



# Mandatory Requirements for Standards Development

## Purpose

This document identifies priorities for the OSAC to achieve its [mission by](#) defining the minimum topics to cover when developing standards. In addition, [Supplemental Work Products by OSAC Units](#) that support the development and implementation of standards shall be aligned to these minimum topics.

Scientific Area Committees (SACs) and their Subcommittees (SCs) may approach the development of standards in ways that range from a single standard that covers many related topics to separate standards for each topic or subtopic. A given priority may be addressed by discipline-specific standards, or it may be covered in interdisciplinary standards intended for use by multiple SCs.

In this document,

- “shall” indicates a requirement.
- “should” indicates a recommendation.
- “may” indicates a permission.
- “can” indicates a possibility or a capability.

## Minimum Standard Topics

The organization of the topics in this document is not meant to suggest the order for standards to be developed by a SAC or SC; however, the FSSB or SAC Chairs may ask certain topics to be addressed ahead of others. It is recognized that some of the specific requirements listed under the below topics may not be applicable for all SCs; however, any omissions must be justified in the submission packet for consideration of the standard’s addition to the [OSAC Registry](#).

## Terminology

SACs and SCs shall promote the use of consistent and unambiguous terminology across all forensic disciplines. The [OSAC Lexicon](#) exists to support this effort and when [OSAC preferred terms](#) are available, these terms shall be used in developing standards.

## Competency and Monitoring Standards

SACs and SCs shall facilitate development of standards that address competency within their disciplines. These standards shall address the following topics:

- education requirements
- discipline-specific training programs

- o Subcommittees shall reference the requirements of [ASTM Standard E2917 Standard Practice for Forensic Science Practitioner Training, Continuing Education, and Professional Development Programs.](#)
- licensing
- certification<sup>1</sup>
- competency testing
- continuing education
- proficiency testing<sup>2</sup>, other interlaboratory comparisons, as well as intralaboratory comparisons
  - o Standards shall address the scope, nature, and frequency of proficiency testing, interlaboratory, and intralaboratory comparisons.

### **Evidence Collection and Handling Standards**

SACs and SCs shall facilitate development of standards that address the following topics relating to evidence:

- evidence collection, receipt, and chain of custody
- disposition of evidence
- evidence preservation for re-analysis or future analysis with new or improved technologies

### **Standard Practices or Guidelines that Address Development of Laboratory-Developed Instrumental Test Methods**

SACs and SCs shall facilitate creation of standards that identify the topics to be optimized during the development of laboratory-developed instrumental test methods. These methods are developed to answer one or more questions. This produces a method that is then validated to ensure it is fit for purpose.

Instrumental test method development standards shall address the following topics:

- the question(s) to be answered by the method
- equipment<sup>3</sup> specification and parameters
- metrological traceability
- extraction procedure
- calibration model
- interpretation of observations, data, or calculations

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<sup>1</sup> The OSAC supports the certification of all individuals engaged in the full- or part-time delivery of forensic services. It supports the use of a certification body accredited to ISO/IEC 17024 by an accrediting body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) in accordance with the requirements of ISO/IEC 17011.

<sup>2</sup> OSAC supports the use of a proficiency test provider accredited to ISO/IEC 17043 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement in accordance with the requirements of ISO/IEC 17011.

<sup>3</sup> ISO/IEC 17025, 6.4.1 "... equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) ..."

## Standard Practices or Guidelines that Address Validation and Verification of Test Methods

SACs and SCs shall facilitate the development of standards that address method validation of laboratory-developed test methods or the use of published methods that are not standard test methods. Further, these standards shall address required verification steps when a standard test method or a manufacturer-developed technique is used.

Test methods shall be evaluated to determine whether they work as intended and are fit for purpose. The specific process of method validation or verification will vary depending on the nature and purpose of the method, but both validation and verification must establish how accurate the method is under specified conditions.

Validation and verification must include interpretation of examination or analysis observations, data, or calculations when merely reporting them would not be understood by the user of the report or when different users could reasonably attribute different meanings to them.

The information obtained from method validation and verification activities establishes the types and limitations of items that can be tested with the method, as well as the limitations of results. It also can identify what is required for on-going quality assurance and assists in the assessment of measurement uncertainty or error rates.

The following additional topics shall be addressed in method validation and verification standards for test methods. The way they are addressed may differ from one discipline to another.

- method performance and limitations, such as:
  - sensitivity (*e.g.*, true positive probability, limit of detection, limit of quantitation)
  - specificity or selectivity (*e.g.*, true negative probability, interferences)
  - measurement bias
  - precision (*e.g.*, repeatability, reproducibility)
- robustness of criteria established to assess the suitability of an item for analysis.
- the use of known materials (*i.e.*, known source, known identity, known concentration) that represent the range of anticipated work
- minimum sample size for evaluation of each validation component
- evaluation of modifications made to a previously validated method
- criteria for verification of a standard (or published) method<sup>4</sup> obtained from another Forensic Science Service Provider (*e.g.*, topics of method validation that must be verified; minimum sample size required to evaluate each topic)

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<sup>4</sup> If a Forensic Science Service Provider validates a method and subsequently shares or publishes the validation results, a second Forensic Science Service Provider may use the method without repeating the full validation. Instead, before implementing the method, the second Forensic Science Service Provider may verify that it can use the first Forensic Science Service Provider's method to the same level of performance.

## Quality Assurance Standards

SACs and SCs shall facilitate the development of standards that address the following topics related to quality assurance:

- maintaining metrological traceability
- quality control (*e.g.*, type of control, criteria for acceptability, frequency)
- review of results (*e.g.*, technical review, administrative review, verification)

## Standard Practices, Guides, or Methods for Testing, Examination, or Analysis

SACs and SCs shall facilitate development of standard practices, guides, or methods for testing, examination, and analysis that address the following topics:

- scope and purpose of the method
- pertinent literature references
- suitable sample type(s)
- necessary equipment<sup>5</sup>
- operating parameters of equipment
- quality control measures (*e.g.*, equipment checks, environmental conditions, controls)
- limitations of the method (*e.g.*, factors and conditions impacting ability to observe features of interest, sensitivity, and specificity/selectivity)
- specific steps for performing the method
- observations, data, and calculations to be made

Additional topics to be addressed as applicable include:

- factors and conditions impacting the nature of features under observation
- metrological traceability
- calibration model and range
- sampling protocol
- steps to minimize or mitigate cognitive bias
- identification of task-relevant information
- steps to minimize or mitigate potential contamination
- steps for interpretation of observations, data, or calculations
- limitations to interpretation
- health and safety concerns

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<sup>5</sup> ISO/IEC 17025, 6.4.1 "... equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) ..."

## **Opinion Standards**

When forming or expressing opinions is part of a method, SACs and SCs shall facilitate the development of opinion standards addressing the following topics:

- The basis for the opinion, including what, if any, information beyond the observations, data, calculations, and interpretations that may be considered in forming the opinion.
- Steps to assure that the opinion is supported by the observations, data, calculations, interpretations, and task-relevant contextual information.

## **Reporting Results and Testimony Standards**

SACs and SCs shall facilitate the development of standards that address the reporting of results. These standards shall specify preferred language to be used in written reports and testimony. SACs and SCs should strive for language that will be understood by users, including law enforcement personnel, lawyers, judges, and jurors.

Standards on the reporting of results and testimony shall address:

- basis for interpretations or opinions, including other information used,
- sources of potential bias,
- limitations, (e.g., uncertainty of quantitative measurements, error rates)
- result reporting language.

Further direction on this topic can be found in *Guidance for OSAC Subcommittees Drafting and Updating Standards on Reports and Testimony*.