

Validation of Technical Procedures

1 Introduction

Forensic laboratories must implement procedures to ensure that a selected analytical protocol is capable of producing accurate and reliable results. To demonstrate the performance of a technical procedure, a validation study is performed. A validation study involves evaluation of specific analytical parameters, such as accuracy and/or limit of detection. The Trace Evidence Unit (TEU) and Scientific and Biometrics Analysis Unit - Trace (SBAU-Trace) will define an acceptable range for each of the parameters evaluated. When the selected parameters of an analytical method have been demonstrated to fall within the acceptable ranges and appropriately reviewed, the method is considered validated and can be adopted into the trace evidence (TE) standard operating procedures for routine use. This document provides guidelines for the development and validation of new analytical procedures in the TEU and SBAU-Trace.

2 Scope

This document applies to personnel who develop and validate new technical procedures that will be implemented in the TEU and SBAU-Trace. The performance characteristics that are evaluated will be based on the requirements of the analytical procedure.

3 Records

All records related to instrumental validation studies conducted within the TEU and SBAU-Trace will be maintained with the instrument log books for that instrument. All records related to method validation will be kept as a separate file and maintained in the unit for the TEU and/or SBAU-Trace. This includes any relevant journal articles, instrument optimization charts, or validation data used or generated as part of the validation study.

Instrumental validation studies for newly acquired Fourier Transform Infrared spectrometer (FTIR) systems will be recorded on the *Validation Study for Newly Acquired FT-IR Form* (Appendix A).

4 Validation Process

Validation studies are conducted under the direction and management of an appropriate Technical Leader according to the requirements set forth in *LOM – Practices for Developing Methods and Validating Technical Procedures*. The validation study will include:

4.1 Definition of the scope of the analytical procedure.

4.2 Identification of the characteristic(s) of the technical procedure to validate.

4.3 Optimization of analytical parameters and select experiments to determine the required characteristic(s).

4.3.1 Standardized Technical Procedures

A standardized technical procedure has been documented, validated, and endorsed by a recognized technical organization (e.g., ASTM, AOAC, EPA, USP). In this case, the sample preparation and instrumental parameters have been established, so the only experiments required are those that will demonstrate that the technical procedure can be duplicated within the TEU and/or SBAU-Trace and that similar performance characteristics can be achieved.

4.3.2 Modified Standardized Technical Procedures

A modified standardized technical procedure is one that has been modified outside the specifications of the standardized procedure. In this case, it must be verified that the modifications do not alter the performance characteristics such that the data are no longer appropriate for the intended purpose.

4.3.3 Non-standardized Technical Procedures

A non-standardized technical procedure has been developed externally but has not been previously endorsed by a recognized technical organization (e.g., an analytical procedure published in a technical journal). In this case, the performance characteristics applicable to the intended purpose must be determined and appropriate validation experiments must be conducted.

4.3.4 In-house Technical Procedures

An in-house technical procedure is developed within the TEU and/or SBAU-Trace for subsequent routine use or as a solution to a unique analytical problem. In this case, the performance characteristics applicable to the intended purpose must be determined and appropriate validation experiments must be conducted.

4.4 Conduct experiments to determine the required characteristic(s).

4.5 Technical Review and Approval

Upon completion of the method development and/or validation the validation results will be reviewed, and approval will be recorded according to the FBI Laboratory Operations Manual (LOM) – *Practices for Developing Methods and Validating Technical Procedures*.

5 Competency Testing

All examiners and/or physical scientists who will apply the new procedure to casework must successfully complete competency testing requirements set forth in the LOM - *Developing Methods and Validating Technical Procedures*.

6 Procedure Modifications

There are times when deviating from an established standard operating procedure is necessary. When a deviation occurs, the step-by-step procedures that were used must be documented as stated in section 3, as well as the appropriate approval for deviation as follows:

6.1 Significant Modifications to Previously Validated Procedures

If a significant modification has been made to a previously validated procedure, at a minimum, the modification will be evaluated by comparison of established results with those generated by the current procedure using appropriate samples. These modifications should produce results of the same or improved quality as compared with those obtained by the previously validated procedure. Significant modifications records and approval will be done in accordance with major deviation requirements set forth in the LOM - *Practices for Authorizing Deviations*. Any deviations to procedures must be approved by the appropriate Technical Leader prior to their submission to the Forensic Analysis Support Unit.

6.2 Minor Modifications to Previously Validated Procedures

A minor modification to an existing procedure that does not materially affect the performance of the test does not require additional validation studies. These modifications should improve the efficiency, effectiveness, and/or quality of the test. Minor modification records and approval will be done in accordance with minor deviation requirements set forth in the LOM - *Practices for Authorizing Deviations*.

7 References

- FBI Laboratory Quality Assurance Manual.
- FBI Laboratory Operations Manual.

Rev. #	Issue Date	History
3	05/11/2018	Added Validation Study for Newly Acquired FT-IR form in Appendix A and reference to form in documentation section. Section 4.5 modified wording for approval in accordance with LOM.
4	02/03/2020	Updated SBAU-Trace name in Scope and throughout. Changed Section 3 from Documentation to Records in title and throughout. Updated language in Sections 3, 4, and 5.

Approval

Redacted - Signatures on File

Trace Evidence Unit Chief:

Date: 01/31/2020

Scientific and Biometrics
Analysis Unit Chief:

Date: 01/31/2020

Hairs and Fibers Technical
Leader:

Date: 01/31/2020

Mineralogy Technical Leader:

Date: 01/31/2020

Anthropology Technical
Leader:

Date: 01/31/2020

QA Approval

Quality Manager:

Date: 01/31/2020

Appendix A: *Validation Study for Newly Acquired FT-IR*

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Appendix A: *Validation Study for Newly Acquired FT-IR (cont.)*

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Appendix A: *Validation Study for Newly Acquired FT-IR (cont.)*

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