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[1]. In addition, OSAC's Other Work Products, developed by OSAC Units to support the development and implementation of standards, shall be aligned with these minimum topics.

Scientific Area Committees (SACs) and their Subcommittees (SCs) may approach the development of standards in various ways, ranging from a single standard that encompasses multiple related topics to separate standards for each topic or subtopic. Discipline-specific standards may address a given priority, while interdisciplinary standards can include overarching concepts that address foundational needs of 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 intended to suggest the order in which standards are to be developed by a SAC or SC; however, the SAC Chairs, Standards Review Panel (SRP), or Forensic Science Standards Board (FSSB) may ask that certain topics be addressed ahead of others. It is recognized that some of the specific requirements listed under the topics below may not be applicable to all SCs; however, any omissions must be justified in the submission packet for consideration of the standard's addition to the OSAC Registry.

The submission packet includes a Document Management Workbook. The document management workbook includes a detailed rubric designed for the SC, SAC, and SRP to systematically score the thoroughness and quality of a document's preparation.

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.

[1] OSAC Standards Resources for the development of standards, https://www.nist.gov/adlp/spo/organization-scientific-area-committees-forensic-science/standards-resources.

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Training, Competency, and Continuing Education Standards

SACs and SCs shall facilitate the development of standards that address training, competency, and continuing education within their respective disciplines.

The SC's standards shall meet the requirements of *ASTM Standard E2917 Standard Practice for Forensic Science Practitioner Training, Continuing Education, and Professional Development Programs*.

These standards shall address the following topics:

- education requirements (*e.g.*, degree type, appropriate major, specific courses)
- discipline-specific training programs
- licensing
- certification[2]
- competency testing
- continuing education or professional development

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[2] 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.

Performance Monitoring Standards

SACs and SCs shall facilitate the development of standards that address performance monitoring within their respective disciplines.

These standards shall address the following topics:

- scope, nature, and frequency of proficiency testing,[3] other interlaboratory comparisons, and intralaboratory comparisons
- how results, interpretations, or opinions are reported
- limitations of performance monitoring for the discipline
- common discipline-specific knowledge, skills and abilities, methods, equipment, technology, and item types that are expected to be monitored for performance
- direction on consultation, verification, and technical review of performance monitoring activities
- administrative expectations
- criteria to establish successful performance criteria and methods for the evaluation of the results
- appropriate selection or creation of materials
- common human factors considerations
- requirements for the documentation and retention of records

For direction on this topic, refer to the *Guidance for OSAC Subcommittees Drafting and Updating Standards on Performance Monitoring.*

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[3] 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.

Evidence Collection and Handling Standards

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

- recognition and collection of evidence
- protection of evidence from change, loss, or deleterious change
- receipt, chain of custody, and disposition of evidence
- procedures and/or requirements, labeling, handling, transporting, storing, and preparation of items
- evidence preservation for re-analysis or future analysis with new or improved technologies
- safety measures

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Opinion Standards

SACs and SCs shall facilitate the development of opinion standards addressing the following topics when opinions are a routine practice of their respective disciplines:

- factors and external information an examiner may or should consider when determining an opinion (*e.g.*, an investigative lead, police reports, medical history)
- 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 ensure that the opinion is supported by the observations, data, calculations, interpretations, and task-relevant contextual information
- requirement to clearly identify opinions

The FSSB is also considering the meanings/definitions of the terms “interpretation” and “opinion”; therefore, additional guidance is forthcoming. If an OSAC Unit or discipline plans to work on a document on this topic, it is ***highly*** recommended to reach out to the OPO (forensic@nist.gov) before beginning or continuing the work.

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Interpretation Standards

SACs and SCs shall facilitate the development of interpretation standards addressing the following topics for their respective disciplines:

- defining the interpretation scale
- type of interpretation scale
- objective criteria distinguishing between steps of the scale
- limitations of the scale
- performance data, if applicable
- factors that should be considered when using the scale

The FSSB is also considering the meanings/definitions of the terms “interpretation” and “opinion”; therefore, additional guidance is forthcoming. If an OSAC Unit or discipline plans to work on a document on this topic, it is ***highly*** recommended to reach out to the OPO (forensic@nist.gov) before beginning or continuing the work.

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Quality Management Systems Standards

SACs and SCs shall facilitate the development of standards that address the following topics related to quality management systems and its attributes in their respective disciplines:[4]

- responsible person(s)
- appropriate documentation and retention
- system reviews (e.g., frequency, scope)
- maintaining metrological traceability
- quality controls (e.g., type of control, criteria for acceptability, frequency)
- calibrations (frequency) or checks of equipment (initial, routine, or remedial)
- review of results (e.g., technical review, administrative review, verification)
    - risk management
    - nonconforming casework
    - internal audits
    - use of blind or non-blind verification

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[4] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

Reporting Results and Testimony Standards

SACs and SCs shall facilitate the development of standards for reporting results. These standards shall specify the preferred language for written reports and testimony. SACs and SCs should strive for language that is understandable to users, including law enforcement personnel, lawyers, judges, and jurors.

Standards on the reporting of results and testimony shall address discipline or method-specific:

- disclosure of the basis for interpretations or opinions and information used
- common limitations and potential biases likely to impact interpretation of data, observations, results, and opinions (*e.g.,* uncertainty of quantitative measurements, error rates, sample or method selection)
- language for reporting, including clarity and level of detail required
- known discipline-specific unacceptable practices

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

The FSSB is also considering the meanings/definitions of the terms “interpretation” and “opinion”; therefore, additional guidance is forthcoming. If an OSAC Unit or discipline plans to work on a document on this topic, it is ***highly*** recommended to reach out to the OPO (forensic@nist.gov) before beginning or continuing the work.

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Instrumental Test Method Development Standards

SACs and SCs shall facilitate the creation of standards that identify the criteria 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.

Method development is the process of designing and optimizing procedures for conducting qualitative or quantitative analyses in analytical scientific disciplines. It involves identifying the most effective technique, instrument, parameters, and conditions to achieve the needed sensitivity, bias, precision, or efficiency of the method.

Instrumental test method development standards shall address the following threshold requirements:

- minimum requirements and recommendations
- process for establishing, approving, and receiving authorization of a method development plan before initiating activities

In addition, they should also address the following topics:

- the question(s) to be answered by the method
- development plan
  - customer needs
- equipment[5] specification and parameters
  - automation
  - sample preparation
  - metrological traceability
  - concentration ranges
  - calibration model
  - interpretation of observations, data, or calculations
- identification of individuals assigned to conduct the method development activities
- written procedure for validation activities
- retention time for method development data

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[5] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, 6.4.1 "… equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) …"

Test Method Validation and Verification Standards

SACs and SCs shall facilitate the development of standards that address validation of laboratory-developed test methods or the use of published methods that are not standard test methods. Furthermore, these standards shall outline the required verification steps when a validated standard test method or 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; however, both validation and verification must establish how accurate the method is under specified conditions.

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

> ***Validation*** *is the process of evaluating a system, method, or component, to determine that requirements for an intended use or application have been fulfilled.*
>
> ***Verification*** *is the process of performing a standard method with known reference material(s) to confirm that a laboratory can obtain the expected results. Since standard methods have already been validated by multiple laboratories, subsequent laboratories are only required to perform a verification, not a full validation.*
>
> ***Method development*** *is the process of designing and optimizing procedures for conducting qualitative or quantitative analyses in analytical scientific disciplines. It involves identifying the most effective technique, instrument, parameters, and conditions to achieve the needed sensitivity, bias, precision, or efficiency of the method.*
>
> ***Method validation*** *is the process of performing experiments to obtain objective evidence establishing that the developed method is fit for purpose and to identify the method's limitations under normal operating conditions.*

Method verification is a type of assessment limited to a laboratory's use of an unmodified standard test method. Method verification experiments enable a laboratory to demonstrate its ability to use the standard test method and ensure it performs as intended by meeting or exceeding the published parameters.

Revalidation is necessary when modifications are made to a previously validated method. Possible changes include adding compounds to a method's scope, adjusting the calibration range or model, or upgrading instrumentation. Full revalidation is necessary unless an abbreviated revalidation is justified.

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 can also identify what is required for ongoing quality assurance and assist in assessing 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.

For validation of manufacturer-developed/laboratory-developed/published methods that are not SDO-published standard test methods.

A method validation plan shall be established, approved, and authorized that includes the following:

- scope of method validation (*e.g.,* factors/variables, factor levels)
- the experiments to be conducted
- precise definition of the test method to be validated, including the use of the following throughout the entire validation:
    - equipment (instruments and consumables)
    - same sample preparation and instrumental parameters
- minimum sample size for evaluation of each validation parameter
- the use of known materials (e.g., known source, known identity, known concentration)
- minimum method performance and limitations for acceptance, 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)

For the verification of SDO-published standard test methods.

A method verification plan shall be established, approved, and authorized that includes the following:

- title and source of the standard test method to be verified
- scope of method verification (*e.g.,* factors/variables, factor levels)
- the experiments to be conducted
- minimum sample size for the evaluation of each verification parameter
- the use of known materials (*e.g.*, known source, known identity, known concentration)
- minimum method performance and limitations for acceptance, 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)?

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Testing, Examination, or Analysis Standards

SACs and SCs shall facilitate the 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[6]
- operating parameters of equipment
- effects of operator skill and other human factors on measurements, analysis, or interpretation
- 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, operational or other factors, calculations to be made and recorded

Additional topics to be addressed as applicable include:

- factors and conditions that may impact the nature of features under observation
- metrological traceability
- criteria for controls (*e.g.,* frequency of control measurements, acceptance limits) and other criteria for approval/rejection of results
- calibration model, standards, range, and frequency
- checks of equipment (initial and periodic)
- sampling protocol
- steps to minimize or mitigate cognitive bias
- identification of task-relevant vs. task-irrelevant information with examples of each
- steps to minimize or mitigate potential contamination
- factors an examiner should consider when determining results, both as part of the evidence and beyond the characteristics of the evidence
- disclosure of any information beyond the characteristics of the evidence
- steps for the interpretation of observations, data, or calculations
- limitations to interpretation
- health and safety concerns

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[6] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, 6.4.1 "… equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) …"