Standards and Conformity Assessment

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Abstract

Standards and conformity assessment are important to strengthening the science and quality of forensic science. Standards provide a foundation for consistency between processes related to testing, accreditation, management systems, and personnel certification. This article provides an overview of U.S. and international documentary standards and conformity assessment concepts as they relate to forensic science service providers (FSSPs) and discusses the current state of standards development and associated challenges for implementation.

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Glossary

Accreditation Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. [Source: ISO/IEC 17011:2017] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2017a).

Certification Body Third-party conformity assessment body operating certification schemes. Note: A certification body can be non-governmental or governmental (with or without regulatory authority) [Source: ISO/IEC 17065:2012] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2012a).

Conformity Assessment Demonstration that specified requirements are fulfilled. [Source: ISO/IEC 17000:2020] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2020).

Conformity Assessment Scheme Set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements, and provides the methodology for performing conformity assessment Note 1 to entry: A conformity assessment scheme can be managed within a conformity assessment system. Note 2 to entry: A conformity assessment scheme can be operated at an international, regional, national, sub-national, or industry sector level. Note 3 to entry: A scheme can cover all or part of the conformity assessment functions explained in Annex A. [Source: ISO/IEC 17000:2020] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2020).

Scheme Owner Person or organization responsible for the development and maintenance of a conformity assessment system or conformity assessment scheme. Note 1 to entry: A scheme owner does not necessarily operate the scheme. Note 2 to entry: A system owner or a scheme owner can be a conformity assessment body itself, a governmental authority, a trade association, a group of conformity assessment bodies, or others. [Source: ISO/IEC 17000:2020] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2020).

Standard Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. NOTES standards should be based on the consolidated results of science, technology, and experience, and aimed at the promotion of optimum community benefits. [Source: ISO/IEC Guide 2:1996] (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 1996).

Standards Consortia Organizations, usually made up of representatives from two or more companies within the same industry. Usually for strategic reasons these organizations work together to build standards that they hope will dominate the market, in turn helping the sales of the products built by the member companies. In antithesis to SDOs, consortia do not have representative membership, do not always enforce rigid democratic processes, do not have due process, and do not always require consensus among members. [Source: Benton MC. Standards 101: A Tutorial for IT Managers.] (Benton, 2001).

Standards Developing Organization (SDO) Often used to describe an organization that follows a voluntary consensus standards process when developing standards. [Source: Author.].

Standards Setting Organization (SSO) Incorporates all variants of groups that develop standards, including Special Interest Groups (SIGs), standards-development or standards developing organizations (SDOs), consortia, and other entities. The acronym SSO is often used interchangeably with SDO but, in principle, the former term covers the activities of both setting and managing standards, including associated intellectual property issues. [Source: National Research Council, 2013.] (National Research Council, 2013).

Voluntary Consensus Standards Body Type of association, organization, or technical society that plans, develops, establishes, or coordinates voluntary consensus standards using a voluntary consensus standards development process. [Source: OMB A-119] (U.S. Office of Management and Budget OMB, 2016).

Key Points

- The importance of standards and conformity assessment to forensic science.
- An introduction to documentary standards, concepts, terms, types, processes, major players and stakeholders.
- Describes the current state of standards development in forensic science, and related standards developing organizations.
- An introduction to conformity assessment terms, concepts and types Outlines several barriers to forensic science standards implementation.

The Importance of Standards and Conformity Assessment to Forensic Science

Standards play a key role in the delivery of products and services. Standards provide a foundation for consistency among processes related to testing, accreditation, standardization, and personnel certification (Fig. 1).

Proficiency testing is intended as an evaluation of a participant's performance against pre-established criteria by means of interlaboratory comparisons and is used for the determination of service provider performance. "Proficiency testing is commonly

used by FSSP management to evaluate staff, training, and method validation; appropriateness of test methods; traceability of measurements and calibrations to national standards; calibration and maintenance of test equipment; documentation, sampling, and handling of test items; and quality assurance of data, including reporting of results. In forensic science, proficiency testing is used not only as a measure of the FSSP's overall performance and quality system (e.g., facility, equipment, procedures, and training programs) but also as a tool for monitoring an individual FSSP's continued ability to perform work in a specific discipline or tasks". (National Commission on Forensic Science, 2016).

Standards need to be fit-for-purpose to meet a customer's needs as well as support broad adoption and use. Good quality standards have a positive impact on the quality of results produced. The importance of well-written standards will be discussed later in this article.

Standards (in a forensic context):

- Establish minimum requirements for reliability and quality for forensic science service providers (FSSPs).
  - Forensic science standards are still evolving; establishing minimum acceptable requirements seems to be what practicing forensic scientist believe is most needed currently. Standards, if followed (and audited internally or externally), set a bar for the FSSP. Reliable quality results are not a guarantee but a more likely outcome when standards are used in conjunction with trained personnel and properly calibrated equipment.
- Provide a common language between FSSPs, the legal community, and other customers.
  - Standards also reinforce a common language, one that defines quality and safety criteria used in the delivery of forensic science services. A lack of consistent terminology is a barrier to clear communication between provider and user. What standards or practices were used? What were the limitations? How were error rates measured? Consistent terminology makes it easier to communicate. Standards offer a structured approach for discussing the processes used and the results obtained.
- Support proficiency testing, personnel certification, and performance monitoring.
  - Standards can be used to train new personnel; for example, standards on how to document a crime scene, photograph a tire tread impression, or analyze a sample for cocaine, all provide training materials for new staff. Practitioners should be encouraged to learn how to perform a procedure by following a standard. This training approach has the added value of also reducing the impact of possible biases. When a method or procedure is followed without adhering to a standard, the FSSP risks not producing the desired result. Personal subjective interpretation in the process can be reduced.
- Provide consistency of practice within a laboratory or laboratory system.
  - If FSSPs have all their practitioners using the same standard, (e.g., specific test method for the analysis of ignitable liquids) there should be consistency in analysis and an expectation of reduced variation among practitioners. With some notable variation in a result, a root cause analysis should ensue. Could a reagent have expired? Was the equipment not properly calibrated? Was there a calculation error? Was a step missed? If the standard was followed, finding the problem should be easier.
- Can be used to demonstrate consistency in procedures across FSSPs.
  - Interlaboratory studies (ILSs) are independently organized and coordinated programs in which two or more laboratories evaluate a similar or equivalent test sample (which can comprise various materials, physical artifacts, images, code, and/or data sets) and are conducted with predetermined conditions surrounding the method used. The aim of an ILS is to assess quality assurance; to assess the participating organization or person's performance relative to that of their peers/state of the practice. Types of ILSs include round-robin studies (ring tests/trials), black/white box studies, comparability studies, and method performance studies. Method performance studies are a specific ILS design in which FSSPs employ the same standard or method to evaluate the features of a specific test sample or to determine the boundaries of capability (e.g., DNA mixture interpretation).
- Aid with method validation.
  - The authors of a recent article suggest standardization as an approach FSSPs can use to reduce the burden on their organizations to perform method validation. They state: "For accredited crime laboratories and other Forensic Science Service Providers (FSSPs) performing a method validation can be a time consuming and laborious process, particularly when performed independently by an individual FSSP. In this proposed collaborative method validation model, FSSPs performing the same task using the same technology are encouraged to work together cooperatively to permit standardization and sharing of common methodology to increase efficiency for conducting validations and implementation". (Wickenheiser and Farrell, 2020) Agreeing to follow set standards and specific procedures that have met validation requirements can provide an alternative collaborative approach to method validation that could reduce resources expended by individual FSSPs.
- Are gaining use in judicial settings.
  - The FSSP's ultimate end user is the court of law. In the U.S., Federal Rules of Evidence and state statutes stress the need for forensic evidence to be analyzed with test methods shown to be fit-for-purpose and that generate results with a high degree of reliability. The goal is to have trustworthy results. The use of standards is one means for FSSPs to be transparent about the methodologies used and the associated limitations. Standards reflect general acceptance in the scientific community because of the processes used to create them. Standards set the foundation for FSSPs to obtain reliable and valid results, while improving operations, procedures, processes, products, systems, and training (**Fig. 2**).

There is very little in forensic science literature related to standardization, even less so devoted to the broader field of conformity assessment. To better understand the state of forensic science standards, one must first understand the concepts of quality management, conformity assessment, and the process for the formal standardization of methods and practices.

Fig. 3 depicts the conformity assessment hierarchy. This conformity assessment model is universal across sectors; only the requirements (scheme criteria) and the scheme owner will vary.

At the bottom layer is the object of conformity. The object of conformity will need to adhere to standards, regulatory requirements, and other scheme criteria. The next layer consists of the conformity assessment providers. These organizations verify that the product and service providers have met the standards, requirements, and criteria. These conformity assessment providers are held to international standards known as the "CASCO Toolbox" (CASCO is the International Organization for Standardization (ISO) Committee on Conformity Assessment). At the top layer are the accreditation bodies, who follow another CASCO standard, ISO/IEC 17011. The evaluation of accreditation bodies is based on peer-evaluation. This review and evaluation are done through the signing of Mutual Recognition Arrangements (MRAs), including the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). ILAC is the principal international cooperation for developing and harmonizing laboratory, inspection body, proficiency testing provider and reference material producer accreditation practices. ILAC's primary purpose "is to establish an international arrangement between member accreditation bodies based on peer evaluation and mutual acceptance. The accreditation bodies that are signatories to the ILAC Mutual Recognition Agreement (MRA) have been peer evaluated in accordance with ISO/IEC 17011 to demonstrate their competence". (International Laboratory Accreditation Cooperation, 2022).

The "scheme owner" sets the overall requirements of the conformity assessment system. The scheme owner could be a regulatory body, forensics association, or other entity (e.g., the FBI is the scheme owner of the *Quality Assurance Standards [QAS] for Forensic DNA Testing Laboratories* (U.S. Federal Bureau of Investigation, 2020)). When there is no scheme owner, the "industry" chooses how it will self-regulate. In the U.S., outside of the QAS, there are no federal requirements for forensic science. A handful of U.S. states have requirements for accreditation or licensing (e.g., Texas Forensic Science Commission, (Texas Forensic Science Commission, 2022) and the North Carolina Forensic Science Advisory Board). Except for the United Kingdom (UK), this is the norm in other countries as well. *(More on conformity assessment, CASCO, and the related ISO standards, later in this article.)*.

Introduction to Documentary Standards

Standards are all around us and imbedded into every aspect of our lives. For example, they are involved in the development and manufacture of hundreds of every-day products and devices, from mobile phones, laptops, fire protective gear, medical equipment, etc. While there are different types of definitions as to what a standard is or can be, simply put, a standard is an agreed upon way of doing something. Government agencies or an industry sector can agree to adhere to a set method or procedure for a specific task and follow a "standard". Standards can be in written form (i.e., a documentary standard), in physical form such as measurement tools (e.g., rulers), or standard reference materials (SRM) (e.g., NIST's SRM 2372a Human DNA Quantitation Standard or SRM 2460a Standard Bullet Replica).

The primary driver for the use of forensic science standards is public welfare and safety. The primary users are the legal and criminal justice systems. Forensic results can be misinterpreted or misapplied. Standards that are specific, and well-written, to which personnel are trained, can aid in lessoning errors.

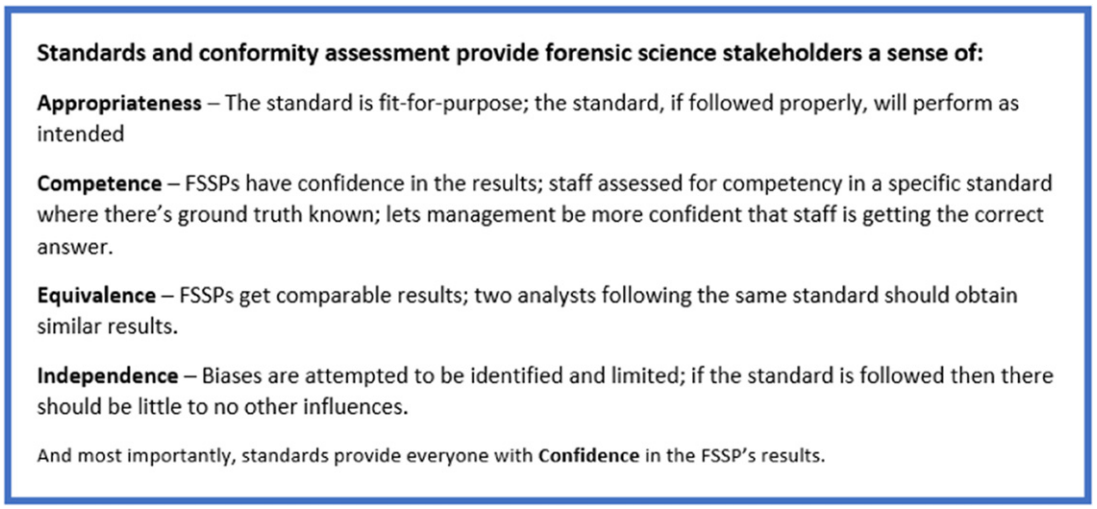

Fig. 2 Purpose of standards and conformity assessment.

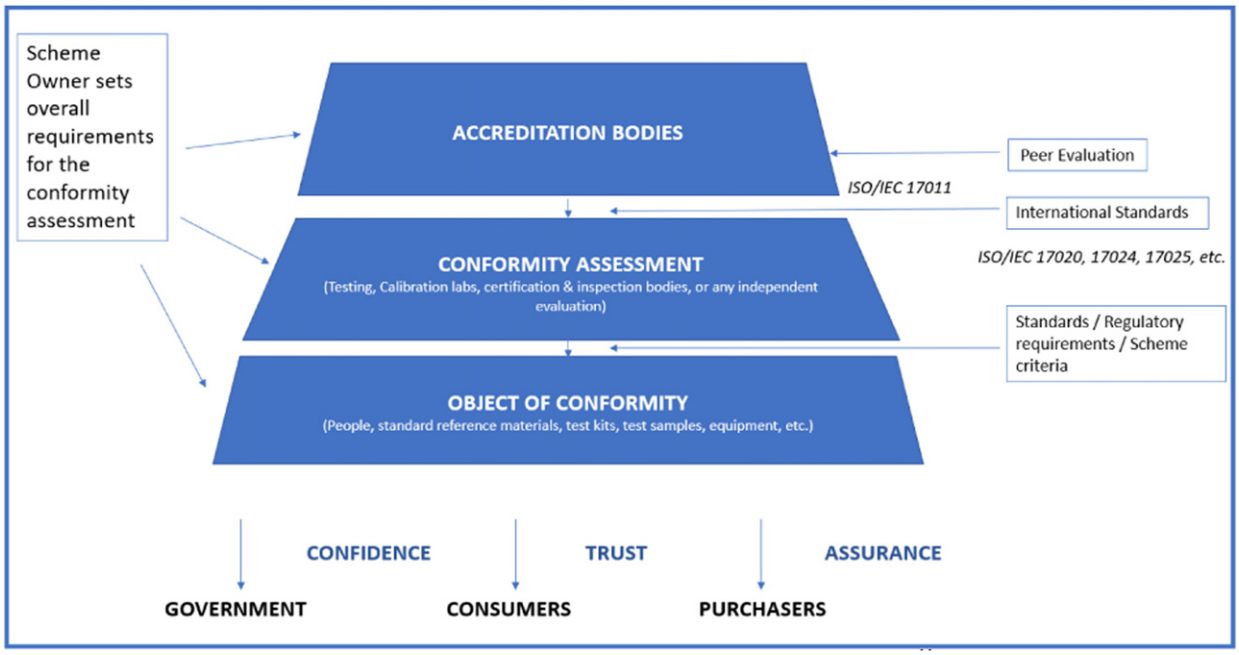

Fig. 3 Conformity Assessment Hierarchy. Source: Adapted from Openaccessgovernment.org, 2019. Who are UKAS and how can accreditation help deliver policy objectives?.

What are Documentary Standards?

This article is focused on documentary standards in forensic science. Documentary standards come in many forms. Regardless of the type of document (data standard, standard practice, etc.), they are all considered "standards." Each standards developing organization (SDO) defines their standard types differently. **Table 1** lists the common types of documentary standards.

How are Standards Developed?

United States standards system

Most nations (and sometimes regions) have their own standards system coordinated by a national standards body that is often governmental. Some countries' standards developing organizations are considered international in scope.

Governments can play several roles in standardization:

- Support standardization as part of their role in stimulating trade and innovation.
- Provide a regulatory foundation.
- Engage in standards and conformity assessment activities.
- Supplement the legal systems by referencing standards in law or regulation.

There are common principles used to develop documentary standards. Most of this article will focus on the U.S. standards system. Compared to the centralized systems occurring in other countries, the U.S. standards systems is complex and nuanced with many players. The U.S. also actively participates in international standards development.

In the U.S., the standards system is:

- Voluntary and decentralized.
- Market-driven, competitive, and duplicative with different SDOs often publishing multiple standards for the same discipline.
- Led by the private sector, not the government (compared to other countries of the world where standardization is primarily a government-led function).
- A public-private partnership, which means the government is engaged, not in a leadership role.
- Reflective of U.S. culture and public-private sector dynamics.
- Heavily reliant upon cooperation and communication among many stakeholder types. In a forensic context that includes forensic science laboratory personnel, the legal community, statisticians, human factors experts, researchers, metrologists, and advocacy groups.

Table 1 Types of documentary standards

Documentary standard type	*Description*
American National Standard (ANS)	Standard published by an ANSI Accredited SDO that follow the procedures for publishing standards as American National Standards.
Best Practice / Practice	Definitive set of instructions or accepted procedures for accomplishing a given task.
Classification and Grading	Systematic arrangement or division based on similar characteristics. Grading applies most often to natural, refined and agricultural products.
Code	Collection of mandatory standards that has been codified by a governmental authority and become part of the laws/regulations.
Code of Practice	Recommend practices and procedures for the design, implementation, utilization and maintenance of services, equipment, and products.
Data	List information or values that must be reported.
De Facto	In fact, or in practice but not spelled out by law. Generally, arises from an uncoordinated process.
De Jure	Based on law.
Guide	Series of options that does not recommend a specific course of action.
Internal / Company	Documents for internal use that outline technical processes, requirements, procedures, materials characteristics, etc.
Interoperability/Interchangeability/ Compatibility	Establish interface measurements and tolerances to enable equipment and sources of various designs to work as systems.
Open	Freely available for adoption, implementation, and updates. Not to be confused with open source, which related to source code.
Performance	Set performance criteria for the solution of matching problems. They do not prescribe solutions. Performance standards can include specifics on which deviations from basic requirements are allowable.
Quality Management Systems	Set requirements for entities to assure a certain level of quality (e.g., ISO 9000 series of standards).
Service	Specify requirements to be fulfilled by performing a service.
Specifications	Explicit set of requirements.
Technical Report	Educational, explanatory, or informational in nature. May describe a new technology or provide implementation advice on a standard or data obtained from a survey or informative report, or information on the perceived "state of the art". May not contain requirements or test methods.
Terminology	Establishes fundamental definitions, terms, and symbols.
Test Methods	Highly prescriptive, definitive procedures that produce results. All details regarding apparatus, test specimen, procedure, and calculations needed to achieve satisfactory estimates of precision and bias are addressed in a test method. (Safety standards often fall into this category.)
Voluntary Consensus	Defined by the coordinated development process used to create the standard. The resulting standard is voluntary. Aims to achieve a balance of stakeholder representation and lack of a dominant interest.

Major players in the U.S.standardization system

American national standards institute (ANSI)

The American National Standards Institute (ANSI) is the private sector administrator/coordinator of the U.S. Standardization System and represents the U.S. in many international standards development efforts. ANSI does not develop standards, rather they accredit U.S. SDOs that choose to publish "American National Standards (ANS)." These SDOs are audited and accredited to the *ANSI Essential Requirements for Due Process for the Development of American National Standards* (American National Standards Institute, 2022). Standards developed through the ANSI process require additional notification and solicitation of comments from the broader stakeholder community. ANSI is also responsible for the coordination of U.S. SDO activities by providing its members with forums for sector discussions as well as support for the management of U.S. Technical Advisory Groups (TAGs) to two international SDOs – the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

U.S. government

U.S. federal agencies, including the National Institute of Standards and Technology (NIST), support representation of U.S. interests in all relevant international standards organizations. U.S. government staff are encouraged to participate in standards development activities both internationally and with U.S. private-sector SDOs, as outlined in federal policy, *Office of Management and Budget (OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (U.S. Office of Management and Budget OMB, 2016). This circular was last revised in 2016, in part to provide guidance on how agencies could meet the intent of the standards and conformity assessment related provisions of the National Technology Transfer Advancement Act (NTTAA) (U.S. Public Law 104–113 National Technology Transfer Advancement Act, 1995). This Act directs agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with the law, or otherwise impractical. It also provides guidance on how agencies can participate in the development of voluntary consensus standards and articulates policies relating to the use of standards by federal agencies.

The community of stakeholders

The principles set out by *A-119* and *World Trade Organization (WTO) Principles for Standards Development* (World Trade Organization, 2015) *(for more information, see below)*, require standards developers to identify stakeholders and "materially interested parties." Stakeholders may include academia, government, regulators, consumers, product manufacturers, and anyone else who has an interest. All these individuals bring different perspectives and represent different interests. SDOs must attempt to balance the "interests" of the stakeholders that are represented. Examples of interest categories include the following, but depend on the discipline being addressed: producers, users, consumers (required in the U.S. for safety standards), and general interest.

Fig. 4 is illustrative of an example SDO committee of ASTM International on autonomous vehicles. Stakeholders at the table might include end users, researchers, the U.S. Government (e.g., NIST, Department of Homeland Security [DHS], Department of Energy [DOE], Department of Defense [DoD], Environmental Protection Agency [EPA]), Conformity Assessment Bodies, and State Regulators.

International standard system and national participation

The international standards system has its voluntary consensus standards development foundations in the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement and associated Decisions.

World trade organization (WTO) principles

The TBT Agreement is a central defining document of the WTO. Designed to ensure that WTO Members' technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to trade, the TBT Agreement also recognizes the important role of non-governmental standards organizations in setting national and international standards, and in certifying compliance with such standards. The TBT Agreement encourages the use of "international standards" to reduce trade barriers. The WTO's TBT Committee adopted a *Decision on Principles for the Development of International Standards, Guides and Recommendations*.

> "Decision 1: The following principles and procedures should be observed, when international standards, guides and recommendations (as mentioned under Articles 2, 5 and Annex 3 of the TBT Agreement for the preparation of mandatory technical regulations, conformity assessment procedures and voluntary standards) are elaborated, to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries. The same principles should also be observed when technical work or a part of the international standard development is delegated under agreements or contracts by international standardizing bodies to other relevant organizations, including regional bodies (World Trade Organization, 2015). Annex 2 goes into details regarding transparency, impartiality, consensus, etc.

Numerous SDOs in the U.S. and in other nations adhere to these WTO Principles for standards development. The standardization community recognizes several organizations as international standards developers. The most referenced are the

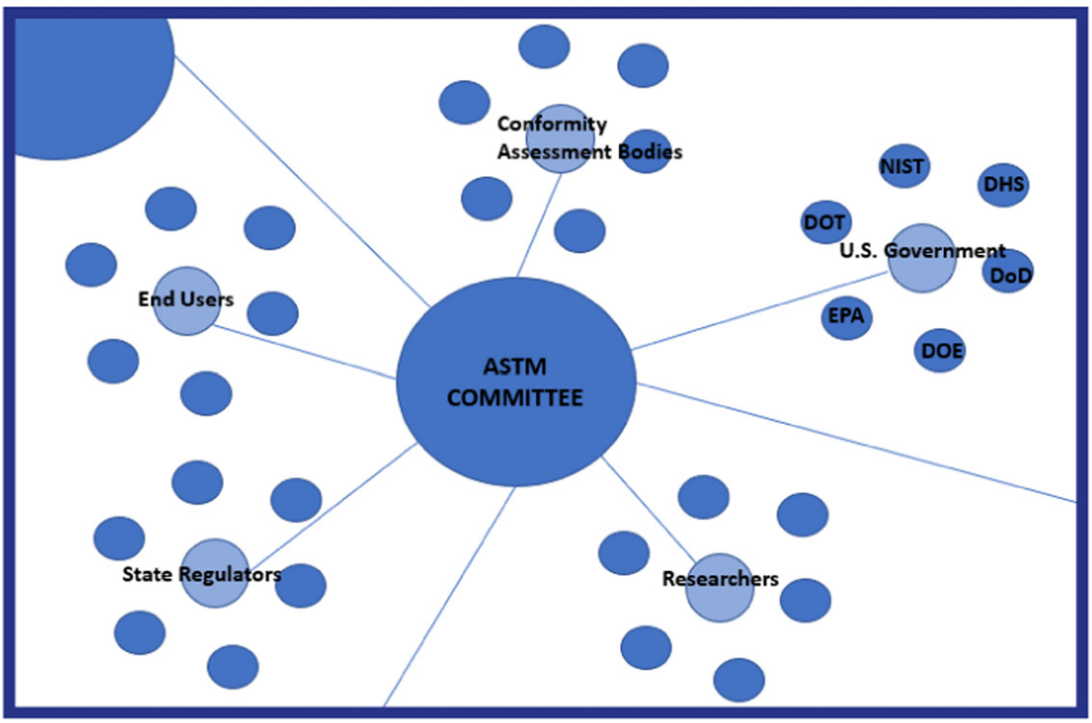

Fig. 4 Example of Stakeholders Participating in an SDO's Technical Committee.

International Electrotechnical Commission (IEC), International Organization for Standardization (ISO), and the International Telecommunications Union (ITU), which is a treaty organization, under the United Nations. Additional organizations (e.g., ASTM International, IEEE Standards Association, SAE International, etc.) develop standards through a process that is consistent with the TBT Committee Decision description of international standards. International consortia standards organizations include World-WideWeb Consortia (W3C), OASIS, and others.

International SDOs with national participation

ISO is a well-recognized international SDO in the forensic science community. ISO has over 225 Technical Committees (TCs) and over 19,000 published standards. Below is an illustration of how this system operates with the U.S. as a participating country in an ISO technical committee. Each country (or nation) has its own national member body. Each member body is invited to participate in various TCs. In Fig. 5, ANSI is the U.S. member body and coordinates U.S. participation in the ISO TCs. A delegation of representatives with subject matter expertize participates on behalf of the national member body. The U.S. position (and each country's position) is established through a Technical Advisory Group or TAG (also called a mirror committee). The U.S. TAG comprises U.S. interested organizations, such as SDOs, manufacturers, end-users, government agencies, researchers, etc. The U.S. TAG reaches consensus on the U.S. vote and gives the U.S. delegation to the Technical Committee the right to represent the country's vote and position in the Technical Committee discussions related to the standard being drafted and balloted. This same process occurs in each country with its own TAG and national member body.

In this figure, the diagram also includes the International Electrotechnical Commission (IEC) and its linkage to ISO. Relevant for forensic sciences is the ISO/IEC Joint Technical Committee (JTC) 1 on Information Technology, Subcommittee (SC) 37, Biometrics, focused on the development of biometrics, algorithm testing, and facial image standards.

Standards setting organizations (SSOs) and standards developing organizations (SDOs)

Standards Setting Organizations (SSOs) vary greatly in size and composition. Some consist of just a few firms that collaborate on a narrow set of technical specifications, sometimes for a single product. Standards for consumer electronics devices and media such as the digital video disc (DVD) were developed in this manner. Other SSOs have thousands of members and oversee multiple standardization activities at any given time.

SSOs fall into three broad categories: (1) those that are formally recognized by some authority (traditional SDOs); (2) "quasi-formal" groups that are typically large and well organized and share many of the characteristics of formally recognized groups; and (3) smaller, privately organized consortia (also known as special interest groups or forums). SDOs are a subset of SSOs.

- In the U.S., there are hundreds of "traditional" SDOs and hundreds more "non-traditional" SDOs.
- Estimates are that 20 SDOs produce 90% of the standards in U.S (American National Standards Institute, 2017).

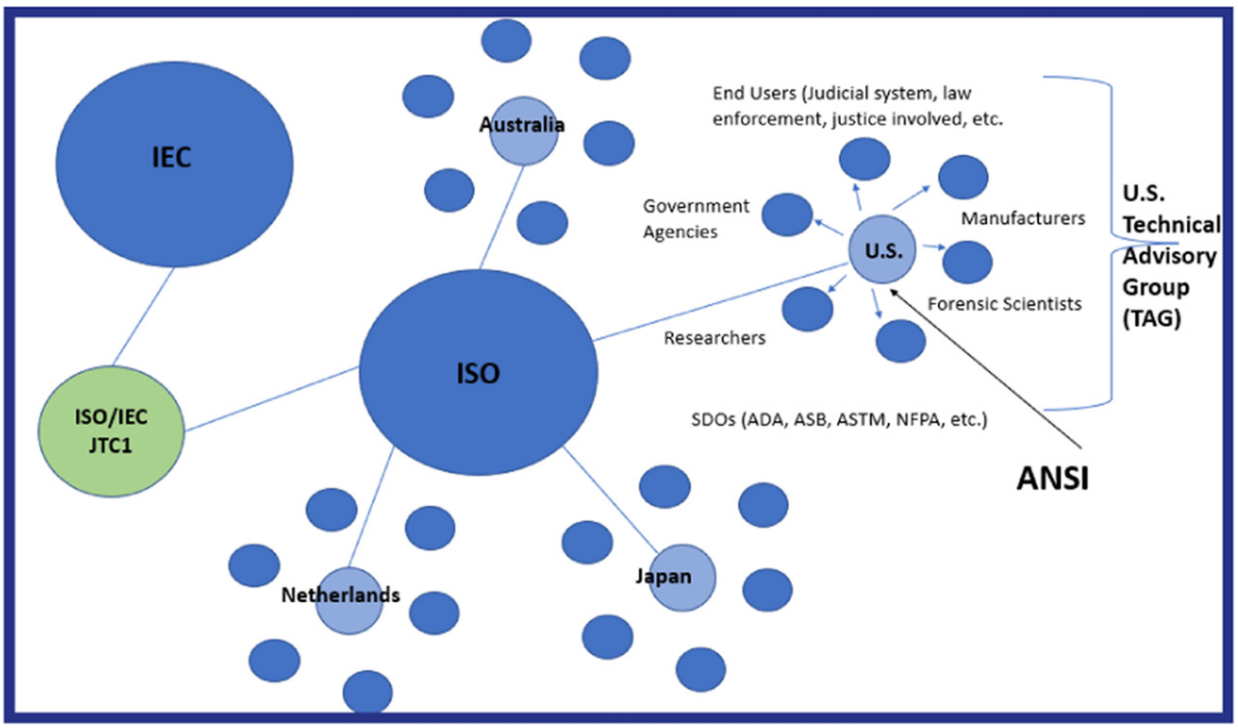

Fig. 5 Example of international standards development with country representation.

- In the U.S., SDOs take the form of professional societies (American Academy of Forensic Sciences Standards Board [ASB], IEEE Standards Association, SAE International, etc.); trade associations (Consumer Technology Association (CTA), NEMA, etc.); testing and certification organizations (Factory Mutual [FM], Underwriter's Laboratories, etc.); and organizations whose primary function is to develop standards (ASTM International, National Fire Protection Association [NFPA], OASIS, etc.)

Standards Setting and Standards Developing Organizations:

- Provide the structure and organization for standards development with online platforms, staffing, and procedures.
- Facilitate the process of standards development through staff and editorial support and online tools.
- Support the work of the committees by overseeing meetings and advising on procedural matters.
- Issue final documentary standards in published form.

SDOs have a business model and often sell their standards (e.g., in the U.S. and in many other nations, SDOs are part of the private sector and standards publishing is a business). SSOs, on the other hand, are often consortia based and their standards are "open source."

The standards development process

Standards development is a cyclical process. As soon as a standard is published, the working group/task group needs to be thinking about its next revision. A new work item to revise a standard can be initiated within months, or even days, after publication.

Fig. 6 depicts the standards development process, which starts with stakeholders identifying a concept for a standard. The initiating stakeholders may develop a draft "seed" document that attempts to describe the specific need for the standard. This document is most often referred to as a work item.

Seed (concept) documents can come from a variety of sources. They can originate from:

- A consensus body/committee/task group at an SDO.
- Internal standards for an organization.
- Licensed standards (e.g., video, or stereo cassette formats, MS-DOS operating systems for personal computers).
- Community standards (e.g., the Scientific Working Group for Digital Evidence [SWGDE] in digital forensics).
- National standards are submitted as seed documents for international standards (e.g., ISO Technical Committee 272 on Forensic Science started their discussions using Australia's standards - *AS 5388 Forensic Analysis, Parts 1–4* (Standards Australia, 2016)).

Elements for Drafting a Good Standard

Standards should have a focused and defined scope that meets a clearly defined purpose for the users of the standard. This may include the subsector or discipline applicability, the type of service or other information such as the relationship of a standard to another standard. The European Telecommunications Standards Institute (ETSI) offers a free publication, their *Guide to Writing World Class Standards*, that includes considerations in developing a scope, (European Telecommunications Standards Institute, 2020).

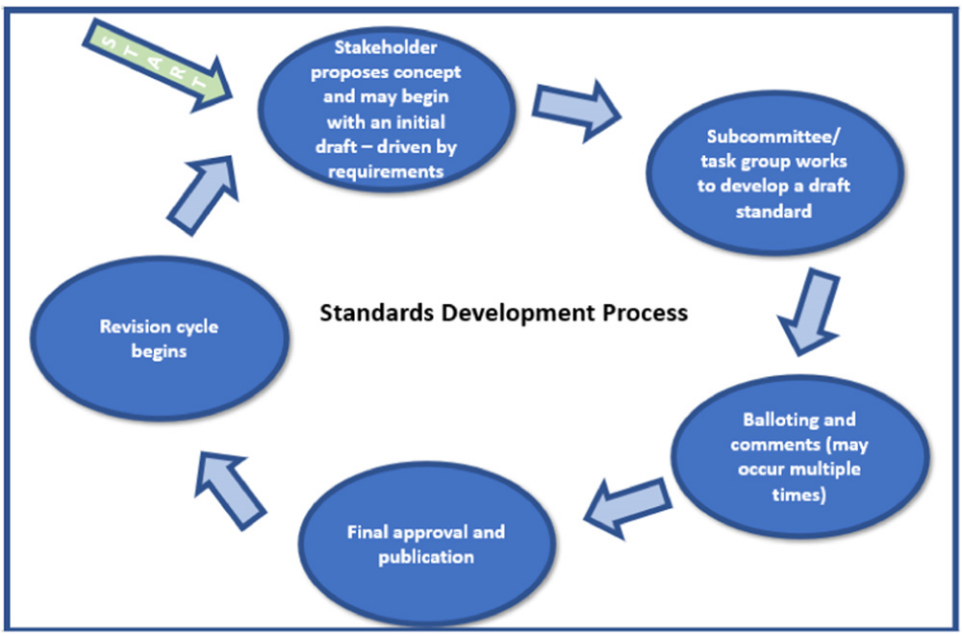

Fig. 6 Standards development process.

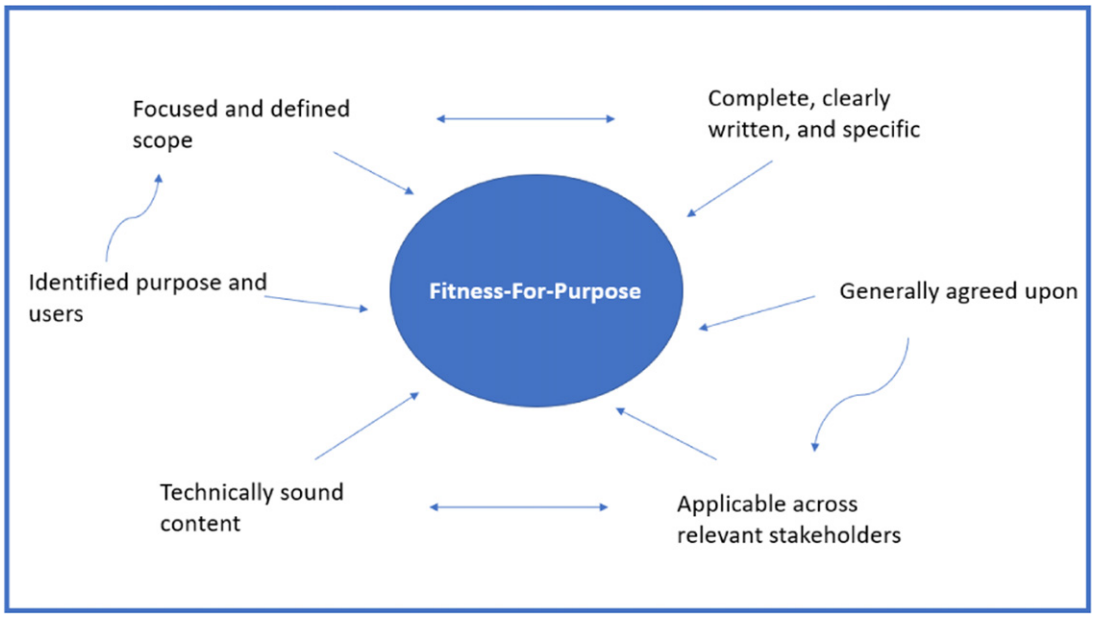

Fig. 7 Elements that comprise fitness for purpose.

A standard needs to be based on technically sound content. Fig. 7 illustrates the elements that make a standard, "fit for purpose" or establish "fitness-for-purpose".

All these elements require general agreement, or what is known as consensus. Consensus takes time and often requires crucial and contentious conversations.

Voluntary Consensus Standards

The term "voluntary consensus standard" was coined as a phrase in the NTTAA legislation mentioned earlier. What makes voluntary consensus standards (VCS) different from other types of standards is the process used to develop them. SDOs meet these requirements differently, and while their processes vary, they all aim to meet the attributes in Fig. 8 below. The attributes of VSCs are also defined in *OMB A-119* and similarly in the *WTO Principles*.

Current State of Forensic Science Standards Development

Standards development in forensic sciences has been going on for decades. Most of the U.S. forensic standards setting groups existed in the form of federally funded Scientific Working Groups (SWGs). Some SWGs still exist and are active in setting standards. ASTM International's Committee E30 Forensic Science, the original U.S. forensic science SDO, has been working actively in standards for forensic evidence analysis and techniques since 1970. In other countries, regionally based groups like the (European Network of Forensic Science Institutes ENFSI, 2022) and specific nations with national standards bodies, such as Australia and China, have developed forensic science standards.

In February 2009, the National Research Council (NRC) published *Strengthening Forensic Science in the United States: A Path Forward* (National Research Council, 2009). This report assessed the state of forensic science made observations related to standards and conformity assessment in forensic science and noted that.

> "Despite the proliferation of standards in many of the forensic science disciplines, their voluntary nature and inconsistent application make it difficult to assess their impact. Ideally, standards should be consistently applicable and measurable. In addition, mechanisms should be in place for their enforcement, with sanctions imposed against those who fail to comply. As such, standards should be developed with a consideration of the relevant measures that will be used to provide a meaningful evaluation of an organization's or individual's level of compliance. Appropriate standards must be coupled with effective systems of accreditation and/or certification that include strong enforcement mechanisms and sanctions." (National Research Council, 2009)

One result from the NRC report was the formation of the Organization of Scientific Area Committees (OSAC) for Forensic Science, which was established in 2014 to facilitate the development of sound standards for forensic science. *(See The Organization of Scientific Area Committees (OSAC) for Forensic Science in this publication).*

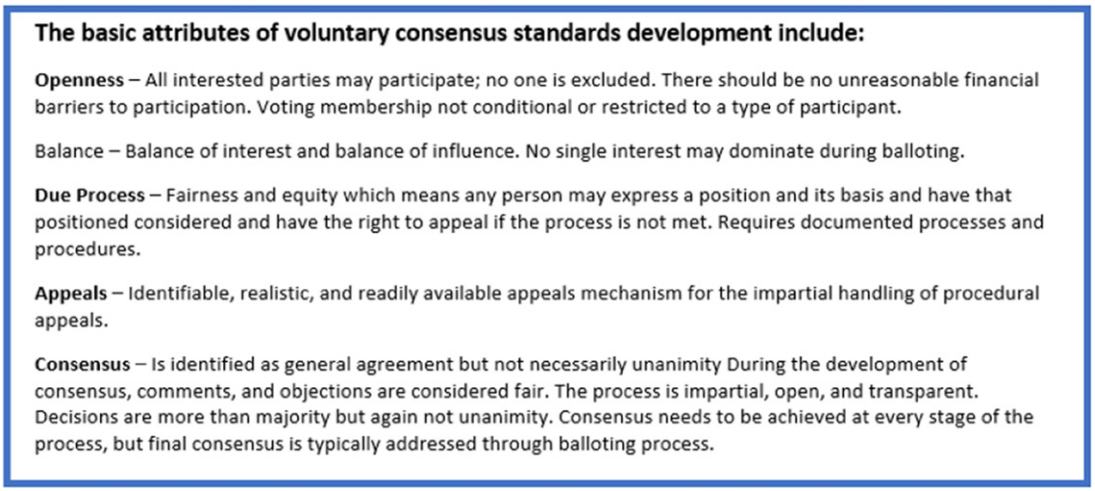

Fig. 8 Basic Attributes of voluntary consensus standards development.

Forensic Science Standards Developing Organizations

The American Academy of Forensic Science Standards Board (ASB), an SDO specifically focused on the development of forensic science standards, was established in 2015. Other SDOs have several specific standards for fire investigation, speaker recognition, and forensic dental analysis. (**Table 2**). For example, ISO and IEC's Joint Technical Committee (JTC) 1 addresses standardization in biometric data, security, algorithms, facial recognition, and friction ridge technology. ISO's Technical Committee (TC) on Forensic Science is focused on a five-part series from evidence collection through reporting. The first standard from this group was *ISO 18385:2016 Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements* (International Organization of Standardization ISO, 2016).

Drivers for Forensic Science Standards

One of the major drivers for standards compliance is often country-specific regulations. In the U.S., the only federal requirement related to forensic sciences is the *Quality Assurance Standard* (QAS), published by the Federal Bureau of Investigation (FBI). *The DNA Identification Act of 1994* (Pub, 1994) makes it mandatory for any laboratory performing DNA analysis to comply with this standard to upload data into the National DNA Index System (NDIS). U.S. accrediting bodies (ABs) provide services at a customer's request for accreditation to this QAS or any other specific standard to be included in their accreditation scope.

Another major driver for standards is market demand. For example, if an organization is a market player in electronics, it's components must comply with the IEEE standard for Wi-Fi (IEEE SA, 2016). Market access is dependent on the interoperability provided by following this standard.

As Linzi Wilson-Wilde notes in a 2018 publication, "Standards do not replace the forensic service provider's procedure documents, methods, or policies. Practitioners continue to determine the appropriate method to apply to a particular process. As standards are voluntary documents, developed by consensus and applied by choice (unless their use is mandated by government or written into a contract), acceptance is contingent upon 'ownership' by a broad base of stakeholders and experts (local, state, federal/national/country agencies, and advisory bodies, academia, and industry)". (Wilson-Wilde, 2018).

Other Standards Setting Organization Developing Forensic Science Standards

As previously noted, not all standards are developed using the voluntary consensus process that includes the principles of openness, balance of interests, due process, process for appeals and consensus. There are many national and international forensic science standards setting organizations who develop forensic standards but do not follow a voluntary consensus standards process. For example, the (European Network of Forensic Science Institutes ENFSI, 2022) has been working in recent years on revising their procedures to be more open and transparent in the development of their standard guides European Network of Forensic Science Institutes ENFSI, 2022 to be more aligned with the practices and procedures of ISO.

Introduction to Conformity Assessment

As noted previously in **Fig. 2**, standards are a key component of conformity assessment. Conformity assessment is how a manufacturer, regulator, service provider, or an independent third party evaluates compliance to standards (**Fig. 9**).

Table 2 SDOs Currently publishing forensic science related standards.

Standards developing organization	*Country*	*Committees/Consensus bodies/Working groups*
American Academy of Forensic Sciences (AAFS) Standards Board (ASB) Consensus Bodies*	United States	Anthropology Blood Stain Pattern Crime Scene Investigation Disaster Victim Identification DNA Dogs and Sensors Firearms and Toolmarks Footwear and Tire Forensic Document Examination Friction Ridge Medicolegal Death Investigation Toxicology Wildlife Forensics
American Dental Association (ADA)	United States	Dental Informatics
AOAC International Forensic Science	United States	Forensic Sciences (limited methods; considered current but very dated)
ASTM International E30 Forensic Sciences	International/ United States	E30.01 Criminalistics E30.11 Interdisciplinary E30.12 Digital and Multimedia Evidence E30.92 Terminology
Audio Engineering Society	United States	AES 3 (2 Channel Digital Audio) SC-03–12 Task Group
ISO Technical Committee 272 Forensic Sciences	International	WG1 Terminology WG 2 Recognition, recording, collecting, transport, and storage WG3 Examination/Analysis/Interpretation WG4 Reporting
ISO/IEC Joint Technical Committee 1 (JTC1) Information Technology Subcommittee 37, Biometrics	International	ISO/IEC JTC 1/SC 37/WG 1 Harmonized biometric vocabulary ISO/IEC JTC 1/SC 37/WG 2 Biometric technical interfaces ISO/IEC JTC 1/SC 37/WG 3 Biometric data interchange formats ISO/IEC JTC 1/SC 37/WG 4 Technical Implementation of Biometric Systems ISO/IEC JTC 1/SC 37/WG 5 Biometric testing and reporting ISO/IEC JTC 1/SC 37/WG 6 Cross-Jurisdictional and Societal Aspects of Biometrics
National Fire Protection Association (NFPA)	United States	Fire Scene Investigation Technical Committee

There is no national-level coordinating organization for conformity assessment globally. Instead, this space includes multiple accreditation bodies of differing scope and size, and many overlap in coverage. A key component of conformity assessment programs is that they are tailored to meet specific private and public sector needs.

ISO manages a formal committee, the ISO Committee on conformity assessment (CASCO). In the U.S. there is a national mirror committee, managed through ANSI, called the International Conformity Assessment Committee (ICAC). CASCO develops international standards and policies for conformity assessment. The ISO 17000 series of standards shown in **Fig. 10**, also known as the CASCO Toolbox, promotes a consistent approach and standardized practices in conformity assessment worldwide. These standards are used in conjunction with a range of other national and international standards and requirements; this varies depending on the object of conformity assessment. Conformity assessment bodies (CABs) perform the conformity assessment services that ensure compliance to standards.

Forensic laboratories are traditionally accredited to *ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories* (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2017b). Also used in scene examination in some nations is *ISO/IEC 17020:2012 Conformity Assessment – Requirements for the Operation of Various Types of Bodies Performing Inspection* (International Organization for Standardization ISO/International Electrotechnical Commission IEC, 2012b). Internationally, there is a supplemental guidance document to ISO/IEC 17025 and 17020, issued by the International Laboratory of Accreditation Cooperation (ILAC), *ILAC G-19:2022 Modules in a Forensic Science Process* (International Laboratory Accreditation Cooperation, 2014, 2022). This document provides guidance for accrediting bodies related to laboratories performing the forensic process. Many accrediting bodies have developed their own supplemental requirements in addition to ISO/IEC 17025 and ISO/IEC 17020 due to the lack of availability of documentary standards in this sector (A2LA, 2021; ANSI Accreditation Board ANAB, 2017; United Kingdom Accreditation Service, 2022). In the UK, United Kingdom Accreditation Service (UKAS), uses the *Forensic Science Regulators' Codes of Practice and Conduct* (United Kingdom Forensic Science Regulatory UKFSR, 2021) as a source of additional requirements for assessing conformance of forensic science activities. In the U.S., third-party accreditation is decentralized, like its standards system. While most other nations have only one accrediting

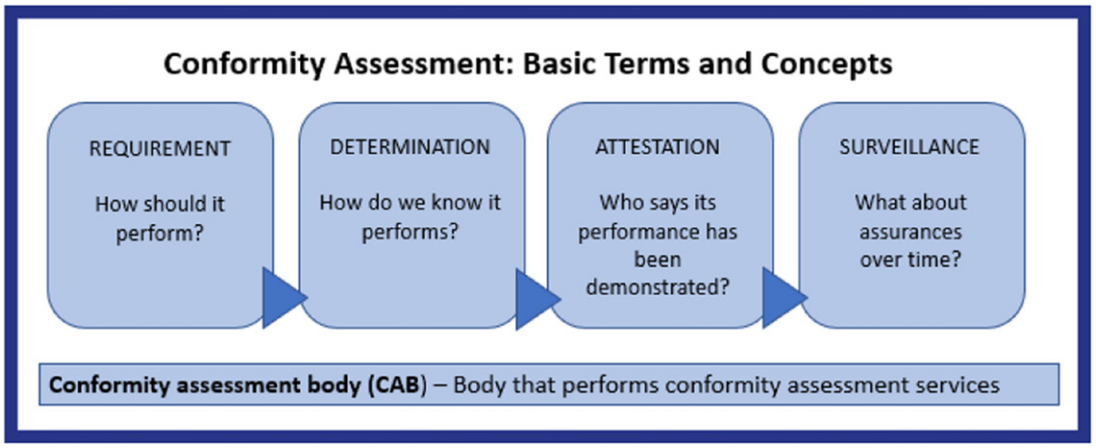

Fig. 9 Conformity Assessment: Basic Terms and Concepts. Source: Adapted from ABCs of Conformity Assessment. Reprinted with permission from National Institute of Standards and Technology (NIST), 2018. NIST SP 2000–01 ABC's of Conformity Assessment.

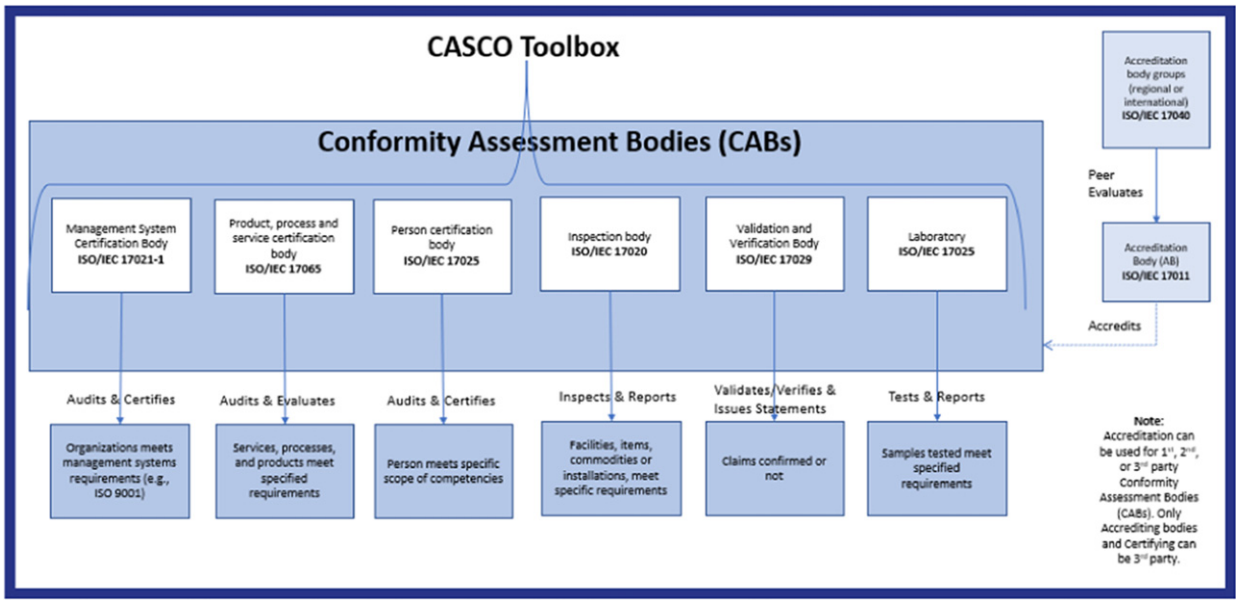

Fig. 10 CASCO toolbox of standards.

body, the U.S. has many. This sets up an environment in which the U.S. ABs have developed different supplemental requirements for forensic accreditation.

As mentioned, conformity assessment programs are tailored to meet specific needs, and no two are identical. When designing a conformity assessment scheme, the risks associated with non-compliance must be considered when determining the necessary rigor of a system.

Types of Conformity Assessment

Conformity assessment activities can be performed by many types of organizations or individuals (Fig. 11). Conformity assessment activities can include supplier's declaration of conformity, certification (conformity, sampling and testing, inspection, certification (of personnel or products), accreditation, and surveillance.

Examples of Conformity Assessment

The following (Fig. 12) are select examples to illustrate the types of conformity assessment as they apply to the criminal justice system.

"Standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment scheme or program. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements) and the products or services themselves. Together standards and conformity assessment activities impact almost every aspect of life in the United States". (National Institute of Standards and Technology NIST, 2022) Why does conformance matter in forensic science?

- Techniques may be denied court admissibility because the testing procedures or results are not recognized.
- Implementing international conformity assessment standards supports trust and assurance.
- International recognition and acceptance are based on confidence and good practices.

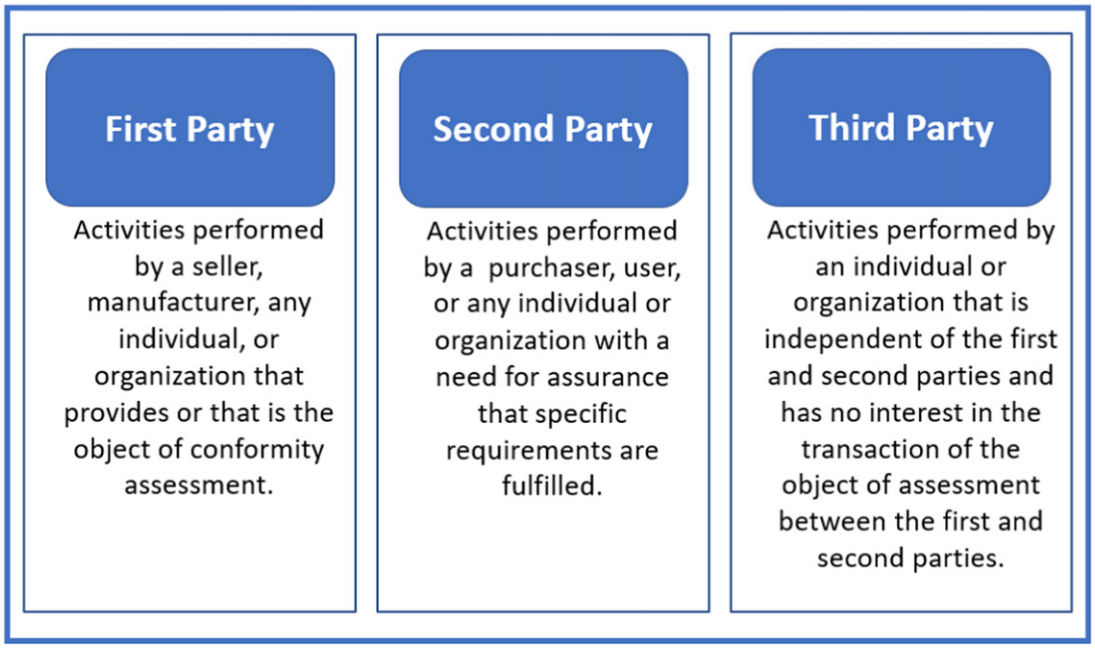

Fig. 11 Types of Conformity Assessment. Source: Adapted from ABCs of Conformity Assessment. Reprinted with permission from the National Institute of Standards and Technology (NIST), 2018. NIST SP 2000–01 ABC's of Conformity Assessment.

Examples of Conformity Assessment

The following are select examples to illustrate the types of conformity assessment as they apply to the criminal justice system.

First Party – A FSSP attests they have implemented a standard (e.g., a standard listed on the *OSAC Registry* from the Organization of Scientific Area Committees (OSAC) for Forensic Science.)

Second Party – The National Institute of Justice (NIJ) manages the NIJ Voluntary Compliance Testing Program to determine which body armor models the minimum performance requirements for inclusion on the *NIJ Compliant Products List*.

Third Party – An International Laboratory Accreditation Cooperation (ILAC) Signatory Accrediting Body assesses an FSSP for a specific scope of work or standard (e.g., a specific test method, the Federal Bureau of Investigation (FBI) Quality Assurance Standard (QAS), the United Kingdom's Forensic Science Regulator (UKFSR) Codes of Practice.)

Fig. 12 Examples of conformity assessment in the criminal justice system.

Challenges to Forensic Science Standards Implementation

Standards have little to no benefit unless they are used. Many different forces can impact the successful implementation of standards in forensic science. Around the world, different national jurisdictional requirements and approaches to the analysis and use of forensic evidence in the criminal justice system can cause challenges in consensus standard setting and adoption. For example, if a technical committee drafts a standard with minimum requirements, it may be too general to fit the needs in different countries. In turn, that loss of specificity may impact the value of the standard to the FSSP. Sociologist Cole, who writes on forensic science standardization, echoes these concerns.

> "Sociologists of standards note that "the power of standardization depends on whether standards are actually implemented." One might adapt for standards the old adage about academic articles: most are never cited; many are never read. Likewise, "[c]ountless standards do nothing." Sociologists point out that "the world is awash in competing standards," and, therefore, "standards risk remaining paper tigers unless they are widely adopted." They add that "[t]he voluntary nature of many standards makes it difficult to develop momentum unless built-in incentives promote compliance." These incentives might range from government requirements to peer pressure—a "crowd effect." It is possible to imagine both of these incentives having an effect on forensic science—governments requiring crime laboratories to conform to standards, or crime laboratories conforming to standards because most of their peers do—but it is at least equally possible that these incentives are not effective". (Cole, 2018)

Forensic Science is not Highly Regulated

In the U.S., other than the federal law requiring DNA laboratories to use of FBI's DNA QAS, there are a limited number of state laws applying to requirements for FSSPs. This is the case in almost every other country, with the United Kingdom being an exception. Other sectors often enforce standards by incorporating them by reference into regulations. Regulations surrounding forensic science, however, are almost nonexistent.

Seeing the Value of VCS

Writing consensus standards is difficult. The process is slow and laborious, and it is challenging for stakeholders with various perspectives to reach agreement. Getting people to participate in the process is harder when the value of standards within a community and among its stakeholders has not been demonstrated.

Historically, forensic standards development has been dominated by forensic professionals with few other stakeholders coming to the table. This was a criticism of the U.S. government's Scientific Working Groups (SWGs), which were created in the early 1990s and operated well into the 21st century, (National Research Council, 2009) with the creation of OSAC. In the last eight years, SDOs have made strides to attract other stakeholders to participate in the standards development process. With the establishment of the OSAC for Forensic Science in 2014, a larger community of stakeholders have been working to bring their diverse perspectives - legal, human factors, statistics, quality, and research - to standards development.

For the first several years of OSAC, people talked at cross-purposes not really understanding each other's concerns. Non-forensic participants had to learn the issues surrounding the uniqueness of case work and how often forensic evidence produces insufficient evidence samples to assure that statistical assertions are correct. Receiving criticisms, even when constructive, is not always easy without becoming defensive. Almost all standards development is done by volunteers. Everyone working on developing these forensic science standards is committed to improving forensic science. Consensus is about being able to "live with it". In recent years, progress in being made by all parties to support the goal of improving the standards and ultimately, the quality and consistency of the results.

The final challenge for this community is that standards development is new to most stakeholders involved in the process. The skill set needed to write good documentary standards and get them through to publication, is unique and must be learned. No one is born knowing how to write a "good" standard. People need to be taught how to formally adjudicate a negative response on a standards ballot or work with a negative voter to understand their concern. The standardization community at large, is committed to the voluntary consensus standards process because they know it most often results in a better documentary standard. This same standardization community also recognizes that not every standard that is published is *good*. The *OSAC Registry* (Organization of Scientific Area Committees OSAC for Forensic Science, 2022) was established to address this possibility and aims to add additional vetting of the technical merit of forensic science standards before approving them for inclusion on the Registry.

Standard developing organizations are a business, and their business model is one that protects and sells their intellectual property. The forensic community does not welcome having to purchase standards and believe they should be available free of charge. To clarify, some SDOs do not charge for their standards and most "open source" standards are free. In the U.S., many SDOs often make efforts to provide certain standards freely available for read-only access as a service to the community.

A Lack of Interdisciplinary Standards

Most forensic science standards being developed focus on discipline-specific topic areas and as a result there are very few interdisciplinary standards available. The formation of OSAC allowed disciplines to identify gaps in needed standards and develop draft seed documents for SDOs While the development and use of discipline-specific standards is helping to strengthen forensic science practice, there is still a need to develop more interdisciplinary documents. There has been some movement in ASTM's E30

Forensic Science Committee and OSAC subcommittees to create chemistry instrumentation and validation standards that would apply across disciplines such as seized drugs, ignitable liquids and explosives, and trace evidence. These groups recognized that although they were analyzing different types of evidence, they were using similar equipment and methods and could reduce the number of standards they needed to follow.

The number of standards that have been developed in the U.S. since 2015 is daunting to most FSSPs. To implement these standards, FSSPs must determine how to effectively incorporate them into their quality management systems. This requires FSSP personnel to review the standards and assess which ones they are already following, which ones they could follow, and where any possible gaps may exist in areas such as trained personnel or equipment. This creates a burden on the FSSP, which often already has limited resources. The development of additional supplemental materials such as checklists may help to reduce the burden of implementation.

Lack of Research to Support Method Validation

A test method provides detailed directions on performing specific tests that produce a result. Many of the current standards are considered best practices or guides, and there are a limited number of test method standards that exist.

FSSPs produce "results" all the time but, in most instances, these results are an opinion or interpretation. Analytical data generated through reliable methods and practices built upon valid core scientific principles and methodology is critical. "There are approximately 409 forensic laboratories in the United States, existing at municipal, county, state, and federal levels. Many of these forensic laboratories manage backlogs with median turn-around times in excess of 30 days. As a result, laboratories frequently focus on casework analysis and have limited time to conduct evaluation, research, validation, and implementation of new technology". (Wickenheiser and Farrell, 2020).

Unfortunately, far too few forensic specific interlaboratory studies are accomplished each year to support method validation needed to support the development of specific standards. To perform these types of studies, ground truth must be known. Setting up these studies takes a lot of time in terms of sample collection, designing the study, sending around samples, comparing results, etc. FSSPs are often unable to participate in these studies because of case load issues and limited resources. If they take people off to do this study, who is going to process the cases?

Validation is method specific. "Validating" a discipline like blood stain pattern analysis, is not possible but validating a blood stain pattern capture method would be useful for the community. OSAC publishes an annual list of research needs to support standards for the various forensic disciplines. Performing and participating in these studies can benefit the forensic science standards community. These types of studies can help to identify whether laboratories consistently have a problem with a step in a standard or to see where everyone is performing well and then just focus on the area that needs strengthening. Specific considerations relevant to forensic science validation are outlined in the *ANZPAA NIFS Empirical Study Design in Forensic Science – A Guideline to Forensic Fundamentals* (Australia New Zealand Policing Advisory Agency ANZPAA/National Institute of Forensic Science NIFS, 2019).

Are Today's Standards too General To Be Useful?

Some stakeholders in the community are critical of the current standards being developed. For example, a few forensic standards have been described as vacuous and too general to be useful (Roux *et al.*, 2021; Morrison *et al.*, 2020; Mohammed *et al.*, 2021; Morrison *et al.*, 2021). The poor quality of some of these standards may be attributed to the fact that standards developers were new to the process or may have fallen subject to less stringent constraints in the efforts to gain consensus. Standards containing generalized wording are open to interpretation. Standards need to be as specific as possible, to avoid a user from having to infer or make assumptions about the steps and how they are performed. Similarly, if the standard is not well written, it can have a negative effect on the quality of the results being produced.

Confusion of how to Apply Standards to the Conformity Assessment Principles

Forensic science is a service industry, primarily driven by the government, not commerce. Even though accreditation is not required in the U.S., some 90% of FSSPs are accredited to ISO/IEC 17025 or ISO/IEC 17020 (Bureau of Justice Statistics, 2014) only a few U.S. states require accreditation of their state laboratories or laboratories doing work for the state. For most FSSPs, the focus continues to be on self-declaration of standards implementation. FSSPs have a lack of understanding and clarity of the role that standards play in laboratory accreditation (i.e., 3rd party conformity assessment). In addition, the process and costs associated with initial and continuing accreditation assessments, continues to be a challenge for FSSPs.

Future Outlook

Since the 2009 NAS Report, there has been a significant culture shift occurring in forensic science as it relates to standards development. Stakeholders have been learning the standards development processes and navigating the challenges of reaching consensus across their different perspectives. While finding consensus may be difficult and time-consuming, it is critical to forensic standardization success. As articulated, both internationally and specifically in the U.S., the uptake in standards development in forensic science disciplines has been exponential, and this trend is expected to continue. The forensic science community of stakeholders is committed to improving the state of forensic science standardization, however challenging.

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