Validation, Verification, and Approval of Technical Procedures, Equipment, and Software

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1 PURPOSE/SCOPE

A. This document establishes validation, verification, and approval procedures for Friction Ridge Discipline technical procedures, equipment, and software.

B. These procedures apply to personnel who address new or modified technical procedures, equipment and software under consideration for use in casework by the FBI Laboratory Friction Ridge Discipline.

C. The Technical Leader will determine the technical procedures, equipment and software addressed under this document.

1.1 Software

Only software used by the FBI Laboratory Friction Ridge Discipline that meets the requirements listed below are covered under this document.

- 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 friction ridge print information,
- Next Generation Identification upgrades, including any Criminal Justice Information Services Division provided interface programs, deemed necessary by the Technical Leader, and
- All other software where the Technical Leader decides testing is necessary.

2 METHOD DEVELOPMENT AND VALIDATION

A. Technical procedures or equipment in the FBI Laboratory Friction Ridge Discipline originating in the FBI Laboratory will follow the *FBI Laboratory Quality Manual* (LAB-100) document.

B. New software or new modules of existing software (commercial or developed in the FBI Laboratory) must be validated per the LAB-100 document.

C. The minimum requirements for a Validation Study are stated in the LAB-100 document.

3 EQUIPMENT AND SOFTWARE CHECKS

3.1 Approved Equipment or Software

A. New acquisition of already approved equipment or software will undergo a check to ensure the item is properly functioning.

B. Equipment or software whose effect on casework is low risk (e.g., marking software, light sources, printers or cameras) may also be addressed with a check.

C. A record of the check will be retained.

    1. Format for the record(s) will be established by the Validation Program Manager.

2. Checks will be approved by either the Validation Program Manager or the Technical Leader.

3.2   Negligible Equipment or Software

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).

3.3   Preventive or Corrective Maintenance of Existing Equipment or Software

A. Preventive or corrective maintenance of existing equipment or software do not fall under these requirements.
B. However, a recorded check is required following corrective maintenance for equipment or software that has been taken offline.

4   VERIFICATION

All other technical procedures, equipment and software not covered in Section 2 and Section 3 will be addressed as described below.

4.1   Verification Plan

A. A plan will describe the steps and expectations for the verification and will be as detailed as needed for the project under consideration.
B. A plan will be technically reviewed and approved by the Validation Program Manager and Technical Leader before testing begins.
C. Plans can be modified after implementation and major updates must be approved by the Technical Leader.
D. The plan will use samples appropriate to the procedures, software, or equipment being tested.

4.2   Completion of the Testing

A. Any verifications that are completed at a Laboratory site and are intended to be used at the second Laboratory site must also be tested at that site (e.g., a procedure approved for Huntsville site must also be tested at Quantico before used in Quantico).
B. The Validation Program Manager, appropriate Unit Chief(s), and Technical Leader will review and approve completed verification products (e.g., reports, summaries, memos) resulting from successful testing.
   1. Products resulting from unsuccessful testing will be reviewed by the Validation Program Manager and Technical Leader only.
C. If testing was unsuccessful, additional research may be conducted for improvement and testing may be redone but a new plan will be generated.
D. Level two documents will be generated and/or updated as needed.
E. The technical procedure, equipment or software cannot be used in casework until the appropriate document is issued.

5 RECORDS FOR VALIDATION, VERIFICATION, AND CHECKS

A. The Validation Program Manager will ensure that all relevant records per the LAB-100 document are retained.

6 TRAINING AND COMPETENCY FOR VALIDATION AND VERIFICATION

A. Competency testing is required for all successful validations and may be required for verifications at the direction of the Technical Leader.
B. The Technical Leader will determine if training is required, how competency will be tested and which personnel will be trained.
C. Personnel in the affected units will be notified when a new or modified version of an existing procedure(s), software, and/or equipment has been approved for use and of any required training or competency tests.
D. Record of any training and the completion of required tests will be retained.
   1. Samples generated during the test will not be retained.
E. Personnel involved in the testing process may be signed off by the Technical Leader, as they demonstrated competency through the study or research.
   1. Documentation of the decision and personnel approval will be retained.

7 OFFSITE EXAMINATIONS

A. When processing of physical evidence occurs at a temporary site, such as a partner laboratory or crime scene, all chemicals, reagents, or equipment are normally brought from the Laboratory.
B. Control testing is done at the site and recorded in the FBI Laboratory file.
C. If the relevant items do not come from the Laboratory, the appropriate testing is conducted based on the technical procedure, equipment or software involved.

8   REVISION HISTORY

Revision	Issue Date	Changes
05	02/22/2022	Formatting updated and document contents reorganized. Section 1 – Removed major upgrades to the search algorithm Section 2 – Modified reference and added software. Section 2.1 - Added study requirements Section 3.3 – Clarified maintenance expectations. Section 5 – Applies to verification, validation, and checks. Section 6 – Applies to verification and validation; Technical Leader will determine training and testing requirements.
06	02/15/2023	Section 1.1 – Clarified Next Generation Identification System expectations. Section 2-C – Added statement to address requirement Section 2.1 – Deleted Section 4.1 – Deleted from previous version Section 4.1 – Validation Program Manager added as approver. Section 4.2-A-1 – Deleted Section 4.2-B and Section 4.2-C – Approvals updated and re-organized. Section 4.2-E – Removed duplication. Section 5 – Record requirements updated. Section 6 – Removed extraneous information and clarified content. Section 7 – Removed and re-numbered.