1. Purpose

   1.1. This procedure describes how documents related to the objectives of the management system, including those from external sources, are prepared or received, authorized, issued, controlled and kept. This quality procedure also defines how changes are controlled and how obsolete documents are removed from use, archived and/or destroyed in compliance with the requirements of the Quality Manual.

2. Scope

   2.1. The controlled documents include, but, are not limited to, the following internal and external documents: Quality Manual and associated records; all internally generated policies, procedures and guidelines; work instructions and other reference documents specifically identified as controlled documents used by Laboratory Services to describe, support and achieve its quality objectives.

   2.2. The majority of the requirements listed in this procedure apply to internally generated documents only. Any requirements that apply to external source documents are clearly identified as such.

   2.3. These quality related documents are identified in the document control software Qualtrax and controlled in accordance with this procedure.

3. References

   ATF-LS Quality Manual

   ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, 2005.

   ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, 2011.

   ATF-LS-4.13 Control of records

   Qualtrax User Manual

4. Procedure

   4.1. Structure and numbering system

4.1.1. The following table outlines the controlled document numbering system, document structure and the distribution of internal documents that form part of Laboratory Services management system.

Table 1. Structure and numbering system for controlled documents

Document ID	Description	Distribution
ATF-QM-[revision #]	Quality Manual	General
ATF-LS-4.X (4.X is the applicable standard)	Management System Requirements defined in ASCLD/LAB-International and ISO/IEC 17025	General
ATF-LS-5.X (5.X is the applicable standard)	Management System Requirements defined in ASCLD/LAB-International and ISO/IEC 17025	General
ATF-LS-4/5.X-F#	Management System Forms	General
Discipline Documents – Named Specific to the Discipline	Methods Manuals	Discipline-specific
Discipline Documents – Named Specific to the Discipline	Work Instructions	Instrument Specific – Posted at Instrument
Discipline Documents – Named Specific to the Discipline	Worksheets	Discipline-specific
Discipline Documents – Named Specific to the Discipline	Training Manuals	Discipline-specific
Safety Manual	Safety Manual	General Site Specific

4.1.2. Obsolete documents that must be kept for reference or for legal or contractual purposes are treated as records, and are identified and stored in accordance with ATF-LS-4.13 Control of records.

4.2. Controlled document requirements

4.2.1. The following information will be readily noted in the document or maintained in document properties of Qualtrax for all internally-generated controlled documents:

- document title or other unique identifier
- effective/ issue date
- revision number
- approving official
- distribution
- number of pages

4.2.2. Unless otherwise identified, all printed system documents are considered uncontrolled. Individuals may print hardcopies of system documents as needed for personal use. It is the employee's responsibility to verify that they are using the current revision of any document.

4.3. External documents

4.3.1. Documents such as external references listed in the references section of technical procedures or work instructions, manufacturer user manuals, Federal regulations and external standards applicable to ATF Laboratory Services are considered externally-generated documents. External documents are identified as controlled documents or uncontrolled documents on the Master List of External Documents. This list maintained as a controlled document and is part of the management system.

4.3.2. External documents identified as controlled that are not available in electronic format, will be clearly labeled as a *Controlled Copy* and their location shall be listed on the Master List of External Documents.

4.4. Content of procedures

4.4.1. Each internally generated controlled document must be given a relevant brief title and an assigned document owner/editor.

4.4.2. Internal procedures should, at a minimum:

- Identify what the policy/ procedure intends to accomplish.
- Describe the boundaries of applicability and may identify organizations, processes, items, and/ or activities affected by the document.
- List documents referenced in the procedure or other related or dependent management system documents.
- Instruct the user what to do and how to do it.

- Note controls appropriate to the procedure which should include information regarding both document controls and technical controls required for the particular work instruction.
- Note responsible parties as appropriate.

4.4.3. Additional requirements for technical procedures
    4.4.3.1. Where applicable, technical procedures will include the following:

- sample preparation methods
- controls
- parameter sheet
- apparatus, equipment and instruments, including maintenance and calibration schedules and procedures
- reagents and standard solutions
- references materials
- consumable supplies
- measurement traceability requirements
- safety precautions

4.5. Work instructions

4.5.1. Work instructions are defined as step-by-step instructions usually associated with instruments and other laboratory equipment. These documents are controlled documents generally maintained in hard copy form posted at or near the instrument/equipment for which the instructions are intended. A list of these documents, along with specific information regarding the document location and owner/editor, will be maintained in Qualtrax. The hard copies of these documents will be marked as required for all controlled documents.

4.6. Forms and worksheets

4.6.1. Unless otherwise stated in a management system or discipline specific controlled document, examiner created worksheets or checklists that are used as a tool for recording information are not considered controlled documents.

4.6.2. If worksheets are required by a laboratory discipline, then the discipline method manual will include the specific worksheet requirements for that discipline. Controlled worksheets will be printed from Qualtrax at each time of use rather than copying previously printed worksheets.

4.7. Controlled document origination

4.7.1. Management or an employee knowledgeable in the subject of the policy/procedure may initiate either a new or revised procedure and/or other internally generated documents.

4.8. Document initiation and revision

4.8.1. All internal controlled document initiations and revisions will be performed in Qualtrax. Table 2 assigns the overall responsibility and authority for each document category.

Column A - type of internal controlled document; requires regular periodic review and revision as necessary;

Column B - person with the responsibility and authority to review and initiate a new document or revision to a controlled document;

Column C – person with the responsibility for the content of the document and authority to approve documents or revisions initiated. Periodic reviews are required by this person and must be documented and maintained;

Column D – person with the responsibility and authority for final approval of a document or revision. Approval by this person is required before the document can be published and available for use.

Table 2. Responsibility and authority for document categories

A	B	C	D
Management System Policies, Procedures and associated forms	Any laboratory employee	Quality Manager	Deputy Assistant Director, Forensic Services
Methods of Analysis and Worksheets; Discipline-specific Training Manuals	Any laboratory employee	Subject Matter Expert	Subject Matter Expert
Safety Manual	Any laboratory employee	Safety Officer	Quality Manager

4.8.2. The document review and approval stage may include additional individuals and may be dependent on the specific change in the document system required. The review and approval process is controlled, entered and recorded in Qualtrax. Assigned user authorities are made by the Deputy Assistant Director, Forensic Services, Laboratory Chiefs and the Quality Manager. The user authorities are recorded in the personnel profiles in Qualtrax.

4.9. Distribution of new or revised documents

4.9.1. Distribution of internally generated new or revised controlled documents will be accomplished via Qualtrax.

4.9.2. Initiation and approval of new or revised documents, as well as distribution of current policies, procedures and guidelines, forms, and worksheets for Laboratory Services will be done through Qualtrax.

4.9.3. After the final approval, the new or revised authorized documents are released and readily available to all appropriate personnel through Qualtrax.

4.9.4. Only the latest revision of a document is approved for use and available for general use via Qualtrax. Qualtrax retains obsolete documents in the archive history. All archive documents will be retained according to ATF-LS-4.13 Control of records.

4.10. Periodic document review

4.10.1. All internally generated documents must be periodically reviewed to determine if revisions are necessary for continued compliance and/or improvement of the management system and scientific operations. The document properties in

Qualtrax identify and records the appropriate review cycles for each controlled document.

4.11. Document revision history

4.11.1. Specific document revision history for internal 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.

4.12. Document dependency

4.12.1. Revising a document may affect other related documents. The document properties noted in Qualtrax lists dependent documents for all controlled system documents. Document owners will record that these dependencies have been addressed when closing out and approving a document revision in Qualtrax.

4.13. Corrections

4.13.1. The Quality Manager may make non-technical corrections such as typographical errors, administrative header/footer information, formatting changes, etc., to system documents without going through the standard Qualtrax tracking approval process. Such corrections will be announced and shall be recorded in Qualtrax.

5. Controls

5.1. Quality Manager

5.1.1. The Quality Manager ensures that all controlled documents meet the requirements set in this procedure prior to releasing a document or revision in Qualtrax and ensures that hard copy controlled documents are maintained appropriately during annual internal audits.

5.2. All employees

5.2.1. All employees are responsible for identifying any controlled documents that may contain inconsistencies, are not working, or require change based on another change in how business is done. This includes any external source documents that may be outdated.

5.3. Laboratory Chiefs

5.3.1. Laboratory Chiefs shall ensure the availability of controlled paper copies of all controlled documents in Qualtrax that are applicable to the lab.