March 21, 2016

National Commission on Forensic Science

Washington, DC

OSAC Update

Mark D. Stolorow

Director, OSAC Affairs, NIST

John Paul Jones II

Associate Director, OSAC Affairs, NIST

William F. Guthrie, Ph.D.

Chief, Statistical Engineering Division, NIST

Member, Chemistry/Instrumental Analysis SAC

Agenda

- Recent meetings
- Big Picture View of OSAC

- OSAC Metrics and Activities
- OSAC Registries & Standards In Process

- Technical Merit

January 2016 OSAC All-Hands Meeting

January 2016 OSAC Leesburg Meeting

With an historic snow storm blanketing the Washington DC Area the prior weekend, an important challenge was getting to the meeting…

OSAC Leesburg Meeting: 600+

February 2016: OSAC Public Status Reports & Open Discussion

Monday, February 22, 2016

- **Digital/Multimedia** Scientific Area Committee
- **Biology/DNA** Scientific Area
- **Crime Scene/Death Investigation** Scientific Area Committee

Tuesday, February 23, 2016

- **Physics/Pattern Interpretation** Scientific Area Committee
- **Chemistry/Instrumental Analysis** Scientific Area Committee

Watch Webcast: http://www.nist.gov/forensics/osac/nist-scientific-area-committee-meetings-february-2016.cfm

A Big Picture View of OSAC Efforts

Provides initial starting material

Creates high-quality guidance materials

Turns OSAC materials into standards

SWG documents
ASTM standards

OSAC Catalog
(719 documents initially compiled)

Organization of OSAC Scientific Area Committees for Forensic Science

Standards Developing Organization

SDO

OSAC Registry of Approved Standards

NCFS

(National Commission on Forensic Science)

Universal Accreditation Recommendation to DOJ

DOJ Requires Accreditation

OVERALL GOAL of OSAC REGISTRY:
<u>Provide</u> <u>trusted</u> <u>discipline-specific standards</u> (and guidelines) that accrediting bodies can use to audit accredited laboratories

Accrediting Bodies audit Forensic Laboratories (providing "teeth" to standards)

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INTEGRATE

Approved Standards

NCFS

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IMPLEMENT

Approved Standards

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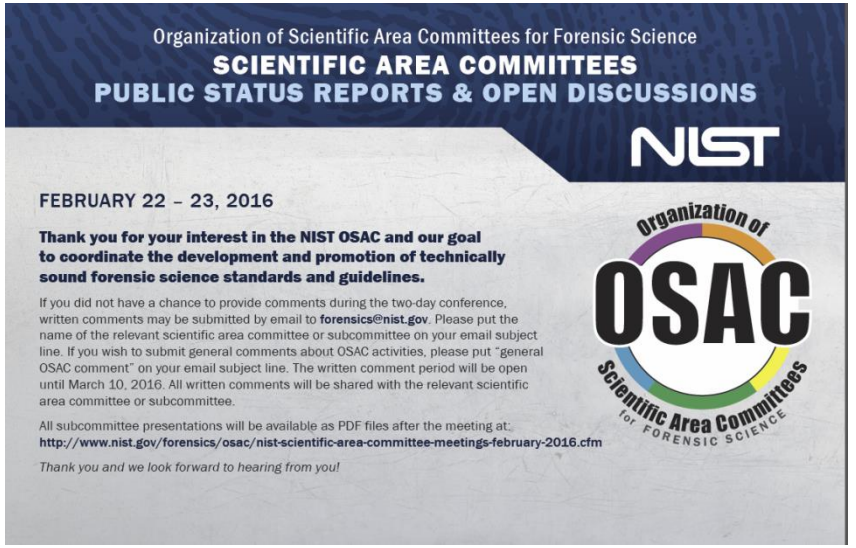
OSAC Affairs Team Members

- Mark Stolorow – Director
- John Paul Jones II – Associate Director
- Sharon Nakich – Project Manager
- Sabrina Springer – Communications Specialist
- LaVonne Brown – Travel Coordinator
- Matthew Gonzalez – Meeting Planner
- 25+ Other NIST Staff Members on OSAC Units

OSAC Affairs is staffed by NIST federal employees and is responsible for supporting OSAC operations, communications and meetings.

OSAC Public Status Reports
(at AAFS meeting, February 22-23, 2016)



- 30 Presentations (on-site & online viewers)
- 392 different web viewers during the 2 days
- 195 viewers - peak online attendance Friction Ridge
- 60 on-site attendees continuously changing for each SAC
- Archived presentations & webcast now available online
- Last Year
  - Only averaged 35 online attendees & 30-50 on-site attendees.
- Thanks NIJ! – OSAC partnered with the NIJ Forensic Technology Center of Excellence operated by RTI International for their registration & webcast support.

http://www.nist.gov/forensics/osac/nist-scientific-area-committee-meetings-february-2016.cfm

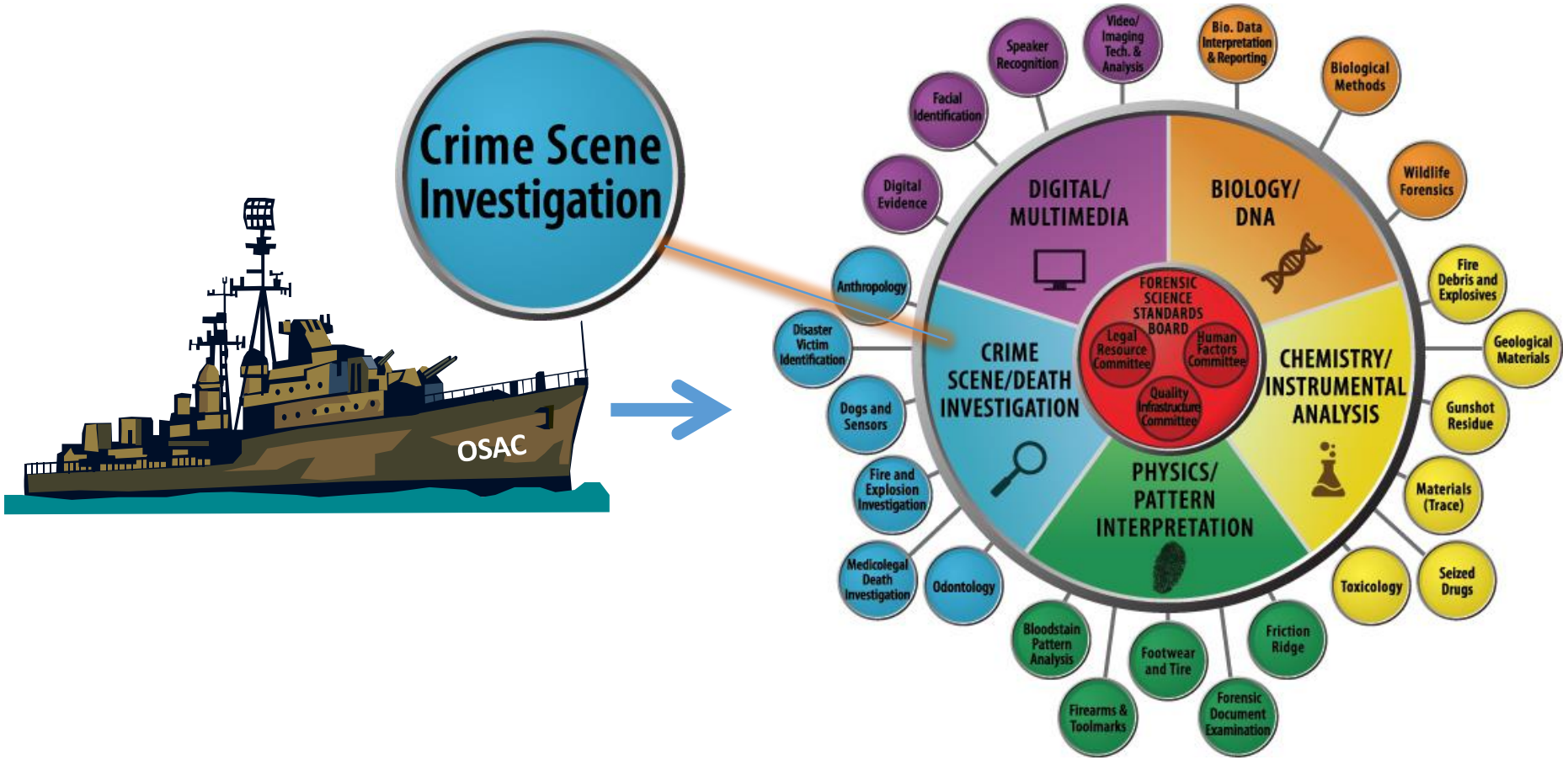
Free Access to ASTM E30 Committee on Forensic Science Standards (approx. 48)

The following **30,000 public criminal justice agencies** shall be provided access to the ASTM Committee E30 on Forensic Science Standards:

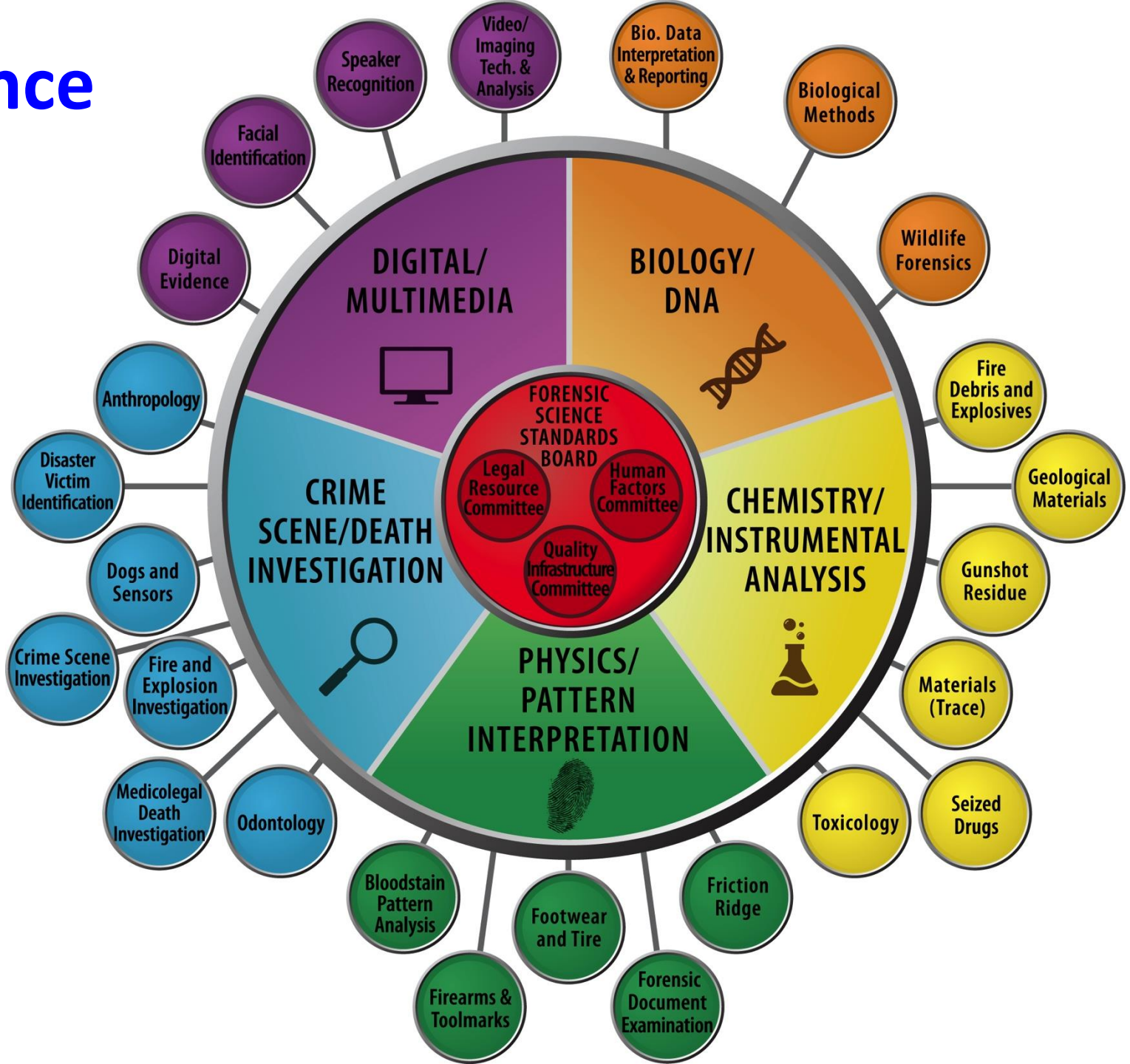
- Organization of Scientific Area Committee Members & Affiliates – approximately 750 individuals
- NIST and Federal/State/Local Crime Laboratories – approximately 412 labs
- Public Defenders Offices – approximately 6,000 offices
- Law Enforcement Agencies – approximately 18,000 offices
- Prosecutor Offices – approximately 3,000 offices
- Medical Examiner/Coroners Offices – approximately 3,000 office

http://www.nist.gov/forensics/osac/osac-registries.cfm

OSAC Moving Forward



OSAC at a Glance



Task Groups at Every Level: 210

2/14/2016 Status:

543 Members

243 Affiliates

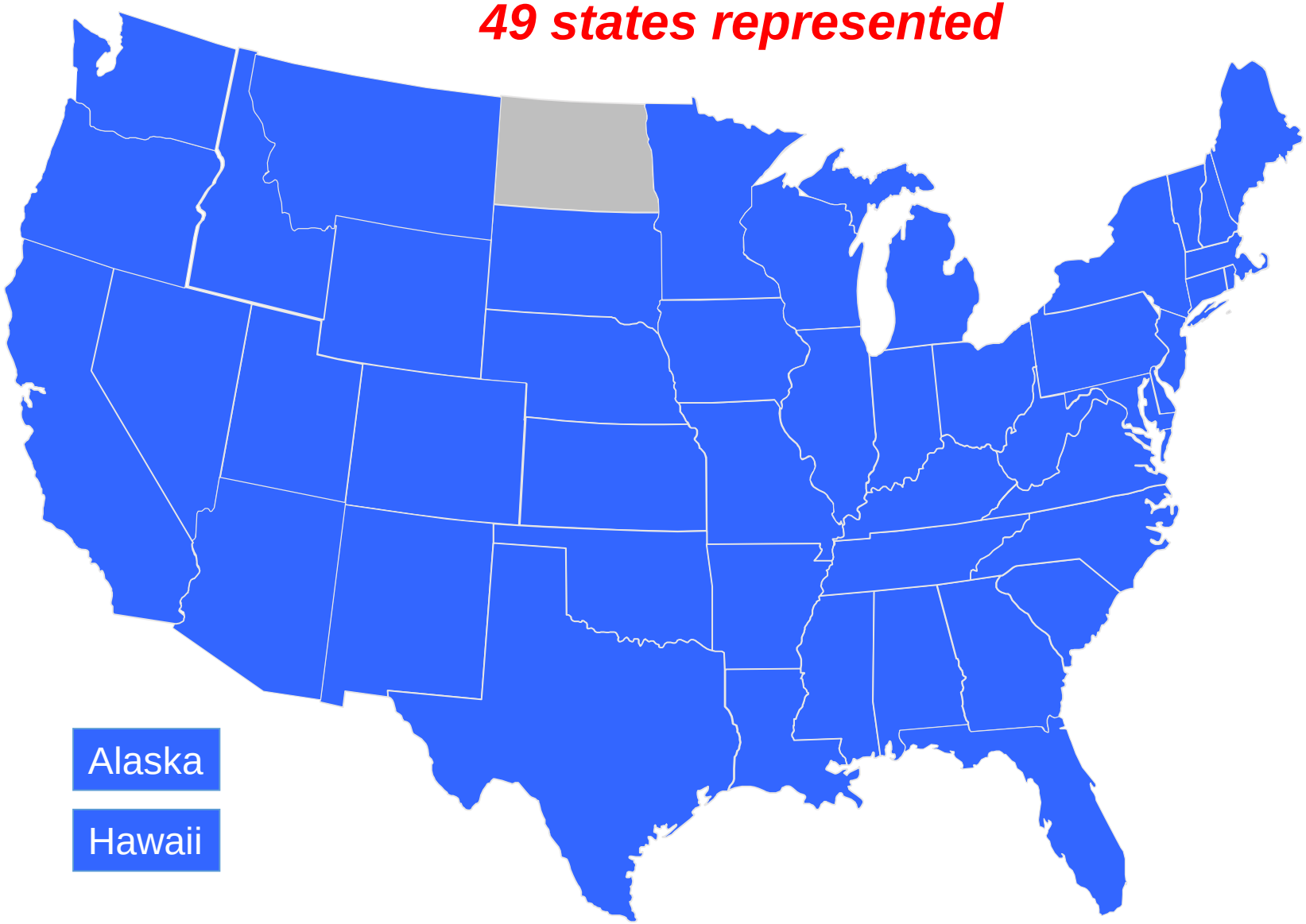
2172 Applications

http://nist.gov/forensics/osac/index.cfm

543 OSAC Members Total

as of 12 February 2016

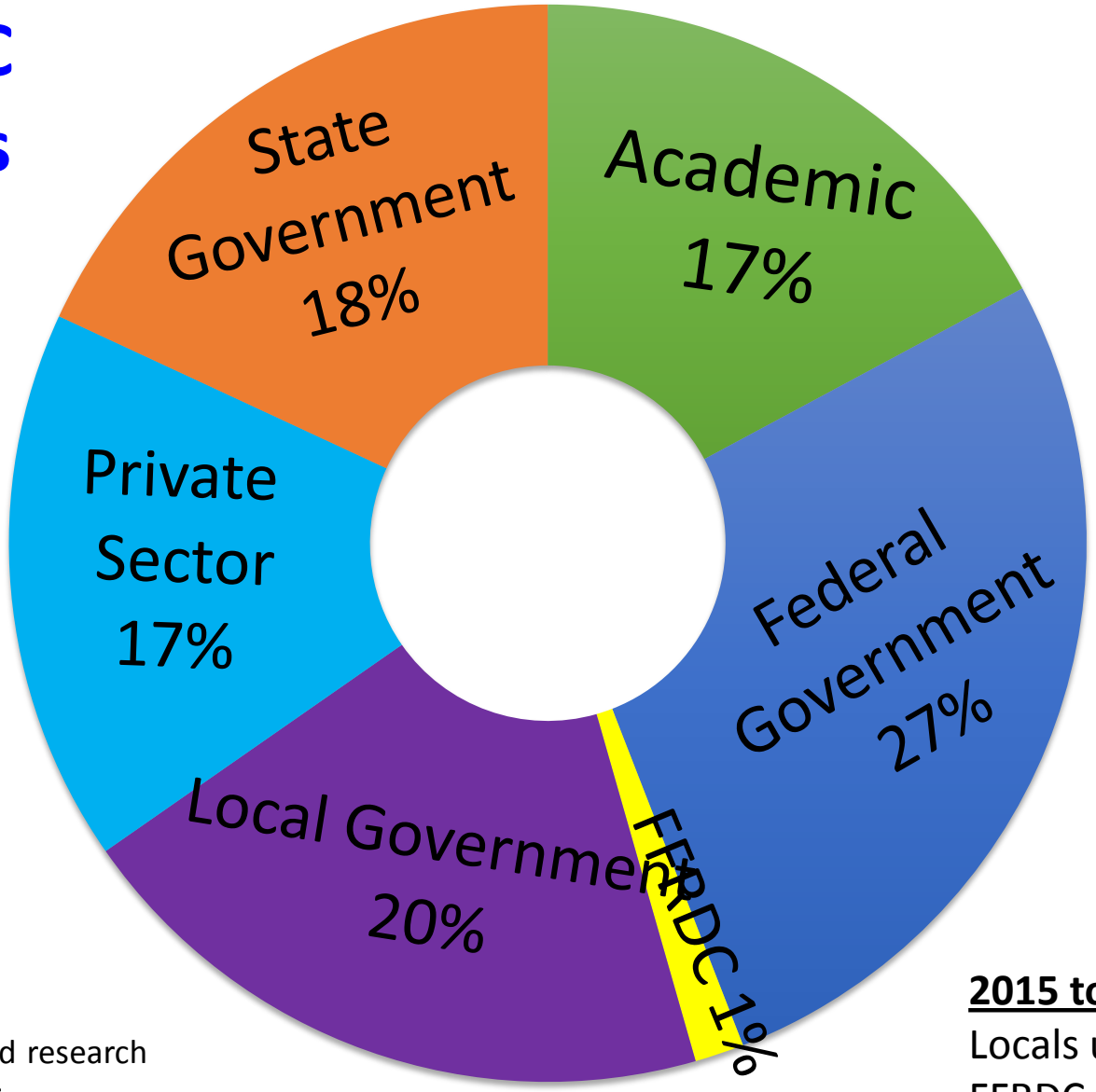
49 states represented



OSAC Members Employer Classification

(as of 12 February 2016)

543 OSAC Members Total



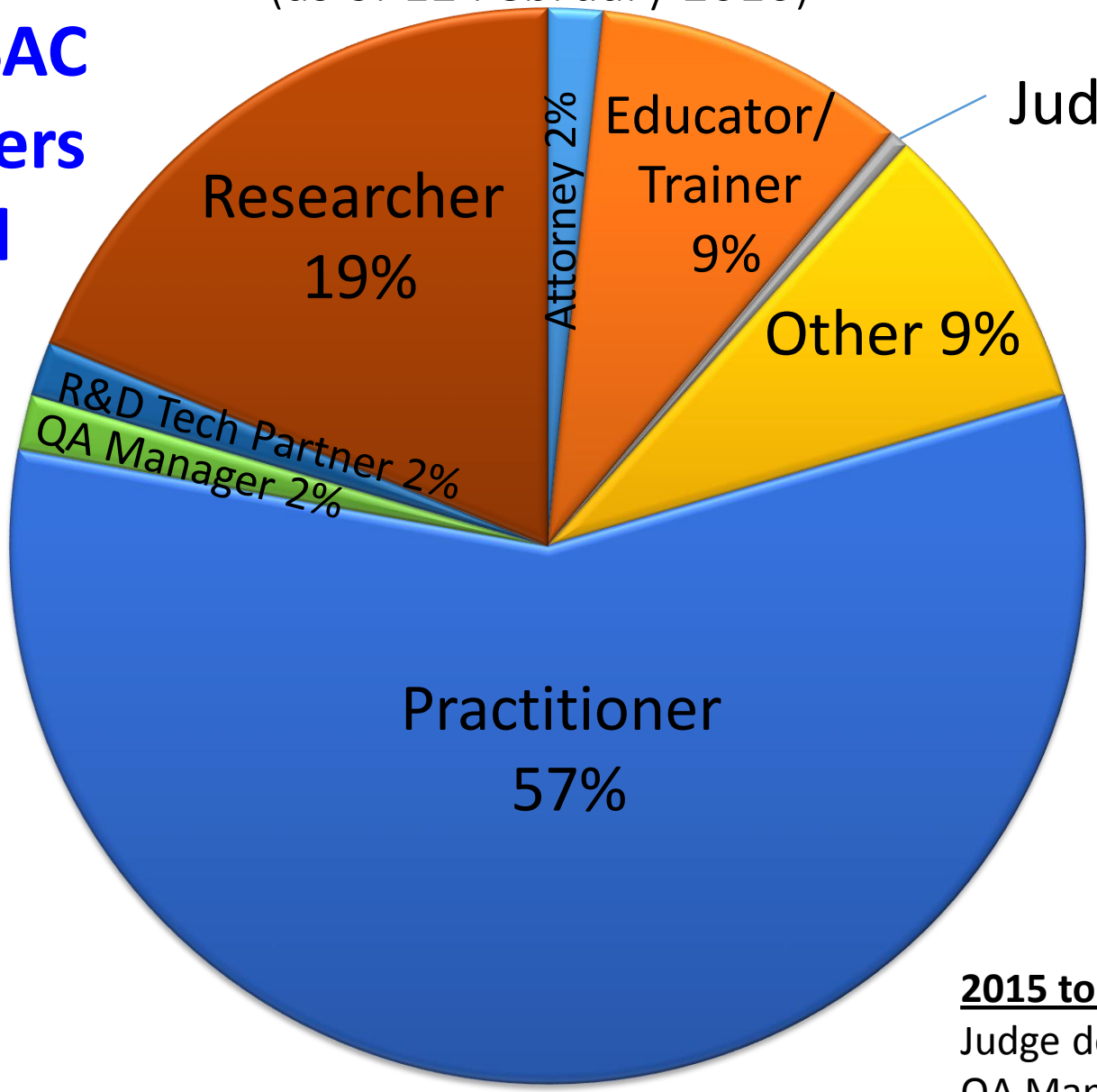
FFRDC = Federally-funded research and development center

2015 to 2016 Change:
Locals up 1%
FFRDC down 1%

OSAC Members Job Classification

(as of 12 February 2016)

543 OSAC Members Total



2015 to 2016 Change:
Judge down .5%
QA Manager up 1%

OSAC Registries: They're Here

OSAC Registries: They're Here

ASTM: E2329-14 Standard Practice for Identification of Seized Drugs, was posted January 27, 2016 (Under Revision)
(NIST Statement on ASTM Standard E2329-14)

No Listings as of 2-18-2016

http://www.nist.gov/forensics/osac/osac-registries.cfm

ASTM: E2329-14 Standard Practice for Identification of Seized Drugs

- Describes minimum criteria for the identification of seized drugs.
- Originally published by the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) through ASTM,
- Describes analysis schemes where two analytical techniques, at minimum, must be employed in order to reach a scientifically supported drug identification.
- The Seized Drugs subcommittee considered implementation of this standard practice throughout US forensic drug laboratories as the essential first step towards improving the discipline.
- Provides the platform for future Seized Drugs documents:
  - Sampling
  - Quality assurance,
  - Measurement uncertainty
  - Others

http://www.nist.gov/forensics/osac/osac-approved-standards.cfm

Pending FSSB Approval Vote:

- **ASTM: E2548-11e1 Standard Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis (for consideration as an OSAC Standard)**
  - This guide covers minimum considerations for sampling of seized drugs for qualitative and quantitative analysis.

- **ASTM: E2330-12 Standard Test Method for Determination of Concentrations of Elements in Glass Samples Using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) for Forensic Comparisons (for consideration as an OSAC Standard)**
  - This test method covers a procedure for quantitative determination of the concentrations of magnesium (Mg), aluminum (Al), iron (Fe), titanium (Ti), manganese (Mn), rubidium (Rb), strontium (Sr), zirconium (Zr), barium (Ba), lanthanum (La), cerium (Ce), neodymium (Nd), samarium (Sm), and lead (Pb) in glass samples.

- **ASTM: E2926-13 Standard Test Method for Forensic Comparison of Glass Using Micro X-ray Fluorescence (µ-XRF) Spectrometry (for consideration as an OSAC Standard)**
  - This test method is for the determination of major, minor, and trace elements present in glass fragments. This test method covers the application of µ-XRF using mono- and poly- capillary optics, and an energy dispersive X-ray detector (EDS).

http://www.nist.gov/forensics/osac/osac-newsletter-february-2016.cfm#registrystatus

Undergoing Comment Adjudication:

- **ASTM E2916-13 Standard Terminology for Digital and Multimedia Evidence Examination (for consideration as an OSAC Guideline)**
  - This document provides standard terminology for the subcommittees of Digital Evidence, Facial Identification, and Video Imaging Technology and Analysis.

- **ASTM E2825-12 Standard Guide for Forensic Digital Image Processing (for consideration as an OSAC Standard)**
  - This document provides digital image processing standards to ensure the production of quality forensic imagery for use as evidence in a court of law. It briefly describes advantages, disadvantages, and potential limitations of each major digital imaging process.

http://www.nist.gov/forensics/osac/osac-newsletter-february-2016.cfm#registrystatus

Undergoing Comment Adjudication:

- **ASTM: E2881-13e1 Standard Test Method for Extraction and Derivatization of Vegetable Oils and Fats from Fire Debris and Liquid Samples with Analysis by Gas Chromatography-Mass Spectrometry (for consideration as an OSAC Standard)**
  - This test method covers the extraction, derivatization, and identification of fatty acids indicative of vegetable oils and fats in fire debris and liquid samples. This procedure will also extract animal oils and fats, as these are similar in chemical composition to vegetable oils and fats. This test method is suitable for successfully extracting oil and fat residues having 8 to 24 carbon atoms.

http://www.nist.gov/forensics/osac/osac-newsletter-february-2016.cfm#registrystatus

Public Comment Period Closed March 18, 2016:

- **ASTM: E1610-14 Standard Guide for Forensic Paint Analysis and Comparison (for consideration as an OSAC Guideline)**
  - This guide is designed to assist the forensic paint examiner in selecting and organizing an analytical scheme for identifying and comparing paints and coatings. *6 comments*

- **ASTM: E2937-13 Standard Guide for Using Infrared Spectroscopy in Forensic Paint Examinations (for consideration as an OSAC Guideline)**
  - This guide applies to the forensic infrared spectroscopy (IR) analysis of paints and coatings and is intended to supplement information presented in the Forensic Paint Analysis and Comparison Guidelines written by Scientific Working Group on Materials Analysis (SWGMAT). This guideline is limited to the discussion of Fourier Transform Infrared (FTIR) instruments and provides information on FTIR instrument setup, performance assessment, sample preparation, analysis and data interpretation.

7 Comments

http://www.nist.gov/forensics/osac/osac-newsletter-february-2016.cfm#registrystatus

Open Public Comment open through April 18, 2016:

- **ASTM: E2388-11 Standard Guide for Minimum Training Requirements for Forensic Document Examiners** *(for consideration as an OSAC standard)*
  - This guide provides minimum requirements and procedures that should be used for the fundamental training of forensic document examiners. This guide may not cover all aspects of training for the topics addressed or for unusual or uncommon examinations.

https://workspace.forensicosac.org/kws/public/documents?wg_abbrev=sac_physics

OSAC Registry Approval Metrics

- 25 Subcommittees elevate published standards/guidelines to the 5 SACs for consideration
- 5 SACs determine if standards/guidelines move forward for resource committee & public comment
- Statistics:
  - RA: Standards/Guidelines considered by SAC: 23
  - RA: Approved for public comment: 10 (43%) 

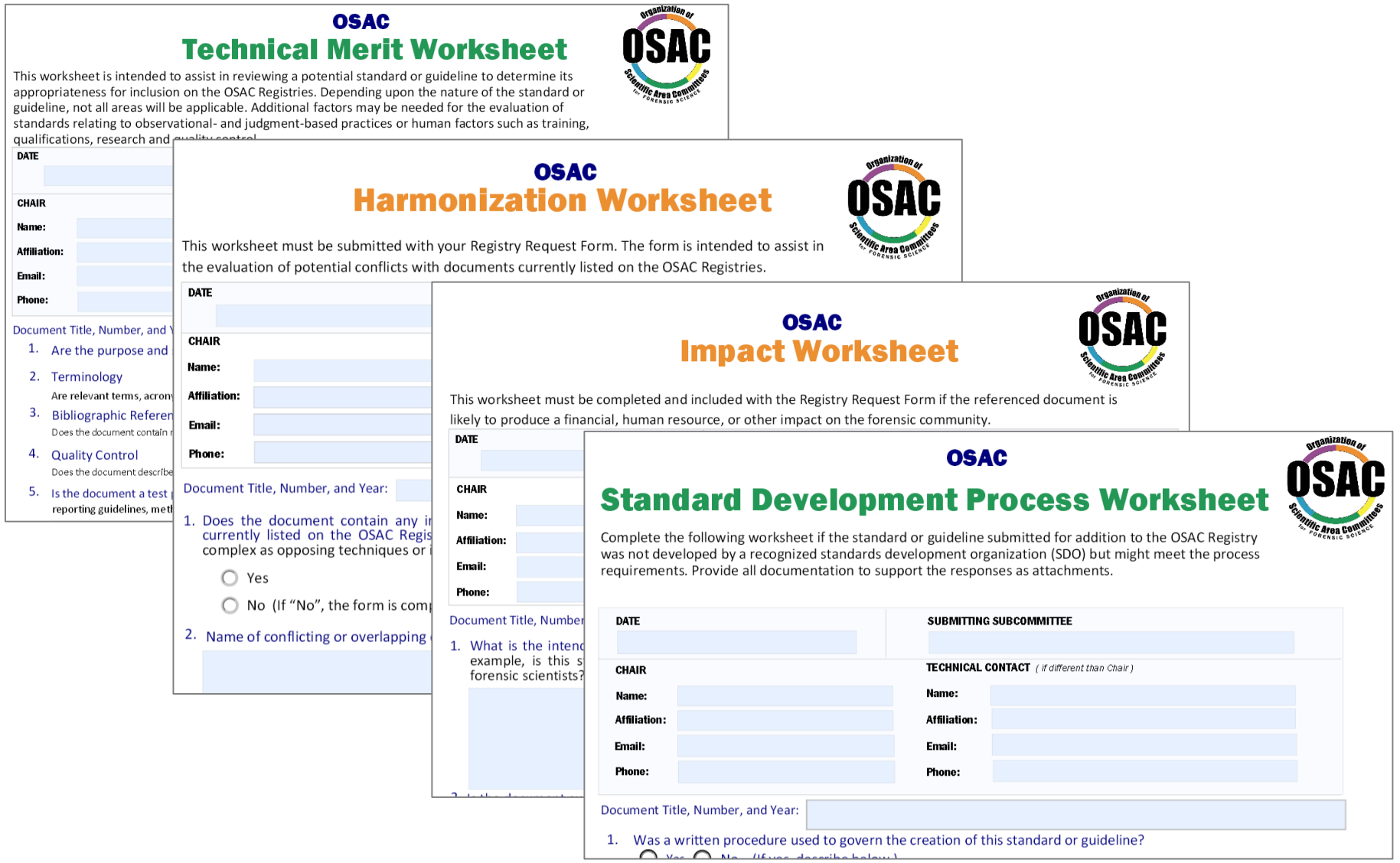
  - RA: Stopped/Sent back for revision: 13 (57%) 

- Additional approval levels beyond this: SAC/FSSB

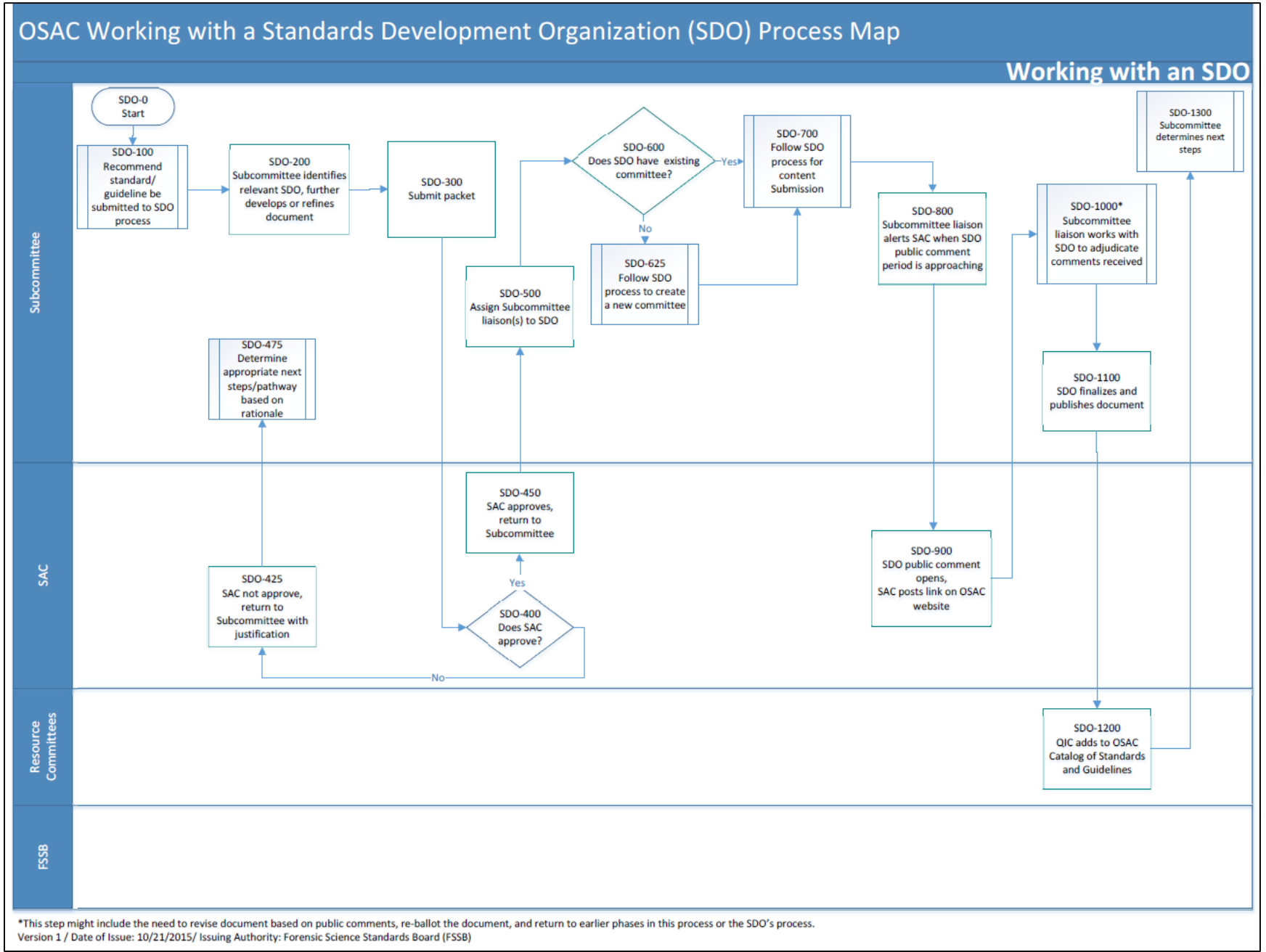
OSAC Projects in Motion

- February 2015: Launched 360+ projects/ideas
- February 2016: Refocused on 144 specific projects (Standards/Guidelines) moving within OSAC processes

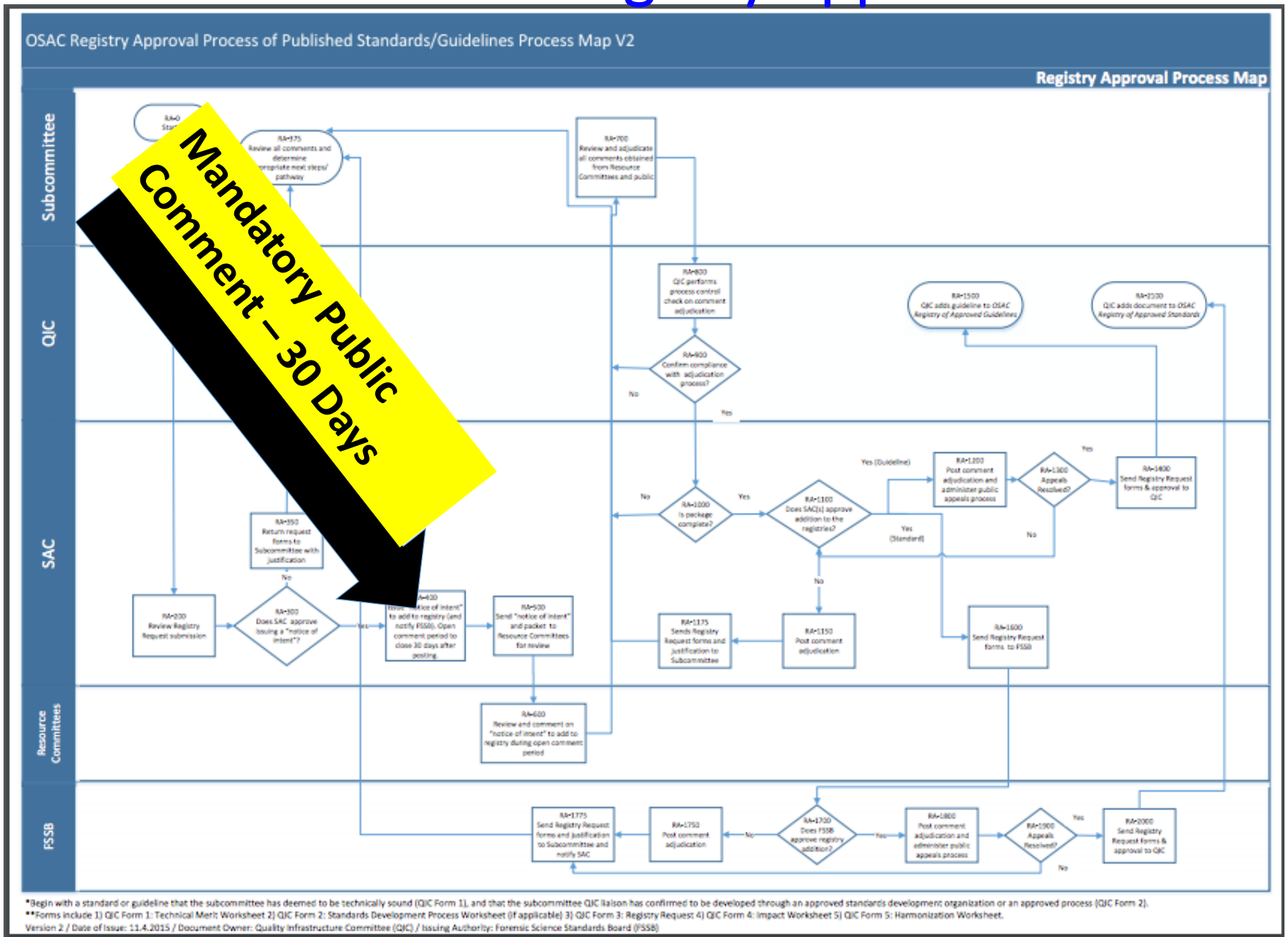
Launched OSAC Evaluation Templates



Launched OSAC's How to Work with an SDO Process



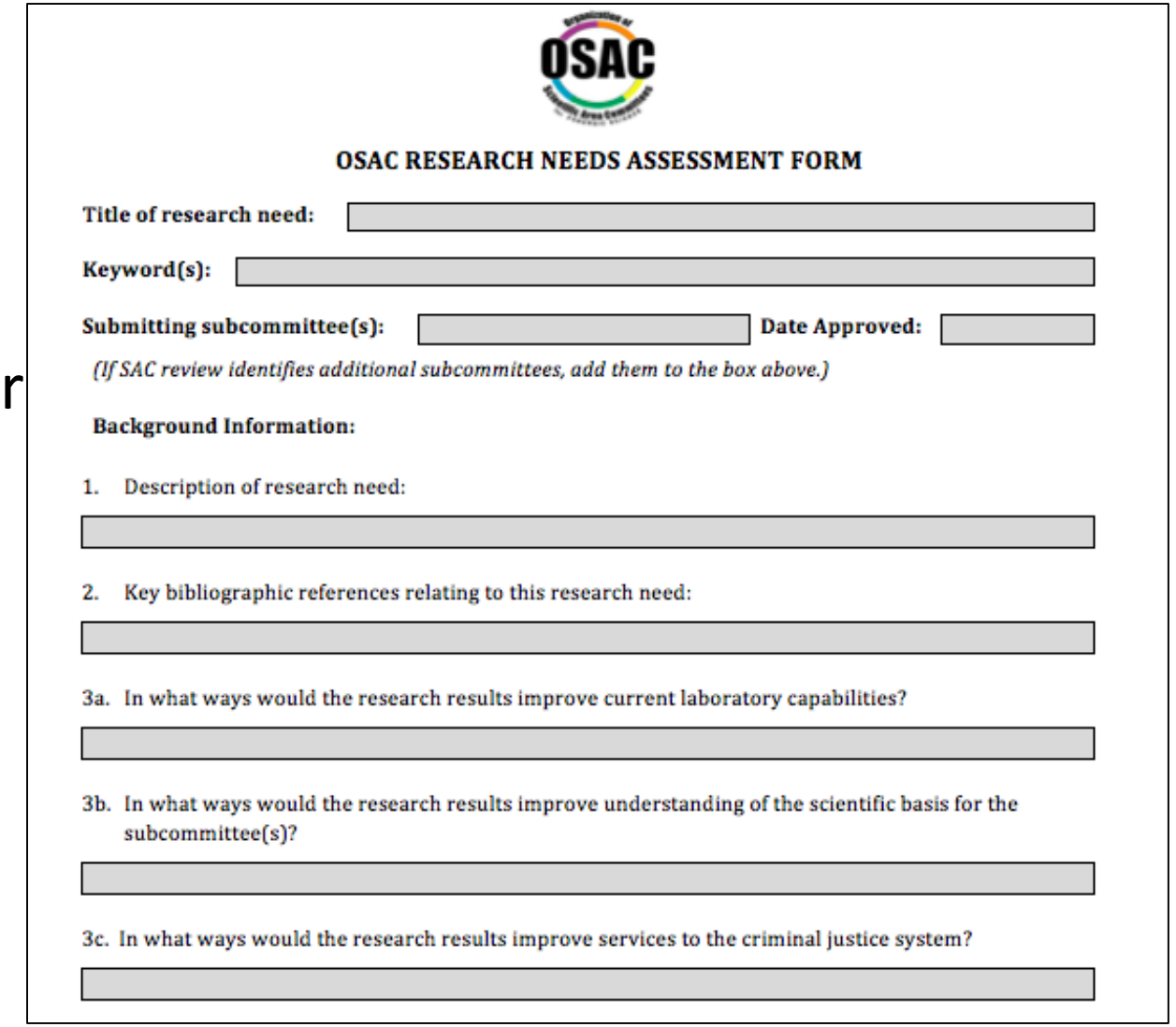
Launched OSAC's Registry Approval Process



*Begin with a standard or guideline that the subcommittee has deemed to be technically sound (QIC Form 1), and that the subcommittee QIC liaison has confirmed to be developed through an approved standards development organization or an approved process (QIC Form 2).
**Forms include 1) QIC Form 1: Technical Merit Worksheet 2) QIC Form 2: Standards Development Process Worksheet (if applicable) 3) QIC Form 3: Registry Request 4) QIC Form 4: Impact Worksheet 5) QIC Form 5: Harmonization Worksheet.
Version 2 / Date of Issue: 11.4.2015 / Document Owner: Quality Infrastructure Committee (QIC) / Issuing Authority: Forensic Science Standards Board (FSSB)

Launched OSAC "Research Needs" Website

- Subcommittee Research Needs Documented
- Posted Publicly for consideration by funding agencies



OSAC RESEARCH NEEDS ASSESSMENT FORM

Title of research need:

Keyword(s):

Submitting subcommittee(s): **Date Approved:**

(If SAC review identifies additional subcommittees, add them to the box above.)

Background Information:

1. Description of research need:

2. Key bibliographic references relating to this research need:

3a. In what ways would the research results improve current laboratory capabilities?

3b. In what ways would the research results improve understanding of the scientific basis for the subcommittee(s)?

3c. In what ways would the research results improve services to the criminal justice system?

http://www.nist.gov/forensics/osac/osac-research-needs-assessments.cfm

Launched OSAC Newsletter

- Monthly Release – 9,500 on distribution list
- Public Comment Period
- OSAC Vacancies
- OSAC Meetings
- Feature Articles
- Accomplishments

Sign up to receive news about NIST Forensic Science.

*Email Address

Submit

Organization of Scientific Area Committees for Forensic Science

August 2015 | Vol. 1, Issue 1

OSAC Newsletter

Inside this issue

Feature Article:

OSAC Publishes the Standards/Guidelines Registry Approval Process

One aim of the OSAC is to identify and promote existing technically sound, consensus-based, and fit-for-purpose documentary standards that are based on sound scientific principles. This is achieved through the *OSAC Registry of Approved Standards* and the *OSAC Registry of Approved Guideline*. A standard or guidelines that is posted on the registry demonstrates that the methods it contains have been judged by forensic practitioners, academic researchers, measurement scientists, and statisticians, to be valid.

Once populated, forensic scientists and practitioners will be able to refer to the *OSAC Registry of Approved Standards* and the *OSAC Registry of Approved Guidelines* for a uniform set of high quality standards on how to produce scientifically sound and statistically valid test results, laboratory results, and courtroom testimony. These standards should help to increase confidence in the criminal justice system and the testimony put forth by practitioners.

The OSAC has recently developed and launched the *OSAC Registry Approval Process of Published Standards and Guidelines*, which is a rigorous process that includes checklist criteria against which existing standards and guidelines are to be analyzed before they are posted to the registries. This includes an analysis of technical merit, the openness of the development process (to ensure balanced interests are represented), consensus,

... Continued page 4

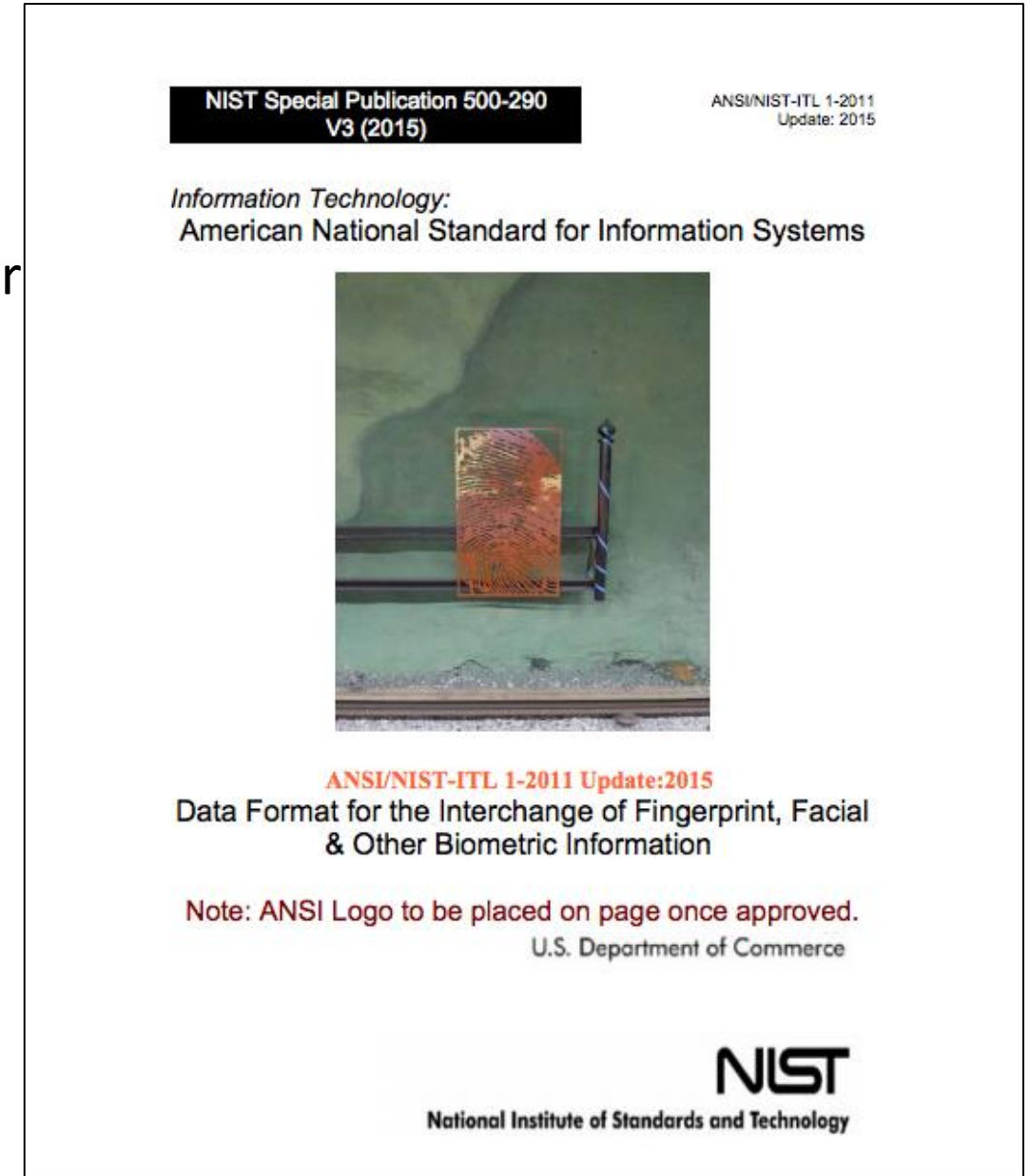
OSAC website: http://www.nist.gov/forensics/osac/

Launched 2 Interdisciplinary Subcommittees: #1

- Virtual Subcommittee #1
  - **ISO/IEC 17025**:2005 General Requirements for the Competence of Testing and Calibration Laboratories
  - **ISO/IEC 17020**:2012 Requirements for the Operation of Various Types of Bodies Performing Inspection

Launched 2 Interdisciplinary Subcommittees: #2

- Virtual Subcommittee #2
- ANSI/NIST/ITL Data format for the Interchange of Fingerprint, Facial & Other Biometric Information



NIST Special Publication 500-290
V3 (2015)

ANSI/NIST-ITL 1-2011
Update: 2015

Information Technology:
American National Standard for Information Systems

ANSI/NIST-ITL 1-2011 Update:2015
Data Format for the Interchange of Fingerprint, Facial & Other Biometric Information

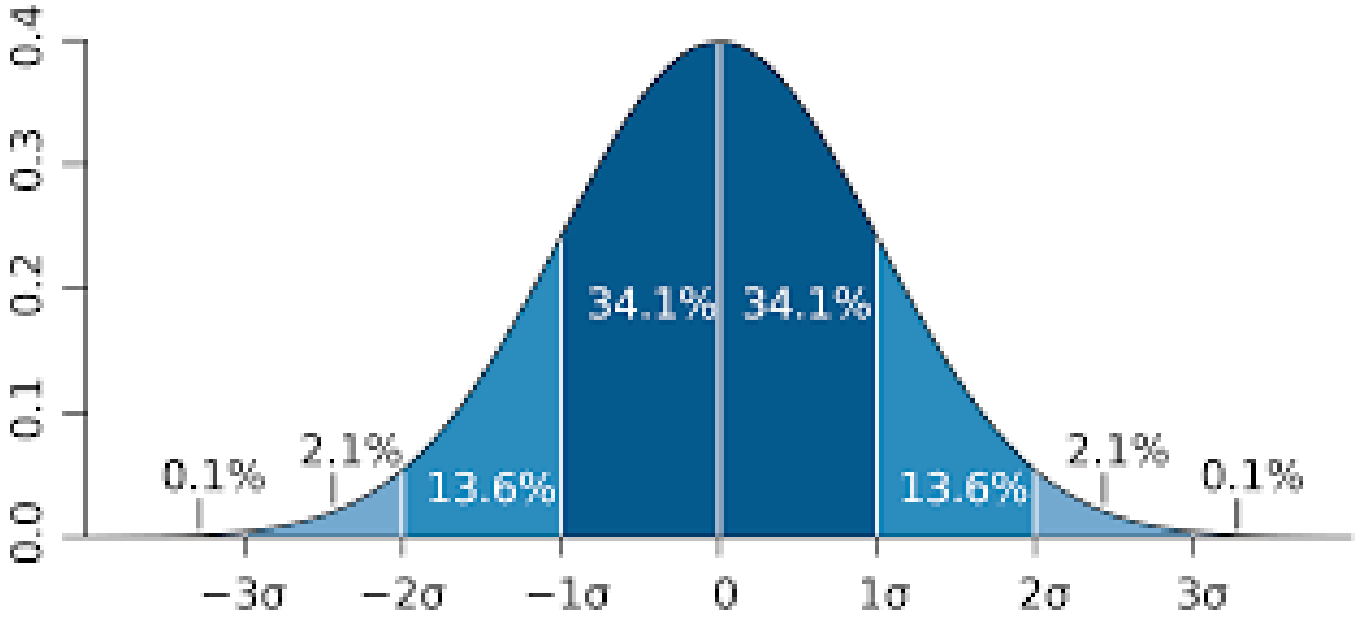
Note: ANSI Logo to be placed on page once approved.

U.S. Department of Commerce

NIST
National Institute of Standards and Technology

Launched FSSB Statistics Task Group

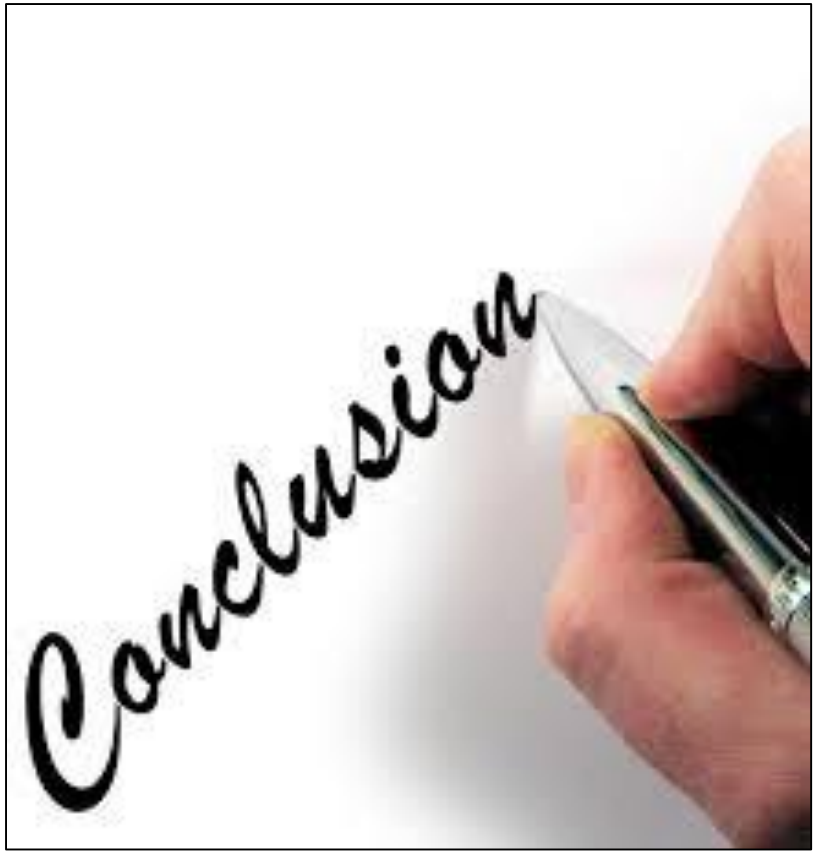
- Statisticians from across OSAC are collaborating
- They can bring items from their OSAC unit to the Task Group for consideration and additional “feedback” or “weight”.



Wikipedia image

Launched OSAC-wide Conclusions Task Group

- Members from relevant OSAC units discussing consistency of common terms related to conclusion statements in reports and testimony.



http://d--h.info/?p=6966

OSAC Recent & Future Meetings

Recent:

- January 25-29, 2016 Full OSAC (600+)
- AAFS Public Reporting February 22-23, 2016
  - (29 presentations) access webcasts & PDFs
  - http://www.nist.gov/forensics/osac/nist-scientific-area-committee-meetings-february-2016.cfm

Future:

- Summer OSAC Meetings – (Phoenix, AZ)
  - 3 Resource Committees – July 12-13, 2016
  - Digital SAC & Subs and Physics SAC & Subs – July 26-29, 2016
  - Chemistry SAC & Subs – August 2-5, 2016
  - Biology SAC & Subs and Crime Scene SAC & Subs – August 23-26, 2016
- OSAC Full OSAC (600+) – April 3-7, 2017

Implementation – 1 Lab – it's a start

- **5.4.2 Selection of Methods**

- *NOTE – The XXXXXXX State Police Drug Chemistry section adheres to standards and guidelines from the Organization of Scientific Area Committees (OSAC) and recommendations by the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) in formulating its testing methods and policies.*

- **5.9 Assuring the quality of test and calibration results**

- **5.9.1 General**

- **5.9.1.1** The drug chemistry section monitors the reliability of forensic examinations with quality control schemes including but not limited to the following:
  - Adherence to *Organization of Scientific Area Committees (OSAC)* standards and guidelines
  - Adherence to *Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG)* guidelines
  - Use of certified reference materials
  - Participation in proficiency testing programs
  - Use of multiple analytical methods
  - Positive and negative controls

Stay Informed

- Receive the OSAC Monthly Newsletter & latest announcements
  - www.nist.gov/forensics
  - Insert your email address

- View publicly available information
  - OSAC Homepage: http://www.nist.gov/forensics/osac/index.cfm

- Apply for Membership or Affiliate Status:
  - OSAC Application:https://www.nist.gov/forensics/osac-application.cfm

QIC Form-01
Technical Merit Worksheet

QIC Training Module

Presented by Will Guthrie

Materials Prepared by Karen Reczek and Will Guthrie

OSAC
Technical Merit Worksheet

This worksheet is intended to assist in reviewing a potential standard or guideline to determine its appropriateness for inclusion on the OSAC Registries. Depending upon the nature of the standard or guideline, not all areas will be applicable. Additional factors may be needed for the evaluation of standards relating to observational and judgment-based practices or human factors such as training, qualifications, research and quality control.

DATE	SUBMITTING SUBCOMMITTEE

CHAIR		TECHNICAL CONTACT (if different than Chair)	
Name:		Name:	
Affiliation:		Affiliation:	
Email:		Email:	
Phone:		Phone:	

Document Title, Number, and Year:

1. Are the purpose and scope clearly stated? ◯ Yes ◯ No

2. Terminology
   Are relevant terms, acronyms, or abbreviations used in the document clearly defined? ◯ Yes ◯ No ◯ N/A

3. Bibliographic References
   Does the document contain references, including scientific or academic, that support its content? ◯ Yes ◯ No ◯ N/A

4. Is the document a test procedure?* ◯ Yes ◯ No *If yes, consider elements such as analysis, protocols, data interpretation, reporting guidelines, method validation, and sampling, and discuss if these are adequately addressed.*

5. Quality Control
   Does the document describe quality control procedures for instruments, equipment, chemicals, reagents, and/or other items? ◯ Yes ◯ No ◯ N/A

6. Uncertainty
   Does the document provide adequate guidance on (i) estimating the uncertainty of the resulting measurement(s) and/or (ii) uncertainty with regards to the conclusions? ◯ Yes ◯ No ◯ N/A

7. Limitations
   Does the document clearly state any known limitations to either the method itself or the interpretation of the resulting findings and conclusions? *For example, does the document identify the known environmental or human factors that affect the accuracy or measurement uncertainty for quantitative or qualitative techniques or processes?* ◯ Yes ◯ No ◯ N/A

8. Safety
   Does the document include information about hazards and precautions to be taken to avoid them? *Hazard identification includes proper chemical handling techniques, personal protective gear requirements, proper operation of equipment and instruments, handling of samples, chemical and biological hood usage, etc.* ◯ Yes ◯ No ◯ N/A

9. Have studies regarding the validation of the test procedure been conducted and results reported?If yes, include reference(s). ◯ Yes ◯ No ◯ N/A

10. Is the document fit-for-purpose? ◯ Yes ◯ No ◯ N/A
    Explain how the document does or does not meet the expectations of the target audience. This audience may include the document user and the consumer of the document results.

11a. Is this a generally accepted practice in the relevant forensic community? ◯ Yes ◯ No ◯ N/A
    If no, explain. If yes, describe how the document represents consensus opinion of knowledgeable practictioners.

11b. Is this a generally accepted practice in the general scientific community? ◯ Yes ◯ No ◯ N/A
    If no, explain. If yes, describe how the document represents consensus opinion of knowledgeable researchers, statisticians, measurement scientists, etc.

12. Is this document considered to be a standard or a guideline?
    ◯ Standard ◯ Guideline

13. What other concerns, issues or aspects were considered while evaluating the technical merit?
    If any OSAC member or unit has significant concerns with this document, the dissenting view(s) must be documented here by the objecting member along with the number of members that agree with the dissenting view(s).

14. Vote Counts (enter # of votes in each box)

	# For	# Against	# Abstain
SAC			
Subcommittee			
Document Task Group			

15. Technical Merit Rating** 1

1 Acceptable
2 Acceptable with minor revisions
3 Acceptable with major revisions
4 Unacceptable

**Test Procedure: Total operation necessary to perform the analysis e.g., preparation of the specimen or sample, of the reference materials or of the reagents, the use of instruments and of formulas for the calculations (when the test is quantitative), the preparation and use of calibration curves and the determination of the number of replicates. (Source of definition: United Nations International Glossary of Terms for Quality Assurance and Good Laboratory Practices UNDOC ST/NAR/26/Rev.1)*

***If Technical Merit is 1, include this worksheet as part of the Registry Request packet for submission to the SAC for approval. If Technical Merit is 2 or 3, evaluate whether document should be revised (by working with the relevant SDO or standards process procedure) prior to submission for addition to the Registry. If Technical Merit is 4, retain this worksheet as a record of document consideration. Other factors may be considered as determined by the submitting OSAC Unit.*

Please submit this worksheet with your Registry Request Form.

Technical Merit (TM) Worksheet - Purpose

- Use to guide discussions on a standard or guideline's*
  - technical strength
  - scientific underpinnings
- Starting point for discussions of appropriateness for inclusion in OSAC registry
- Summary of potential changes when standard up for revision
  - mechanism being developed to facilitate input from TM worksheet into SDO process when revisions initiated

*(will just say "standard" going -> in this talk)

How to Use

- A technical point of contact should be assigned to each standard under consideration
  - Subcommittee or task group member
- Point of contact facilitates discussion among task group and subcommittee to arrive at agreement on responses
- Responses primarily intended to be drafted and finalized in Task Group and Subcommittee deliberations

How to Use

- Once TM worksheet completed at each stage, votes to approve
- Approval requires 2/3 majority
  - Approved TM worksheets submitted to SAC for registry approval process
  - Returned TM worksheets retained for further work or as a record of consideration
- Additional annotations (with ID) should note SAC or Resource committee input during registry approval process

OSAC

Technical Merit Worksheet

This worksheet is intended to assist in reviewing a potential standard or guideline to determine its appropriateness for inclusion on the OSAC Registries. Depending upon the nature of the standard or guideline, not all areas will be applicable. Additional factors may be needed for the evaluation of standards relating to observational and judgment-based practices or human factors such as training, qualifications, research and quality control.

DATE	**SUBMITTING SUBCOMMITTEE**

CHAIR		**TECHNICAL CONTACT** *(if different than Chair)*	
Name:		**Name:**	
Affiliation:		**Affiliation:**	
Email:		**Email:**	
Phone:		**Phone:**	

Document Title, Number, and Year:

1. Are the purpose and scope clearly stated? ◯ Yes ◯ No

2. Terminology

   Are relevant terms, acronyms, or abbreviations used in the document clearly defined? ◯ Yes ◯ No ◯ N/A

3. Bibliographic References

   Does the document contain references, including scientific or academic, that support its content? ◯ Yes ◯ No ◯ N/A

4. Is the document a test procedure?* ◯ Yes ◯ No *If yes, consider elements such as analysis, protocols, data interpretation, reporting guidelines, method validation, and sampling, and discuss if these are adequately addressed.*

Test Procedure: Total operation necessary to perform the analysis e.g., preparation of the specimen or sample, of the reference materials or of the reagents, the use of instruments and of formulas for the calculations (when the test is quantitative), the preparation and use of calibration curves and the determination of the number of replicates. (Source of definition: United Nations International Glossary of Terms for Quality Assurance and Good Laboratory Practices UNDOC ST/NAR/26/Rev.1)

- References from literature are key, to demonstrate sound scientific basis
- If standard is a test procedure, review framework sketched out
- Other types of standards require task group to provide appropriate review framework

5. **Quality Control**
Does the document describe quality control procedures for instruments, equipment, chemicals, reagents, and/or other items?

Yes No N/A

6. **Uncertainty**
Does the document provide adequate guidance on (i) estimating the uncertainty of the resulting measurement(s) and/or (ii) uncertainty with regards to the conclusions?

Yes No N/A

7. **Limitations**
Does the document clearly state any known limitations to either the method itself or the interpretation of the resulting findings and conclusions? *For example, does the document identify the known environmental or human factors that affect the accuracy or measurement uncertainty for quantitative or qualitative techniques or processes?*

Yes No N/A

8. **Safety**
Does the document include information about hazards and precautions to be taken to avoid them?
Hazard identification includes proper chemical handling techniques, personal protective gear requirements, proper operation of equipment and instruments, handling of samples, chemical and biological hood usage, etc.

Yes No N/A

- Like whole TM worksheet, terms listed here reflect current best effort, but can be revised if necessary
- Quality control - evaluation of procedure during operations (i.e. case work)
- Suggested revision for Q7: change “any” -> “all” known limitations
- Safety another key point for inclusion on OSAC Registry

9. Have studies regarding the validation of the test procedure been conducted and results reported?If yes, include reference(s). ◯ Yes ◯ No ◯ N/A

10. Is the document fit-for-purpose? ◯ Yes ◯ No ◯ N/A

Explain how the document does or does not meet the expectations of the target audience. This audience may include the document user and the consumer of the document results.

- Method validation – operation of procedure using realistic, known scenarios to verify the correctness or accuracy of results, another key point
- Q10 – evaluation method practicality/usability with regard to cost, throughput, analyst training, etc.

11a. Is this a generally accepted practice in the relevant forensic community? ◯ Yes ◯ No ◯ N/A

If no, explain. If yes, describe how the document represents consensus opinion of knowledgeable practictioners.

11b. Is this a generally accepted practice in the general scientific community? ◯ Yes ◯ No ◯ N/A

If no, explain. If yes, describe how the document represents consensus opinion of knowledgeable researchers, statisticians, measurement scientists, etc.

12. Is this document considered to be a standard or a guideline?

◯ Standard ◯ Guideline

- Generally accepted practice indicates a procedure with historical precedent and support as reasonable by a substantial fraction of analysts
- After discussion of rules involving “shalls” and “shoulds”, it was agreed that SAC ultimately decides whether a document will be a standard or guideline

13. What other concerns, issues or aspects were considered while evaluating the technical merit?

If any OSAC member or unit has significant concerns with this document, the dissenting view(s) must be documented here by the objecting member along with the number of members that agree with the dissenting view(s).

- Goal- capture technical concerns of majority, subgroups, or individuals
- Support for each point of dissent at each stage of process should be noted
- Recognizing all points-of-view improves efficacy of decision-making when complete agreement can’t be reached, can encourage further investigation at succeeding levels of review, when needed

14. Vote Counts (enter # of votes in each box)

	# For	# Against	# Abstain
SAC			
Subcommittee			
Document Task Group			

15. Technical Merit Rating** 1

1 Acceptable → **Go forward to SAC**

2 Acceptable with minor revisions

3 Acceptable with major revisions → **Revise**

4 Unacceptable → **Retain for the record**

***If Technical Merit is 1, include this worksheet as part of the Registry Request packet for submission to the SAC for approval. If Technical Merit is 2 or 3, evaluate whether document should be revised (by working with the relevant SDO or standards process procedure) prior to submission for addition to the Registry. If Technical Merit is 4, retain this worksheet as a record of document consideration. Other factors may be considered as determined by the submitting OSAC Unit.*

Please submit this worksheet with your Registry Request Form.

QIC Form 1 / Version 3 / Date of Issue: 1.18.2016 / Issuing Authority: Forensic Science Standards Board (FSSB)

- Q14 – suggest reordering rows to reflect typical progression from task group to Subcommittee to SAC, adding a second row for SAC vote after public comment
- Q15 – Synthesis of preceding questions indicating final disposition of standard

OSAC Decision-Making: Voting, Consensus, and Unanimity

- Unanimity – full agreement by every member of group
- In contrast, consensus is a process by which a decision is reached that is ACCEPTABLE to all
- Standards-making groups generally do not require unanimity
  - 2/3 vote is required to make decisions in OSAC
- However, goal is to reach consensus as often as possible

Gradients of Agreement for Consensus

1- Wholehearted Endorsement: “I really like it”

2- Support with Reservations: “I can live with it, though imperfect”

3- Abstain: “This issue does not affect me” (or recusal for conflict of interest)

4- More Discussion Needed: “I don’t understand the issues well enough”

5- Serious Disagreement: “I am not on board with this”

- Votes with these five categories facilitate decision-making and ensure all points-of-view are fully addressed
  - Issues discussed until all votes fall in categories 1 through 3 (for example)
  - Fundamental disagreements, where consensus can’t be reached, resolved by 2/3 majority

Summary

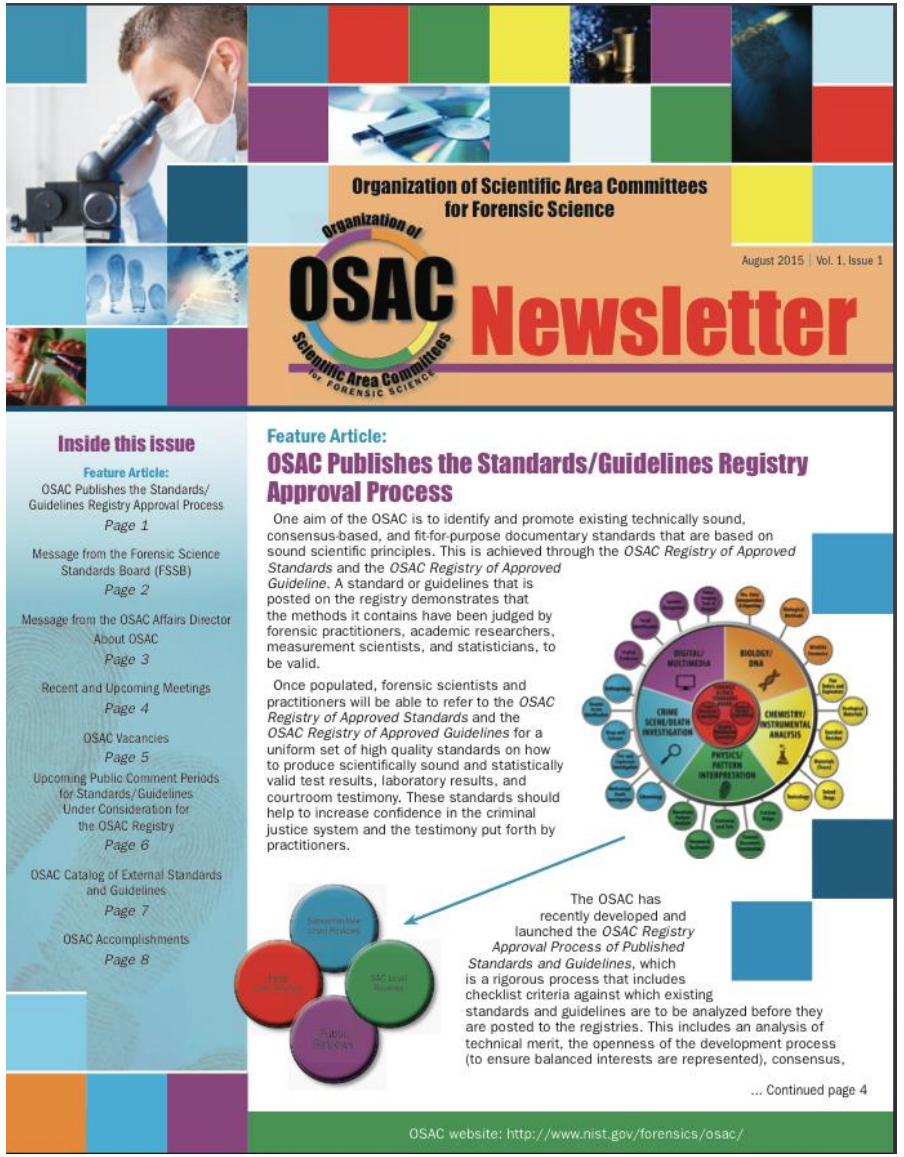
- Goal of OSAC decision-making processes is to take advantage of wide-ranging viewpoints to maximize quality of forensic science standards
  - Harmonizing different points-of-view when possible
- Technical Merit Worksheet documents
  - Strengths and weaknesses of standards considered for OSAC registry
  - Record of decision-making processes of Task Group, Subcommittee, SAC
- Technical Merit Worksheet is a living document to be refined with experience
  - Currently on 3rd revision
  - Learning by doing

Questions?

mark.stolorow@nist.gov

john.jones@nist.gov

william.guthrie@nist.gov



Organization of Scientific Area Committees for Forensic Science

August 2015 | Vol. 1, Issue 1

OSAC Newsletter

Inside this issue

Feature Article:

OSAC Publishes the Standards/Guidelines Registry Approval Process

One aim of the OSAC is to identify and promote existing technically sound, consensus-based, and fit-for-purpose documentary standards that are based on sound scientific principles. This is achieved through the *OSAC Registry of Approved Standards* and the *OSAC Registry of Approved Guideline*. A standard or guidelines that is posted on the registry demonstrates that the methods it contains have been judged by forensic practitioners, academic researchers, measurement scientists, and statisticians, to be valid.

Once populated, forensic scientists and practitioners will be able to refer to the *OSAC Registry of Approved Standards* and the *OSAC Registry of Approved Guidelines* for a uniform set of high quality standards on how to produce scientifically sound and statistically valid test results, laboratory results, and courtroom testimony. These standards should help to increase confidence in the criminal justice system and the testimony put forth by practitioners.

The OSAC has recently developed and launched the *OSAC Registry Approval Process of Published Standards and Guidelines*, which is a rigorous process that includes checklist criteria against which existing standards and guidelines are to be analyzed before they are posted to the registries. This includes an analysis of technical merit, the openness of the development process (to ensure balanced interests are represented), consensus,

... Continued page 4

OSAC website: http://www.nist.gov/forensics/osac/

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www.nist.gov/forensics

http://www.nist.gov/forensics/osac/osac-newsletter-february-2016.cfm#bigpicture

A Big Picture View of OSAC Efforts: Message to OSAC Members and Stakeholders

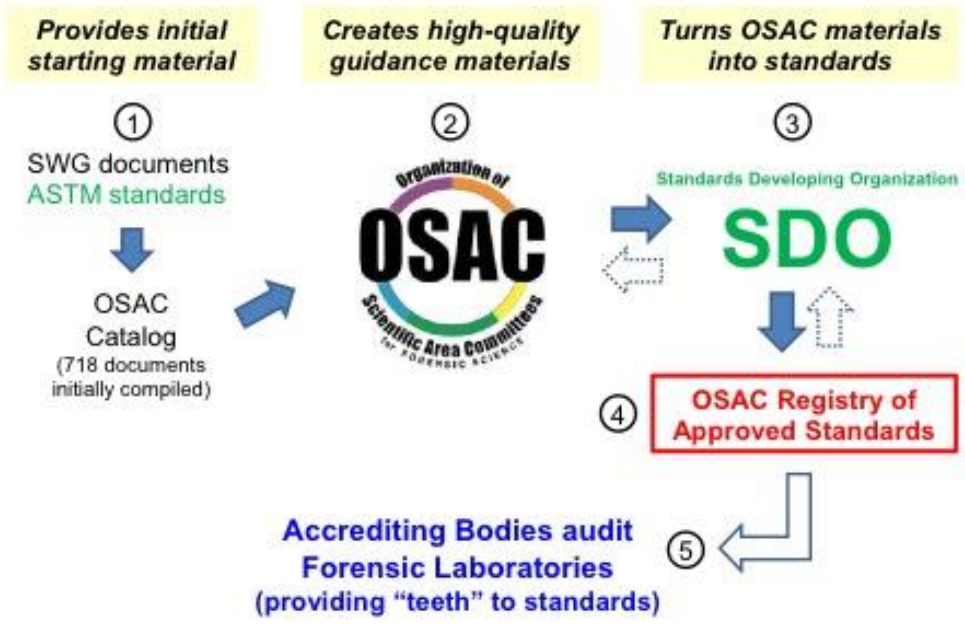
Invited input from John M. Butler, Ph.D. (NIST Fellow & Special Assistant to the Director for Forensic Science)

John M. Butler has a unique perspective on OSAC as a member of the Biology/DNA Scientific Area Committee and as someone who was part of the initial NIST team that designed the overall OSAC structure. He is also Vice-Chair of the National Commission on Forensic Science.

Change is always challenging, and context often helps when coping with change. When we see a big picture view and how we fit into that big picture, then we can better appreciate our specific roles and execute them more effectively. In addition, it is important to keep in mind that new organizations take time to develop mature processes and thus patience is required in the early stages of any successful endeavor.

At the recent OSAC meeting held in Leesburg, I noticed some frustration on the part of individuals who were trying to decide how to craft language and consider scope for documents under development. Although the OSAC plenary session included presentations on Standards Developing Organizations (SDOs), working with SDOs, and the importance of technical merit in standards developed, I think that without an understanding of the big picture the value of these presentations may not have been fully appreciated by many who attended. In fact, the role of SDOs relative to OSAC efforts appears in some cases to be misunderstood.

Before the end of the OSAC meeting in Leesburg, I decided to sketch out a big picture view of what OSAC is trying to accomplish in efforts to strengthen forensic science. An image similar to what is shown here was used in short presentations to the Biology SAC and the Friction Ridge Subcommittee and is now being shared with a wider audience.



Snapshot of the OSAC "Big Picture"

An important purpose of the OSAC effort is to populate an *OSAC Registry of Approved Standards*, which can then be used by accrediting bodies to audit forensic laboratories during their accreditation review against discipline-specific requirements. If the OSAC process works as planned, then the documentary standards and guidelines on the *OSAC Registry* can be trusted to be of high-quality. Producing a high-quality document requires both technical merit and appropriate due process in standards development.

From a big picture view, there are five steps in preparing, producing, and using information on the *OSAC Registry of Approved Standards*. Each of these will be reviewed below. Future OSAC newsletters may include more detail on aspects of this OSAC "ecosystem."

1. Use Existing Content, if it is Available. First, rather than "re-inventing the wheel" initial starting material is available to the OSAC from previous efforts in the forensic science community. As Isaac Newton famously shared about the value of scientists learning from previous work: "If I have seen further than others, it is by standing upon the shoulders of giants." Numerous documents have been produced over the years by Scientific Working Groups (SWGs). These SWG documents, while providing helpful guidance from a few practitioners to a larger group of practitioners, have not been through a rigorous process of vetting with what is referred to in the standards world as a "consensus body" and therefore simply rubber-stamping these SWG documents would not provide an opportunity to improve and strengthen them.

In early 2015, an *OSAC Catalog of External Standards and Guidelines* was compiled by NIST staff in an effort to bring together existing standards, guidelines, and best practices that were already available. Of the 718 documents listed in the initial 2015 OSAC catalog, 344 are from 20 different SWGs. In addition, there are over 300 documents from US and other standards developing organizations, of which there are approximately 140 ASTM documents. These SDO documents have been through a reasonable standards developing process, but may not have been previously vetted to the quality level desired for being included on the *OSAC Registry*.

2. Use Existing OSAC Resources to Enhance Content. The OSAC process may involve review of initial SWG documents, existing SDO standards and guidelines, and other materials, creation of new guidance materials, and deliberations on the quality of existing documents. In addition to forensic practitioners, the OSAC subcommittee membership includes academic researchers, statisticians, and measurement scientists to help infuse a deeper scientific viewpoint on discussions and documents. Feedback from three resource committees within OSAC can provide further input to strengthen documents in areas involving quality, laboratory impact, legal ramifications, and human factor aspects of guidance materials being developed.

3. Partner with an SDO. OSAC is not a legal entity and does not have the authority to create voluntary consensus standards by itself, nor is OSAC a standards developing organization in the true sense of the term. NIST, which currently administers OSAC, follows the federal government standards policy known as the National Technology Transfer and Advancement Act of 1995 (NTTAA) and the Office of Management and Budget's (OMB) Circular A-119 last updated in 1998. Therefore, in order to turn OSAC documents into formal, recognized standards, OSAC

needs to partner with an SDO (Standards Developing Organization). SDOs use consensus bodies of interested stakeholders to evaluate or create standards. It is important to point out that OSAC members may be part of an SDO's consensus body to help shepherd a document through the process.

An SDO is a legal entity created for the express purpose of developing consensus standards through following due process. Coordination of the private sector-led standards system for the United States is performed by the American National Standards Institute (ANSI). Each year ANSI publishes the *ANSI Essential Requirements for Due Process* that SDOs must follow to be accredited by ANSI. These requirements include openness, lack of dominance, a balance of interests, coordination and harmonization between existing documentary standards, notification of standards development (i.e., a public comment period) to enable participation by anyone who may be affected by the standard, careful consideration of views and objections raised by all participants, a consensus vote, and an appeals process.

The American Academy of Forensic Sciences (AAFS) recently established the Academy Standards Board (ASB). Another SDO that has worked with the forensic community since 1970 is ASTM International.

Process matters in creating acceptable standards within an SDO. These steps all take time and therefore standards development time is often measured in months or even years instead of days or weeks. But the benefit of a well-run standards development process is that the document has been refined and polished during multiple stages of review from considering various perspectives during document development. The dotted arrow on the image suggests that following the SDO process of turning OSAC documents into a formal standard, it may go back to OSAC deliberations to see if the document is "fit-for-purpose" – and if not, then additional round(s) of development may be required if OSAC wants to consider putting this standard on its *Registry of Approved Standards*.

Standards hold users to specific requirements through use of language such as "shall" or "must". Guidelines on the other hand use "should" or "may" to indicate best practices that may not be as stringent as the demands of a standard. Standards can come in many forms. For example, ASTM produces documentary standards in the form of guides, practices, test methods, specifications, classifications, and terminology documents. Anyone working on writing guidance material that can be turned into a standard would benefit from reviewing and carefully reading previously written standards to get an idea of the length and scope of the documents.

4. Next Goal: OSAC Registry. The *OSAC Registry of Approved Standards* is intended to serve as a trusted repository of high-quality standards to address discipline-specific requirements. Standards under consideration for inclusion on the OSAC Registry will need to pass muster in terms of both process (mentioned above in section 3 on SDOs) and technical merit. Technical merit means that the document has appropriate scope, is "fit-for-purpose", makes appropriate consideration for potential bias and uncertainty in measurement, and represents a reliable method as defined by validation studies performed that assess the limitations of the technique.

Although the initial process is the same, OSAC was designed to permit guidelines to be put on the OSAC Registry of Approved Guidelines with subcommittee and SAC approval. Inclusion of standards on the OSAC Registry of Approved Standards requires an additional approval at the FSSB level. However, having documents included on the OSAC Registry of Approved Standards (or Guidelines) does little good if no one uses them or "enforces" them.

5. Implementation. Holding forensic laboratories to the details present in documentary standards is the fifth and final step in our OSAC big picture view. This step involves accrediting bodies providing "teeth" to the standards while assessing the capabilities of and auditing accredited forensic laboratories. Current accrediting bodies in the forensic science world include the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), the ANSI-ASQ National Accreditation Board (ANAB), and the American Association for Laboratory Accreditation (A2LA). A representative from each of these organizations sits on the Quality Infrastructure Resource Committee of OSAC.

When OSAC was originally being designed, the NIST team met with representatives of these three accrediting bodies and several others interested in forensic accreditation. There was agreement among the attending representatives that if OSAC would build a system to create and promote quality standards, then they (the accrediting bodies) would identify how to best incorporate these standards in their future conformity assessment of forensic laboratories. While accredited laboratories are audited today to ISO/IEC 17025, there are very few discipline-specific documentary standards that the laboratories can be audited against. Currently, the use of forensic specific or discipline-specific standards is not required by law. The only exception is forensic DNA laboratories that are held to the FBI Quality Assurance Standards due to Congressional mandate from the DNA Identification Act of 1994.

Why does having a better understanding of this OSAC "ecosystem" matter?

Hopefully seeing the big picture will help forensic practitioners, who have previously only known how SWG documents or laboratory protocols were created, to move beyond their current SWG world view. Simply documenting protocols does not turn them into standards. A reasonable standards development process and careful consideration of technical merit may mean that some SWG documents or even previous ASTM standards do not make the cut and not end up on the *OSAC Registry of Approved Standards* (or Guidelines). Populating the OSAC Registries is intended to provide trusted discipline-specific standards that accrediting bodies can use to audit forensic science service providers.

If you are an OSAC member or affiliate trying to draft guidance material that may become a standard, it will be helpful to read previously written standards perhaps from other fields just to get a flavor of how standards are written. In some cases, it can be better to have a suite of standards that are interlocking rather than a single large document trying to be all things to all users. A good standard will be focused, concise, and specific so that a laboratory can be effectively audited against the listed requirements.

OSAC and SDOs should not be expected to rubber-stamp SWG documents. If we are just attempting to protect our own protocols or simply "kick the can down the road", then we will not

move the forensic community forward with the science available in the 21st century. Culturally, this may be very hard to do. It is natural that we become emotionally invested in what we write. Therefore, it becomes a challenge for any author to be able to see their document in a critical fashion. Hence the reason why feedback from stakeholders and future users of the documents we create is so important – to gain additional valuable perspective, to see things that we cannot see when we are too close to a document. Unfortunately, we may feel that comments and suggestions made to a document are personal attacks rather than opportunities to improve and strengthen a document. If we can move past our personal feelings as we move documents through the OSAC process, we have the potential to strengthen the entire field when the final, improved document is completed and used.

The processes touched upon here will make more sense as they are tried and tested—and perhaps refined as OSAC matures. We are very early in this effort to move the entire forensic community forward onto more sound scientific footing. The creation of rigorous scientific standards that will stand the test of time and the scrutiny of the legal system is a large endeavor and will require the commitment and engagement of the entire community to succeed. In pacing ourselves as we work on OSAC and SDOs to strengthen the forensic community, it is worth remembering that we are running a marathon and not a sprint.

For more information on standards and the OSAC Registries, see the presentation given by members of the NIST Standards Coordination Office to the National Commission on Forensic Science in January 2015. These slides are available at http://www.justice.gov/sites/default/files/ncfs/pages/attachments/2015/02/19/day1-nist_standards-training-jan2015-final.pdf.