Best Practice Recommendations for Internal Validation of Software used in Forensic DNA Laboratories

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?

This standard provides recommendations for the validation performed by forensic science service providers (FSSPs) of software that is used in forensic DNA testing. The validation performed by the FSSP prior to use is commonly referred to as an internal validation. This standard applies to software that impacts the integrity of the evidence, is used in the analytical testing process, is used for the interpretation of analytical data, or is used for the generation of statistics.

These recommendations are not intended to be exhaustive. They do not cover all aspects of software engineering, development, and testing. Additional guidelines and standards may be applicable to specialized software packages, such as ANSI/ASB 018, 1ˢᵗ Ed., 2020 that focuses on probabilistic genotyping software.

WHY IS THIS STANDARD IMPORTANT? WHAT ARE ITS BENEFITS?

FSSPs are responsible for designing the internal validations that they perform. Software used in forensic DNA testing are numerous and varied. This standard provides recommendations to assist an FSSP with this responsibility addressing:

a) Software used as a component, part, or accessory of instrumentation.
b) Software that impacts the chain of custody documentation.
c) Software that impacts the decision process and/or influences conclusions or reporting.
d) Software created by the FSSP to assist with calculations and/or data transfers.

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

This standard and the recommendations that it contains, will be used by FSSPs that perform forensic DNA testing. The recommendations apply to the internal validation that should be performed prior to the implementation of new software programs and also guides the user through the evaluation of new versions or modules and modifications or updates to previously validated software.

Two approaches to internal validation are recommended: 1) the FSSP performs the internal validation of the software utilizing information from the developer, or 2) the FSSP uses a third party, in whole or in part, to perform an internal validation that meets the recommendations in this standard.

Internal validations are recommended to follow a predefined plan depicted in the standard. Step one is an objective assessment of the criticality and complexity of the software program or module, a risk assessment. The standard provides recommended test types for each determined risk level as well as guidance on test cases and test data used in the internal validation.

Recommendations for defining internal validation acceptance criteria and the records to be maintained are also included in this standard.