FBI Laboratory
Practices for Document Control

1 Purpose

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

In the FBI Laboratory quality system, laboratory requirements reside in the QAM and Laboratory Operations Manual (LOM). In addition, units, disciplines, and/or categories of testing will have level 2 and, where applicable level 3 documents. Blank forms are included in the accompanying document and are controlled documents.

2 Scope

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

3 Practices

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

3.1 Level 1 Documents

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

3.1.1 Level 1 documents, except for the FBI Laboratory Safety Manual are generated by Forensic Analysis Support Unit (FASU) personnel.

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

3.2 Level 2 Documents

A level 2 document applies to a specific unit(s), discipline(s), and/or category(ies) of testing and is generated by FBI Laboratory personnel. Types of level 2 documents are specified in each of

the following subsections and include any accompanying forms.

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

3.2.2 Quality manual documents (e.g., identifying secondary evidence, calibration program, purchasing products and services, abbreviations and/or symbols, i3 procedures), non-technical procedures (e.g., evidence management, quality assurance activities, photography), FBI Approved Standards for Scientific Testimony and Report Language (ASSTR), and report writing procedures.

3.2.3 Training manuals.

3.3 Level 3 Documents

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

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

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

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

3.4 Level 1 and Level 2 Document Format

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

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

- Left justified.
- Prepared in Times New Roman 12-point font except for the title, the header of the document, and figures/tables.
- Title centered at the top of the document in Times New Roman 14-point bold.

- Have a header (See section 3.4.1 for header formatting requirements).
- Have two lines between major sections (i.e., those with a single number). All other sections or paragraphs will be separated by one line (those with two or more numbers).
- Have section headings numbered with the title of the heading followed by two spaces after the last number. The number and the section heading will be 12-point bold.
- Numbered sections without a heading will be 12-point bold. Any text that immediately follows the number will be indented with a preferred distance of 0.75" from the left margin. Subsequent paragraphs in the same section will be left justified.
- Bullets or lists will be aligned. If the list is part of a paragraph, it will be indented with a preferred distance of 1" from the left margin.
- Have a revision history (See section 3.4.2 for revision history formatting requirements).
- Have a signature block (See section 3.5.2.1 for signature block formatting requirements).
- Include forms, as applicable, (See section 3.4.3 for form formatting requirements).
- When figures include calculations, other fonts may be used to display special characters.

3.4.1 Header Format

Each page of a level 1 and level 2 document, except forms, will have a header that:

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

3.4.2 Revision History Format

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

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

3.4.3 Forms

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

3.5 Level 1 and Level 2 Document Preparation

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

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

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

3.5.1 Level 1 and Level 2 Document Reviews and Records

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

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

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

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

3.5.1.1 Technical Review

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

3.5.1.2 Quality Assurance Review

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

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

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

3.5.2 Level 1 and Level 2 Document Approval

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

For level 1 document issuance:
The Laboratory Director and the Quality Manager are authorized and will approve issuance of the QAM and LOM. The Deputy Bureau Designated Environmental, Safety, and Health Official (DESHO) and Laboratory Director are authorized and will approve issuance of the FBI Laboratory Safety Manual.

For level 2 documents as described in section 3.2.1 issuance:
The applicable Unit Chief(s) and Technical Leader(s), as determined by the unit(s), discipline(s), and/or categories of testing listed in the scope, are authorized and will approve issuance.

For level 2 documents as described in sections 3.2.2 and 3.2.3 issuance:
The Quality Manager, applicable Unit Chief(s), and where applicable, Technical Leader(s), as determined by the unit(s), discipline(s), and/or category(ies) of testing listed in the scope, are authorized and will approve issuance.

3.5.2.1 Document Signature Block

The signature block will include all authorized personnel who approved issuance of the document. The approver's title will be to the left of the signature line and their name will be typed below the signature line. The date will be to the right of the signature line. The signature block will be at the end of the main body of the document before the appendix(ices).

3.5.3 Level 1 and Level 2 Document Posting

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

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

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

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

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

3.5.4 Level 1 and Level 2 Document Revisions

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

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

3.5.5 Level 1 and Level 2 Document Archives

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

3.5.5.2 If archived physical copies are maintained, the retained archived document(s) must be labeled (e.g., "archived", "superseded", "discontinued"), and include the signatures of the approvers/issuer. Effective dates of the document must be indicated on the archived physical copy. Alternatively, physical copies of archived, controlled documents may be destroyed after a revision is issued or a document is discontinued if the official archive copy is maintained on BUNET, LABNET, and UNET.

3.6 Other Formats for Controlled Level 1 and Level 2 Documents

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

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

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

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

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

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

3.7 Control of Level 3 Documents

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

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

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

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

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

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

3.7.4 Level 3 Initial Document Review

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

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

3.7.5 Level 3 Document Approval

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

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

3.7.6 Level 3 Document Records

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

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

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

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

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

3.7.7 Level 3 Document Modifications

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

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

3.7.8 Level 3 Document Archives

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

3.8 Controlled Document Notifications

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

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

3.8.2 For level 2 documents, affected personnel that will be notified within one business day via email will be determined by the unit(s), discipline(s), and/or category(ies) of testing

listed in a document's scope. Email notification for a level 2 document will be retained by each affected unit or by the applicable support unit.

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

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

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

3.9 Working Electronic Copies of Level 1 and Level 2 documents

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

3.10 Annual Review

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

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

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

3.10.2.1 The annual review(s) of these documents will be recorded and retained in the unit or the applicable support unit. Records will include the name of the reviewer(s), the title or unique identifier of each document reviewed, its revision number or date published, and the date(s) the

documents were reviewed. Internal or external audits and/or quality assurance reviews do not satisfy this requirement.

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

3.10.3 The Quality Manager will ensure level 3 documents as described in section 3.3.3 are reviewed annually to ensure they are the current and correct version for the needs of the FBI Laboratory. Records will include the name of the reviewer(s), the title or unique identifier of each document reviewed, its revision number or date published, and the date(s) the documents were reviewed. Internal or external audits and/or initial reviews do not satisfy this requirement.

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

3.11 Level 1 and Level 2 Document Requests

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

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

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

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

4 Records

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

- Reviews of level 1 documents and *Document Review Forms* will be retained in the FASU for at least one accreditation cycle.
- Records of completed annual reviews of controlled documents will be retained by the appropriate unit through one accreditation cycle.
- Superseded/archived/discontinued physical copy versions of level 1, level 2, and level 3 documents as described in section 3.3.1 will be retained permanently by the appropriate party if not archived on BUNET, LABNET,

or UNET.

- Email notification of issuance, revision, or discontinuance of level 1, level 2, and level 3 documents as described in sections 3.3.1 and 3.3.3 will be retained by each affected unit or by the applicable support unit, through one accreditation cycle.
- Current master lists for any unit that maintains physical copies and/or electronic copies on other media will be retained by the unit or supporting unit through one accreditation cycle.

5 References

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

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

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

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

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

Rev. #	Issue Date	History
15	10/21/19	Clarified in section 3.5.1 that FASU personnel will review validation records. Revised 3.5.1.2.1 and added 3.5.1.2.2 to state who will perform quality assurance reviews of documents. Added section 3.5.3.2.1 that was inadvertently deleted in previous version to state that a document printed from BUNET or LABNET, will be an uncontrolled copy. Added sections 3.7.5.1 and 3.8.3.2 to cover all types of level 3 documents. Minor edits throughout for clarification and numbering.
16	12/21/20	Grammatical and formatting changes throughout. Added: UNET as alternate location throughout. 1 – Added: laboratory; Replaced: quality manuals, technical procedures/standard operating procedures (SOPs), training manuals, and/or controlled equipment manuals with level 2, and, where applicable, level 3 documents. 3.2.2 – Added: i3 procedures, non-technical procedures, FBI ASSTR, and report writing procedures. 3.5 – Added: or the document is submitted in the manner requested by FASU. 3.5.4.1 – Removed: Forms will be archived within the document. 3.5.5.1 – Added: Forms will be archived within the document. 3.10 – Removed: do not have to be conducted at the end of a calendar year. 4 (final bullet) – Added: will be retained by the unit or supporting unit through one accreditation cycle. 5 – Added: LOM and ISO/IEC 17020

Redacted - Signatures on File

Approval

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020

Appendix A: *FBI Laboratory Document Review Form* (7-263)

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Appendix B: *Formatting Example*

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Appendix B: *Formatting Example* continued

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Appendix B: *Formatting Example* continued

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