



ANSI-ASQ National Accreditation Board

Comments to the National Commission on Forensic Science

Submitted By

Keith Greenaway

ANSI-ASQ National Accreditation Board

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Executive Summary

The following bullet points provide a brief summary on our proposal which incorporates the ideas and requirements currently used by a multitude of U.S. federal agencies:

- Primary objective is to provide a solution to the National Commission on Forensic Science showing how our industry can work with the Commission (i.e. DOJ and NIST) to fix what is broken. With regard to forensic science, our industry provides services that can help support the government's role in protecting our citizens
- The success of the current private sector-led U.S. standardization system is reflected in the National Technology Transfer and Advancement Act of 1995 (NTTAA)
- The foundation for using accredited third-party accreditation bodies is to build the accreditation process based on international standards – ISO/IEC 17025, ISO/IEC 17020, ISO/IEC 17043, ISO 15189 and ISO/IEC 17024
- Reliance on the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) infrastructure
- Specific forensic science industry requirements vetted through the Commission (such as those generated by the SWGs) and approved for use in accreditation
- Accreditation bodies accredit forensic science service providers (FSSPs) using both international and industry standards, which are specified in scopes of accreditation
- End users gain confidence knowing the results are from accredited organizations and can be relied upon
- The Commission, delegated to DOJ-NIST, must have ownership of the oversight process and set the recognition criteria for accreditation bodies
- Accreditation bodies would apply using an application developed by DOJ-NIST for review and approval by DOJ-NIST. DOJ-NIST would also provide oversight and conflict resolution for what we will call the DOJ-NIST Forensic Science Accreditation Program, or FSAP
- The accreditation body's role is to provide attestation that the results received from an accredited organization are valid and technically competent. Accreditation bodies would ensure the methods (or standards) as defined by DOJ-NIST are listed and validated on the organization's scope of accreditation
- DOJ-NIST becomes the scheme owner by overseeing the process, without having to develop and maintain the standards.

Background

ANSI-ASQ National Accreditation Board is providing this proposal to assist the National Commission on Forensic Science in their work to improve the practice of forensic science.

ANSI-ASQ National Accreditation Board is a non-profit, nongovernmental organization jointly owned by the American Society for Quality (ASQ) and the American National Standards Institute (ANSI).

We provide accreditation services to public and private sector organizations for laboratories, proficiency test providers, inspection bodies, reference material producers, management systems certifiers, and (through ANSI) product and personnel certifiers.

ANSI-ASQ National Accreditation Board operates predominately in the realm of international standards, which are developed through an open consensus-based process. Two organizations provide oversight of and an infrastructure for recognition of national accreditation bodies: The International Laboratory Accreditation Cooperation (ILAC) was established to oversee accreditation of laboratories and inspection bodies and the International Accreditation Forum (IAF) was established to oversee accreditation of management systems, product, and personnel certification bodies. Accreditation bodies recognized by ILAC and/or IAF accredit conformity assessment bodies (e.g., forensic laboratories and forensic crime scene units) to international standards. Accredited conformity assessment bodies audit and/or test to determine competence and issue certificates attesting to competence, which are relied on by end users.

The National Technology Transfer and Advancement Act of 1995 (NTTAA) directs federal government agencies to use wherever feasible standards and conformity assessment solutions developed or adopted by private, voluntary consensus standards bodies in lieu of developing government-unique standards or regulations.

OMB Circular A-119 further enforces the requirement to use voluntary consensus standards, stating: “All federal agencies must use voluntary consensus standards in lieu of government unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical...” and “both domestic and international” voluntary consensus standards must be used.

A number of approaches are used to verify that a service or product conforms to standards. In what is known as the first-party approach or self declaration, essentially the organization declares, "I meet the standards and I am ok." This can be a viable approach to the degree that one trusts the organization because the organization's own declaration is the only assurance provided.

In the second-party approach, an organization is contractually obligated to make sure it meets specific customer requirements and the customer (the second party) may conduct its own tests, inspections, and/or audits of the first party. A key provider may "certify" as much as it can, typically at the very top level, leaving out everyone lower in the supply chain.

In the third-party system, a third party that is independent of the organization and its customers conducts tests, inspections, and/or audits of the organization and provides its attestation of conformance with standards.

Where appropriate schemes have been established, the third party may be accredited by an oversight body so that additional checks and balances are imposed across the spectrum of services provided. An accredited third-party process provides the best means to ensure that services and products conform with standards.

Unfortunately, some third-party organizations are not accredited by globally recognized bodies and operate according to internally managed controls rather than international requirements. Known as third parties without oversight, these organizations may conduct tests, inspections, and/or audits at a single point in time without providing ongoing oversight and/or conduct tests, inspections, and/or audits to requirements or processes they have established, rather than relying on recognized standards. Operating with little or no accountability and questionable impartiality, third parties without oversight have historically represented a problematic approach because they tend to use internally developed requirements or standards.

With accredited third-party programs, by contrast, oversight is in place to prevent inappropriate practices. When organizations are accredited by accreditation bodies recognized by ILAC and/or IAF, an added level of oversight provides greater assurance of the soundness and credibility of their work.

We believe accredited third-party conformity assessment with ILAC-IAF oversight consistently provides products, services, and test results that meet or exceed customer and regulatory requirements. Both industry and regulators have embraced this concept such as manufacturing, water quality, food, aerospace, etc.

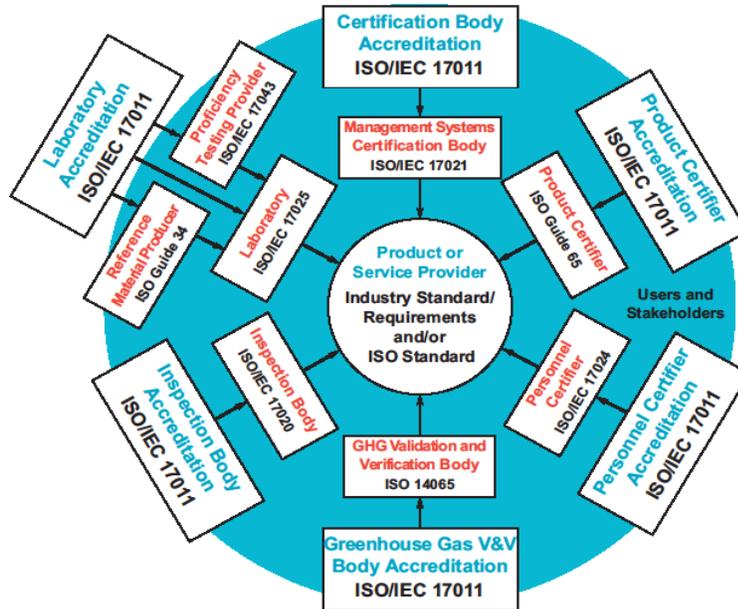
To have a truly effective conformity assessment system in the United States, we need appropriate oversight that works in partnership with regulators and industry and provides confidence in the entire life cycle of services and products. This is best achieved through accredited third-party conformity assessment with ILAC-IAF oversight because it provides documented assurance of conformance with international standards from an independent third-party that has been evaluated and deemed competent to carry out its specific work.

The accredited third-party conformity assessment process is founded on management systems that require an organization to establish clear specifications, build and operate well defined and repeatable processes, ensure accurate and reliable test results, and establish controls to monitor to ensure desired results and continual improvement. Our industry can provide solutions to ensure forensic science service providers are competent to carry out their work.

Figure 1 is a generic third-party conformity assessment model illustrating the activities of the ANSI-ASQ National Accreditation Board under the ACLASS, FQS, ANAB, and ANSI brands. (Each of these activities is also offered competently and credibly by other U.S. ILAC- and IAF-member accreditation bodies.) We developed this model in conjunction with the National Institute of Justice and the National Institute of Standards and Technology to support a private-public sector partnership for third-party conformity assessment activities.

Figure 1

Generic Third-Party Conformity Assessment Model



This proven model works across international borders and within multiple industries through the existing recognition infrastructure of ILAC and IAF.

Proposal

Our primary objective is to provide a solution to the National Commission on Forensic Science showing how our industry can work with DOJ and NIST to fix what is broken. With regard to forensic science, our industry provides services that can help support the government’s role in protecting our citizens.

The foundation for using recognized third-party accreditation bodies is to build the accreditation process under the ILAC and IAF infrastructure, using international consensus-based standards such as ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories; ISO/IEC 17020, Requirements for the operation of various types of bodies performing inspection; ISO/IEC 17043, General requirements for proficiency testing; ISO 15189, Medical laboratories – Requirements for quality and competence; and ISO/IEC 17024, Conformity assessment – General requirements for bodies operating certification of persons.

The U.S. regulator, which we will refer to as DOJ-NIST, must have ownership of the oversight process and set the recognition criteria for accreditation bodies. The base requirement should be that accreditation bodies must be signatories of the ILAC and/or IAF multilateral recognition arrangements (MRAs). In essence, DOJ-NIST must become the scheme owner of the overall process.

The program owned by DOJ-NIST must be developed in compliance with the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119. Accreditation bodies would apply using an application developed by DOJ-NIST for review and approval by DOJ-NIST. DOJ-NIST would also provide oversight and conflict resolution for what we will call the DOJ-NIST Forensic Science Accreditation Program, or FSAP.

The accreditation body's role is to provide attestation that the results received from an accredited organization are valid and technically competent. It is important to understand that methods used by accredited organizations are outside the accreditation body's authority. Accreditation bodies would ensure the methods (or standards) as defined by DOJ-NIST are listed and validated on the organization's scope of accreditation. These defined methods should be the *minimum* requirements, and accreditation organizations must be allowed to use other methods and list them on their scope of accreditation.

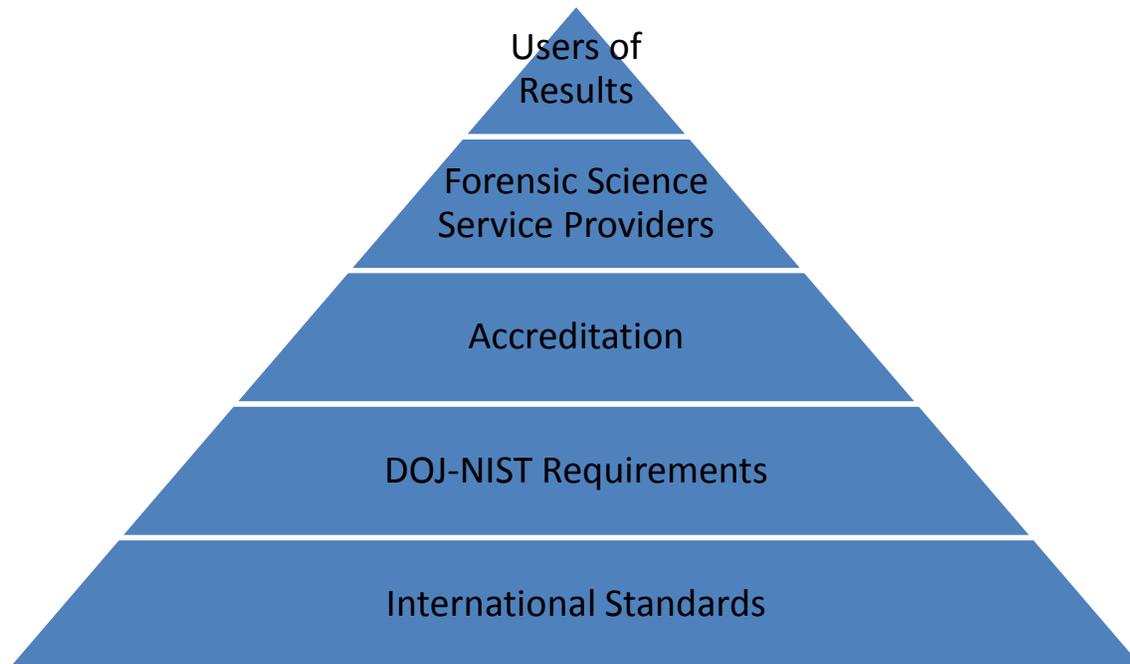
The benefit of such an arrangement for DOJ-NIST is that this oversight already exists within the U.S. government and is being employed today by several U.S. regulators; hence, DOJ-NIST could become the scheme owner by overseeing the process, without having to develop and maintain the standards. To allow users to readily identify accredited organizations, DOJ-NIST would provide official verification of acceptable accredited organizations recommended by accreditation bodies based on their established assessment processes.

Relying on the recognition infrastructure of ILAC and IAF would provide assurance that the accreditation process is applied consistently. It would also provide an added level of oversight to ensure the soundness and credibility of the work of accredited organizations. Accreditation by an ILAC- or IAF-member body would indicate that the organization has achieved a prescribed level of competence to perform specific conformity assessment activities. We do not advocate replacing DOJ-NIST oversight; rather, ILAC and IAF oversight would complement and support the oversight role of DOJ-NIST.

Outlined below is our recommendation of what DOJ-NIST should adopt, based on current requirements used by several U.S. regulators.

- Process based on international standards – ISO/IEC 17025, ISO/IEC 17020, ISO/IEC 17043, ISO 15189, and ISO/IEC 17024 – as the foundation.
- Specific forensic science industry requirements vetted through DOJ-NIST (such as those generated by the SWGs) and approved for use in accreditation.
- Accreditation bodies accredit forensic science service providers (FSSPs) using both international and industry standards, which are specified in scopes of accreditation.
- End users gain confidence knowing the results are from accredited organizations and can be relied upon.

Figure 2
Pyramid of Process



DOJ-NIST Responsibilities

We propose the following requirements for DOJ-NIST to properly oversee the forensic science accreditation program:

- Fund DOJ-NIST representative(s) in the DOJ/NIST FSAP.
- Fund DOJ-NIST FSAP to establish and provide oversight for the program.
- Maintain and update DOJ-NIST FSAP requirements.
- Review and approve accreditation body applications.
- Publish list of recognized accreditation bodies.
- Maintain list of accredited forensic science service providers.
- Provide oversight of third-party assessments and accreditation bodies.
- Resolve disputes on interpretations of DOJ-NIST FSAP requirements.
- Organize meetings of DOJ-NIST and accreditation bodies at least annually to continually improve the program.

Conditions and Criteria for Recognition of Accreditation Bodies

We propose the following requirements for accreditation bodies to attain and maintain DOJ-NIST recognition. The accreditation body shall agree in writing to:

- Comply at all times with the DOJ-NIST FSAP conditions and criteria for recognition.
- Operate its accreditation program in accordance with ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- Maintain an effective quality management system and submit to DOJ-NIST an electronic copy of the accreditation body's quality management system documentation with the application for recognition.
- Maintain its status as a United States-based signatory of the ILAC MRA and/or the IAF MLA.
- Inform DOJ-NIST in writing at least six months prior to the accreditation body's ILAC and/or IAF peer evaluation, invite DOJ-NIST to participate in the evaluation, and provide DOJ-NIST with copies of all documentation related to the evaluation within 30 days of receipt.
- Participate in meetings with DOJ-NIST at least annually as part of continual improvement efforts for the DOJ-NIST FSAP and brief DOJ-NIST on the status of the program, common deficiencies,

and issues related to accreditation of forensic science agencies to the requirements of the DOJ-NIST FSAP.

- Inform DOJ-NIST in writing within 30 days of any change in ILAC and/or IAF MRA signatory status.
- Maintain adequate financial resources for the accreditation body's operation.
- Implement a training program that includes documented procedures and requirements to ensure that assessors are competent to evaluate forensic science service providers prior to performing assessments and continue to be provided new and refresher training. Per ISO/IEC 17011, training should be conducted as needed to ensure the accreditation body maintains a sufficient number of competent personnel for the work performed.
- Report to DOJ-NIST within 30 days any major changes that affect the accreditation body's:
 - Legal, commercial, organizational, or ownership status
 - Organization and management (e.g., key managerial staff)
 - Policies or procedures, where appropriate
 - Location
 - Personnel, facilities, working environment, or other resources, where significant
 - Authorized representative
 - Other matters that may affect the capability, scope of recognized activities, or compliance with the DOJ-NIST FSAP requirements
- At the discretion of DOJ-NIST, allow DOJ-NIST authorized representatives in coordination with the accreditation body, to witness any assessments performed for compliance with the requirements of the DOJ-NIST FSAP.
- Verify that all assessment findings are resolved and corrective actions have been implemented before granting accreditation to a forensic science service provider.
- Remain fair and impartial in all interactions with forensic science service providers and make its services available to all interested forensic science service providers without regard to size, scope of accreditation, or membership in any organization, unless directed otherwise by DOJ-NIST. (Neither the accreditation body, its parent company nor any subsidiaries may operate or engage in the operation of a forensic testing organization).
- Safeguard all information identified as confidential by forensic science service providers seeking or granted accreditation.

- Verify proficiency testing data in accordance with the appropriate international standard requirements.
- Maintain documentation related to DOJ-NIST FSAP accreditations for at least five years.
- Maintain a list of all forensic science service providers currently accredited under the DOJ-NIST FSAP on the accreditation body's website. At a minimum, this list must contain:
 - Forensic science service provider's name, address, and phone number
 - Forensic science service provider's point of contact
 - Accreditation effective date
 - Accreditation expiration date
 - Scope of accreditation
- Upon request, provide DOJ-NIST with copies of accredited forensic science service providers' assessment documentation related to DOJ-NIST FSAP, including corrective action plans and documentation of resolution of nonconformities. (Forensic science service providers consent to this as a condition of their accreditation.)
- Notify DOJ-NIST in writing within five business days of any action that adversely affects the accreditation status of a DOJ-NIST FSAP-accredited forensic science service provider, and update the accreditation body's website to document such action.
- Conduct a complete on-site re-assessment of each forensic science service provider at least once every two years.
- Perform annual surveillance of each forensic science service provider to include at a minimum review of management review and internal audits, complaints, corrective action reports, and PT activity. (Surveillance need not be performed on site.)
- Forward any questions related to DOJ-NIST FSAP methods to DOJ-NIST for resolution, and abide by the decisions of DOJ-NIST.
- Assume responsibility for decisions to accredit forensic science service providers and ensure decisions are separate from assessments. (The accreditation body cannot fully or partially delegate the accreditation decision to another organization.)
- Assess documentation demonstrating the impartiality and freedom of forensic science service provider management personnel from undue internal or external commercial, financial, or other pressures and/or influences that could adversely affect the quality of their work, as required by the appropriate international standard. DOJ-NIST expects that accreditation bodies will systematically monitor the impartiality of forensic science service providers on an ongoing basis.

- Upon a satisfactory outcome, attest to the technical competence of the forensic science service provider. At a minimum, the approved methods for which the organization has been accredited should be within the scope of accreditation.