ANSI/ASB Standard 038, First Edition
2020

Standard for Internal Validation of Forensic DNA Analysis Methods

Standard for Internal Validation of Forensic DNA Analysis Methods

ASB Approved May 2020

ANSI Approved August 2020

410 North 21st Street
Colorado Springs, CO 80904

Foreword

Internal validation is an integral step in the implementation of DNA methodologies and the development of standard operating procedures used in forensic testing. Internal validation establishes the uses and limitations of a methodology prior to laboratory implementation. The purpose of this document is to provide general requirements for the internal validation of all forensic DNA analysis methods.

This document is intended to be an umbrella document to subsequent validation standards, each of which will cover more detailed term definitions, specific methodologies, and their corresponding technical specifications.

This document was revised, prepared, and finalized as a standard by the DNA Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Biology/DNA Biological Methods Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science.

The AAFS Standards Board (ASB) is an ANSI-accredited Standards Developing Organization with the purpose of providing accessible, high quality science-based consensus forensic standards. The ASB is a wholly owned subsidiary of the American Academy of Forensic Sciences (AAFS), established in 2015 and accredited by the American National Standards Institute (ANSI) in 2016. The ASB consists of Consensus Bodies (CB), which are open to all materially interested and affected individuals, companies, and organizations; a Board of Directors; and Staff.

The following applies to all ASB documents:

the term **'shall'** indicates that a provision is mandatory, and can be audited for compliance

the term **'should'** indicates that a provision is not mandatory, but recommended as good practice.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

Keywords: *internal validation, DNA, forensic DNA analysis methods*

Table of Contents

Standard for Internal Validation of Forensic DNA Analysis Methods

1 Scope

This document details the general requirements for performing an internal validation of all forensic DNA analysis methods within a forensic DNA laboratory.

2 Normative References

There are no normative references for this standard. Annex A, Bibliography contains informative references.

3 Terms and Definitions

3.1
developmental validation
The acquisition of test data and determination of conditions and limitations of a new methodology; this generally occurs while the conditions and parameters are being worked out prior to the establishment of a defined assay, procedure or product. Internal validation studies typically follow developmental validation studies.

3.2
forensic DNA analysis
The use of DNA technologies for the evaluation of biological evidence that may be involved in legal matters.

3.3
internal validation
The accumulation of test data within the laboratory for developing the laboratory standard operating procedures and determining the limits of the method(s). Internal validation demonstrates that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory.

3.4
interpretation
The process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison.

3.5
methodology
Methodology refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantification, amplification, and detection.

3.6
validation
The process of performing and evaluating a set of experiments that establish the efficacy, reliability, and limitations of a method, procedure or modification thereof; establishing recorded documentation that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

4 Requirements

4.1 The laboratory shall conduct internal validation studies on all forensic DNA analysis methodologies prior to implementation.

4.2 The laboratory shall conduct additional internal validation studies if there is an alteration to the previously validated procedure, reagents, software, or instrumentation that has an impact on the efficacy or the reliability of the analysis.

4.3 Internal validation studies shall be documented to include the validation plan, all testing results and conclusions, all raw data (including unedited electronic files), and statistical calculations (if applicable) used to support conclusions. The documentation shall include any unexpected results (e.g., contamination events) and an explanation for each result must be documented. A summary of the above shall also be retained.

4.3.1 If any deviations from the developmental validation are detected, a statement of explanation and an investigation shall be conducted and documented.

4.3.2 If any results from internal validation studies fall outside the scope of developmental validation, a statement of explanation shall be documented.

4.3.3 Where methodology-specific internal validation requirements exist, if a required study is determined to be not applicable, an explanation shall be documented.

4.4 Quality assurance parameters, interpretation protocols, and analytical procedures shall be derived from internal validation studies, including any applicable limitations.

4.5 Information from developmental validation studies and internal validation studies from other forensic laboratories may be obtained, reviewed, and utilized. If relied upon, this information shall be maintained as part of the internal validation documentation.

If the laboratory conducted or participated in the developmental validation of the methodology, the developmental validation studies conducted by the laboratory may be used to satisfy applicable elements of the internal validation requirements. This information shall be maintained as part of the internal validation documentation.

4.6 The DNA Technical Leader or other appropriate personnel shall determine if an internal validation, or portions of an internal validation, are transferable between laboratories within a multi-laboratory system. Any aspect of the internal validation that is determined to be non-transferable shall be conducted at each laboratory within a multi-laboratory system.

If the internal validation is transferable between laboratories within a multi-laboratory system, the studies may be shared among laboratories within the system. If relied upon, this information shall be maintained as part of the internal validation documentation.

4.7 Internal validation studies shall be approved by the DNA Technical Leader or other appropriate personnel prior to implementation of the methodology for casework or database applications. Approval shall be documented by the DNA Technical Leader or other appropriate personnel, at a minimum, with initials and the date of review.

5 Conformance

In order to demonstrate conformance with this standard, the laboratory shall have the following:

a) documentation of all internal validation studies;

b) documented quality assurance parameters, interpretation protocols, and analytical procedures derived from internal validation studies;

c) documented approval by the DNA Technical Leader or other appropriate personnel prior to implementation.

Annex A
(informative)

Bibliography

This is not meant to be an all-inclusive list as the group recognizes other publications on this subject may exist. At the time this standard was drafted, these were the publications used for reference. Additionally, any mention of a particular software tool or vendor as part of this bibliography is purely incidental, and any inclusion does not imply endorsement.

1] Butler, J.M. *Quality Assurance and Validation. In: Advanced Topics in Forensic DNA Methodology*. Elsevier, 2011

2] Federal Bureau of Investigation, *Quality Assurance Standards for DNA Databasing Laboratories*[a].

3] Federal Bureau of Investigation, *Quality Assurance Standards for Forensic DNA Testing Laboratories*[a].

4] ENSFI. *Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process*[b].

5] SWGDAM. *SWGDAM Validation Guidelines for Forensic DNA Analysis Methods*[c].

[a] Available at https://www.swgdam.org/publications
[b] Available at http://www.enfsi.eu/sites/default/files/documents/minimum_validation_guidelines_in_dna_profiling_-_v2010_0.pdf
[c] Available at https://www.swgdam.org/#!publications/c1mix

Academy Standards Board
410 North 21st Street
Colorado Springs, CO 80904

www.asbstandardsboard.org