

Standard Practices for Method Validation in Forensic Toxicology, First Edition, 2019



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?

Toxicology screening, confirmatory, and quantitative tests are conducted using analytical methods.

Validation provides evidence that analytical methods are fit-for-purpose and allows for an understanding of their limitations under normal use.

This document establishes minimum standards for the validation of the analytical methods used in forensic toxicology laboratories.

Required validation experiments are based on the use of the analytical method (i.e., screening, confirmation, or quantitation).

WHY IS THIS STANDARD IMPORTANT? WHAT ARE ITS BENEFITS?

Adherence to the standard ensures that the analytical methods used in toxicological testing are fit-for-purpose.

The standard provides direction to the forensic toxicology community regarding minimum parameters to evaluate, appropriate experimental design, and the required performance expectations for the individual validation experiments.

Forensic toxicology laboratories are encouraged to meet these minimum standards.



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

This standard provides direction on method development, method validation, and proper record retention for these activities.

Internal method development requires a laboratory to establish the steps required to extract (or isolate) analyte(s) from a biological sample, instrumental settings needed to detect the analyte(s), and data evaluation steps required to finalize the analysis, such as assigning a quantitative (numerical) value.

Method development must be finalized prior to starting method validation, as any changes made may affect the validation results. If method validation results suggest that modifications to the method are required, the entire process of method development followed by method validation is restarted.

Method validation expectations start with a validation plan that states the validation experiments that will be undertaken, and the performance requirements that must be met for the method to be considered fit-for-purpose.

Validation parameters in the standard include bias, calibration model, carryover, interference studies, ionization suppression or enhancement, limit of detection, lower limit of quantitation, and precision. Specific requirements depend on the intended use of the method (i.e., screening, confirmation, quantitation).

