# Standard for Internal Validation of Forensic DNA Analysis Methods

*Biological Methods Subcommittee*
*Biology/DNA Scientific Area Committee*
*Organization of Scientific Area Committees (OSAC) for Forensic Science*

**OSAC Proposed Standard**

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Prepared by
Biological Methods Subcommittee
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## Disclaimer:

This document has been developed by the Biological Methods Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science through a consensus process and is *proposed* for further development through a Standard Developing Organization (SDO). This document is being made available so that the forensic science community and interested parties can consider the recommendations of the OSAC pertaining to applicable forensic science practices. The document was developed with input from experts in a broad array of forensic science disciplines as well as scientific research, measurement science, statistics, law, and policy.

This document has not been published by an SDO. Its contents are subject to change during the standards development process. All interested groups or individuals are strongly encouraged to submit comments on this proposed document during the open comment period administered by the American Academy of Forensic Science Standards Board (www.asbstandardsboard.org).

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## 1. SCOPE

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

## 2. NORMATIVE REFERENCES

The following referenced documents are the foundation of these best practices. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document applies.

ENSFI. Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process.
[http://www.enfsi.eu/sites/default/files/documents/minimum_validation_guidelines_in_dna_profiling_-_v2010_0.pdf](http://www.enfsi.eu/sites/default/files/documents/minimum_validation_guidelines_in_dna_profiling_-_v2010_0.pdf)

SWGDAM. *SWGDAM Validation Guidelines for Forensic DNA Analysis Methods.*

[https://www.swgdam.org/#!publications/c1mix](https://www.swgdam.org/#!publications/c1mix)

## 3. TERMS and DEFINITIONS

3.1 Contamination is exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence.

3.2 Developmental validation is the acquisition of test data and determination of conditions and limitations of a new methodology.

3.3 DNA Analysis is the use of DNA technologies for the evaluation of biological evidence that may be involved in legal matters.

3.4 Internal Validation is the accumulation of test data within the laboratory for developing the laboratory standard operating procedures and demonstrating that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory.

3.5 Precision is the degree of mutual agreement among a series of individual measurements, values and/or results.

3.6 Sensitivity studies are a set of critical studies performed during developmental and/or internal validation of DNA or other test methods designed to define the lower and upper limits/ bounds of an assay to accurately detect an analyte.

3.7 Validation is 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 use on casework or database samples.

4.2   The laboratory shall conduct additional internal validation studies if an alteration that has the potential to influence results is made to a validated forensic DNA analysis methodology.

4.3   Internal validation studies shall be documented to include, at a minimum, a summary of all testing results and conclusions, raw data, and statistical calculations (if applicable) used to support conclusions.

4.4   Quality assurance parameters, interpretation guidelines, and analytical procedures shall be derived from internal validation studies.

    4.4.1   Information from developmental validation studies and internal validation studies from other forensic laboratories may be utilized, if made available for review.

4.5   Developmental validation studies may be used to satisfy applicable elements of the internal validation standards if the laboratory conducted or participated in developmental validation of the methodology.

4.6   Results from internal validation studies that contradict developmental validation shall be investigated. A statement of explanation for the contradiction shall be included in the final internal validation document if the data are accepted for analytical procedure development.

4.7   Results from internal validation studies that fall outside the scope of developmental validation shall be included in the final internal validation document if the data are utilized for analytical procedure development.

4.8   Where methodology specific internal validation standards exist, if a required study is determined to be not applicable, an explanation shall be provided in the final internal validation document.

4.9   Each laboratory within a multi-laboratory system shall conduct applicable internal validation studies impacted by location-specific factors (precision, sensitivity, susceptibility to contamination, etc.).

    4.9.1   Internal validation studies that are not location-specific may be shared among laboratories within the system, if made available for review.

4.10 Internal validation studies shall be approved by the DNA Technical Leader prior to implementation of the methodology for casework or database applications. Approval shall be documented by the Technical Leader, 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:

5.1 Documented internal validation studies and any alterations on all forensic DNA analysis methodologies intended for forensic casework or database applications prior to implementation.

5.2 Quality assurance parameters, interpretation guidelines, and analytical procedures derived from internal validation studies.

5.3 Documented approval by the DNA Technical Leader prior to implementation.

## 6. ANNEX

### Annex A – Foundational Principles

None

### Annex B – Bibliography

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

FBI, *Quality Assurance Standards for DNA Databasing Laboratories.*
https://www.swgdam.org/#!publications/c1mix

FBI, *Quality Assurance Standards for Forensic DNA Testing Laboratories.*
https://www.swgdam.org/#!publications/c1mix