

OSAC Technical Merit Worksheet



What is a Technical Merit Worksheet

The Technical Merit Worksheet is intended to facilitate the review of a published documentary standard to determine its appropriateness for inclusion on the *OSAC Registry*. Assessment of technical merit is the most important step in the Registry Approval Process.

How to Complete This Form

In order to facilitate this review, all OSAC groups shall hold meeting(s) at the Task Group, Subcommittee, SAC and FSSB levels to discuss the standard's technical merit and document the discussions to complete the worksheet. There are 12 elements listed below to consider regarding the technical merit of the standard being deliberated for registry addition: purpose, scope, terminology, clarity, measurement uncertainty, error rates, quality assurance factors, validation, legal resource committee concerns, human factors committee concerns, quality infrastructure committee concerns, and statistics task group concerns.

OSAC unit(s) shall discuss each of these elements as it relates to the contents of the standard being considered. All OSAC unit members will receive a copy of the standard and should review it in advance of discussion.

The key points of discussion shall be summarized and documented on the worksheet so that each subsequent unit (SC, SAC, FSSB) can see the elements of discussion and the various viewpoints that were considered regarding the technical merit of the standard. This includes strengths of the standard which were identified and any dissenting opinions or limitations of the standard noted. If some particular criterion is determined to be not applicable for this standard, a brief explanation must be provided as to why the topic does not apply.

In form field #14, after discussion of each of the technical merit elements is completed, record all affirmative, negative and abstention votes made by the Task Group and Subcommittee. Record the date the vote/ballot was completed. If the group did not achieve full consensus on the merit of the standard, include the majority/minority opinions and summarize the justification for the decision to consider the minority point(s)-of-view not persuasive to the majority.

Additional items to consider prior to completing the following Technical Merit Worksheet

Document any additional topics that may be needed to provide a clear understanding to those not active in the development of the standard of its intent, technical merit and need.

A *Comment Adjudication Template* should be established as early as practicable and should be used in conjunction with this Technical Merit Worksheet to ensure comments and comment resolution are documented throughout the Registry Approval Process.

SAC Review and Final Vote

In form fields 16-18, the SACs are required to decide if the standard has or does not have acceptable Technical Merit. The SAC must record all affirmative, negative, and abstention votes and record the date the vote/ballot was completed. The SAC must also document any disagreement with the Task Group or Subcommittee's assessment including proposed changes to the technical merit rating requiring submission to the SDO for revisions before moving the standard forward etc.

Header of Form**Submitting Subcommittee(s)/SAC(s)****Chair and Technical Contact**

List the primary sponsoring Subcommittee(s) or SAC(s) Technical Contact. In addition, list all Subcommittees and SACs that have been included in review of the technical merit of this standard for Registry Approval (e.g., more than one Sub/SAC, if the standard is a multi-disciplinary standard.) Put the additional names of the Subcommittees/SAC and technical contacts in the box at the top of the Worksheet, if needed.)

DATE:		SUBMITTING SUBCOMMITTEE(S)/SACs:	
CHAIR		TECHNICAL CONTACT (if different from Chair)	
Name:		Name:	
Affiliation:		Affiliation:	
Email:		Email:	
Phone:		Phone:	
CHAIR		TECHNICAL CONTACT (if different from Chair)	
Name:		Name:	
Affiliation:		Affiliation:	
Email:		Email:	
Phone:		Phone:	
CHAIR		TECHNICAL CONTACT (if different from Chair)	
Name:		Name:	
Affiliation:		Affiliation:	
Email:		Email:	
Phone:		Phone:	

Standard Acronym, Number, Year and Title

List the standard's identification acronym, number and year (including an editorial version or re-approval year, if applicable), and the full title. List the name of the publishing organization (i.e. name of the SDO.)

Examples:

NFPA 921: 2014 Guide for Fire and Explosion Investigations. National Fire Protection Association (NFPA.)

ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.

International Organization for Standardization (ISO.)

ASTM E2548-11e1: Standard Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis (ASTM International.)

Standard Acronym, Number, Year and Title:	
Standard Publisher:	
Document if this is not the most current edition/version of this standard, and why it is being recommended vs. a more current edition/version.	

1. Purpose of Standard

Explanation

The defined purpose of the standard should summarize the intent of the standard including information related to what area it addresses to “standardize” (i.e. process, procedure, etc.) and where the delineated steps will affect the quality and consistency of the end result.

Discussion Points

What is the purpose of this standard? What issue, need, process, testing, etc. is being addressed? How does this standard relate to other relevant standards (*surrounding and competitive*)?

Purpose: (2-3 sentences)	
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2. Scope

Explanation

The scope describes intent and limitation of the standard. The scope is written as a series of statements of fact. There should be no requirements, recommendations or permissions in the scope.

Discussion Points

- Are the title, scope and standard in alignment with the purpose of the standard and each other (e.g., are these sections of the standard consistent/harmonized/coherent)?
- Does the standard make it clear why someone would use the standard? In what application?
- Is the scope of the standard (what is covered and what is not) written in a clear and concise way?
- Does the standard clearly state any known limitations to either the process or the interpretation of the resulting findings and conclusions? Limitations in applicability should be identified in the worksheet.

Scope: [insert scope as written in the standard]	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	

Resolution of dissenting opinions	
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3. Terminology

Explanation

There is a terminology component in all standards. Include terms that are defined or used differently than what is found in a generic dictionary, to ensure all users are speaking the common language required for a full understanding. The use of standardized terminology is essential to clearly and accurately communicate instructions and expected outcomes. Define those terms that are used in the standard. The standard may also cite another document such as a terminology standard. The standard may not be complete if it does not have definitions or citations to another source of definitions.

Discussion Points

- Are the relevant terms, acronyms, or abbreviations clearly defined in the standard?
- Are there missing terms and definitions?
- Does the standard reference any external source for terminology? Supporting documentation is preferred over a weblink and may be appended to the standard.
- What was the content of the discussion regarding the suitability of terms? Note any terms that were identified as problematic such as easily confused with commonly used definitions, have multiple meanings, etc.
- Are any terms included in the terminology section that are not mentioned elsewhere in the standard?

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinions	

4. Clarity and Detail of the Process or Procedure

Explanation

Well-written standards have minimal ambiguity and limit alternative interpretation. They should focus on standardizing only those steps that must be done consistently across laboratories/organizations to ensure equivalent results. It is possible that some parts of the process delineated in the standard may be performed differently and not degrade the quality and consistency of the end result.

Standards need to be understood by an audience broader than the forensic examiner since the results that arise from the use of these standards are used throughout the judicial system, for scientific research, and have potential impact on members of the public.

Discussion Points

- Is it complete, useful, sound, repeatable, and reproducible? Does it provide valid results?
- Discuss if steps may be ambiguous or may be easily misinterpreted by some readers who have a different point of view. How can any potential ambiguities found be minimized?

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinions	

5. Measurement Uncertainty

Explanation

If the use of the standard entails measurement¹, discuss how the uncertainty in those measurements is to be assessed and reported. All measurements are unavoidably subject to multiple sources of both random and systematic measurement error that can only be estimated. However, the potential magnitude of the specific unknown errors in any measurement must be assessed and reported so that the measurement can be used for effective decision making.

Measurement uncertainty is often assessed using statistical methods. A thorough statistical characterization of a combination of test results made using the measurement system combined with results made on the recovered forensics evidence using the same system can often provide high confidence in the resulting interpretation of the evidence. Explicit and specific standards that describe how measurements will be made and analyzed will help all stakeholders understand how the evidence has been processed and how to interpret it. Such standards will also help ensure that results will all be obtained following best practices and will be of consistent quality and character regardless of the forensic analyst who performs the measurement analysis.

Discussion Points

- Does use of this standard result in any measurements being made that effect the outcome of the analysis or interpretation?
- If any measurements are made, does the standard provide adequate guidance on estimating the uncertainty of the resulting measurement(s) or quantitation or does it guide you to another standard or document for this information?
- Are all measurements produced by the execution of this standard accompanied by appropriate uncertainty statements? Do these uncertainty statements include uncertainty from both random and systematic sources?
- Do uncertainty statements include inherent uncertainty due to calibration standards and calibration measurements? Do they include any appropriate uncertainty due to material heterogeneity?

¹ **measurement** - set of operations having the object of determining a value of a quantity [SOURCE: ISO 3534-2]

- Are the assumptions underlying the statistical analysis clearly defined? Does the standard offer the possibility of also providing results based on alternative assumptions in order to judge how sensitive the measurement is to underlying assumptions?
- Is standardized software available to carry out all measurement computations?
- Does the standard provide guidance to ensure that conclusions are not over stated with regard to measurement uncertainty?
- Are the effects of operator skill or human factors on the measurement documented or explained?

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinions	

6. Error Rates

Explanation

If the use of the standard entails decision making use of methods where the correct performance of the decision-making process cannot be inherently judged, how will the error rates arising from decision-making be assessed and reported? All binary decisions (e.g. yes/no decisions, detected/not detected, etc.) are unavoidably subject to both false positive and false negative errors that may never be completely known in real case work. However, the general performance characteristics of any well-defined decision process must be assessed and reported in a way that the efficacy of the decision-making process can be judged in absolute terms, compared with other potential processes, and used effectively.

Error rates are often assessed using statistical methods applied to test results obtained under known conditions (e.g. drugs present at specified concentration or not, same or different source comparisons of fingerprints, etc.). Explicit and specific standards that describe how decisions will be made and that document the performance of such decisions for different case-relevant scenarios will help the stakeholders understand how the evidence has been processed and how to interpret it. Such standards will also help ensure that decisions will be made following best practices and will be consistent in quality and character, regardless of the forensic analyst who performed the standard.

Although most forensic science procedures that result in a decision will require statistically-determined error rates, there are some types of forensic procedures that may not. For example, the correctness of decisions based on physical reconstructions may be able to be inherently judged by the relevant decision makers (lawyers, judge, or jury) if the the results of the reconstruction are reported using photographs that show the exactness of the physical fit. In such cases, it may not be necessary to include the reporting of statistically-assessed error rates.

Discussion Points

- If the standard results in the report of a decision (e.g., positive or negative) , does this standard include a process for evaluating the error rate of this result? If not, does it guide you to another standard or document for this information?

- Do the methods for assessing error rates also include methods for assessing their uncertainty?
- Are there numeric examples that illustrate computations required to obtain reported error rates along with associated uncertainties?
- Does the standard include guidance on how to describe the populations and samples used to assess error rates? If results for any particular populations are given, are those well described or characterized and are the effects that would arise from using other populations discussed?

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinion	

7. Other Quality Assurance Factors

Explanation

Quality assurance covers a broad range of topics, many of which are already detailed in other sections of this worksheet. There are several important quality assurance considerations (see below) that are not otherwise mentioned and are important to consider with respect to technical merit. A methodology must include the quality assurance procedures necessary to ensure statistically-equivalent results will be obtained when the methodology is properly followed by different users in different facilities.

Discussion points

- Does the methodology define any specific factors or data that need to be recorded to ensure repeatability of results?
- Are there any environmental requirements or considerations to ensure the methodology is robust?
- Specific to the methodology, are there requirements for good sample collection, handling, preservation, and storage?
- Are appropriate positive and negative control samples included and specified? If necessary, does the methodology define any specific criteria for the analysis of the controls which are necessary to ensure the quality of test results (e.g. frequency and timing of controls.)
- Does the methodology clearly describe any additional required calibrations, checks or reference materials which must be conducted prior to or concurrent with sample analysis? (e.g., equipment calibration, or how must the reference material be analyzed to ensure accurate results.)
- Does the standard provide guidance to ensure that conclusions are not overstated such as sample language that can be used for reporting and limitations of analysis, etc.?

- Is the type or extent of the result, conclusion, or opinion that can be drawn from the methodology clearly specified?

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinion	

8. Validation of Process or Procedure

Explanation

List documents that provide background information and references to published papers on the validation of the methods, processes, etc. outlined in the standard. These should not be references to other documentary standards, but rather, references to scientific publications. List all references cited in the standard.

Discussion Points

- Have any studies regarding the performance of the standard been conducted and results reported? If so, are these studies referenced in this standard?
- Are the studies representative of the real situations the standard addresses?
- Are the studies based on application of the actual standard as written?
- Have interlaboratory studies been conducted and are they referenced in the standard?
- If the answer to any of the above points is “no”, is there is a plan in place for completing this task prior to Registry Approval? If not, explain why this would not be appropriate.

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinion	

9. Statistics Task Group Concerns

Discussion Points

- Discuss any Stats TG concerns.

Discussion:	
Strengths:	
Limitations noted or dissenting opinion(s):	
Mitigating factors which reduce impact of limitations or dissenting opinion(s):	
Resolution of dissenting opinions	

10. Other**Discussion Points**

- What other issues or aspects, not covered above, did the group consider while evaluating technical merit?

Other:	
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11. Subcommittee Final Vote on Technical Merit

Record all affirmative, negative and abstention votes made by the Task Group and Subcommittee. Record the date the vote/ballot was completed.

	Date	Votes for:	Votes Against:	Votes Abstaining:
Subcommittee (required)				

12. Subcommittee Majority / Minority Opinion Discussion

If the group did not achieve full consensus on the merit of the standard, include the majority/minority opinions and summarize the justification for the decision to consider the minority point(s)-of-view not persuasive to the majority.

Majority/minority opinion:	
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13. Technical Merit Assessment (check one)

☐ This standard has acceptable Technical Merit

This group has reviewed the standard per the Technical Merit Instructions Guide and recommends this standard for inclusion on the *OSAC Registry*.

☐ This standard does not have acceptable Technical Merit

This group has reviewed the standard per the Technical Merit Instructions Guide and does not recommend this standard for inclusion on the *OSAC Registry* for reasons documented on the Technical Merit Worksheet.

If the Technical Merit evaluation determines that revisions are necessary, the standard should be withdrawn from the Registry Approval Process. If Technical Merit is unacceptable, retain this worksheet as a record of standard consideration.