This document has been accepted by the Academy Standards Board (ASB) for development as an American National Standard (ANS). For information about ASB and their process please refer to asb.aafs.org. This document is being made available at this stage of the process so that the forensic science community and interested stakeholders can be more fully aware of the efforts and work products of the Organization of Scientific Area Committees for Forensic Science (OSAC). The documents were prepared with input from OSAC Legal Resource Committee, Quality Infrastructure Committee, and Human Factors Committees, as well as the relevant Scientific Area Committee. The content of the documents listed below is subject to change during the standards development process within ASB, and may not represent the contents of the final published standard. All stakeholder groups or individuals, are strongly encouraged to submit technical comments on this draft document during the ASB's open comment period. Technical comments will not be accepted if submitted to the OSAC Scientific Area Committee or Subcommittees.

Standard for the Validation of Procedures in Bloodstain Pattern Analysis

DRAFT DOCUMENT

Standard for the Validation of Procedures in Bloodstain Pattern Analysis

Keywords: *Developmental validation, internal validation, specificity, sensitivity, quality assurance, validation report*

The purpose of this document is to provide standards to assist in the validation of new procedures as they relate to Bloodstain Pattern Analysis (BPA).

Foreword

This document provides standards for the developmental and internal validation of new Bloodstain Pattern Analysis (BPA) procedures and equipment. Validation is a component of quality assurance and will ensure that procedures are based on scientific principles and are reliable, accurate, and relevant. Undertaking validation can identify areas where improvements to current procedures are required and where new procedures need to be developed. This document has been prepared by the Organization of Scientific Area Committees (OSAC) Subcommittee on Bloodstain Pattern Analysis based on a document originating with the Scientific Working Group on Bloodstain Pattern Analysis (SWGSTAIN).

It is recognized that BPA is practiced both by individuals privately and by those employed by a agencies offering forensic services. This document is not intended to supplant the validation standards set forth for accredited laboratories that already have established validation procedures, but may assist these agencies in the refinement of their procedures relative to BPA. In addition, this document is intended to provide the framework for other agencies in the development of validation of procedures.

Table of Contents

1 Scope

This document applies to the validation of procedures for bloodstain pattern analysis casework and new equipment. It also applies to the internal validation of established procedures existing within the BPA community when such procedures are being used for the first time within an agency.

2 Normative References

Scientific Working Group on Bloodstain Pattern Analysis (SWGSTAIN): Guidelines for the Validation of New Procedures in Bloodstain Pattern Analysis, issue date 04/11/2011

3 Terms and Definitions

3.1

Accurate Procedure

A procedure that produces results in agreement with the true value.

3.2

Agency

An entity such as an individual, a law enforcement department, a private company, or a government or private laboratory that in this context provides BPA as one of its functions.

3.3

Developmental Validation

See Validation.

3.4

Internal Validation

See Validation.

3.5

New Procedure

A procedure that is new to the BPA community and has not been validated via publication in a peer reviewed journal or documented through an agency's internal validation Standard Operating Procedures (SOP).

3.6

Procedure

An established practice to be followed in performing a specified task.

3.7

Recommend

~~Appropriate~~ Suggested but not mandatory.

3.8

Relevant Procedure

A procedure that provides answers to the questions being asked.

3.9

Reliable Procedure

A procedure that produces repeatable results when applied as designed.

3.10

Shall

Done without exception.

3.11

Should

Expected to be done~~, unless otherwise documented for noncompliance~~ (requires non-compliance be documented).

3.12

Validation

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic analysis and includes the following:

1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel BPA methodology for use in case work.
2) Internal validation is an accumulation of test data within the agency to demonstrate that established methods and procedures perform as expected in the agency.

4 Requirements

4.1. Overview

4.1.1. Validation includes developmental validation and internal validation. *Developmental validation* involves the testing of ~~new~~ procedures in BPA. *Internal validation* involves testing of procedures that are new to an agency.

4.1.2. Developmental validation is typically performed within the broader BPA community and internal validation is performed by individual agencies.

4.1.3. The agency shall validate all procedures for bloodstain pattern analysis prior to casework. In instances where an unvalidated, case-specific procedure is available and evidence may be

~~compromised~~ lost, destroyed, or altered if the procedure is not used immediately, ~~internal~~ validation may be performed after the procedure is used and prior to reporting results. An example is implementation of a technique that an analyst learned at a conference and the technique may prove useful and a scene may not be held after the analyst's work is completed.

4.1.4. The agency shall maintain copies of publications, notes and records that provide details on the validation studies conducted on the procedures.

4.2. Developmental Validation

4.2.1**.** Developmental validation shall be documented appropriately and peer reviewed within the scientific community. Publication in a peer reviewed journal would be an example of such a review.

4.2.1.1. Documented testing of the procedure using control samples shall include but is not limited to the assessments of the following performance parameters, when they are applicable to the procedure being validated. The developmental validation shall include the following:

4.2.1.1.1. Specificity

4.2.1.1.2. Sensitivity

4.2.1.1.3. Reliability

4.2.1.1.4. Accuracy

4.2.1.1.5 Testing limitations

4.2.1.1.5.1. Considerations include ~~but are not limited to~~ the effect of the procedure on sequential processing and adherence to standard forensic protocol and testing

4.2.1.2. A list of existing documentation related to the ~~new~~ procedure

4.2.1.3. A description of the applicability of the procedure

4.2.1.4. A list of required equipment and materials

4.3. Internal Validation

4.3.1. When implementing procedures, internal validation shall be performed, documented and peer reviewed within the agency's quality assurance program or some equivalent review process. The validation of new equipment shall be done. The scope and purpose of internal validation are to demonstrate the procedure produces accurate and reliable results within the agency as designed.

4.3.1.1. The intent of internal validation is not to repeat the developmental validation; therefore, the scope or extent of the parameter testing may be of a more limited nature. There shall be documented testing of the procedure being implemented using control samples. References and publications containing the developmental validation should be available in support of the internal

validation. This testing shall include ~~but is not limited to~~ assessments of the following performance parameters, when they are applicable to the procedure being validated:

4.3.1.1.1. Specificity (as differentiated from Developmental Validation): Example-does the procedure or product or equipment give the appropriate results with positive and negative controls?

4.3.1.1.2. Sensitivity (as differentiated from Developmental Validation): Example-does the product detect (presumptive) blood at the greatest reported dilution as stated by the manufacturer?

4.3.1.1.3. Reliability

4.3.1.1.4. Accuracy

4.3.1.2. If a substantive modification of a physical or analytical component that could affect the results is made to a validated procedure within the agency, the modified procedure shall be validated.

4.3.2. Suggested strategy for the validation of procedures

4.3.2.1. Develop a plan

4.3.2.2. Define participants and responsibilities

4.3.2.3. Define the application, purpose and scope of the procedure

4.3.2.4. Define the performance parameters (see 4.2.1.1 and 4.3.1.1) and acceptance criteria

4.3.2.5. Design experiments

4.3.2.6. Verify control samples, standards, reagents and equipment performance

4.3.2.7. Perform experiments

4.3.2.8. Adjust experimental parameters 4.3.2.9. Perform adjusted experiments, if necessary

4.3.2.10. Evaluate procedure performance according to acceptance criteria

4.3.2.11. Determine if a procedure has been validated in accordance with the requirements listed above. If not, reevaluate the procedure and repeat the validation process.

4.3.2.12. Develop SOP~~s~~ for the procedure

4.3.2.13. Define type and frequency of quality control checks for the procedure

4.3.2.14. Document validation experiments and results in the validation report

4.3.3. A validation report shall be prepared. The report shall include the following where applicable:

4.3.3.1. Objective(s) and scope of the procedure

4.3.3.2. List of control samples, standards, and reagents

4.3.3.3. Procedures for quality checks of standards and reagents used

4.3.3.4. Health and safety considerations

4.3.3.5. Procedure parameters

4.3.3.6. Listing of equipment and its performance requirements

4.3.3.7. Detailed conditions by which the experiments were conducted, including sample preparation

4.3.3.8. Statistical procedures and representative calculations

4.3.3.9. Procedures for quality control

4.3.3.10. Procedure acceptance criteria

4.3.3.11. Participant(s) who developed and initially validated the method

4.3.3.12. Summary and conclusions including review dates and references