



Organizational Priorities & Minimum Requirements for Standards Development

1. Mission

The mission of the Organization of Scientific Area Committees (OSAC) for Forensic Science is to strengthen the nation's use of forensic science by facilitating the development of scientifically sound standards, and by promoting the adoption of those standards in the forensic science community.

2. Aims

Consistent with the Charter and Bylaws, the aims of the OSAC are to:

- facilitate the development of standards and evaluate standards for placement on the OSAC Registry
- promote the use of standards on the OSAC Registry in the forensic science community by accreditation and certification bodies and the legal system
- provide insight on each forensic science discipline's research and development needs
- enlist a broad community of interested individuals and institutions in these efforts
- establish and maintain working relationships with pertinent organizations

3. Purpose

This document identifies priorities for OSAC to achieve its mission and identifies minimum requirements for the development of standards. Forensic science seeks to answer fundamental questions such as: What substances are in this questioned sample? Does a sample contain an illicit substance? Did a questioned sample and a known sample originate from the same source? What is the provenance of the sample? What caused an injury or damage? When did an event occur?

Forensic scientists develop methods to answer such questions. As a result of continuous improvements and scientific discoveries, method creation and standard development in forensic science are on-going activities.

Scientific Area Committees (SACs) and Scientific Area Committee Subcommittees (SCs) may approach the development of standards in many ways that range from a single standard that covers multiple areas to multiple standards for a single area. At times a priority area may be covered by discipline-specific standards or by interdisciplinary standards intended for use by multiple SCs.

SACs and SCs should work with a Standards Development Organization (SDO). All standards on the OSAC Registry shall be developed by a process that follows the principles of openness, balance, consensus, and harmonization¹.

4. Terminology

In this document, the following verbal forms are used:

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

OSAC SACs and SCs shall promote the use of consistent and unambiguous terminology across all forensic disciplines. When OSAC preferred terms are available, these terms shall be used in developing standards.

5. Legal Precedence

By themselves, standards published by an SDO are not regulatory. Statutorily, administratively or judicially imposed requirements may compel adherence to or departure from a published standard (e.g., FBI DNA Quality Assurance Standards).

6. Competency Standards

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

- educational requirements
- discipline-specific training programs
- licensing
- certification
 - OSAC supports the use of a certification body accredited to ISO/IEC 17024² 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 17011³.
- competency testing
- continuing education
- proficiency testing, other interlaboratory comparisons, and intralaboratory comparisons
 - Standards shall address the scope, nature, and frequency of proficiency testing, interlaboratory, and intralaboratory comparisons. OSAC supports the

¹ Organization of Scientific Area Committees, Charter and Bylaws.

² ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons.

³ ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

use of a proficiency test provider accredited to ISO/IEC 17043⁴ by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement in accordance with the requirements of ISO/IEC 17011⁵.

7. Physical Evidence Standards

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

- training for proper recognition and preservation of physical evidence
- receipt, chain of custody, and disposition by the forensic service provider
- preservation for re-analysis or future analysis with new or improved technologies

8. Scientific Validity & Research

OSAC encourages research to establish scientific validity, advance forensic science, and support the standards-development process. Scientific validity is established by the existence of a suitable theory and empirical studies. Publication in peer-review scientific journals or reports is encouraged. Validated methods generate repeatable and reproducible results with known accuracy and are appropriate to the intended application.

SACs and SCs shall identify areas in which additional scientific inquiry is warranted.⁶ OSAC shall make lists of prioritized research topics available to the public. These research recommendations may be considered by other organizations as they develop their research priorities or solicit funding for forensic science research. OSAC encourages collaborative, interdisciplinary research that will promote a forward-looking profession, broaden scientific awareness, and advance the practice of forensic science.

9. Method Development Standards

Method development produces a method that answers a specific question or yields a result relevant to the answer. Once a method has been developed, validation is required to ensure it is fit for purpose.

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

- purpose of the method
- expected outcome (e.g., reduced noise in an audio signal or concurrent amplification of DNA loci)
- pertinent literature references
- suitable sample type(s)
- necessary instruments, software, and other equipment
- expected or acceptable operating parameters for equipment and instruments

⁴ ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing

⁵ ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

⁶ [OSAC Research and Development Needs](#).

- metrological traceability, if applicable
- calibration model and range, if applicable
- expected limit of detection (LOD), if applicable
- expected limit of quantification (LOQ), if applicable
- specific steps on how to perform the method
 - sampling protocol, if applicable
 - required reagents (including volumes and formulations), if applicable
 - required consumables, if applicable
- steps to minimize or mitigate cognitive bias, if any
 - description of the information that will be available at the time that the method is performed
- steps to minimize or mitigate potential contamination
- interpretation of the results
 - the statistical model to be used, if applicable
 - evaluation of the variation in the relative frequency of characteristics across different reference populations, if available
- health and safety concerns, if applicable

10. Method Validation Standards

Methods shall be evaluated to determine whether they work as intended and are fit for purpose. The specific process of evaluation will vary depending on the nature and purpose of the method, but the evaluation must establish how accurate the method is under the established conditions. All SACs and SCs shall facilitate the development of standards that address method validation.

For each topic, this document does not set a minimum sample size. This aspect shall be addressed in the standard(s) developed.

The data from method validation will inform:

- the types of items that can be tested, including any limitations
- staff training
- required on-going quality assurance procedures
- limitations of results (*i.e.*, Observations, Data, Calculations, Interpretations, and Opinions)

10.1 Framework of Forensic Science Methods and Types of Results they Generate

For the purposes of method validation, forensic science processes can be subdivided into four categories.⁷ This framework applies across forensic science disciplines but still allows flexibility in standards development. A SAC or SC may address topics under several categories in a single standard, or it may develop one or more standards to address activities within each category.

The categories are:

1. Evidence identification, collection, and preservation
2. Evidence enhancement, restoration, or recovery

⁷ A Framework for Harmonizing Forensic Science Practices and Digital/Multimedia Evidence, OSAC Technical Publication 002, <http://dx.doi.org/10.29325/OSAC.TS.0002>
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3. Analysis
4. Interpretation

CATEGORY 1: Evidence Identification, Collection, and Preservation

Often the processes of evidence identification, collection, and preservation occur as “investigative activities”.

Examples of evidence identification, collection, and preservation performed by a forensic service provider include:

- collection of digital and multimedia evidence
- identification of drug and other types of evidence through the use of dogs and other sensors
- collection of trace evidence from articles recovered at a scene
- identification and collection of body fluid stains on fabrics or other articles

CATEGORY 2: Evidence Enhancement, Restoration, or Recovery

Examples of evidence enhancement, restoration, or recovery include:

- multimedia evidence - processing steps used to reduce noise in a signal
- digital file - inserting a header to make a file machine readable
- DNA analysis - the amplification process
- latent impressions - chemical processing to make the impression more visible
- scene photography - use of alternate light sources or side-lighting to make impressions and stains more visible
- firearms/toolmarks - serial number restoration.

CATEGORY 3: Examination/Analysis

This category incorporates all types of methods.

Examples include:

- measuring the refractive index of glass
- recording the metadata of a digital file
- annotating points of minutiae in a latent print impression
- instrumental methods to identify a sample
- annotating features in a facial comparison analysis;
- establishing the camera station (i.e., physical location) for a photogrammetric analysis
- measuring the mass of a substance
- measuring the length of a firearm

CATEGORY 4: Interpretation

Interpretation Explanation(s) for the Observation(s), Data, and or Calculation(s)

Interpretation is required when reporting of the observations, data, or calculations would not be understood by the reader of the report.

Examples include:

- evaluation of instrumental data to identify an item of evidence as containing cocaine
- evaluation of chromatographic data to arrive at the concentration of ethanol in a sample of ante-mortem blood
- comparison of a questioned impression to a known impression
- evaluation of capillary electrophoresis data to arrive at a DNA profile

10.2 Components of Method Validation

This section identifies the components of method validation and the categories of forensic processes to which these components apply. Individual SACs/SCs shall determine for each method which components of validation are necessary to ensure that the method works as intended and is fit for purpose.

The use of known materials (known source, known identity, known concentration) that cover the range of anticipated work applies to Category 3 & 4. The validation process shall evaluate the following.

- robustness of criteria established for assessing the suitability of an item for analysis [applies to processes in Categories 3 & 4]:
 - o repeatability (consistency of results obtained by a single person using the same instrument or process)
 - o reproducibility (consistency of results obtained across staff within a forensic service provider or by different forensic service providers)
- method performance:
 - o sensitivity [applies to processes in Category 3 and 4]:
 - true positive probability
 - limit of detection (LOD)
 - limit of quantitation (LOQ) [if reported, applies to processes in Category 3]
 - o specificity [applies to processes in Categories 3 & 4]
 - true negative probability
 - o quantification of bias [applies to processes in Category 3 and 4]
 - o quantification of precision [applies to processes in Category 3]
 - repeatability
 - reproducibility
 - o evaluation/estimation of measurement uncertainty [in quantitation, applies to processes in Category 3]
- robustness of data interpretation steps [applies to processes in Category 4]:
 - o repeatability
 - o reproducibility

11. Reporting Results and Testimony Standards

All SACs and SCs shall facilitate the development of standards that address the reporting of results. These standards shall specify language to be used in written reports and testimony. SACs and SCs should strive for language that will be understood as intended by customers who include law enforcement personnel, lawyers, judges, and jurors. Standards on the reporting of results and testimony shall address:

- basis for interpretations and opinions including what other information is and is not pertinent for use
- assumptions
- sources of potential bias
- known limitations
- measurement uncertainty
- required information for written reports

12. Quality Assurance Standards

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

- maintaining metrological traceability
- quality control
- review of results (e.g., technical review, administrative review, or verification)
- proficiency testing, other interlaboratory comparisons, and intralaboratory comparisons
 - Standards shall include, where applicable, the scope, nature and frequency of proficiency testing. OSAC supports the use of a proficiency test provider accredited to ISO/IEC 17043⁸ by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement in accordance with the requirements of ISO/IEC 17011⁹.

13. Accreditation

OSAC supports the accreditation of all entities engaged in the full- or part-time delivery of forensic services.

- OSAC supports accreditation programs based on International Organization for Standardization (ISO) standards (e.g., ISO/IEC 17025¹⁰, ISO/IEC 17020¹¹), supplemental standards specific to forensic science and associated guidance documents (e.g., based on ILAC G19¹²).
- OSAC supports the use of an accrediting body that is a signatory to the ILAC (International Laboratory Accreditation Cooperation) Mutual Recognition Arrangement in accordance with the requirements of ISO/IEC 17011.

14. Outreach

To strengthen the nation's use of forensic science and advance professional practice, OSAC is committed to effective communication and outreach with:

- international standards organizations
- standards development organizations (SDOs)

⁸ ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing

⁹ ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

¹⁰ ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

¹¹ ISO/IEC 17020, Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

¹² ILAC G19, Modules in a Forensic Science Process.

- justice system
- forensic science service providers
- accrediting bodies
- certifying bodies
- professional scientific organizations
- professional forensic science organizations
- academia and the broader scientific community
- peer-reviewed scientific journals
- public and private funding agencies that support research
- suppliers of forensic related products
- the general public