

RESPONSE TO OSAC REQUEST FOR INFORMATION

FROM THE NATIONAL ASSOCIATION OF MEDICAL EXAMINERS

Thank you for this opportunity to provide input on the OSAC 2.0.

The National Association of Medical Examiners (NAME) is the national professional organization of physician medical examiners, medicolegal death investigators and death investigation system administrators who perform the official duties of the medicolegal investigation of deaths in the United States.

Many members of NAME have been involved in all levels of the OSAC structure, including on the subcommittees, the SACs, the Resource Committees and the FSSB. We therefore believe we have a good understanding of the current structure and are in a strong position to comment and offer suggestions for improvement.

Specifically, with respect to standards relating to the practice of medicine, as in forensic pathology, the relevant physicians should develop those standards through NAME and not through a more general SDO process. It is important to NAME that the OSAC 2.0:

- 1) Acknowledge that Forensic Pathology is the practice of medicine.
- 2) Accept that Forensic Pathologists should set the standards of the medical practice of Forensic Pathology, as is true in all other medical specialties,
- 3) Support NAME, as the professional organization representing forensic pathologists and medicolegal death investigation, as the appropriate organization for creating the standards.
- 4) Recognize and institutionally back NAME standards as the standards for the practice of forensic pathology and the medical aspects of medicolegal death investigation.

To answer more directly some of the questions posed in the Request:

(A) Purpose:

What is your opinion regarding whether the OSAC is fulfilling these purposes under the current structure?

The OSAC has educated the forensic science community on the process for developing consensus-based standards and guidelines. As noted above, NAME believes that these SDO processes are not applicable to the practice of medicine. Nonetheless, this approach has utility for some subcommittees, especially those that are not so judgment-based, and don't require the integration of medical history (scene investigation), and autopsy examination.

Naturally, adapting to the SDO process has been slow and there were challenges in getting started. Additionally the infrequency of subcommittee in-

person meetings has hampered the necessary face-to-face discussions that are required to create the draft standards and guidelines.

What is your opinion regarding whether these purposes/functions are appropriate for the OSAC and whether the purposes should be modified in any way?

To reiterate, the OSAC process must recognize that Forensic Pathologists practice medicine and undergo a rigorous training and certification process to do so. There is no precedent or rational justification for an outside body of non-practitioners to create medical practice standards.

The challenge in the OSAC process is that disciplines that depend on experience and judgment do not translate as well to the SDO process. The National Commission on Forensic Sciences reinforced that courtroom opinions based on experience and judgment are valid.

What is your opinion regarding what role, if any, the OSAC should be playing in addressing the recommendations of the 2009 National Academies of Sciences report, "Strengthening Forensic Science in the United States: A Path Forward" (<https://www.nap.edu/read/12589/chapter/1>)?

The OSAC is the first organization that has included members from all the forensic sciences, as well as outside experts. The NAS emphasized collaboration and OSAC has provided an opportunity for this. The OSAC subcommittees assist SDOs in determining what standards are needed.

Specifically, with respect to standards relating to the practice of medicine, as in forensic pathology, development of those standards should be set by the physicians involved through NAME and not through a more general SDO process. The OSAC MDI should not be a replacement for NAME's medical practice standards setting, but should be an adjunct that can focus on the non-medical aspects of medicolegal death investigation.

The OSAC 2.0 should, when it comes to medicolegal death investigation, work to address the recommendations of the NAS report by promoting further accreditation of medical examiner/coroner (ME/C) systems, by working to ensure certification of practitioners, and by working to guarantee that ME/C systems are free of undue influence of law enforcement, prosecutors, politicians and others. The OSAC 2.0 should explicitly take the position that medical standards are the province of medical specialties and the OSAC will support and promote standards that have been developed for Forensic Pathologists by Forensic Pathologists for 25 years. Medical guidelines and standards are created outside the federal framework, as standards bodies for physicians should be composed only of physicians, and this does not meet the SDO notion of "balance". No other area of medical practice in this country is governed by practice standards made by non-medical practitioners or anything like the SDO process.

One of the primary criticisms of disciplines other than forensic pathology in the NAS report was the perceived lack of a scientific basis for some of the activities considered "forensic science". A corollary to this is that any standards promulgated

by an organization dedicated to increasing that scientific validity should themselves have a validated basis. Accordingly, the OSAC should demand that standards not merely be “consensus” standards, but that they reflect valid scientific principles rather than common wisdom. The OSAC should thus identify areas of uncertain validity to direct investigations not only in forensic science, but also in consensus standards themselves.

(B) Oversight and independence:

Please provide your views regarding what type of entity should host the OSAC (e.g., governmental, professional association, etc.).

The entity that hosts the OSAC should support the OSAC financially, administratively and organizationally but without attempting to control the operation and output. It is critical that the OSAC be free from political and other influences.

Ideally, the organization should be as recommended by the NAS report: an independent stand-alone National Institute of Forensic Sciences – not in NIST or DOJ or any other government agency.

If there is not a stand-alone Institute, then NIST is a competent and appropriate group to assist in standards-setting, in fact the best place for this. They are not only the arbiters for federal standards policy, but they also have a large community of applied scientists (to be contrasted with NSF and NIH)--to include an excellent set of forensic scientists. They also sometimes overemphasize their own scientists and science over others and other work done outside NIST or not funded by NIST. However, their location within the Department of Commerce (DOC) gives them a commercial perspective that is not well-suited to the government-basic forensic science enterprise. Lastly, their record of technology transfer to the larger forensic science community, particularly the state and local forensic scientists and non-governmental forensic scientists has not been strong or perhaps at best has been hit or miss. On the other hand, the power of NIST's measurement science and statistical prowess has not been fully harnessed by the OSAC and should become more engaged in figures of merit and ensuring standards are science-based and statistically sound. The independence of this standards-setting process from law enforcement is a strength and should be continued, but the fact that the OSAC is funded by DOJ subverts this independence.

What is your opinion about the preferred characteristics of a host organization for an effective OSAC?

See above.

What are your views as to the type of organization that should provide oversight to the OSAC?

The organization has to have the financial stability and staff to support the OSAC. The organization should be neutral regarding the direction the OSAC takes in determining standards, rather than attempting to direct implementation of standards to advance an agenda created outside of the OSAC.

The organization should transcend elections, and political parties, or it will move from one short-lived structure to another, and have no impact.

Do you believe that the OSAC should have more/less independence from a host organization?

The OSAC should be completely independent with respect to function and output.

(C) *Work products and aims:*

What is your opinion regarding whether the OSAC is fulfilling these aims as structured?

The primary work products of the OSAC are the Registry and the putative standards that are referred to SDOs. Several of the standards placed on the registry have already been used and accepted by the forensic community for years, so bring no real change. The OSAC has also produced a terminology list and a list of research priorities. The availability of forensic standards to those that need them is incomplete, despite attempts to fund their availability--because some SDOs charge for their standards, which is beyond the control of NIST; this will be a continued tension. There is no marketing effort of the Registry. There will be growing pains as the set of national standards is first established--as was witnessed by the very first issued standard. In fact, it appears that standards are being written with insufficient scrutiny and attention to form, harmonization, or even scientific basis. There is a real concern that standards are being developed beyond the capability of smaller labs and practitioners--despite their ability to provide input during windows of opportunity--because it is the large labs that are represented. There is also too little input of the international community or even the consideration of their existing standards.

What are your views as to the type of work products the OSAC should produce?

The OSAC should develop standards, guidelines, and best practices and advocate for the funding necessary for their implementation.

The OSAC should identify areas of research and development and advocate for their support.

The OSAC should not produce standards for the practice of medicine.

What do you believe are the essential elements of work products?

Initial drafts of standards and guidelines, which can then be sent to an ANSI accredited SDO organization.

Identify areas of needed research to strengthen the scientific foundation of forensic science practice.

Identify areas for training and education.
Create standards that are scientifically valid, not merely the result of consensus thinking.

Please provide your opinion as to whether there should be implementation/enforcement of the work products.

Implementation can be done through the appropriate discipline-specific accreditation and certification organizations. Funding can be used as a “carrot” for implementation and likewise a “stick” with compliance a condition for funding.

Do you believe that the OSAC should develop “best practices” and other materials that are not formal “standards”?

The OSAC should develop the appropriate level of document and in many situations those may well be best practices or guidelines and not standards.

General comment: A study should be commissioned on the actual implementation and use of Registry standards by practitioners, accreditation bodies and the courts.

(D) *Structure:*

What are your views as to whether the current the OSAC structure works efficiently?

The subcommittee structure works for drafting standards and guidelines, although the infrequency of in-person subcommittee meetings has hampered this effort. The SAC oversight is useful in avoiding redundancy, but adds a layer of bureaucracy that delays the process.

Overall the current structure is far too complicated. The resource committees in particular bring little obvious value to the process. The QIC has done most of the work for the organization in creating processes, but when this is done, the committee could probably be replaced by a single organization employee, or a smaller committee. The LRC and HF resource committees often collaborate, and seem to have positioned themselves to be oppositional to the rest of the organization.

There will no doubt be pressure to create further subcommittees, but any new subcommittees should be science-based. There is arguably too great a presence of and control by federal practitioners.

Do you believe that another structure should be utilized?

The OSAC Resource Committees (HFC, LC and QIC) add unnecessarily to the complexity of the OSAC and result in delays for subcommittees producing documents.

In an independent Institute with a more simple structure, there would be a section for each discipline that would report to a board comprised of section chairs with the appropriate administrative support. Each section would include practitioners and researchers in that discipline. The role of professional organizations, such as NAME, should be formally recognized and integrated into the process.

Please provide your opinion about whether there are any issues in the current work product development process that should be addressed structurally.

Documents coming from the subcommittees should not have to go through so many layers of approval before they can be submitted to a SDO. This has resulted in significant delays.

In your view, does the reliance on standards development organizations function as intended (please include the reasons for your opinion)?

Yes, an outside SDO allows review by all the appropriate external stakeholders.

(E) Participation:

What are your views as to the community the OSAC should serve?

Everyone who is in any way affected by forensic science will ultimately be served by the OSAC, but the OSAC should support the forensic science disciplines.

In your opinion, what stakeholders must be a part of the OSAC (e.g. practitioners, researchers, forensic science societies, accreditation bodies, scientific societies, human factors experts, metrologists, standards development organizations, legal practitioners)?

These are all appropriate stakeholders, but practitioners, forensic science and other scientific societies, and accreditation bodies should develop draft standards for forensic science practice. The others are appropriate for giving feedback, but should not themselves be setting standards. Non-licensed persons should not be telling licensed professionals how to do their job. This is especially true for Forensic Pathologist Physicians.

It is important to recognize that there are different goals involved when integrating nonprofessional stakeholders into a standards-making process, and those goals may be at cross purposes. It is the experience of the forensic pathology community that nonprofessional stakeholders often have specific agendas that are important to their work, but which are destructive to the practice of ethical forensic pathology. Prosecutors want to aid in the prosecution of cases, and often make suggestions that will increase the rate of false positive results. Defense attorneys

have proposed interventions that will greatly increase the rate of false negative results. Funeral home directors have suggested changes in some jurisdictions that inhibit investigation but make processing the body for a funeral more convenient. Social scientists have argued from numerous agendas that we should classify cases according to various theoretic and social criteria. While all of these interests are important, all of them work to sacrifice the scientific validity of forensic pathology for the sake of these disparate, essentially non-scientific needs. In fact, NAME has devoted a great deal of energy to protect forensic pathologists from this kind of corruption and influence; it would be unfortunate for such inappropriate influences to become formalized at the federal level.

If the goal of this process is, as stated, to increase the scientific validity of our work, then that goal is not served by integrating these anti-scientific agendas into the standards process. A consensus process that inserts these disparate goals into what is supposed to be a scientific process will fail.

If you think that any of these entities should be excluded, please explain why and identify other venues for the views of the excluded entities to be incorporated into forensic practice, if appropriate. In your view, should some stakeholders serve more limited roles and, if so, how and why?

At the OSAC level it is critical to have greater representation by practitioners and subject matter experts. The strength of the OSAC is the participation of the community and this should be continued. At the SDO level is where others can have input.

It is appropriate to have stakeholders who are not subject matter experts play an advisory role in the standards process, but not as voting members.

(F) *Funding:*

What is your opinion as to the funding model that the OSAC should employ—Entirely funded by the Federal government, by non-Federal funds, or a combination of funding sources? (Please include your thoughts on the role of funding sources such as membership fees, certification fees, and meeting registration fees.)

NAME believes the OSAC should be entirely funded by the Federal government, codified through legislation, and receive a direct line item. No other organization has the resources to support the OSAC and without a consistent reliable funding source, the OSAC is not sustainable. Only the Federal government has adequate funding to maintain the necessary structure, organization, administration, in-person meetings, and travel costs. It is particularly necessary for the OSAC subcommittees to have in-person meetings in order to develop the draft documents to submit to the SDOs for further development into standards.

While membership fees, certification fees, and meeting registration fees may work in other industries to support standards development projects, these would be entirely inappropriate in the forensic science realm. The vast majority of forensic science practitioners are public employees and most forensic science laboratories are NOT for-profit corporations, but rather city, county or state publically funded entities, with barely enough financial support to perform their daily duties. They do not have the ability to support an OSAC structure through fees. Reliance upon donations, fees, and non-Federal sources will not provide the necessary stability.

What are your views about the implications of funding models for the other traits, particularly oversight and independence?

Funding models other than the Federal government seriously risk diminishing the independence of the OSAC; in a “pay-to-play” model, only those entities and organizations with sufficient resources to send people to in-person meetings will have their views represented. Charging members or participants is likely to result in drawing people with extreme perspectives and not those with a more balanced view.

Independence is paramount.

Concept 1: Current Framework and Function

Overview

In this concept, OSAC would continue to function within its current structure and with its current core mission—the development, review, approval and placement of industry-leading standards and best practices to the OSAC Registry. OSAC would continue to operate and be funded as it is currently, but may be overseen/funded by NIST, by another federal agency, or by another appropriate organization.

Management

NIST or another agency/organization would manage the overall structure and continue to fund OSAC as it is currently formulated (see OSAC Organizational Structure).

Work Products

OSAC would develop a registry of standards and related documents such as best practices and guides.

Standards

OSAC would facilitate the development of standards and best practices for the OSAC Registry. OSAC would ensure that standards have a high degree of technical merit and are developed via an appropriate process. OSAC would also ensure a balance of interests and transparency. In general, OSAC would rely on standards developing organizations (SDOs), but provide a mechanism for public comment, as many SDOs do not perform this function.

Key Differences from Current OSAC

OSAC would continue to function as is within the currently formulated organizational chart, subject to future revisions by the parent agency/organization. Oversight and financial support of OSAC may continue to reside within NIST or be transferred to another federal agency or appropriate non-federal organization.

NAME Thoughts and Concerns

NAME prefers this concept, #1.

The current structure was established this way with the four purposes of the OSAC in mind (providing technical leadership necessary to:

- 1) facilitate the development and promulgation of consensus-based documentary standards and guidelines for forensic science;
- 2) promoting standards and guidelines that are fit-for-purpose and based on sound scientific principles;
- 3) promoting the use of the OSAC standards and guidelines by accreditation and certification bodies;
- 4) and establishing and maintaining working relationships with other similar organizations.)

There is value in independence of the standards-setting function and thus the OSAC should be outside the DOJ. NIST has expertise in metrology, statistics, and standards-setting and so it is particularly useful to have their involvement and engagement. NAME believes that the OSAC should either be an independent Institute or stay at NIST and be directly funded, not through the DOJ.

Whatever host organization is chosen, it must be able to provide the financial, organizational and administrative needs of the OSAC.

Concept 2: Community-based Standards

Overview

In this concept, OSAC would consist of two primary structures: Scientific Area Committees (SACs) and a Forensic Science Standards Board (FSSB). The SACs would be staffed by forensic science practitioners who would identify needed standards, advocate for research and development to support needed standards, and find standards that meet forensic needs. The FSSB would be staffed with scientific experts who would address issues of scientific merit. Standards would be placed on a registry based on SAC and FSSB concurrence. Lab managers, accreditors, regulators and others would use the registry as a source for vetted standards.

Management

NIST or another federal agency would manage the overall structure by awarding grants to forensic science organizations to staff the SACs and to scientific and professional organizations to staff the FSSB.

Work Products

OSAC's only work product would be a registry of standards and related documents such as best practices and guides.

Standards

Standards would be developed by any organization that chooses to engage in this area. OSAC would ensure that standards have a high degree of technical merit and are developed via an appropriate process. OSAC would also ensure a balance of interests and transparency. In general, OSAC would rely on standards developing organizations (SDOs), but provide a mechanism for public comment, as many SDOs do not perform this function.

Key Differences from Current OSAC

The subcommittees would be replaced with standards developing organizations. The FSSB would be composed of experts from outside the forensic science community.

NAME Thoughts and Concerns

NAME does not support this concept.

It is useful to have the interactions between the OSAC subcommittees and the outside SDOs, as in the current structure. Having a FSSB composed of experts from outside the forensic science community is viewed by NAME as completely inappropriate. The current balanced membership in the consensus bodies of the SDOs provides enough outside expertise in this process. This scenario has the potential of degenerating into a political process, reacting to "emergencies".

Concept 3: Federal/State/Local Partnership

Overview

In this concept, OSAC would develop model laws for use by regulators and state/local legislative bodies. The goal would be to promote uniformity across forensic laboratories. This is especially important given that most forensic practice happens at the state and local level, rather than the federal level. Model laws would cover issues of forensic laboratory quality, and would extend to the entire legal system, including matters of accreditation, certification, training, and requirements for standards and best practices. OSAC would consist of legislative, legal, forensic, and other experts serving as representatives of federal, state and local governments. (This concept is based on the National Conference on Weights and Measures ([link is external](#)).)

Management

NIST or another federal agency would establish a new organization and would fund its startup. The organization could become financially self-sustaining by charging fees for training and credentialing.

Work Products

The primary work products would be model laws specifying licensing and proficiency requirements, rules of evidence, accreditation and other performance requirements. Products would also include educational material.

Standards

OSAC would develop minimum requirements for standards and best practices including evaluation criteria. The development of specific standards would happen outside of OSAC.

Key Differences from Current OSAC

Instead of focusing on populating a registry of standards, OSAC would mainly focus on producing model legislation. In this scenario, instead of accrediting bodies monitoring for compliance with standards, legal requirements would mandate an infrastructure that supports and improves forensic science.

NAME Thoughts and Concerns

NAME does not support this concept.

NAME prefers to have standards implemented through accreditation. Professional standards need to allow variance for exceptional circumstances, as long as the variance is explained and justified; model legislation and legal standards do not allow this necessary degree of flexibility.

Concept 4: Standards Readiness Assessment and Improvement Program

Overview

In this concept, OSAC would assess standards, identify research needs, and coordinate the development, testing and evaluation of forensic methods, protocols and technologies. This function is critically important because standards have diminished value when the underlying scientific basis is not well understood. OSAC would look at all forensic science disciplines from established to novel. For example, single source DNA analysis is mature and has established protocols, large validation studies, and well understood uncertainties. Other areas in forensic science may lack established protocols, large scale validation studies, or a sufficient understanding of uncertainties. OSAC would publish reports assessing whether forensic methods have a sufficient basis of research to support the development of technically-sound standards. These reports would also identify the research needed for developing standards or improving them.

Management

NIST or another federal agency would lead the work and may establish partnerships with additional federal and private sector entities.

Work Products

OSAC would produce peer reviewed publications based on results from literature surveys and from OSAC-coordinated studies on standards readiness, method development, validation, inter-laboratory comparison, and reference data and materials. The resulting reports would be used to understand the correct use and limitations of evidence and supply standards developing organizations (SDOs) with the data and materials they need to implement new documentary standards or improve existing ones. OSAC would also produce gap assessments.

Standards

OSAC would produce reports that SDOs would use to understand whether existing documents should be revised, and to know what technology is ready for standardization. SDOs would be responsible for writing, correcting, and distributing documentary standards

Key Differences from Current OSAC

A library of resulting scientific studies would replace the registry. The committee structure would be replaced by a steering committee that assists OSAC in prioritizing work areas. OSAC would support the development of reliable technical documentary standards by functioning as a clearinghouse and coordinator of information on the development, validation, and uncertainty of forensic technologies and methods. Emphasis would be placed on both existing and new technologies. This will enable a path to implementation for existing methods as well as new approaches developed in the field by federal, state, and local agencies, in academia, and in other research organizations.

NAME Thoughts and Concerns

NAME does not support this concept.

NIST and the forensic community have invested an enormous amount of time and money developing the current OSAC structure and procedures. It appears that this Concept would completely replace the work done to develop the OSAC and would be a waste of the resources previously committed. The proposed review of scientific studies should be part of the OSAC subcommittees' work plans. Also, this scenario has great potential for excluding forensic pathologists from research funding.