F-124 Review Form-Exam*

- 5.3. The completion of the review process and the signatures of the author and reviewers on the final report shall signify the completion of the examination request.
- 5.4. Review forms shall be maintained in accordance with *ATF-LS-8.4 Control of records*.
- 5.5. Draft reports not being controlled by the LIMS shall be discarded after the completion of the examination request.



ATF-LS-7.7.2 Testimony reviews	ID: 7009 Revision: 6
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## 1. General

- 1.1. When testimony related to a Laboratory Services employee's work is requested, the testimony must be authorized by the Laboratory Chief prior to the disclosure of information in court or other legal proceedings.
- 1.2. An attempt will be made to review all testimony. Testimony will be reviewed in accordance with the *Department of Justice Testimony Monitoring Framework* and may be done by observation or transcript review.
  - 1.2.1. Laboratory Services strives to conduct a technical review of testimony in as many instances as feasible. However, at least 25% of testimony within an accreditation cycle shall be technically reviewed by an individual who has been competency tested in the technical task(s) for which the testimony is provided.
- 1.3. An annual assessment of all testimony reviews shall be conducted and shall include a record of any personnel who are eligible to testify but did not do so within the review period.

## 2. Review mechanisms and scope

### 2.1. Observation

- 2.1.1. Testimony may be observed by an examiner, Section Chief, or Laboratory Chief. The observer must have been competency tested and court qualified in at least one area of forensic science.
- 2.1.2. The testimony review by observation shall include an assessment of the following.
  - Performance under direct and cross-examination
  - Presentation of information in a clear and understandable manner
  - Witness' ability to stay within their scope of expertise and provide opinions and interpretations that are accurate and properly qualified
  - Correspondence of the testimony with the case record
  - Conformance with any required standards for uniform language
  - Appearance and demeanor of the witness
- 2.1.3. The assessments listed above are applicable for both general monitoring and a technical review of the testimony.

### 2.2. Transcript review



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2.2.1. A transcript of the testimony may be reviewed by an examiner, Section Chief, or Laboratory Chief.

2.2.2. The review of testimony by transcript shall include an assessment of the following.

- Performance under direct and cross-examination
- Presentation of information in a clear and understandable manner
- Witness' ability to stay within their scope of expertise and provide opinions and interpretations that are accurate and properly qualified
- Correspondence of the testimony with the case record
- Conformance with any required standards for uniform language

2.2.3. The assessments listed above are applicable for both general monitoring and a technical review of the testimony.

### 2.3. Supplemental feedback

2.3.1. In addition to the above methods of testimony review, feedback should be solicited from court officials, law enforcement personnel, or other non-laboratory personnel to assess the quality of the testimony from an end-user perspective.

## 3. Feedback to the Witness

3.1. Following documentation of the review, the reviewer shall provide feedback to the witness, preferably in person. The witness, reviewer, Section Chief, and Laboratory Chief shall initial and date the record of review to acknowledge the substance of the review and that the feedback was provided to the witness; to ensure management is aware of the review; and to ensure compliance with any required notifications.

3.2. If there are concerns regarding the testimony, a risk assessment will be conducted in accordance with *ATF-LS-8.5 Actions to address risks and opportunities*.

3.2.1. If the testimony review indicated a substantive violation of DOJ criteria, then notifications to ATF counsel and the prosecutor shall be made in accordance with the *Department of Justice Testimony Monitoring Framework*.

## 4. Records

4.1. Court appearances shall be documented in the case record.

4.2. Testimony reviews shall be documented on *ATF-LS-F-7.7.2 Testimony Review Form* or the electronic equivalent. All records of testimony review shall document that the



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required elements were reviewed. Testimony review and supplemental feedback records shall be maintained by the laboratory in accordance with *ATF-LS-8.4 Control of records*.

- 4.3. Other records relating to testimony shall be maintained in the case record. Examples of these types of records include the subpoenas, any transcripts received, and any pre-testimony summaries provided by the witness to the court.



ATF-LS-7.7.3 Performance monitoring program policy	ID: 7010 Revision: 6
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## 1. Policies

1.1. Laboratory Services shall maintain a performance monitoring program, including a performance monitoring plan based on each laboratory's accreditation scope.

1.1.1. Each laboratory shall administer at least one external proficiency test in each discipline annually, where available.

1.1.2. The performance monitoring plan should address, to the maximum extent possible, the components, parameters, items, equipment, and technologies listed on the scope of accreditation for each discipline within the accreditation term (i.e., every 4 years).

1.1.2.1. The performance monitoring plan should account for these required tests. Each test does not have to include all aspects of the work performed each time.

1.1.3. All personnel shall successfully complete at least one interlaboratory comparison, proficiency test, or intralaboratory comparison per calendar year in each discipline in which they are authorized to work.

1.1.3.1. Solely performing verifications is considered to be testing and is subject to these requirements.

1.1.4. Monitoring the types of activities that do not entail analytical results, opinions, or interpretations and that are not included within the laboratory's scope, such as swabbing or test-firing, may be accomplished via a variety of means. Case file review or direct observation can be used to monitor these types of activities. These means of monitoring shall be done by personnel who are authorized to perform the activity.

1.1.5. For Forensic Biology, the performance monitoring program shall ensure that the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* are met.

1.1.5.1. The performed date shall be defined as the date the proficiency test was distributed by Quality Programs. For Forensic Biology, one test must be performed in the first six months of the year and a second test in the last six months of the year. The interval between tests must be at least four months but no longer than eight months.





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- 1.2. The program shall be monitored by Quality Programs and laboratory management to ensure the fulfillment of these requirements.
    - 1.2.1. The performance monitoring plan shall coincide with the requirements of accreditation and will address the range of accredited testing services. The plan should include nonaccredited services and the various types of evidence and/or examination scenarios that are associated with each discipline. The plan is subject to change as needed.
    - 1.2.2. All tests shall be completed within the calendar year. For tests taken at the end of the calendar year, the evaluation can occur in the subsequent calendar year.
    - 1.2.3. The performance monitoring records maintained by Quality Programs shall be reviewed and kept current. These records shall be available to top management.
  - 1.3. Quality Programs shall serve as the primary point of contact for all external test providers.
  - 1.4. Proficiency tests shall be obtained from external providers that can fulfill the laboratory's requirements, specifically the simulation of casework.
    - 1.4.1. When possible and appropriate, tests shall be obtained from a competent provider as defined by the laboratory's accreditation service provider.
  - 1.5. Quality Programs, in coordination with Laboratory Chiefs, shall gain approval from the accrediting body prior to acquiring tests from nonaccredited test providers, and observation-based performance monitoring.
    - 1.5.1. When the requirements of 1.4.1 cannot be met, tests will be designed and administered by qualified Laboratory Services personnel who are or have been authorized to perform the activity or testing (i.e., an intralaboratory comparison). Personnel involved in the design or manufacture of the test cannot be a test participant.
    - 1.5.2. Additional tests may be conducted.
2. Procedure
    - 2.1. Refer to *ATF-LS-7.7.3.1 Performance monitoring process*.
    - 2.2. Responses to the accreditation service provider shall be succinct and timely. Any requested records shall be provided by the laboratory. The response will be coordinated



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between the Laboratory Chief and Quality Programs. Quality Programs shall maintain a record of all communications.

### 3. Records

3.1. Case records shall include the technical records and the test evaluation records. All other program records shall be maintained by Quality Programs.

3.2. Records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



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## 1. General

### 1.1. The performance monitoring process requirements are as follows:

- expected results shall not be known or readily available to the test participant until after the test has been completed;
- criteria shall be established for successful completion prior to the administration of the test;
- a mechanism shall be employed to ensure the quality of a test prior to administration such as preliminary testing for chemical, electrical, and mechanical analyses, and/or third-party observation of test sample preparation;
- tests shall be conducted like casework including the creation of a case record and the use of approved test methods to the extent possible;
- the results shall be evaluated against the expected results and feedback provided to the test participant.

## 2. Planning

### 2.1. Near the end of the fiscal year, Quality Programs shall coordinate with the Laboratory Chiefs to arrange performance monitoring tests for the next calendar year.

2.1.1. When possible, alternating test participants should be considered. This facilitates the availability for technical reviews and verifications by authorized personnel who are not participants in the test being reviewed.

### 2.2. Quality Programs shall manage the performance monitoring test procurement records. After the initial subscription, additional tests may be ordered during the year at the request of laboratory management.

### 2.3. Quality Programs is responsible for ensuring that tests meet the requirements of the program prior to the test administration.

## 3. Administration

### 3.1. Tracking

3.1.1. Quality Programs shall assign a unique identifier to each test, in lieu of the investigation number. The unique identifier should incorporate the provider's test designations.

### 3.2. Distribution

3.2.1. Each test shall be designated with a laboratory case number.



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3.2.1.1. Records for observation-based performance monitoring shall be associated with a laboratory case number to maintain the associated technical records.

3.2.2. A test shall be accompanied by any test provider's forms and an internal coversheet that includes the test specifics, such as the unique identifier and the due date. The test scenario provided by the supplier constitutes the request for examination.

3.2.3. Tests will be assigned to test participants based on the performance monitoring plan and in accordance with *ATF-LS-7.1 Review of requests, tenders and contracts*.

3.2.4. Section Chiefs are responsible for the timely completion of performance monitoring tests.

### 3.3. Examination

3.3.1. To the extent possible, test participants will work the performance monitoring test as if it were an actual case examination.

3.3.1.1. Tests shall be accommodated with reasonable and logical exceptions to the administrative procedures due to the nature of the testing process.

3.3.1.1.1. Case acceptance notifications to the customer are not required for performance monitoring tests.

3.3.1.1.2. Section Chiefs can require completion of a test by all test participants prior to conducting verifications and/or technical reviews.

3.3.1.1.3. Information may be included in the test submission that is normally not reported in order to meet test requirements.

3.3.1.2. While it is recognized that collaboration and/or consultation on an examination may be a best practice for case examinations, test participants shall consult with the Section Chief prior to such activities on performance monitoring tests to preserve objectivity to the maximum extent possible.

3.3.1.3. If there is an issue with the test, the test participant shall notify their Section Chief. If necessary, Quality Programs may contact the test provider. When a test provider is contacted about a test in progress, the communication shall be documented in the technical record. If appropriate, the relevant Laboratory



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Chief(s) shall be advised of the communication. A test participant may not communicate with a test provider about a test in progress.

3.3.1.3.1. Quality Programs may request a limited extension from a test provider, but this is expected to be a rare occurrence. The test provider will notify the accreditation service provider of the extension.

3.3.1.4. All communications shall be noted.

3.3.2. The test participant shall ensure the test provider's request for examination has been addressed, including the completion of any accompanying forms. When laboratory procedures do not permit the fulfillment of a request, the reason shall be noted.

#### 3.4. Reviews

3.4.1. Technical and administrative reviews shall be conducted in accordance with *ATF-LS-7.7.1 Review of case records, reports and notifications*.

3.4.1.1. In instances where the Section Chief is a test participant, another Section Chief or the Laboratory Chief will manage the reviews.

#### 3.5. Authorization and Submission

3.5.1. If a test result is to be disclosed to the accreditation service provider by the test provider, it shall be authorized by the Laboratory Chief.

3.5.2. The final submission of online forms to the test provider cannot occur prior to the authorization by the Laboratory Chief. If necessary, Quality Programs can recall a submission.

3.5.3. Test results shall be submitted to the test provider by Quality Programs on or before the due date via the mechanism stipulated by the provider.

#### 3.6. Evaluation

3.6.1. Test providers shall supply Quality Programs with the test manufacturer's summary report and individual test report.

3.6.2. For internal performance monitoring tests, the manufacturer information shall be provided to Quality Programs prior to the distribution of a test. When there are



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three or more participants in a test, a summary report shall be prepared to include the expected results and all reported results.

- 3.6.3. The test provider's reports shall be made available to laboratory management at the conclusion of a test.
- 3.6.4. The Section Chief shall evaluate the test and provide feedback to the test participant. This review shall be documented.
  - 3.6.4.1. Successful completion generally means obtaining the expected results. For observation-based tests, this means completing activities in accordance with the technical procedure.
    - 3.6.4.1.1. If a test participant's submitted results are not consistent with the expected results, the discrepancy shall be evaluated in accordance with *ATF-LS-8.5 Actions to address risks and opportunities*.
  - 3.6.4.2. If a nonconformity has been identified, refer to *ATF-LS-7.10 Nonconforming work policy*.
  - 3.6.4.3. Following evaluation of the test, the Section Chief shall inform Quality Programs of the test status.
- 3.6.5. Forensic biology performance monitoring tests shall be evaluated in accordance with criteria specified in the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.
- 3.6.6. When necessary, laboratory management may initiate an investigation to address any potential nonconformities prior to the receipt of the test provider's summary report.
- 3.6.7. When the Section Chief is a test participant, the evaluation shall be conducted by another Section Chief or the Laboratory Chief.

#### 4. Disposition

- 4.1. Tests shall be returned to Evidence Control upon submission of test results.
- 4.2. Following receipt of the test provider's report and the determination that the test has been successfully completed or remediated, the test items shall be disposed of or retained for training purposes. If retained, they are considered destroyed.



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## 5. Records

5.1. The technical records shall be maintained in a case record.

5.2. The following records shall be maintained for each performance monitoring test.

- Discipline monitored
- Test provider's information, including test design
- Expected results
- Records submitted to the test provider
- Appropriate technical records, i.e., case records
- Evaluation of results
- Actions taken for unexpected results
- Feedback provided to the examiner

5.3. The Laboratory Chief shall be responsible for any records relating to corrective actions. When resolved, Quality Programs shall be notified.

5.4. Quality Programs shall document that each laboratory's plan and summary of results were reviewed at least annually. This record shall be maintained by Quality Programs and shall include area of testing, test provider information, test identifier, test distribution information, name of the test participant, test submission information, and the test status.

5.4.1. Examples of test status include successful, under investigation, unsuccessful, remediated (with cross-reference to subsequent tests), incomplete, and cancelled.



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## 1. General

- 1.1. When the requested examinations and/or tests have been completed, the examiner will issue a report of the findings. The report shall be accurate, objective, and unambiguous.
  - 1.1.1. A completed test or examination is one in which the request has been fully addressed and a result, conclusion, or opinion has been recorded in the technical records.
- 1.2. Through a general agreement with ATF Field Operations, the ATF Laboratories issue simplified reports of results. Detailed information listed below is maintained in the case record.
  - 1.2.1. Date of receipt of the evidence.
  - 1.2.2. The date(s) of performance of the laboratory activities
  - 1.2.3. Laboratory activities conducted at another ATF laboratory facility
  - 1.2.4. Specific methods applied to the evidence; additions to and deviations or exclusions from examination methods.
- 1.3. The report shall address the Laboratory Examination Request and include the information required by the approved technical methods (e.g., the interpretation of test results) as necessary. Refer to technical documents for more specific guidelines for reporting.
  - 1.3.1. When the customer cancels an examination in progress, the report shall note the customer's request to cancel the examination as the justification for partial testing.
  - 1.3.2. Refer to *ATF-LS-7.5 Technical records* regarding cancellation requests that occur prior to testing.
- 1.4. Forensic Science Laboratory reports should not include photographs or diagrams; however, in unusual circumstances when photographs or diagrams are necessary to add clarity, they may be included as an appendix. In these situations, the Results of Examination section must reference the appendix.
- 1.5. If a report includes multiple authors, the content shall clearly indicate the work for which each examiner is responsible.





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1.6. Reports shall include an accreditation reference unless reporting results for non-accredited services.

1.6.1. Accredited and non-accredited services shall not be within the same report.

1.7. The report shall undergo review in accordance with *ATF-LS-7.7.1 Review of case records, reports, and notifications*.

1.8. The laboratory is responsible for all information provided in the report, except when information is provided by the customer. Data material to the examinations that is provided by the customer shall be clearly identified and a disclaimer shall be included when that information affects the validity of the results.

1.9. A report shall clearly identify examination results that are supplied by a subcontractor. Refer to *ATF-LS-6.6 Externally provided products and services* for more specific reporting requirements.

1.9.1. The Laboratory Services report shall not refer to the accreditation status of a subcontracted laboratory.

1.9.2. Approval shall be obtained from the subcontractor if excerpts from their reports are used within a Laboratory Services report. This approval may be part of the contract or documented on a case-by-case basis.

1.10. Report distribution

1.10.1. The report with the original signature of the examiner, handwritten or digital, shall be sent to the customer.

1.10.2. A copy of the report shall be retained in the case record.

1.10.3. Copies of reports may be distributed to the relevant prosecutor or field office. Additional copies of the report may be distributed outside of Laboratory Services as authorized by the customer. Refer to *ATF-LS-4.2 Confidentiality* for additional distributions.

2. Report format

2.1. The established Laboratory Services report formats shall be used.



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2.2. If the accreditation requirements cannot be met in the report due to legal requirements or sensitivity classifications, documentation of any such requirements shall be included in the case record.

3. Reports generally require the following sections; additional sections may be included as necessary.

### 3.1. Header

3.1.1. Name and address of the laboratory.

3.1.2. Accreditation reference, including the name of the accrediting body, except where omission is required by section 1.5.

3.1.3. Title: Laboratory Report.

3.1.4. Customer information: Name, title, agency, and address.

3.1.5. Report date: the date the report was completed.

3.1.6. Laboratory case number.

3.1.7. Reference to Investigation Number or other agency case number.

3.1.8. Title of Investigation.

3.1.9. Type of Exam: discipline of testing.

3.1.9.1. Multiple types of examinations may be consolidated in a report when the author is authorized to perform the examinations.

3.1.9.2. Preliminary, supplemental, or amended reports shall be identified as such under the type of exam.

### 3.2. Exhibits

3.2.1. All items received by the examiner shall be listed. When no physical evidence is submitted, this section is not required.



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3.2.1.1. A lab-separated or lab-generated item not a subject of the discipline being reported does not need to be listed. This includes laboratory sub-designated items transferred only for chain of custody.

3.2.2. Both the LIMS-generated item number and the customer's item number will be listed. The description of items will generally correspond with the Laboratory Examination Request unless the original description is incorrect.

3.2.2.1. The condition of an item shall be included when it is relevant to the interpretation of the results.

### 3.3. Results of Examination

3.3.1. When only a portion of the items received have been tested, the report shall include a statement to the effect that the results relate only to the items tested.

3.3.2. The report shall address all items listed.

3.3.2.1. The LIMS-generated item number shall be used to identify items. The customer's item number may be used as a supplemental identifier.

3.3.3. The report shall communicate the examination findings, opinions, and/or interpretations.

3.3.3.1. Units of measurement shall be included where appropriate. When a measurement is used as a general descriptor, reporting an uncertainty is not required.

3.3.3.2. The test or environmental conditions shall be documented in the report if they affect the interpretation of the results.

3.3.4. The creation of lab-separated and lab-generated evidence shall be reported by the examiner that creates the sub-exhibit in LIMS or by an examiner within the associated discipline.

3.3.4.1. The following sub-exhibits created for DNA analysis will be reported by a DNA examiner: hair roots, DNA extracts created from fired cartridge cases.



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- 3.3.5. The following statement will be included at the end of this section in reports for the testing areas in which the Department of Justice has a Uniform Language for Testimony and Reports (ULTR) in effect.

*These conclusions conform with the relevant Department of Justice policy on Uniform Language for Testimony and Reports available at [www.justice.gov](http://www.justice.gov).*

- 3.3.6. Sub-sections may be included.
- 3.3.7. A general description of the method(s) used for testing shall be listed for all items tested in accordance with discipline requirements.
- 3.3.8. For items that were not tested, it is not necessary to list “No Analysis” as a general description, if it is clear elsewhere in the report that testing was not performed. This includes sub-items that were separated or created which will be the subject of a separate report.
- 3.3.9. Significant variations to the approved test methods, including additions, deviations, or exclusions, are included in the case record.

#### 3.4. Disposition

- 3.4.1. Disposition section may be omitted if no evidence was received.
- 3.4.2. A brief statement describing the disposition of the items, including lab-separated and lab-generated items, will be included in all laboratory reports involving physical evidence.
- 3.4.3. When only the item packaging is to be returned to the customer, this section shall include a statement regarding the disposition of the actual item (e.g., its consumption in analysis or its destruction).

##### 3.4.3.1. Examples:

The items will be returned to the customer upon completion of all requested examinations.

The exhibit was consumed in analysis.



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The powder in exhibit X will be destroyed. The original packaging for exhibit X will be returned with the remainder of the evidence.

### 3.5. Signatures

3.5.1. The report shall have the name, title, and signature of the examiner, the technical reviewer, and the administrative reviewer.

3.5.1.1. The signature of the examiner authorizes the results.

3.5.1.2. The administrative reviewer's authorization of the release and issuance of the report is documented by their dated signature on the report.

3.5.2. Digital signatures are permitted only when the document cannot be modified after the digital signature has been applied or when the software makes it evident that the document has been modified.

3.6. Appendices may be used to provide clarification for information provided in the report or supplemental information.

## 4. Other required information

4.1. Page numbering: Multi-page reports shall be paginated at the bottom center of the page along with the total number of pages to signify the end of the report, e.g., Page 1 of 3, Page 2 of 3. Appendices and other information that appear after the signature page must be included in the numbering.

4.2. The laboratory case number shall be on each page of the report.

4.3. If examinations occurred at a non-ATF laboratory, the name, city, and state of that laboratory shall be included in the report.

4.4. Explanations or qualifying information shall be included under the following circumstances.

4.4.1. Presumptive results

4.4.1.1 The report shall clearly identify when a test result is presumptive.

4.4.2. Significance of associations



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4.4.2.1. The significance of associations shall be properly qualified in the report as defined within the technical reporting documents and in general accordance with the forensic discipline. When appropriate, the results may be qualified by a single statistic or qualitative statement.

#### 4.4.3. Inconclusive or uninformative results

4.4.3.1. When no definitive conclusion can be reached, the report shall clearly communicate the reason.

4.5. Sampling activity and uncertainty of measurement must be included in reports per the accreditation requirements.

4.5.1. If evidence has been submitted to the laboratory that was collected using a formal sampling plan and presented to the laboratory by the customer as a sample representative of the whole, it shall be stated that the results apply only to the sample received and cannot be extrapolated to the untested whole. This does not apply to most evidence submitted to the laboratory, which is commonly submitted as best evidence, not as representative evidence.

### 5. Other reports

5.1. A preliminary report of partial examinations may be issued prior to the final report. A preliminary report may be necessary when time-sensitive investigative information must be communicated prior to the completion of the requested examination.

5.2. A supplemental report shall include a reference to the original report. A supplemental report may be necessary when additional examinations or information needs to be reported.

5.3. Amended reports shall communicate any changes to the original report. Material changes that affect the examination results require an amended report. Nonmaterial changes, such as typographical corrections, require documentation in the case record but do not always require an amended.

5.3.1. The original version of the report in the laboratory case record shall be clearly marked that it has been replaced by the amended version. When the original version of the report is stored electronically, annotation in the LIMS may serve to indicate that it has been replaced by an amended version.



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5.4. Preliminary, supplemental, and amended reports are written, distributed, and maintained in the same manner as final laboratory reports.

5.5. The type of report will be included under the Type of Examination in the report header.

5.6. A statement before the Exhibits section shall include the justifications for preliminary, supplemental, or amended reports.

5.7. Additional technical reviews are not necessary on amended reports that do not affect technical results.

## 6. Activity Notifications

6.1. Notifications, such as for DNA collection completion or database association, are not reports.

6.2. Notifications, such as for DNA collection completion or database association, may be sent via email or as a memo with a copy of the correspondence retained in the case record in accordance with *ATF-LS-8.4 Control of records*.

6.3. Initial database entries (e.g., NGI, CODIS) shall be included in the relevant laboratory report. Searches that result in an association shall be communicated to the customer by either a report, official memorandum, or notification.

## 7. Preliminary release of results

7.1. Information related to interpretations and results that are subject to change during the review process, may be communicated to the customer prior to issuing a final report. The customer shall be informed that the results are preliminary, pending review, and should not be considered final until an official ATF Laboratory report is issued.

7.1.1. If information related to interpretation and results is released it will be recorded in the case communications log.

7.1.1.1. A disclaimer similar to the following will be included in email communications to the customer.

“The information provided in this email is still pending review and should not be considered final until an official report from the ATF Laboratory is issued.”



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7.2. Verification of results, when required by discipline specific procedures, shall be completed and documented prior to the release of any preliminary results. Exceptions must be authorized and documented in the case record.





ATF-LS-7.9 Complaints	ID: 7012 Revision: 3
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## 1. General

- 1.1. Complaints received by Laboratory Services or Quality Programs from internal or external sources regarding any aspect of the laboratory's operations are taken seriously and shall be evaluated, investigated, and resolved.
- 1.2. The Laboratory Chief is responsible for handling complaints within their lab. The Deputy Assistant Director, Forensic Services, is responsible for handling complaints that affect all of Laboratory Services or Quality Programs.
- 1.3. Top managers shall track received complaints to ensure resolution. An annual review of complaints shall occur according to *ATF-LS-8.9 Management reviews*.
- 1.4. Laboratory personnel shall cooperate with the investigator.
- 1.5. Internal complaints originate from Laboratory Services and Quality Programs personnel. This includes complaints about the management system documents and processes.
  - 1.5.1. Requests for document changes do not necessarily constitute a complaint. These shall be handled according to *ATF-LS-8.3 Management system documentation*.
- 1.6. External complaints originate from customers and other sources.
  - 1.6.1. Routine monitoring of casework and customer service may result in negative feedback regarding turnaround times or other issues. While it is recognized that this feedback should be addressed, it will not necessarily require the implementation of this procedure.

## 2. Procedure

- 2.1. Refer to the *ATF-LS-7.9.1 Complaints process*.

## 3. Records

- 3.1. Complaints shall be documented on the *ATF-LS-F-7.9 Complaint form*.
- 3.2. All associated records received or generated in relation to the complaint shall be retained as part of the complaint record.
- 3.3. Complaint records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-7.9.1 Complaints process	ID: 7013 Revision: 4
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## 1. General

- 1.1. The Laboratory Services policies regarding complaints are in *ATF-LS-7.9 Complaints*. This document defines the process for the receipt, evaluation, investigation, response, and resolution of complaints.
- 1.2. If the complaint is determined to be valid, it shall be referred to top management.
- 1.3. Top management may designate supervisors, the Quality Manager, or other laboratory personnel to facilitate any part of the process.

## 2. Receipt

- 2.1. Laboratory Services and Quality Programs personnel shall record complaints on the *ATF-LS-F-7.9 Complaint form*.
- 2.2. Complaint submission should follow the chain of command.
  - 2.2.1. If complaints are communicated directly to the Laboratory Chief, the immediate supervisor shall be informed.
- 2.3. The Laboratory Chief or the Deputy Assistant Director, Forensic Services shall acknowledge receipt of a complaint and retain a record of the communication with the complainant.

## 3. Evaluation

- 3.1. An initial evaluation conducted by the supervisor or manager that receives the complaint shall determine if the complaint relates to laboratory activities. They shall gather and verify all necessary information to validate the complaint.
- 3.2. If the complaint is not deemed valid, this process shall terminate with a notification to the complainant and the relevant top manager with documentation of the reason in the complaint record.

## 4. Investigation

- 4.1. If the complaint is valid, the supervisor, the Quality Manager, or their designee shall investigate the complaint.
- 4.2. The complaint record shall note all actions taken and relevant factors.



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## 5. Response

- 5.1. An action plan shall be developed, which should include a time frame for completion.
- 5.2. As appropriate to the complaint, the top manager shall review the plan prior to execution.
- 5.3. If the investigation identifies a nonconformity, refer to *ATF-LS-7.10 Nonconforming work policy*.

## 6. Resolution

- 6.1. A top manager shall review the assembled complaint record and is responsible for the final resolution. This shall be documented in the complaint record.
  - 6.1.1. When the top manager is directly involved in the subject of the complaint, they shall be recused from the review and approval process.
  - 6.1.2. Notification to relevant members of the management team should take place before the final resolution.
- 6.2. When possible, progress reports and the outcome shall be communicated to the complainant. These communications shall be documented in the complaint record.
  - 6.2.1. The individual directly involved in the subject of the complaint shall be recused from communicating the outcome to the complainant.



ATF-LS-7.10 Nonconforming work policy	ID: 7014 Revision: 4
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## 1. General

1.1. When the laboratory operations do not conform to the management system requirements, the accreditation requirements, or any customer-specified requirements, Laboratory Services shall investigate to determine the impact and possible course of action.

1.1.1. The response to a nonconformity will be based upon the impact and potential for recurrence. Types of responses are based on lab-established risk levels and include concession, correction, and corrective action.

1.2. The nonconforming work process ensures that:

- the responsibilities and authorities are defined;
- the risk level of the nonconforming work is evaluated, including any impact on previously reported results;
- a decision is made by laboratory management on the risk level of the nonconforming work;
- when necessary, the customer is notified, and work is recalled;
- the responsibility for authorizing the resumption of work is defined.

1.3. Non-conforming work is categorized as the following risk levels.

### 1.3.1. Concession

1.3.1.1. A concession occurs when a nonconformity causes a negligible or tolerable impact, and it is determined that no action is deemed necessary.

### 1.3.2. Correction

1.3.2.1. A correction is a response to a nonconformity that has manageable consequences that can be addressed with a simple remedy. It generally is applied to the specific nonconformity and does not address the process. There is a minimal likelihood of recurrence.

1.3.2.2. Multiple, related, or similar corrections may rise to the level of a corrective action.

### 1.3.3. Corrective action

1.3.3.1. A corrective action is appropriate when there is a moderate to high impact or risk of recurrence. A corrective action is intended to address not only the specific nonconformity but also its root cause in order to minimize the likelihood of recurrence. Refer to *ATF-LS-8.7 Corrective Actions*.



ATF-LS-7.10 Nonconforming work policy	ID: 7014 Revision: 4
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## 2. Procedure

2.1. Refer to *ATF-LS-7.10.1 Nonconforming work process*.

## 3. Records

3.1. Laboratory Services shall prepare and retain records of nonconforming work and the actions taken. This shall include a reference to the relevant management system requirement, a description of the observed nonconformity, and the response.

3.2. All records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.

3.2.1. Nonconformity records related to an individual laboratory shall be maintained by the Laboratory Chief.

3.2.2. Nonconformity records related to the Laboratory Services system shall be maintained by the Quality Manager.



ATF-LS-7.10.1 Nonconforming work process	ID: 7015 Revision: 4
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## 1. General

- 1.1. Internal monitoring mechanisms, external audits for accreditation, complaints, or customer feedback may disclose a nonconformity.
- 1.2. When notifications outside of Laboratory Services regarding nonconforming work are necessary, they shall be documented.
  - 1.2.1. The Deputy Assistant Director, Laboratory Chief, and Quality Manager shall be notified prior to contacting the accrediting service provider regarding nonconforming work.
- 1.3. If an issue does not violate a specific management system requirement but raises awareness of a potential improvement, refer to *ATF-LS-8.5 Actions to address risks and opportunities*.
- 1.4. Responsibilities and authorities
  - 1.4.1. All personnel have the responsibility to report nonconforming work and are authorized to stop work when the quality of technical work has the potential to be adversely affected.
  - 1.4.2. Section Chiefs are responsible for assigning responsibility for the management of nonconforming work that falls within their span of control. They are authorized to withhold reports and to approve corrections and referrals to the corrective action process for such nonconformities. For disciplines other than Forensic Biology, they are authorized to resume work and release reports for their respective disciplines.
    - 1.4.2.1. For the Forensic Biology discipline, the DNA Technical Leader is authorized to initiate, suspend, and resume analytical operations or an individual's work; to withhold reports; and to release withheld reports.
  - 1.4.3. Quality Programs is responsible for providing guidance, as needed, throughout the process. The Quality Manager is responsible for assigning responsibility for the management of nonconforming work that relates to Quality Programs or the Laboratory Services system. The Quality Manager is authorized to approve corrections and referrals to the corrective action process for such nonconformities.
  - 1.4.4. Laboratory Chiefs are responsible for assigning the management of nonconforming work that affects more than one section of the laboratory. They are authorized to withhold reports and to approve corrections and referrals to the corrective action process. These authorities may be delegated to a member of the management team.



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## 2. Procedure

### 2.1. Identification and initial documentation

2.1.1. When a nonconformity is identified, a manager shall be notified.

2.1.1.1. Responsibility for addressing the nonconformity shall be assigned by management based on the nature and scope of the nonconformity.

### 2.2. Preliminary investigation and immediate action

2.2.1. A preliminary investigation shall determine the impact of the nonconformity and the potential for recurrence. This investigation shall determine if casework has been adversely affected or if the nonconforming work could adversely affect future casework.

2.2.2. Immediate corrections to address the nonconformity or to prevent additional recurring nonconformities are made at this step.

2.2.3. It may be necessary to stop work or withhold reports. When possible, the Section Chief and Technical Leader will be consulted prior to stopping work; however, the Section Chief must be notified as soon as possible.

### 2.3. Evaluation

2.3.1. Following the preliminary investigation, an evaluation shall be conducted to determine the risk level of the nonconformity. The evaluation process should consider the following:

- effect on the work product,
- impact on previous results,
- impact on the integrity of evidence,
- effect on customer service,
- frequency of occurrence and the potential for recurrence,
- impact on the laboratory's ability to meet its mission, and
- other relevant factors.

2.3.2. The evaluation may involve consultations with appropriate personnel, such as a Section Chief, Laboratory Chief, Technical Leader, Quality Manager, and Primary Instrument Operator depending on the nature and scope of the nonconformity.



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2.3.3. Based on the evaluation of the impact and the likelihood of recurrence, a determination shall be made regarding the risk level as defined in *ATF-LS-7.10 Nonconforming work policy*.

## 2.4. Response

### 2.4.1. Concession

2.4.1.1. No action is required.

### 2.4.2. Correction

2.4.2.1. An action to address the specific nonconformity shall be taken.

2.4.2.1.1. For a minor issue such as an administrative error on an issued report, notification of the Section Chief or designee shall suffice. This notification shall occur through the normal process of issuing the amended report.

2.4.2.2. Laboratory management shall approve corrections.

### 2.4.3. Corrective action

2.4.3.1. An action to correct the nonconformity shall be taken in accordance with *ATF-LS-8.7 Corrective actions*. A root cause analysis is required.

2.4.4. Detected nonconformities shall be documented and should be tracked. Tracking of corrective actions should also include monitoring their progress to ensure timely completion or modification of the plan, if necessary.

2.4.5. If Forensic Biology work was stopped or reports withheld and the immediate correction addressed the problem, then the DNA Technical Leader shall authorize the resumption of technical work and release of reports. For work stoppages in other disciplines, the Section Chief shall authorize the resumption of technical work and release of reports.

## 3. Records

### 3.1. Concessions and Corrections

3.1.1. When a nonconformity is resolved as a concession or correction, the documentation may be brief, such as an entry in a spreadsheet or table. The record shall include the following:





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- a description of the nonconformity,
- a reference to the management system requirement,
- an explanation of the correction applied or justification for the categorization as a concession, and
- approval.

3.1.2. The correction record shall include all relevant supporting documentation or copies thereof.

### 3.2. Corrective actions

3.2.1. Corrective actions shall be documented on the *ATF-LS-F-8.7 Corrective Action Report*.

3.2.2. The corrective action record shall include all relevant supporting documentation or copies thereof.



ATF-LS-7.11 Control of data and information management	ID: 7074 Revision: 4
Authority: Deputy Assistant Director, Forensic Services	Page: 1 of 2
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## 1. General

1.1. Laboratory Services shall ensure the data and information collected and maintained in software applications is secure and available to perform the laboratory activities.

1.2. The following requirements apply to the security of software applications and the electronic records that reside on the ATF network. These requirements do not apply to equipment with computers that are not connected to the ATF network.

*ATF O 1340.5 Records Management Program*

*ATF O 1340.11 ATF Records and Information Management Certification*

*ATF H 7250.1 Automated Information System Security Program*

*ATF H 7200.2 Systems Life Cycle Handbook*

1.3. The Information System Security Office (ISSO) is responsible for the system security accreditation.

## 2. System security accreditation

### 2.1. Authorization to Operate (ATO)

2.1.1. A current ATO from the ISSO is required for the operation of Laboratory Services applications to create, capture, store, and access electronic records; these include Qualtrax and StarLIMS, which are commercial-off-the-shelf (COTS) applications, and FireTOSS, which is Government Off-The-Shelf (GOTS).

2.1.2. The ATO ensures that the security requirements have been met or remediated for the governance, assessment, protection, validation, response, monitoring, detection, and training of responsible parties.

2.1.2.1. The ATO demonstrates that an application on the ATF IT system:

- is protected from unauthorized access;
- is safeguarded against tampering and loss;
- is operated in compliance with DOJ and ATF requirements;
- is maintained in a manner that ensures the integrity of the data and information;
- is accountable, requiring back-ups, for the recording of failures and documentation of appropriate immediate and corrective actions; and
- has instructions readily available for administrators and users.

2.1.3. The ATO and supporting documentation are maintained by the ISSO.

## 3. IT system and software changes



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- 3.1. Any changes to the software configuration or modifications to COTS software shall be authorized, documented, and validated before implementation.
  - 3.2. Application installations and changes shall be documented.
  - 3.3. COTS software in general use within its designed application range is considered sufficiently validated. Validation records for user-developed software shall be maintained by the laboratory.
4. Data transfers and calculations
- 4.1. Calculations and data transfers that may be subject to human error shall be verified and the verification shall be documented.
    - 4.1.1. Macros and other non-COTS software that perform calculations or data transfers shall be verified prior to use in casework and the verification shall be documented.
    - 4.1.2. Calculations and data transfers performed manually for a specific case are checked as part of the technical review.



ATF-LS-8.2 Management system documentation	ID: 7095 Revision: 4
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## 1. General

- 1.1. Laboratory Services shall establish, document, and maintain controlled documents related to the requirements of the management system.
- 1.2. Laboratory management shall ensure the management system requirements are acknowledged and implemented at all levels of the laboratory organization.
- 1.3. The following terms require Laboratory Services documentation (e.g., controlled documents, records): agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.
- 1.4. Maintenance of the document control program will ensure the competence, impartiality, and consistent operation of Laboratory Services. This commitment is demonstrated with the Qualtrax records. Laboratory management may provide interpretation guidance as necessary.
- 1.5. Laboratory management shall be committed to the development and implementation of the management system by periodic review of management system documents.
- 1.6. All personnel involved in laboratory activities shall have access to the controlled documents related to their responsibilities.

## 2. Procedure

- 2.1. Qualtrax is used to record and maintain management of controlled documents through the following:
  - Creation of new and revised controlled documents
  - Review and approval process, including designated user authorities (e.g., Document Manager)
  - Distribution and retention
- 2.2. References
  - *Qualtrax Basic User Quick Reference Guide*
  - *Qualtrax Advanced User Quick Reference Guide*
  - *ATF-LS-8.3 Control of management system documents*

## 3. Records



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- 3.1. Records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.
- 3.2. Designated Qualtrax user authorities are assigned by the Laboratory Services Deputy Assistant Director, Laboratory Chiefs, and the Quality Manager. They are recorded in the personnel profiles.
- 3.3. Only the latest revision of a document is approved for use and available for general use. Qualtrax retains obsolete documents in the archive history.
  - 3.3.1. Obsolete documents that must be kept for reference or for legal or contractual purposes are treated as records, identified, and stored.
- 3.4. Document revision history for internally controlled documents is noted in the document properties section of Qualtrax for all documents adopted and/or revised after the installation of the software. The revision history includes general notes of changes made during the revision process. Prior versions of documents may be retrieved by the Quality Manager.



ATF-LS-8.3 Control of management system documents	ID: 9600 Revision: 4
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## 1. General

- 1.1. Laboratory Services shall control internal documents related to the management system and operation of the laboratories in the procedure outlined in this document.
- 1.2. All laboratory personnel are responsible for identifying any controlled documents that may contain inconsistencies or require change.
- 1.3. Controlled documents are classified according to the following table.

Level	Scope	Type	Examples
1	Laboratory Services	Quality Manual	Management System Documents; Policies, Procedures, Forms
2	Disciplines / Areas of Testing	Discipline Technical Documents	Methods of Analysis: Standard Approach, Policies and Procedures; Training Manuals; All DNA technical documents
3	Users of specific laboratory technologies	Work Instructions / Test procedures (non-DNA)	Instrument use instructions; detailed procedures

- 1.4. Qualtrax and FireTOSS are authorized document control software systems and are the designated official storage locations for all controlled documents.
- 1.5. Controlled documents shall have a unique identifier, which is assigned by the document control software.
- 1.6. A record of the creation, review, approval, and distribution of controlled documents is maintained by the document control software.
- 1.7. Controlled copies of documents may be maintained outside of the document control software. Controlled copies outside of the official location must comply with the following:
  - 1.7.1. Controlled copies of documents shall be labeled as controlled copies.
  - 1.7.2. A list of all controlled copies of documents maintained outside of the document control software shall be maintained. The list shall include the location of the controlled copy, its version, and any other relevant information.



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1.7.3. Controlled copies maintained outside of the document control software shall be destroyed and replaced when new versions are published.

1.8. Copies outside of the document control software that are not in accordance with 1.7 and its subparts are considered uncontrolled.

## 2. Creation of a new or revised document

2.1. All laboratory personnel are authorized to recommend a new document or revision of a document.

2.2. All controlled documents will include the following information:

- unique identifier,
- approving authority,
- revision number or effective date, and
- pagination, including the total number of pages.

2.2.1. Discipline-Specific Documents (Level 2) should include the following information when applicable:

- Scope,
- Instrumentation/Reagents,
- Safety Considerations,
- Procedure or Analysis,
- Quality Assurance and Controls, and/or
- References.

## 3. Review and approval

3.1. Reviews and approvals will be performed in accordance with the following table, which outlines the responsibility and authority for each document level.

Level	Document Manager	Approving Authority
1	Quality Manager	Deputy Assistant Director, Forensic Services
2	Technical Lead	Technical Lead
3	Assigned Section Chief	Assigned Section Chief



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3.2. All controlled documents shall be reviewed according to the following schedule:

Level	Minimum frequency of review
1	Annually
2	Every 2 years*
3	Every 2 years

\*The review cycle for DNA documents shall conform with the requirements of the QAS.

3.3. Revisions may be more frequent than required by 3.2.

3.4. Level 1 and Level 2 documents generally have a two-week review period in Qualtrax prior to approval. Level 3 documents generally can be approved without a Qualtrax review period.

3.5. Additional individuals may be included in the review and approval process.

3.6. If following review, it is determined that no revisions are necessary, then the document shall be verified up to date within the document control software system.

3.7. The Document Manager should assess the effects of document revisions on other related documents.

3.8. The Qualtrax Administrator and the Quality Manager are authorized to make non-technical corrections (e.g., typographical errors, administrative header/footer information, formatting changes) to system documents. These corrections are tracked in Qualtrax and do not require approvals.

#### 4. Distribution

4.1. Upon publication, the new or revised documents are released and readily available to all laboratory personnel.

4.2. Current documents may be provided to third parties in accordance with *ATF-LS-4.2 Confidentiality*.

4.3. Depending upon anticipated usage, a disclaimer may be included outlining that the documents are:

- developed by and designed for Laboratory Services;
- not developed with the intent of setting a standard for other laboratories; and
- restricted from further distribution by anyone outside of ATF Laboratories.





ATF-LS-8.3 Control of management system documents	ID: 9600 Revision: 4
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4.3.1. Example:

The attached are controlled documents developed by Laboratory Services. These are internal, working documents, which were not developed with the intent of setting a standard for other laboratories. While these documents may be a helpful guide to other forensic laboratories in developing their management system requirements, they were designed for use specifically in ATF Laboratories. Our controlled documents are reviewed and revised at least annually, so to inhibit circulation of archived versions, further distribution by anyone outside of ATF Laboratories should be restricted.



ATF-LS-8.4 Control of records	ID: 7059 Revision: 5
Authority: Deputy Assistant Director, Forensic Services	Page: 1 of 6
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## 1. General

- 1.1. The preparation, retention, and disposal of Laboratory Services' quality, technical, and administrative records shall adhere to this procedure. Additional technical records requirements are in *ATF-LS-7.5 Technical records*.
- 1.2. The Laboratory Chief has the ultimate responsibility for the records produced by the laboratory.
- 1.3. The Laboratory Services requirements supplement the following ATF Orders.
  - *ATF O 1340.5 Records Management Program*
  - *ATF O 1340.7 ATF Records Control Schedule*
- 1.4. Documentation for all casework accepted under *ATF-LS-7.1 Review of requests, tenders and contracts* shall be addressed in the case record.
  - 1.4.1. If an alternate record storage location is used, the location shall be specified in the technical procedures or in the case record.
- 1.5. Quality records include policies and procedures related to the management of Laboratory Services.
- 1.6. Case records include administrative and technical records.
  - 1.6.1. Refer to the following for structure of the case records.
    - *ATF-LS-8.4.1 Forensic Science Laboratory case record structure*
    - *ATF-LS-8.4.2 Fire Research Laboratory project record structure*
- 1.7. Administrative records include chain of custody records, lab-generated communication, records received from customers, and case summaries. Data and information resulting from testing do not constitute administrative records.
  - 1.7.1. Chain of custody records include electronic LIMS records, control cards, action sheets, inter-laboratory evidence transfer forms, and other records of evidence transfer. These records shall be maintained as part of the case record.
    - 1.7.1.1. For FACETS cases, the control card(s) and action sheet(s) are used to document chain of custody within the laboratory. Control cards are maintained in the Evidence Control room during testing then stored in the case file following return of the evidence to the customer. Action sheets are maintained in the case file.



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- 1.7.2. Pertinent communications related to the case shall be maintained in the case record.
- 1.7.3. Casework summaries, including Rule 16 Expert Testimony Disclosure statements, shall be retained as case records. These summaries shall be subject to administrative review.
- 1.7.4. Changes to administrative records shall be done in accordance with the requirements in *ATF-LS-7.5 Technical records*.
- 1.8. Technical records are any records pertaining to the analysis and results of examinations, including verification records and signed reports.
  - 1.8.1. The requirements for technical records are in *ATF-LS-7.5 Technical records*.
- 1.9. Laboratory records shall be readily retrievable and retained in LIMS, FireTOSS, or designated file storage locations to prevent damage, deterioration, or loss.
- 1.10. Due to the transition from paper to electronic case records, the laboratory has both types. The requirements detailed in this document address the nature of each type of case record which applies to any case records with a combination of the two.
2. Identification and labels
  - 2.1. The individual creating or assembling a record is responsible for ensuring the proper identification and labeling of records according to this procedure.
  - 2.2. Quality records shall be readily identifiable to the task and shall be dated to when the task was performed.
  - 2.3. Case records shall include the laboratory case number.
    - 2.3.1. Submission numbers greater than one shall be included with the laboratory case number in administrative records only.
    - 2.3.2. When multiple hard copy case jackets are used for a single case, they shall be numbered to identify the sequence of the individual case file and total number (e.g., 1 of 2, 2 of 2).
  - 2.4. Administrative records



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2.4.1. Evidence Control personnel shall ensure that the Laboratory Exam Request Form 1441 or FRL Request Memo received by the laboratory is labeled with the ATF Investigation Number (IN).

2.4.2. The first page of each administrative records file shall be labeled with the laboratory case number or contained in the metadata.

2.4.3. When administrative records factor into the analysis and interpretation of the results, the labeling requirements for technical records shall apply.

## 2.5. Technical records

2.5.1. Each page of a record, including both sides of a two-sided record and envelopes that contain technical records, shall be labeled with the following information or available in the metadata for electronically-generated records.

- Laboratory case number
- Page with the total number of pages indicated on the first page

This includes paper records that will be scanned and uploaded to an electronic storage location.

2.5.2. For laboratory report requirements, refer to *ATF-LS-7.8 Reporting of results*.

2.5.3. Envelopes in the case record that contain technical records, such as photographs or storage media, shall be marked with the quantity and type of media that it contains.

2.5.4. The laboratory case number shall be associated with each photograph or electronic image. This may be done by creating a record that references the image file name to the case record (e.g., a contact sheet labeled with the laboratory case number).

2.5.5. Any technical records contributed by another Laboratory Services examiner who performed examinations, analyses, or testing for the case shall be initialed by both the examiner who conducted the work and the examiner responsible for the report.

## 3. Preservation of recorded observations and data

3.1. Recorded observations and data collected shall be preserved. These requirements shall apply to records in any media. Refer to *ATF O 1340.5 Records Management Program, mixed-media files*. These requirements are not intended to apply to contemporaneous changes that occur while the examination is in progress (e.g., notes taken electronically).



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- 3.2. Hand-written records shall be prepared with permanent media, except where discipline procedures recommend colored pencils or other non-permanent media.
- 3.3. Technical records originally captured in pencil (e.g., a rough sketch) can be supplemented in a permanent manner by photocopying, scanning, or taking a photograph.
- 3.4. Changes to the technical record and administrative case records shall be done in a manner that does not obliterate the original entry. Record changes shall be documented to identify what changed, by whom, and when.
  - 3.4.1. Changes made to paper records generally entails a strike-through with the correct information written adjacently. Both the original and the amended data files shall be retained.
  - 3.4.2. Changes made to electronically-stored case records must be identifiable, whether on the record itself or in the metadata. The individual making the change shall ensure that any corresponding paper copies are updated accordingly.
  - 3.4.3. Measures shall be taken to avoid loss or change of original, electronically-recorded data. Corrections may be on a paper copy, subsequently retained as an electronic record along with the original. Alternatively, a log associated with the record may be used to indicate any changes.
- 3.5. The examiner shall verify that electronic conversion of original records is complete and fully legible (correct document, pages appropriately numbered, all pages converted, no cropped or blank pages). The technical reviewer shall check that electronically-converted records are complete (e.g., the number of pages specified are present, the pages are legible and not cropped). The original records shall be maintained until after the technical review and administrative review are complete.

#### 4. Protections

- 4.1. Laboratory records shall be held secure and in confidence in accordance with *ATF-LS-4.2 Confidentiality*.
- 4.2. The Deputy Assistant Director, Forensic Services shall designate a Laboratory Services point of contact to the Office of Chief Counsel.
- 4.3. Accessibility
  - 4.3.1. Access to quality and technical records shall be limited.



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- 4.3.2. Access to official file storage locations shall be limited to personnel authorized by the Laboratory Chief.
- 4.3.3. Access to electronic file storage locations shall require password-protected user profiles.
- 4.4. Electronic files shall be periodically backed up.
- 4.5. Designated records custodians shall be responsible for the collection and maintenance of specific records or file storage locations, and for producing the records upon request.
5. Storage and retention
- 5.1. StarLIMS and FireTOSS are authorized storage for electronic records.
- 5.2. Existing case records shall be retained for a minimum of 50 years from when the laboratory case number was generated.
- 5.3. Quality records shall be maintained for a minimum of the previous and current accreditation cycles, unless noted below or superseded by ATF Orders.
- Personnel qualification records (ATF-LS-6.2) – *Term of employment plus four years*
    - Training, competency, authorization
    - Professional development
  - Equipment records (ATF-LS-6.4) – *Life of equipment*
  - Subcontractor qualification records (ATF-LS-6.6)
  - Vendor records for materials that matter (ATF-LS-6.6)
  - Method validation records (ATF-LS-7.2) – *Indefinite*
  - Evidence handling records (ATF-LS-7.4)
    - Evidence Control storage access records
    - Laboratory evidence inventory records
  - Review records
    - Case records (ATF-LS-7.7.1)
    - Testimony (ATF-LS-7.7.2) – *Four years*
  - Proficiency test records (ATF-LS-7.7.3)
  - Accreditation records (ATF-LS-8.2)
  - Document control records (ATF-LS-8.3) – *Indefinite*
  - Records of risks and opportunities (ATF-LS-8.5)
  - Corrective action records (ATF-LS-8.7)
  - Internal audit records (ATF-LS-8.8)
  - Management system review records (ATF-LS-8.9)
  - Customer feedback records



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- Feedback records related to an individual laboratory shall be maintained by the Laboratory Chief.
- Feedback records related to the Laboratory Services system shall be maintained by the Quality Manager.
- Acting designations – *Four years*

## 6. Circulation

6.1. Original case records shall be exclusively used to complete internal laboratory services.

6.1.1. Copies of case records shall be made and used as needed for legal proceedings or other requests.

## 7. Maintenance

### 7.1. Active case records

7.1.1. Case records that are subject to current use shall be readily accessible and stored in official file storage locations.

7.1.2. Removal of physical case records from a file storage location and transfer of records shall be documented.

### 7.2. Inactive case records

7.2.1. Closed case records may be archived with the National Archives and Records Administration (NARA) in accordance with *ATF O 1340.5 Records Management Program*.

7.2.2. Inactive case records may become active again due to subsequent investigations.

## 8. Disposal

8.1. The disposal of laboratory records shall be done in accordance with *ATF O 1340.5 Records Management Program*.



ATF-LS-8.5 Actions to address risks and opportunities	ID: 7023 Revision: 4
Authority: Deputy Assistant Director, Forensic Services	Page: 1 of 2
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## 1. General

1.1. Laboratory Services shall consider and be appropriately responsive to the risks and opportunities associated with the laboratory activities in order to:

- give assurance that the management system achieves its intended results,
- enhance opportunities to achieve the purpose and objectives of Laboratory Services,
- prevent or reduce undesired impacts and potential failures in the laboratory activities, and
- achieve improvement.

1.2. The Laboratory Services quality system documents establish the framework to facilitate effective decision making regarding risks and opportunities, taking into consideration the consequences of the actions of the laboratories.

1.3. The Laboratory Services' safety programs shall consider the risks and opportunities as they relate to health and safety.

1.4. Laboratory Services shall identify and select opportunities for improvement and implement any necessary actions.

1.4.1. Actions taken to address risks and opportunities shall be proportional to the potential impact on the services provided by Laboratory Services and the potential impact on the validity of laboratory results.

1.4.2. Corrective action plans shall include a reasonable timeframe and periodic monitoring to ensure their completion.

## 2. Procedures

### 2.1. Risk management

2.1.1. Risk management shall be conducted to:

- identify the risk;
- evaluate the risk, including the potential impacts and the likelihood of recurrence;
- mitigate and control the risk; and
- review the action(s) taken to determine the effectiveness.

2.1.2. Routine risk management is addressed in the following documents.

- *ATF-LS-7.10 Nonconforming work policy*
- *ATF-LS-8.7 Corrective actions*





ATF-LS-8.5 Actions to address risks and opportunities	ID: 7023 Revision: 4
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## 2.2. Opportunities for improvement

2.2.1. Opportunities for improvement shall be continuously sought and incorporated into the management system when feasible. Generally, the actions to address opportunities are proactive or applicable to future events.

## 2.3. Mechanisms for identifying risks and opportunities

2.3.1. The Laboratory Services' internal monitoring mechanisms provide a means to identify risks and opportunities for consideration.

### 2.3.1.1. References:

- *ATF-LS-7.7.1 Review of case records, reports, and notifications*
- *ATF-LS-7.7.2 Testimony reviews*
- *ATF-LS-7.7.3 Proficiency testing program policy*
- *ATF-LS-8.3 Control of management system documents*
- *ATF-LS-8.8 Internal audits*
- *ATF-LS-8.9 Management reviews*

2.3.2. Risks and opportunities for consideration can originate from customers.

### 2.3.2.1. References:

- *ATF-LS-7.9 Complaints*
- *ATF-LS-8.6.2 Customer feedback process*

2.4. The management system requirements shall be revised in response to risks and opportunities in accordance with *ATF-LS-8.2 Management system documentation*.

2.5. The effectiveness of actions taken to address risks and opportunities shall be evaluated during the annual management reviews. Refer to *ATF-LS-8.9 Management reviews*.

2.5.1. When specified by a plan, monitoring records can contribute to the determination of effectiveness.

## 3. Records

3.1. Records documenting how risks and opportunities were identified and addressed shall be created and maintained according to the applicable quality system documents.

3.1.1. Records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-8.6.2 Customer feedback process	ID: 7058 Revision: 4
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## 1. General

- 1.1. Laboratory Services shall seek customer feedback. Analysis of the feedback shall be used to improve the management system, laboratory operations, and customer service.
- 1.2. Sources of customer feedback include the following.
  - Surveys
  - Engagement during organized functions, such as conferences and training
  - Complaints and compliments
- 1.3. Laboratory management shall ensure that feedback is documented and evaluated.
- 1.4. Refer to *ATF-LS-8.5 Actions to address risks and opportunities* to select the mechanism most appropriate for the response.
- 1.5. The response of the laboratory, if any, shall be documented, including any subsequent communications with a customer.

## 2. Procedures

### 2.1. Surveys

#### 2.1.1. Survey types

- 2.1.1.1. A survey form shall accompany the distribution of Forensic Science Laboratory reports to the customer.
- 2.1.1.2. Written or oral surveys may be conducted during customer engagement activities. The Fire Research Laboratory shall conduct at least one group survey per year.

- 2.1.2. The survey results shall be evaluated by laboratory management to identify and address any risks or opportunities. Refer to *ATF-LS-8.5 Actions to address risks and opportunities*. Survey evaluations shall be reviewed by the relevant Section Chief and Laboratory Chief and the reviews shall be documented.

### 2.2. Complaints

- 2.2.1. Complaints are handled in accordance with *ATF-LS-7.9 Complaints*.
- 2.2.2. The complaint shall be evaluated with reference to *ATF-LS-8.5 Actions to address risks and opportunities*.



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### 2.3. Compliments

2.3.1. Compliment records should be maintained.

2.3.2. Sources of compliments include the following.

- Communication to laboratory management specifying personnel
- Official ATF or other governmental awards (e.g., special act, on-the-spot)
- Official recognition by professional organizations

### 3. Records

3.1. Records of feedback, evaluation, and response shall be maintained in accordance with *ATF-LS-8.4 Control of records*.



ATF-LS-8.7 Corrective actions	ID: 7016 Revision: 4
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## 1. General

1.1. Corrective actions shall occur when the preliminary investigation and evaluation conducted as part of *ATF-LS-7.10 Nonconforming work policy* indicate that any of the following has occurred.

- A moderate to high impact from the nonconformity
- A detrimental impact on the validity of the laboratory's results
- An increased likelihood of recurrence
- Doubt about the conformity of the laboratory's operations with the management system

1.2. Laboratory Services shall respond to detected nonconformities according to *ATF-LS-7.10 Nonconforming work policy* and determine if similar nonconformities exist or could potentially occur.

1.3. Corrective actions shall be appropriate to the root cause and proportional to the effects of the nonconformity.

1.4. Corrective actions will:

- take action to control and correct the nonconformity,
- address the consequences of the nonconformity,
- evaluate the need for action by reviewing and analyzing the nonconformity and conducting a root cause analysis,
- implement the necessary actions,
- monitor the effectiveness of actions taken,
- update management system documents, risks, or opportunities for improvement as appropriate; and
- be reviewed by the Quality Manager and approved by Top Management.

1.5. Notifications

1.5.1. The Laboratory Chief and Quality Manager shall be notified of nonconformities resulting in corrective actions.

1.5.2. The laboratory CODIS Administrator shall be notified when a nonconformity impacts DNA records entered into CODIS.

1.5.3. Interested parties shall be notified in accordance with accreditation and ATF legal investigative requirements.

1.5.4. It is recommended that the status of corrective actions be communicated to the Quality Manager, relevant Key Management, and affected parties throughout the process.



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## 2. Procedure

2.1.1. Refer to *ATF-LS-8.7.1 Corrective actions process*.

## 3. Records

3.1. Corrective actions shall be documented on the *ATF-LS-F-8.7 Corrective Action Form*.

The corrective action record shall note:

- nonconformity description, including relative scope,
- applicable management system requirement,
- root cause,
- action taken, and
- effectiveness of the action taken.

3.2. Corrective action records shall be maintained in accordance with *ATF-LS-8.4 Control of records* and *ATF-LS-7.10 Nonconforming work policy*.



ATF-LS-8.7.1 Corrective actions process	ID: 7017 Revision: 3
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## 1. General

1.1. Laboratory Services personnel shall implement the corrective actions process when the preliminary investigation and evaluation of a nonconformity conducted per *ATF-LS-7.10.1* meet the criteria established in *ATF-LS-7.10 Nonconforming work policy*.

### 1.2. Responsibilities and authorities

1.2.1. The Deputy Assistant Director, Forensic Services is responsible for approving all corrective action reports that relate to Quality Programs or the Laboratory Services system. This authority may be delegated to the Laboratory Chief or the Quality Manager.

1.2.2. Laboratory Chiefs are responsible for approving corrective action reports within their laboratory.

1.2.3. The DNA Technical Leader is responsible for approving corrective action plans related to or affecting casework or proficiency tests in their discipline prior to their implementation.

1.2.4. The Quality Manager is responsible for reviewing the corrective action report and ensuring its adherence to accreditation and management system requirements.

1.2.5. Responsibility for managing and implementing corrective actions may be assigned to a Section Chief, Technical Leader, the Quality Manager, or other personnel based on the nature and scope of the corrective action.

1.3. Corrective action plans shall be tracked and periodically checked to ensure completion. The periodic checks shall be documented.

## 2. Procedure

### 2.1. Root cause analysis

2.1.1. A corrective action required for any nonconformities identified and documented via *ATF-LS-7.10 Nonconforming work policy* shall begin with a root cause analysis.

### 2.2. Corrective action plan

#### 2.2.1. Development



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- 2.2.1.1. An action plan appropriate to the magnitude of the nonconformity and based on the root cause analysis shall be developed by Laboratory Services personnel that are designated by Top Management. Consultations with relevant personnel, such as Technical Leader, Section Chief, Laboratory Chief, and Quality Manager, shall be noted.
- 2.2.1.2. The plan shall specify what the action(s) will entail (e.g., percentage of casework, areas of testing, examinations).
- 2.2.1.3. The plan shall include a time frame for completion.
- 2.2.1.4. The plan should account for past, present, and future casework.
- 2.2.1.5. The plan may include extended monitoring to evaluate the effectiveness of the actions.

#### 2.2.2. Review

- 2.2.2.1. The corrective action plan shall be reviewed by the Quality Manager, who may recommend additional actions. This review shall be documented.
- 2.2.2.2. If the corrective action is related to or affects DNA casework or proficiency tests, the corrective action plan shall be reviewed and approved by the DNA Technical Leader prior to execution.

#### 2.3. Execution

- 2.3.1. The plan shall be executed and documented. Preparation of a summary is recommended to monitor progress.
- 2.3.2. Modifications of the plan shall be documented, and significant changes shall be communicated to relevant Top Management. If monitoring demonstrates that the completed actions were ineffective, the plan shall be revisited and modified as necessary.
- 2.3.3. If the corrective actions are covered by other laboratory procedures, all applicable procedures shall be followed.

#### 2.4. Closure

- 2.4.1. A corrective action record shall remain active until the plan has been fully executed and the effectiveness of the completed actions has been evaluated.



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2.4.2. The relevant Top Manager shall review the assembled corrective action record.

2.4.2.1. When further action is necessary, the plan shall be revisited including the adjustment of time frames.

2.4.3. The documented approval by the Top Manager shall constitute the closure of the corrective action.

2.4.3.1. Corrective action records related to an individual laboratory shall be approved by the Laboratory Chief.

2.4.3.2. Corrective action records related to Quality Programs or the Laboratory Services system shall be approved by the Deputy Assistant Director, Forensic Services.

## 2.5. Reactivation

2.5.1. An inactive corrective action record may be re-opened if it is later determined that the actions were not effective.

## 3. Records

3.1. All associated records received or generated in relation to the corrective action shall be retained as part of the corrective action record.

3.2. Corrective action records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.





ATF-LS-8.8 Internal audits	ID: 6315 Revision: 3
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## 1. General

1.1. Laboratory Services shall conduct self-checks to ensure continued compliance with accreditation and management system requirements. These annual audits shall provide information on whether the management system conforms to the accreditation requirements.

1.1.1. Additional limited scope audits required and coordinated by top management shall follow these requirements.

1.2. Audit teams will include subject matter experts in the various laboratory disciplines (i.e., technical auditors) and be led by the Quality Manager.

1.3. System changes resulting from audit activities shall be communicated to the relevant personnel.

1.4. The audit team shall observe the confidentiality of each laboratory's audit.

## 2. Audit process

### 2.1. Planning

2.1.1. Audits are coordinated by Quality Programs, including the selection of auditors, the scheduling and execution of the audit, and the preparation of the audit records. Laboratory management shall coordinate limited scope audits with guidance from Quality Programs as needed.

2.1.2. The audit plan shall be announced at least 30 days in advance and will include the following information as applicable to an annual or limited scope audit.

2.1.2.1. Date(s): The term is limited to the time necessary for auditors to complete the review of records.

2.1.2.2. Methods: The collection of information shall entail a review of records, interviews, and direct observation of a sample of accredited services within each discipline.

2.1.2.3. Scope: Annual audits shall include all accredited services and should include non-accredited services. Limited scope audits may include some or all services depending on the scope and purpose.



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- 2.1.2.3.1. The annual internal audit should take into consideration the results of the prior annual audit to verify the effectiveness of the resultant actions. The documented review of the corrective action records by Quality Programs may suffice for this review or additional records may be requested during the annual audit.
- 2.1.2.4. Requirements: The requirements for the annual audit include those specified by the management system documents. The plan for limited scope audits will specify applicable requirements.
- 2.1.2.5. Auditors: The audit team shall be composed of qualified Laboratory Services personnel and other qualified external auditors (if necessary) from laboratories with an accreditation scope comparable to that of the ATF laboratory. All audit team members shall be trained in conducting audits.
- 2.1.2.5.1. A qualified auditor is one that has been authorized to perform casework in the area or activity being audited.
- 2.1.2.5.1.1. Quality Programs shall retain the records for external auditor qualification and laboratory accreditation.
- 2.1.2.5.1.2. Forensic Biology auditors shall meet the auditor qualification requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.
- 2.1.2.5.2. Auditors shall be familiar with the management system requirements.
- 2.1.2.6. Records: All records required by the management system documents are subject to review during the annual audit. The following records will be consolidated in the designated audit location when feasible.
- List of record custodians
  - Case records, including reports; these include physical files and LIMS records
  - Records for external providers of products and services
  - Customer feedback records
  - Complaint records
  - Records of nonconformity, corrections, and corrective actions
  - Personnel qualification records, including training, competency, and authorization
  - Laboratory access authorization records
  - Proficiency test records
  - Audit records



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- Management review records
- Equipment qualification records
- Method validation records
- Records of case record reviews and testimony reviews

2.1.2.6.1. When technical records are reviewed remotely, it shall be noted in the audit report.

2.1.2.6.2. The plan for limited scope audits shall specify the records to be reviewed.

## 2.2. Conducting the audit

2.2.1. A representative selection of records will be used to assess conformance with the requirements. Additional records may be requested by auditors as necessary.

2.2.2. Auditors shall document the records reviewed. All audit records, other than the audit plan and the report, are considered work papers and are not required to be retained once corrective action plans have been developed.

2.2.2.1. Technical auditors shall complete and document at least one audit trail per discipline. The review of additional selected case records shall focus on technical content.

2.2.2.2. Objective evidence should accompany completed worksheets to facilitate any subsequent investigation by the laboratory.

2.2.3. A preliminary summary of the records reviewed shall be provided to the Laboratory Chief at the conclusion of the audit. Any nonconformities listed in the summary are pre-decisional and subject to resolution or revision prior to the issue of the report.

2.2.4. An audit report, including any findings of nonconformity, shall be prepared by the team leader and provided to the Laboratory Chief with a copy to the Deputy Assistant Director, Forensic Services within 30 days of the completion of the audit.

2.2.4.1. Forensic biology audit reports shall conform to the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.



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2.2.5. Corrections and corrective actions shall be implemented in accordance with *ATF-LS-7.10 Nonconforming work policy* and *ATF-LS-8.7 Corrective actions*. These shall be done in a timely manner.

2.2.5.1. The audit team leader will convey any findings that require a stop work order to the Laboratory Chief and to the Deputy Assistant Director, Forensic Services as soon after the observation as possible.

2.2.6. Areas of improvement may be discovered during the audit, which can be referred for further action. Refer to *ATF-LS-8.5 Actions to address risks and opportunities*.

### 2.3. Records

2.3.1. The audit record consists of the plan and the report. These records shall be maintained in accordance with *ATF-LS-8.4 Control of records*.

2.3.2. Records of nonconforming work and corrective actions resulting from the audit are maintained according to *ATF-LS-7.10 Nonconforming work policy* and *ATF-LS-8.7 Corrective actions*.



ATF-LS-8.9 Management review policy	ID: 7018 Revision: 5
Authority: Deputy Assistant Director, Forensic Services	Page: 1 of 1
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1. General

1.1. The management system shall be reviewed annually to ensure its continuing suitability, adequacy, and effectiveness. The review ensures accountability for the fulfillment of the Laboratory Services mission and the accreditation requirements and facilitates the improvement of services.

2. Reviews of the management system will be conducted by top management on an annual basis for the prior calendar year and will generally be done during the first quarter of the calendar year.

2.1. Laboratory Chiefs are responsible for providing input from their laboratory for the Laboratory Services management review.

2.2. The Deputy Assistant Director, Forensic Services is responsible for ensuring that a management system review for the Laboratory Services system is conducted.

3. The management review shall address the topics listed in the accreditation requirements, but the format of the review may vary.

4. Input may be solicited by top management from the Quality Manager, Section Chiefs, Technical Leaders, and other personnel as deemed appropriate.

5. The management review shall evaluate the effectiveness of any implemented improvements and the status of actions from prior year's management reviews.