



# Organizational Priorities & Minimum Requirements for Standards Development

## Background

### Purpose

Forensic science seeks to help 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 and use methods to help answer such questions. Method creation and standard development in forensic science are on-going activities.

This document identifies priorities for the OSAC to achieve its mission and identifies minimum requirements for the development of standards. In addition, Supplemental Work Products by OSAC Units that support the development and implementation of standards shall be aligned to these organizational priorities.

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.



## Terminology

In this document,

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

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.

## Minimum Standard Topics

The order of the topics in this document is not meant to dictate the order of standard development by a SAC or SC.

## Competency and Monitoring Standards

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

- education requirements
- discipline-specific training programs
- licensing
- certification
  - OSAC supports the use of a certification body accredited to ISO/IEC 17024<sup>1</sup> 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>.
- 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 use of a proficiency test provider accredited to ISO/IEC 17043<sup>3</sup> by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement in accordance with the requirements of ISO/IEC 17011<sup>4</sup>.

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<sup>1</sup> ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons.

<sup>2</sup> ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

<sup>3</sup> ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing

<sup>4</sup> ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

## **Evidence Collection and Handling Standards**

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

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

## **Method Development Standards**

SACs and SCs shall facilitate development of standards that identify the topics to be optimized during method development. Methods are developed to answer one or more questions. Method development produces a method that is then validated to ensure it is fit for purpose.

Method-development standards shall address the following topics, as appropriate:

- the question to be answered by the method
- equipment<sup>5</sup> specification and parameters.
- metrological traceability
- extraction procedure
- calibration model
- interpretation of observations, data, or calculations

## **Method Validation Standards**

SACs and SCs shall facilitate the development of standards that address method validation.

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

Method validation must include interpretation of examination or analysis observations, data, or calculations when merely reporting of the observations, data, or calculations 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 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 topics shall be addressed in method validation standards, but the manner in which they are addressed may differ from one discipline to another:

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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) ..."

- method performance and limitations:
  - 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).
- item selection:
  - 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>6</sup> used by another Forensic Science Service Provider (e.g., topics of method validation that must be verified; minimum sample size required to evaluate each topic).

### 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, or verification).

### Examination and Analysis Method Standards

SACs and SCs shall facilitate development of standards that address examination and analysis methods within their disciplines that address the following topics:

- scope and 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 equipment<sup>7</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;

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<sup>6</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 is capable of using the first Forensic Science Service Provider's method to the same level of performance.

<sup>7</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) ..."

- 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.

### **Opinion Standards**

When forming or expressing opinions is part of a method, SACs and SCs shall facilitate the development of standards that address the development of an opinion, that address 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 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 that was used;
- sources of potential bias;
- limitations (*e.g.*, uncertainty of quantitative measurements, error rates);
- result reporting language.

## **Broader Priorities**

### **Research**

SACs and SCs shall identify areas in which additional scientific inquiry is needed.<sup>8</sup> The OSAC shall make lists of prioritized research topics available to the public. The OSAC encourages collaborative, interdisciplinary research that will promote a forward-looking

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<sup>8</sup> [OSAC Research and Development Needs](#)

profession, broaden scientific awareness, and advance the practice of forensic science.

## **Accreditation**

The OSAC supports the accreditation of all entities engaged in the full- or part-time delivery of forensic services. It supports accreditation programs based on International Organization for Standardization (ISO) standards (e.g., ISO/IEC 17025<sup>9</sup>, ISO/IEC 17020<sup>10</sup>), and supplemental standards specific to forensic science and associated guidance documents (e.g., based on ILAC G19<sup>11</sup>). It also 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.

## **Certification**

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.

## **Outreach**

To strengthen the nation's use of forensic science and advance professional practice, the OSAC is committed to effective communication and outreach to forensic science stakeholders. Outreach shall include:

- international standards organizations;
- standards developing organizations;
- justice system;
- forensic science service providers;
- accrediting bodies;
- certifying bodies;
- proficiency test providers;
- professional scientific organizations;
- professional forensic science organizations;
- forensic scientific working groups;
- academia and the broader scientific community;
- peer-reviewed scientific journals;
- public and private research funding agencies;
- suppliers of forensic-science related products; and
- the general public.

OSAC shall engage with these groups by seeking feedback during OSAC comment periods,

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<sup>9</sup> ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

<sup>10</sup> ISO/IEC 17020, Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

<sup>11</sup> ILAC G19, Modules in a Forensic Science Process.

hosting OSAC stakeholder feedback sessions, delivering presentations during professional conferences, offering webinars through OSAC and with external partners, sharing assessments of research needs, providing monthly publications on the status of standards, and corresponding with SDOs.