

Standard for Internal Validation of Forensic DNA Analysis Methods



WHAT IS AN AAFS STANDARD FACTSHEET?

The AAFS produces clear, concise, and easy-to-understand factsheets to summarize the contents of technical and professional forensic science standards on the OSAC Registry. They are not intended to provide an interpretation for any portion of a published standard.

WHAT IS THE PURPOSE OF THIS STANDARD?

Validation studies establish the efficacy and reliability of a method, procedure, or modification to a procedure used in forensic testing. Internal validation demonstrates that the established protocols for the technical steps of the test and for data interpretation perform as expected when used by a forensic science service provider (FSSP).

This standard outlines requirements for performing an internal validation of forensic DNA analysis methods performed by an FSSP and the documentation to be maintained. This standard is intended to be an umbrella document. Subsequent standards will cover specific methodologies and their corresponding technical specifications.

WHY IS THIS STANDARD IMPORTANT? WHAT ARE ITS BENEFITS?

Adherence to this standard promotes the performance and documentation of internal validations on new or modified processes.

The validation study defines the necessary quality assurance parameters and the limitations of the method.

Procedures for interpretation and analysis are derived from the validation studies. FSSPs performing forensic DNA analysis are encouraged to meet this standard.



HOW IS THIS STANDARD USED, AND WHAT ARE THE KEY ELEMENTS?

This standard provides direction for conducting and documenting internal validation studies on forensic DNA analysis methodologies. Internal validation is required prior to implementation and when there is an alteration to a previously validated procedure, reagents, software, or instrumentation that has an impact on the efficacy or the reliability of the analysis.

Quality assurance parameters, interpretation protocols, analytical procedures, and limitations of the method are derived from the internal validation studies.

Conformance to this standard requires documentation of all internal validation studies, quality assurance parameters, interpretation protocols, and analytical procedures derived from internal validation studies. Documented approval by the DNA Technical Leader or other appropriate personnel prior to implementation is also required to demonstrate conformance.