Scientific Working Group on Bloodstain Pattern Analysis (SWGSTAIN): Guidelines for the Validation of New Procedures in Bloodstain Pattern Analysis

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Objective

Validation is a component of quality assurance intended to assist in the implementation of new procedures. Validation will ensure that new procedures are based on scientific principles and are reliable, accurate, and relevant. Undertaking validation may identify areas where improvements are required and where new procedures need to be developed. This document provides validation guidelines for the implementation of new procedures for bloodstain pattern analysis (BPA).

Introduction

SWGSTAIN comprises BPA experts from North America, Europe, New Zealand, and Australia. The objective of SWGSTAIN is to serve as a professional forum in which BPA practitioners and practitioners from related fields can discuss and evaluate methods, techniques, protocols, quality assurance, education, and research relating to BPA. It is the ultimate goal of SWGSTAIN to use these professional exchanges to address substantive and operational issues within the field of BPA and to work to build consensus-based best-practice guidelines for the enhancement of the discipline of BPA.

Statement of Purpose

The following are guidelines to assist in the validation of new procedures as they relate to bloodstain pattern analysis.

Definitions

Validation is the process of demonstrating that a procedure is reliable, accurate, and relevant in the hands of the practitioner performing the procedure.

A *reliable procedure* is one which produces consistent results when applied as designed.

An *accurate procedure* is one which produces results in agreement with the true value.

A *relevant procedure* is one which provides answers to the questions being asked.

An *agency* is any entity such as an individual, a law enforcement department, a private company, or a government or private laboratory that provides BPA as one of its functions.

New procedures are defined as those that are new to an agency or those that are new to BPA.

Must – done without exception

Should – expected to be done

Recommend – appropriate, but not mandatory

Guidelines

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.

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

The agency must validate all new procedures for bloodstain pattern analysis casework. In instances where an unvalidated, case-specific procedure is available and evidence may be compromised if the procedure is not used, validation must be performed after the procedure is used and prior to reporting results.

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

1. Developmental validation must be documented appropriately and critically reviewed within the scientific community. Publication in a peer reviewed journal would be an example of such a review. The developmental validation must include the following:

    1.1 Documented testing of the procedure using control samples. This documented testing should include but is not limited to the

assessments of the following performance parameters, when they are applicable to the procedure being validated. Not all performance parameters will apply to every procedure.

1.1.1 Specificity

1.1.2 Sensitivity

1.1.3 Reliability

1.1.4 Accuracy

1.1.5 Robustness

1.1.6 Testing limitations

1.2 A list of existing documentation related to the new procedure

1.3 A description of the applicability of the procedure

1.4 A list of required equipment and materials

2. When implementing established procedures, internal validation must be performed, documented and critically reviewed within the agency's quality assurance program or some equivalent review process. The scope and purpose of internal validation are to demonstrate the new procedure works as designed within the agency. The intent is not necessarily to repeat the developmental validation. Internal validation must include the following:

2.1 Documented testing of the procedure being implemented using control samples. This testing should include but is not limited to assessments of the following performance parameters, when they are applicable to the procedure being validated. Not all performance parameters will apply to every procedure.

2.1.1 Specificity

2.1.2 Sensitivity

2.1.3 Reliability

2.1.4 Accuracy

2.1.5 Robustness

2.1.6 Testing Limitations

2.2 If a substantive or consequential alteration of a physical or analytical component is made to a validated procedure within the agency, the modified procedure must be validated.

3. Suggested Strategy for the Validation of Procedures[1]

3.1 Develop a plan

3.2 Define participants and responsibilities

3.3 Define the application, purpose and scope of the procedure

3.4 Define the performance parameters (see 1.1 and 2.1) and acceptance criteria

3.5 Define experiments

3.6 Verify control samples, standard, reagents and equipment performance

3.7 Perform experiments

3.8 Adjust experimental parameters or acceptance criteria if necessary

3.9 Perform adjusted experiments, if necessary

3.10 Evaluate procedure performance according to acceptance criteria

3.11 Determine if procedure has been validated. If not, reevaluate procedure and repeat the validation process.

3.12 Develop SOPs for the procedure

3.13 Define type and frequency of quality control checks for the procedure

3.14 Document validation experiments and results in the validation report

4. A validation report should be prepared that may include the following[2]:

4.1 Objective and scope of the procedure

4.2 List of control samples, standards, and reagents

4.3 Procedures for quality checks of standards and reagents used

4.4 Health and safety considerations

4.5 Procedure parameters

4.6 Listing of equipment and its performance requirements

4.7 Detailed conditions on how the experiments were conducted, including sample preparation

4.8 Statistical procedures and representative calculations

4.9 Procedures for quality control

4.10 Procedure acceptance criteria

4.11 Participant(s) who developed and initially validated the method

4.12 Summary and conclusions review dates - references

[1] http://www.labcompliance.com/tutorial/methods/default.aspx

[2]Method Validation, LabCompliance