1D. Method Validation and Method Verification

Introduction

In forensic science, methods are used to answer a question (e.g., how much does an item weigh? what is the concentration of a chemical in a substance? is there a DNA profile on the item?). Before methods can be used to examine an item they must be validated or verified to impart confidence in the output. Method validation establishes, through documented experimentation, that a scientific method is fit for purpose--in layman's terms, when used as specified it does what it is intended to do. Method verification involves a process to ensure that a previously validated method performs as expected when used by others.

Method Validation

Method validation involves three phases: development, optimization, and implementation. Depending on what has been done by other organizations, a forensic science service provider (FSSP) may not need to complete all of these phases (see Table 1 and Figure 1) prior to use.

Method validation:

- Phases can be performed by one or more individuals or teams
- Does not include opinion statements
- Establishes limitations of the method and reported results
- Aids in identifying what is required for ongoing quality assurance (QA) and quality control (QC)
- Aids in assessing measurement uncertainty or error rates

Table 1 The three phases of method validation

Phase One
Method development is typically performed by research scientists and published in a peer-reviewed journal
Phase Two
Method optimization commonly establishes: • "Fit-for-purpose" criteria • Equipment specifications and operating parameters • Metrological traceability • Sample preparation approach • Sample analysis approach • The observations, data, or calculations generated • Interpretation of observations, data, or calculations
Phase Three
Method implementation uses known materials (i.e., source, identity, concentration) that represent the range of anticipated work to evaluate "fit-for-purpose" criteria: • Method performance and limitations (i.e., precision, bias, sensitivity, specificity) • Determination of item suitability for examination

Method Verification

Verification provides objective evidence that the method performs at the stated performance level of the original validation. The validated method is used with no modification.

The components of phase three that are susceptible to variation when the method is used by a different organization, another facility within a single organization, or a different analyst using different equipment are evaluated, generally with a smaller number of samples.

After Method Validation or Method Verification

Use of the method by multiple staff provides intermediate precision data. Use by other organizations or multiple facilities within a single organization after verification provides reproducibility data. Both, along with quality control (QC) and performance monitoring data, provide ongoing information to support that the method continues to perform as validated and continues to meet the fit-for-purpose criteria.

This additional data may allow refinements to measurement uncertainty or error rates and may identify opportunities for further method optimization. Additional optimization is considered method modification. Modifications return the method validation process to phase two, which must be followed by phase three to re-evaluate any criteria impacted by the modification.

Challenges

Limitations on the number of samples and types of samples required to adequately represent the range of anticipated work are not unique to forensic science. The number and types of samples used may impact method performance statistics. The samples used may increase the number or magnitude of limitations to observations, data, or calculations, which may also impact an interpretation or an opinion.

Consensus standards used for the accreditation of FSSPs use general terms such as "fit-for-purpose," "appropriate," "meeting the customer's requirements," and "needs of the customer" when characterizing a method. Performance criteria used to define these general terms may be included in consensus standards that are test methods. Generally, when performance criteria are not specifically defined in a standard, they are determined by the FSSP based on their understanding of the customer's needs.

These challenges generate differing opinions on the choices made related to the number and type of samples used in method validation and method verification and on the criteria used to establish that a method is fit-for-purpose.

Forensic Science Examples

In addition to Figure 2, see ANSI/ASB 018, Standard for Validation of Probabilistic Genotyping Systems on the OSAC Registry.

Figure 1 General flow of method validation

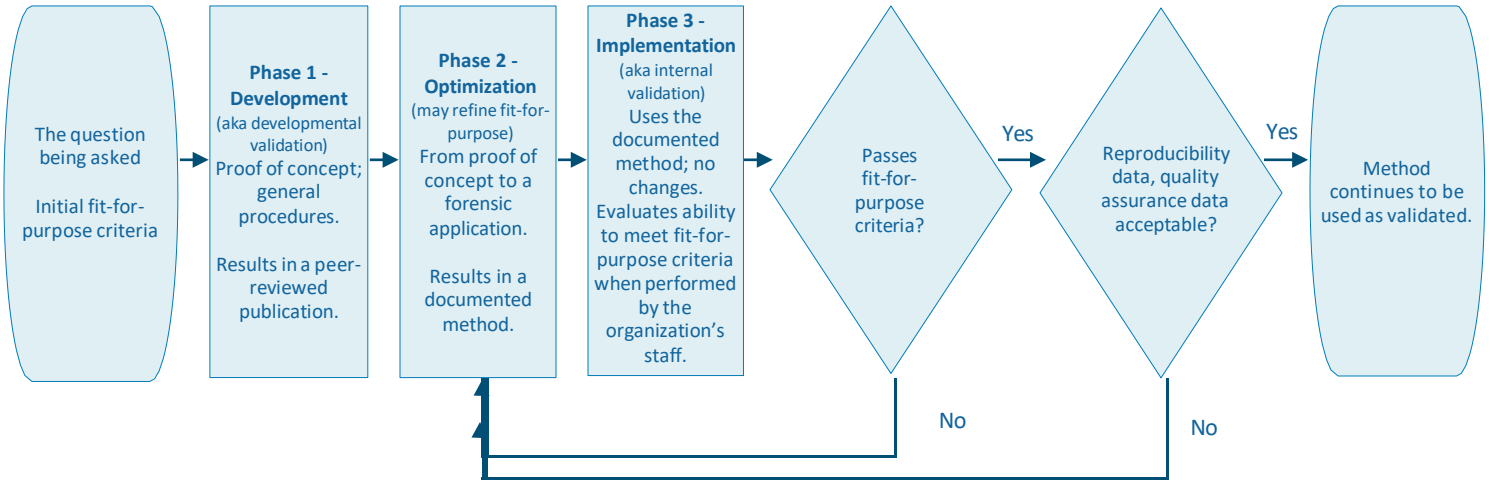
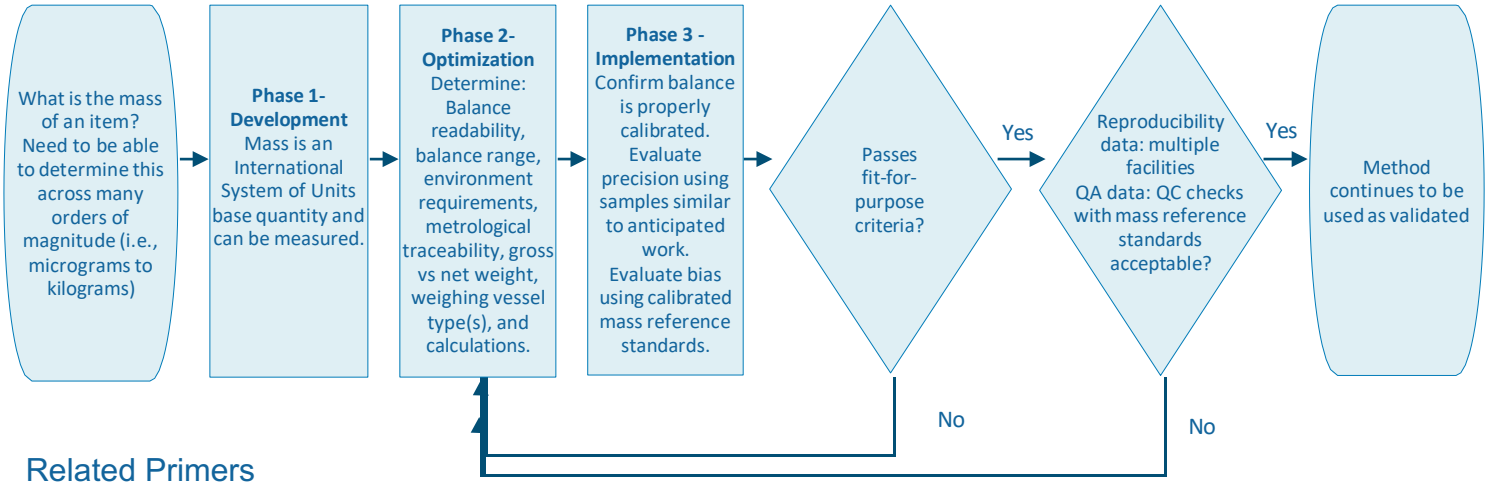


Figure 2 Forensic science example for determining the mass of an item



Related Primers

- Documentary Standards
- Method Performance Statistics
- Metrological Traceability
- Performance Monitoring: Methods, People, Organizations
- Quality Assurance versus Quality Control

Learn More

To learn more about validation and verification, see:

Eurachem's Planning and Reporting Method Validation Studies – Supplement to Eurachem Guide on the Fitness for Purpose of Analytical Methods

NIST's Validation Information to Aid Forensic DNA Laboratories

OSAC's Human Factors in Validation and Performance Testing of Forensic Science

Research article of Bradford et al., Accuracy and reliability of forensic latent print decisions

Key Takeaways

1. Method validation is performed prior to use in an examination.
2. Method validation consists of three phases - development, optimization, and implementation.
3. Method validation establishes the limitations of the method and reported results.
4. Method verification is appropriate when the validated method has not been modified.
5. Method validation and method verification are different from ongoing quality control.

Glossary: Primer 1D Method Validation and Method Verification

Term	Definition	Reference	Primer Nos.
Interpretation	Explanations for the observations, data, and calculations	Organization of Scientific Area Committees for Forensic Sciences. (2022). Retrieved from OSAC Lexicon: https://www.nist.gov/glossary/osac-lexicon	1D Method Validation & Method Verification
Method	A combination of procedural steps used to perform a specific technical process	FBI Quality Assurance Standards for DNA Testing Laboratories, 2020	1D Method Validation & Method Verification
Opinion	View, judgment, belief – takes into consideration other information in addition to observations, data, calculations, and interpretations	Organization of Scientific Area Committees for Forensic Sciences. (2022). Retrieved from OSAC Lexicon: https://www.nist.gov/glossary/osac-lexicon	1D Method Validation & Method Verification
Quality	The degree to which a set of inherent characteristics of an object fulfills requirements	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control; 1D Method Validation & Method Verification
Result	The product of the forensic service provider. This term is broad and includes observations, data, calculations, interpretations, and opinions	Organization of Scientific Area Committees for Forensic Sciences. (2022). Retrieved from OSAC Lexicon: https://www.nist.gov/glossary/osac-lexicon	1C Quality Assurance vs. Quality Control; 1D Method Validation & Method Verification
Validation	Verification, where the specified requirements are adequate for an intended use	ISO/IEC 17025:2017 General Requirements For The Competence Of Testing And Calibration Laboratories, Geneva, Switzerland	1D Method Validation & Method Verification
Verification	Provision of objective evidence that a given item fulfills specified requirements	ISO/IEC 17025:2017 General Requirements For The Competence Of Testing And Calibration Laboratories, Geneva, Switzerland	1D Method Validation & Method Verification