FBI Latent Print Units
Procedures for Development, Validation, Verification, and Modification of Technical Procedures, Methods, and Equipment

1 Purpose

This document establishes development, validation, verification, and modification procedures for the Latent Print Units and supplements the FBI Laboratory Quality Assurance Manual, and the FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures.

2 Scope

These procedures apply to personnel who address new or modified technical procedures, methods, and equipment (which includes software) under consideration for use in casework by the Latent Print Units. The size and scope required for each technical procedure, method, and equipment to be validated, verified and/or modified will depend on available information and/or research previously conducted.

3 Procedures

The Technical Leader will determine what technical procedures, methods, and equipment will be addressed under this document. The Technical Leader will ensure the requirements set forth in this document, the FBI Laboratory Quality Assurance Manual, and the FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures are followed and all records retained.

3.1 Levels

If a technique or piece of equipment is novel, it must undergo more rigorous testing before being accepted. Procedures or equipment that have been accepted by standards or technical organizations, or well supported by scientific literature, internal/external research, or by the manufacturer still need to be verified. The Levels below break down scenarios seen in the Latent Print Units.

3.1.1 Level I Scenarios (Method Development/Validation)

A Level I scenario applies to novel procedures, chemicals, or equipment as well as any modifications deemed by the Technical Leader to require method development or a validation. Testing will be conducted to test the following, if applicable, unless previously tested and documented in publications, internal research, or external research:

- Accuracy

- Precision
- Scope
- Robustness
- Specificity
- Sensitivity

3.1.2 Level II Scenarios (Verifications/Significant Modifications)

A Level II scenario applies to procedures, chemicals, or equipment that have been accepted by standards or technical organizations, or are well supported by scientific literature, internal/external research, or the manufacturer. Significant modifications to previously validated or verified procedures or equipment can be included under Level II scenarios per the Technical Leader.

3.1.3 Level III Scenarios (Equipment or Software Check)

A Level III scenario is not a validation or verification, but instead applies to approvals of new equipment or software that should not significantly impact the current procedure (e.g., a new processing chamber that is from the same manufacturer and is a similar model). All equipment must still meet the Laboratory's requirements. See Appendix A for an example of equipment check records. Prior to use in case work, the final equipment or software check record must be approved by the following individuals:

- location Laboratory Manager or applicable Program Manager
- Validation Program Manager or Technical Leader.

Negligible equipment or software does not need a recorded equipment or software check (e.g., tweezers, ambient light lamps, magnifying glasses, word processing software, virus software). Additionally, maintenance or performance checks of equipment or software do not fall under these requirements.

3.1.4 Offsite Examinations

When processing of physical evidence occurs at a temporary site, such as a partner laboratory or crime scene, all chemicals, reagents or equipment are brought from the Laboratory. Control testing is done at the site and recorded in the case record. If the relevant items do not come from the Laboratory, the appropriate validation or verification is conducted based on the scenarios listed above.

3.2 Software

Software used by the Latent Print Units that meets the requirements listed below must be recorded with sufficient detail and validated or verified to show adequacy.

- Software that may significantly and adversely affect the integrity of friction ridge print images or supporting data (e.g., digital history),

- Software that produces reportable statistical conclusions based on latent print information, or
- Software where the Technical Leader decides validation is necessary.

Software in general use that does not fall under the conditions listed above does not need to be validated or verified.

3.2.1 Next Generation Identification, including any Criminal Justice Information Services Division provided interface programs is maintained and tested by the Criminal Justice Information Services Division. A record of the tests will be retained. The Latent Print Units will additionally verify or validate major upgrades to the latent print algorithm and other upgrades deemed necessary by the Technical Leader.

3.3 Requirements for Method Development, Validation, and Verification

The Technical Leader, with input from the Validation Program Manager, will determine which procedures, methods and/or equipment will require method development or a validation as defined in the FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures. A Level I scenario is expected to always fall under the previously mentioned document while a Level II or Level III scenario is expected to not fall under the document. All method development or validations for procedures, methods and/or equipment will follow the FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures requirements in addition to the latent print specific requirements below.

3.3.1 Research and Development of Method Development, Validation Study, or Verification

External literature, internal research, and/or knowledge of the procedure(s), chemical(s), software, and/or equipment will be used to determine the theoretical basis, limitations, critical aspects, and the conditions under which accurate results can be obtained.

3.3.1.1 If a new or modified procedure(s), chemical(s), software, and/or equipment has been reviewed and evaluated by the appropriate experts, a verification may be more appropriate than a validation.

3.3.1.2 Prior to drafting a plan, previous research may be used to determine relevant factors to establish the developmental validation or verification of a procedure.

3.3.1.3 Relevant peer-reviewed literature, internal research, or external research used for the study will be retained or referenced within the records.

3.3.2 Method Development, Validation or Verification Plan

A method development, validation or verification plan will be written with input from the Validation Program Manager and then technically reviewed and approved by the Technical

Leader before the method development, validation or verification process begins. The plan will include the following:

- Objectives
- Scope
- Expected limiting factors
- Design of the study
- Minimum thresholds needed to determine validity

3.3.2.1 Chemicals, substrates, and other materials may be prepared before the plan is finalized, but the experiments will not occur until the plan is written, reviewed, and approved.

3.3.2.2 The plan will be created with consideration of the scope and be used to determine if the procedure meets the needs of the customer. Besides functionality, the following factors may also be used to determine the threshold(s) for development, validation or verification:

- Accuracy
- Adequacy
- Availability
- Sensitivity
- Ease of Use
- Operating Condition(s)
- Reproducibility
- Risks
- Robustness
- Safety
- Selectivity

Thresholds will also factor in current and alternative techniques, literature, the needs of the intended users, and/or study feasibility.

3.3.2.3 Any major revisions to the plan design will be reviewed and approved by the Technical Leader. Any portion of the study affected by the revision will be held until approval is obtained. The new plan will be followed after approval.

3.3.2.4 The plan will use test samples appropriate to the procedures, chemicals, software, or equipment being validated or verified.

3.3.3 Level I or Level II Study Completion

3.3.3.1 Upon completion of a study, a study report will be generated to detail the findings of the study. The study report will include the following:

- The limitations of the procedure, reported results, opinions, and interpretations.
- Conditions under which reliable results can be obtained.
- Critical aspects of the procedure that must be controlled and monitored.

- Scope and accuracy of the procedure to meet the needs of the given application.
- Associated data analysis and interpretation.
- Establishing the data required to report a result, opinion, or interpretation (if applicable).
- A statement concluding if the procedure(s), chemical(s), software, and/or equipment is valid for its intended use or if the study was discontinued.

A summary will be produced for validations per the FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures.

3.3.3.2 The appropriate Unit Chief(s) and the Technical Leader will review and approve the completed study (to include all reports and summaries) and the approvals will be recorded on the study report.

3.3.3.2.1 If the study is unsuccessful, additional research may be conducted for improvement. The updated study may follow the same threshold and factors of the original study. If the original study's metrics are not suitable, a new plan must be established, reviewed, and approved. The scope may be adjusted based on technique limitations learned from the previous study.

3.3.3.3 Level two documents will be generated and/or updated as needed based on the outcome of the verification or validation study. The document modifications or generation can occur prior to or concurrent with any required competency testing. The procedure(s), chemical(s), software, and/or equipment cannot be used in casework until the appropriate document is updated or generated.

3.3.4 Level I and Level II Records and Competency

The Validation Program Manager will compile the records, to include any plans and reports, and ensure the records are retained. All records must be sufficient to allow replication of the study by another qualified expert. Any other relevant records such as notes or logs will be retained.

3.3.4.1 Personnel in the affected units will be notified when a new or modified version of an existing procedure(s), chemical(s), software, and/or equipment has been verified or validated for use and of any required competency tests. Competency testing will be required for validations and required for verification only at the direction of the Technical Leader. Authorization to conduct the method will be retained.

3.3.4.1.1 Competency tests will assess an individual's ability to use the procedure(s), chemical(s), software, and/or equipment in a laboratory setting. Record of the completion of the test will be retained and any samples generated during the test will not be retained.

3.3.4.1.2 Competency records and additional authorization records will be maintained for each examiner/person, when applicable.

3.3.4.2 The Technical Leader will determine which personnel will be trained and how competency will be tested. Personnel involved in the validation or verification process may be signed off by the Technical Leader and appropriate Unit Chief(s), as they demonstrated competency through the study or research. Documentation of the decision and personnel approval will be retained.

3.3.5 After Implementation

Follow up will be performed on any issues that occur after implementation of the new procedure(s), chemical(s), software, and/or equipment.

4 References

FBI Laboratory Operations Manual, Practices for Developing Methods and Validating Technical Procedures. Federal Bureau of Investigation, Laboratory Division. Latest Revision.

FBI Laboratory Operations Manual, Practices for Writing Standard Operating Procedures. Federal Bureau of Investigation, Laboratory Division. Latest Revision.

FBI Laboratory Quality Assurance Manual. Federal Bureau of Investigation, Laboratory Division. Latest Revision.

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

Scientific Working Group of Friction Ridge Analysis, Study and Technology, Standard for the Validation and Performance Review of Friction Ridge Impression Development and Examination Techniques (Latent/Tenprint). Latest Version.

Rev. #	Issue Date	History
2	02/07/18	Minor grammar, wording and punctuation changes throughout document. Title and Section 1 modified to include expansion of document scope. Section 2, added modifications as well as equipment. Section 3, added equipment and removed Technical Leader direction. Section 3.1 through Section 3.1.4, moved from further in the document and clarified to remove blanket validation references. Section 3.2 and Section 3.2.1, moved from further in the document. Section 3.3 added. Section 3.3.1 through Section 3.3.2.4 plus Section 3.3 through Section 3.5 moved to end and renumbered. Section 3.3.3 through Section 3.3.3.2 and Section 3.3.4, summary is now a report; but summary per Lab document added. Section 3.3.5, removed last statement. Appendix A updated.
3	08/21/19	Title modified. “Acceptance” and “Internal Validation” changed to “verification” in document. Section 1, “development” added. Section 2, software added to scope. Section 3.1.1, updated to include only method development and validation. Section 3.1.2, added “or verified” and allowance for Technical Leader. Section 3.1.3, added “or verification”, added software throughout section, to include examples, modified approvals, and added last sentence. Section 3.1.4, added “or verification”. Section 3.2, expanded to software used by unit, added “or verified”, expanded to friction ridge prints and included supporting data. Additionally, removed commercial off the shelf software and added software in general use. Section 3.2.1, updated testing requirements. Section 3.3, expanded to include method development and verification and modify expectations for use of Laboratory document. Section 3.3.1 through Section 3.5.4, expanded to include Method Development and verification. Section 3.3.3.1, updated to include verification and method development as well as better mirror the Laboratory document. Section 3.3.3.2 through Section 3.3.3.3, expanded to include method development and verification. Section 3.3.4 through Section 3.3.4.2, records and competency further clarified for validations and verifications and intent of testing. Section 3.3.5, Heading changed.

Approval Redacted - Signatures on File

Latent Print
Technical Leader Date: 08/02/2019

Latent Print Operations
Unit Chief Date: 08/02/2019

Latent Print Support
Unit Chief Date: 08/02/2019

Scientific and Biometrics
Analysis Unit Chief Date: 08/02/2019

QA Approval

Quality Manager Date: 08/02/2019

Appendix A: *Example Equipment Check Templates*

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