Document #17

Standard for the Validation and Performance Review of Friction Ridge Impression Development and Examination Techniques

(Latent/Tenprint)

1. Preamble

1.1. This document provides direction for validating technical procedures or methods (hereafter referred to as 'techniques') prior to being introduced into operational casework. This document also provides direction for the performance check of technical procedures and methods prior to the techniques being deployed in their operational setting.

1.2. Validation assesses the ability of techniques to meet specified objectives, their benefits and limitations, and the optimal conditions under which results can be obtained. Performance check assesses the ability of techniques to meet specified objectives and verify the optimal conditions under which results can be obtained.

1.3. Validation and performance check are part of scientific best practices, quality assurance procedures, and laboratory accreditation requirements.

2. Scope

These guidelines apply to all novel, modified, or newly implemented techniques that pertain to casework.

3. Responsibilities

3.1. Validation may be conducted internally or externally.

3.2. Each organization is responsible for the validation or the implementation of the technique utilized in casework and will ensure that:

3.3. The validation is conducted by qualified individuals with access to appropriate resources.

3.4. The technical review of the validation process is conducted by qualified individuals, different than the ones who performed the validation study.

3.5. The end users or operators are qualified and appropriately trained in the use of the technique.

3.6. Ongoing tests are conducted after implementation to ensure that the technique continues to perform as expected.

3.7. Validation is appropriately documented and disseminated to interested parties.

4. Overview of the Validation Process

4.1. The new technique will be evaluated during four phases: review of theory, performance evaluation on ideal samples, performance evaluation on realistic samples, and evaluation of the implementation.

4.2. The validation process includes the following:

4.2.1. A validation plan will be prepared and documented (Section 5).

4.2.2. A requirement collection procedure will determine which factors will be considered to evaluate the benefits and limitations and how they will be measured (Section 6).

4.2.3. The four phases of the validation process are conducted (Section 7)

4.2.4. Validation is deemed successful if the technique satisfies the performance criteria defined beforehand for each of the relevant factors (Section 8).

4.2.5. The review of the process and results must be reviewed (Section 9).

4.2.6. The process and results must be documented (Section 910).

5. Validation Plan

5.1. The validation plan must be written prior to beginning the validation process. The validation plan must include the objectives of the validation study, an outline of all of the steps to be conducted, a sampling and data collection plan, and the relevant factors and defined success criteria (identified during requirements collection).

5.2. The validation plan must be technically reviewed by a qualified individual, external to the validation team, prior to the beginning of the study and when appropriate while conducting the study. The validation plan can be revised during the validation study if needed; any such revisions must be documented.

6. Requirements Collection

6.1. The requirement collection process will determine the following:

6.1.1. Factors to be considered during the validation study to assess the benefits and limitations of the technique.

6.1.2. Methods by which those factors can be measured.

6.1.3. Minimum thresholds used to gauge acceptable.

6.2. The relevant factors to be considered during the validation study may include accuracy, selectivity, detection limits, reproducibility, robustness, total and marginal cost, safety, ease of use, availability, operating conditions, and risks. The specific factors considered for a technique will vary substantially. The role of the requirements collection process is to determine all of the relevant factors that must be considered.

6.3. Methods must be devised to measure the desired factors, within the context and limitations of the validation, and available test data. These methods can be quantitative, qualitative, or categorical. Quantitative methods must be reported with an estimate of precision and uncertainty.

6.4. Thresholds must be established for each measurement method of the relevant factors to determine whether validation of the technique is successful. These thresholds will be based on the status quo, other alternative techniques, or theoretical success criteria, with consideration to the needs of the intended users.

7. Phases of the Validation Process

7.1. A complete validation process will assess the benefits and limitations of the new technique using the four following phases:

7.1.1. Review of the theory

The validation of a technique requires a thorough understanding of its theoretical basis. It is necessary to establish that a valid theoretical basis exists when a novel technique is introduced. This can be achieved by reviewing literature or by having novel theory reviewed by appropriate experts.

7.1.2. Performance evaluation on ideal samples

The new technique needs to be assessed on samples collected under controlled conditions. This initial evaluation is designed to establish an ideal baseline for the performance of the technique. This phase must demonstrate that the new technique performs adequately to proceed to the next phase of the validation process.

7.1.3. Performance evaluation on realistic samples

The new technique needs to be assessed on realistic samples, collected from, or mimicking, operational data. This phase of the validation process is designed to assess whether the technique satisfies the operational needs of laboratories or agencies. Because of the nature of the test samples, the level of performance observed during this phase of the validation procedure will be a reflection of the expected level of performance in actual casework. This phase must demonstrate that the new technique shows a sufficient level of performance to proceed to implementation. This stage of validation may assist in determining the operating parameters that will be used in implementation.

7.1.4. Evaluation of the technique in the relevant or actual environment

The performance of the new technique and the individuals performing the technique needs to be assessed immediately after implementation but prior to use in casework. This phase of the study is performed on comparable samples as in 6.1.3. However, the study will be performed on a fully operational system, deployed in its operational environment and operated by its end users. The performance is reassessed periodically to monitor the effective operation of the technique and the performance of the individuals performing these functions.

7.2. It may be appropriate to initiate selected phases of the validation process at different stages in implementing a technique. The phases to be conducted will depend on how novel the technique is.

7.2.1. If a technique is novel, it will require validation through all four phases.

7.2.2. If the technique is based on established theory, the validation process can start with the performance evaluation on ideal samples.

7.2.3. If the technique has been technically reviewed and evaluated by appropriate experts on ideal samples, a limited validation consisting of performance evaluation on realistic samples and evaluation of the implementation of the technique in its designated operational environment is acceptable.

7.2.4. If the technique has been technically reviewed and evaluated by appropriate experts on realistic samples in laboratory conditions, a limited validation consisting solely of the evaluation of the technique in its designated operational environment is acceptable.

7.2.5. The modification of an existing technique or the use of an existing technique outside of its original scope will also require the evaluation of its implementation and performance in the new environment.

7.3. The limited validation of a technique as described in 7.2.2, 7.2.3, and 7.2.4 may be referred to as “performance check” or “verification” in the referenced documents (Section 11).

8. Success

8.1. A technique will be successfully validated if it meets the thresholds for the relevant performance factors, as defined in requirements collection (Section 6).

8.2. If a technique fails to be successfully validated, it will be rejected and not accepted for use in casework.

8.3. Alternatives, if validation is unsuccessful, include:

8.3.1. Further research can be conducted to improve the technique. The validation of the revised technique should be based on the factors and thresholds defined previously.

8.3.2. A limited validation process can be conducted with modified factors or thresholds following a new requirements collection and new user approval.

8.4. Any deviations from the original plan must be documented.

9. Technical Review

One or more technical reviewers will evaluate the validation study before use in casework. A technical reviewer must be a qualified individual. The review process determines whether validation as conducted should be accepted, rejected, or requires minor or major changes.

10. Documentation

10.1. Documentation needs to include the validation plan, a validation report and the result of the validation review. The validation plan and report must be sufficient to ensure that any qualified individual could evaluate what was done and replicate the validation process.

10.2. In addition to the report, the documentation must include any relevant laboratory notes, reports, laboratory books, or log books. Validation data or samples should be retained if practical.

10.3. Should the validation start at any later stage than stage 1, the documentation needs to include the validation reports or peer-reviewed papers used to bypass the early stages.

10.4. Validation research should ideally be peer reviewed and published. At the minimum, validation reports need to be made available to others when relevant.

11. Further Reading

11.1. ASCLD/LAB; 2005 Manual; American Society of Crime Laboratory Directors, Laboratory Accreditation Board; 2005.

11.2. ASCLD/LAB-International; Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories; DRAFT; American Society of Crime Laboratory Directors, Laboratory Accreditation Board; 2009.

11.3. FBI; FBI Laboratory Operations Manual: Practices for Validating Technical Procedures; Federal Bureau of Investigation; 2007.

11.4. ISO/IEC 17025; General requirements for the competence of testing and calibration laboratories, Second edition; International Organization for Standardization, Geneva, Switzerland, 2005.

12. Revision Table

Version	Effective Start	Effective End	Posted	Archived	Change
1.0	08/18/10	11/16/12	10/11/10	11/16/12	Original issue
2.0	11/16/12	N/A	11/24/12	N/A	No change to content Reformatted (start of new version number)