Voluntary Standards and Accreditation: An Introduction for Lawyers

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December 1, 2024

An understanding of how voluntary standards intersect with accreditation requirements begins with an understanding of the regulatory environment in which those standards and requirements operate. The United States does not have a nationwide forensic science regulator to set and enforce forensic science standards. Instead, outside of a number of state exceptions,[1] forensic science in the United States is largely governed through the adherence of forensic science service providers to voluntary accreditation schemes rather than top-down regulation. Such voluntary accreditation is widespread among large public labs; as of 2020, 90.4% of publicly funded crime labs were accredited.[2] The only federal law mandating forensic regulation in any form is the DNA Identification Act of 1994's requirement that laboratories must comply with the Quality Assurance Standards set by the Federal Bureau of Investigation, undergo external audits every two years demonstrating such compliance, and maintain accreditation, in order to use or participate in the National DNA Index System (NDIS).[3] Note that this law does *not* affirmatively require laboratories to follow the Quality Assurance Standards; it only prevents them from accessing NDIS if they fail to do so.

[1] *See, e.g.,* 37 Tex. Admin. Code § 15 (Tex. Forensic Sci. Comm., Crime Laboratory Accreditation).

[2] Bureau of Justice Statistics, *Publicly Funded Forensic Crime Laboratories,* 2020, at 16, https://bjs.ojp.gov/document/pffcl20.pdf.

[3] 34 USCA § 12592; *see also* Karen Reczek, *Standards and Conformity Assessment, Encyclopedia of Forensic Sciences (Second Edition)* at 636; Federal Bureau of Investigation, *Frequently Asked Questions on CODIS and NDIS,* https://www.fbi.gov/how-we-can-help-you/dna-fingerprint-act-of-2005-expungement-policy/codis-and-ndis-fact-sheet.

Forensic science services providers typically become accredited through one of two private sector accrediting bodies: the ANSI National Accreditation Board (ANAB)[4] or A2LA.[5] These bodies, in turn, assess laboratories for compliance with an accreditation standard. Most forensic laboratories are accredited to ISO/IEC 17025,[6] which sets forth "[g]eneral requirements for the competence of testing and calibration laboratories."[7] Alternatively, ISO/IEC 17020, which sets forth "[r]equirements for the operation of various types of bodies performing inspections"[8] may also be used to accredit some disciplines (e.g., crime scene investigation and less commonly, comparison disciplines.[9]).

Both ISO/IEC 17025 and ISO/IEC 17020 are broad and flexible standards that, in large measure, require adherents to create policies and procedures, but leave significant discretion to laboratories as to what those required policies and procedures will contain and how the standards' other requirements will be met. *See, e.g.,* ISO/IEC 17025 § 7.2.1.1 ("The laboratory

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[4] For more, *see* ANAB, ANSI National Accreditation Board, https://anab.ansi.org/.

[5] For more, *see* A2LA, https://a2la.org/accreditation/forensics/. Another accrediting body, the American Board of Forensic Toxicology, previously accredited toxicology labs. As of 2022, the ABFT no longer provides accreditation or reaccreditation; its standards may continue be used by ANAB as voluntary supplements to ISO/IEC 17025 until 2027. *See* American Board of Forensic Toxicology, *Laboratory Accreditation*, https://www.abft.org/laboratory-accreditation/.

[6] Sean Doyle. *QHFSS DNA Laboratory – ISO/IEC 17025 Conformance and Accreditation*, Forensic Science International: Synergy (Vo 8, 2024, 100449) https://www.sciencedirect.com/science/article/pii/S2589871X23001365#bib51 ("Most forensic science laboratories worldwide have gained accreditation to this International Standard [ISO/IEC 17025] as a means of demonstrating to forensic science stakeholders, principally criminal justice systems, the competence of the management of the laboratory, its consistent operation, the competence of its staff, the validity of its methods and the reliability of its results.") .

[7] ISO/IEC 17025:2017, https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html (hereinafter, ISO/IEC 17025).

[8] ISO/IEC 17020:2012, https://www.iso.org/standard/52994.html (hereinafter, ISO/IEC 17020).

[9] Doyle, *supra* note 6, at 2.

shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.").

The gap between these requirements and how they can be met in practice are filled in a number of ways. In addition to assessing compliance with the overarching accreditation standard, accrediting bodies also have their own additional requirements that must be met to maintain accreditation.[10] The FBI Quality Assurance Standards (QAS) discussed above also provide requirements specific to DNA that at least those labs that want to participate in NDIS must follow.[11] As discussed below, however, these requirements, like IEC/ISO 17025 and 17020, are typically relatively high level and do not dictate many aspects of laboratory policy or procedure. Laboratories then have a choice. They can (and often do) simply determine for themselves discretionary policies and procedures to meet ISO/IEC 17025 or 17020, which results in a wide array of practices and quality across laboratories, or they can implement voluntary consensus

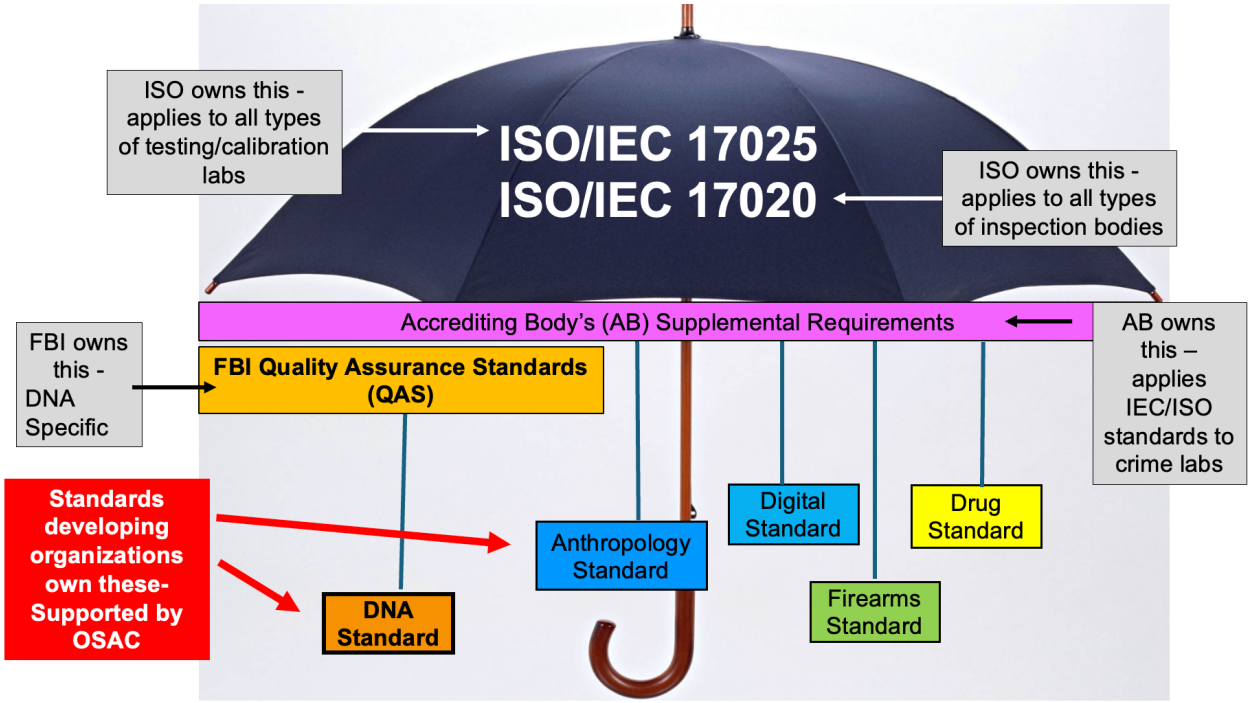
[10] ANAB maintains additional requirements with "applicable requirements from International Laboratory Accreditation Cooperation (ILAC) policies and specific accreditation requirements for forensic laboratories" for both forensic testing/calibration and inspection. *See* ANAB, *Accreditation Requirements for Forensic Testing and Calibration,* AR 3125 at § 1.1 (2023), https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=12371; *ANAB, Accreditation Requirements for Forensic Inspection,* AR 3120 at § 1.1 (2023), https://anab.qualtraxcloud.com/Showdocument.aspx?ID=14476.

A2LA also has additional accreditation requirements, which among other requirements, incorporate some of ILAC's relevant policies. *See* A2LA, *R221 – Specific Requirements – Forensic Examination Accreditation Program: Testing and Calibration*, https://a2la.qualtraxcloud.com/ShowDocument.aspx?ID=5676; *R318 - Specific Requirements - Forensic Examination Accreditation Program-Inspection*, https://a2la.qualtraxcloud.com/ShowDocument.aspx?ID=5675.

[11] Use of the QAS can, as described below in the section on voluntary standards, support the requirements for accreditation to ISO/IEC 17025 in the first instance, but separate audits for the QAS are also required by law every two years for NDIS access. 34 USCA § 12592(b).

standards, like those produced by standards developing organizations (SDOs) and supported by the Organization of Scientific Area Committees (OSAC) for Forensic Science. These additional voluntary standards, discussed in more detail below, not only help provide specificity to ISO/IEC 17025 and ISO/IEC 17020's broad requirements but can help achieve a more consistent (and ideally more scientifically sound) set of practices from laboratory to laboratory.

The relationship of these various standards and requirements can be visualized as below:



Although the voluntary standards from standards developing organizations sit below the overarching requirements of ISO/IEC 17025/17020, they are not superfluous. Take for example a laboratory accredited by ANAB to ISO/IEC 17025 which conducts DNA purification and isolation and is trying to fulfill the training requirements necessary for its accreditation. ISO/IEC 17025 is extremely broad on this point, requiring only that the laboratory have a procedure for which it maintains records: "The laboratory shall have procedure(s) and retain records for: . . .

training of personnel."[12] The laboratory must look next to any supplemental requirements set by its accrediting body, ANAB, which says that "[t]he training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include:

> a) the knowledge, skills, and abilities needed to perform work;
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> b) general knowledge of forensic science;
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> c) the application of ethical practices in forensic science;
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> d) criminal law, civil law, and testimony;
>
> e) provisions for retraining;
>
> f) provisions for maintenance of skills and expertise:
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> g) criteria for acceptable performance.[13]

This gives somewhat more detail on what must be included in the laboratory's training plan, but it is not discipline specific and does not dictate specific training topics beyond those broad areas relevant to all forensic science.

Next, assuming the laboratory follows the FBI QAS, it must look there to find any relevant training requirements. The *QAS for Forensic DNA Testing Laboratories* is somewhat more specific; for training, it requires, among other things, that:

> The laboratory shall have a training program documented in a training manual for qualifying analysts and technicians. The training program shall:
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> > 6.1.1 Address all DNA analytical, interpretation, and/or statistical procedures used in the laboratory.

[12] ISO/IEC 17025, *supra* note 7 at § 6.2.5.

[13] ANAB, *Accreditation Requirements for Forensic Testing and Calibration (2023)*, AR 3125, § 6.2.2.2.

> 6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in casework.
>
> 6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis.
>
> 6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review.
>
> 6.1.4 Include an assessment of oral communication skills and/or a mock court exercise.
>
> 6.1.5 Include requirements for competency testing.[14]

As this standard is specific to DNA analysis, it is less general than the ISO/IEC standards and ANAB requirements and to that extent contains somewhat more detail about what a training program should include. However, it does not describe specific requirements in granular detail, and a laboratory looking to create a training program for DNA purification and isolation would be left to its own devices to determine relevant topics for training— which results in different laboratories training to different topics.

This is where voluntary standards can come to the fore. These standards provide more detailed, actionable guidance to laboratories, and in so doing, promotes consistency and reliability in forensics. The DNA laboratory in this example could look to ANSI/ASB Standard 023, *Training in Forensic DNA Isolation and Purification Methods*, a standard on the OSAC Registry, which requires training in

> a) Composition of DNA within cells…
>
> b) Impact of exposure to heat, humidity, mechanical breakage, and chemicals on DNA stability to include the mechanisms of DNA degradation…
>
> c) Cell lysis and separation of DNA from other materials…

[14] Standard 6.1, *Quality Assurance Standards for Forensic DNA Testing Laboratories*, (effective July 1, 2020), https://www.swgdam.org/_files/ugd/4344b0_d73afdd0007c4ed6a0e7e2ffbd6c4eb8.pdf.

d) Methods for DNA isolation and purification used in the laboratory. . .

e) Methods based on sample type used in the laboratory. . .

f) DNA Yield . . .

g) PCR inhibitors . . .

h) Contamination . . .

1) Quality control in the DNA isolation and purification process to include, reagent blank control(s) and any other extraction controls . . .

j) Storage, preservation, and retention of extracted DNA according to laboratory policy . . .

k) Troubleshooting. . .[15]

Each of these topics is further broken down into subtopics that also must be trained; the standard also includes requirements for practical training and competency.[16] (The full requirements can be found in Annex A, along with a table comparing the training standards.).

Of all the relevant requirements that apply to the laboratory in this example, only this standard gives direct and granular guidance about what a training program in DNA purification and isolation must look like. Without adoption of a standard such as this one, ten laboratories, all accredited to ISO/IEC 17025 by the same accrediting body and all subject to the FBI QAS, might have analysts trained to do DNA purification and isolation under ten very disparate programs. If, by contrast, all ten laboratories have voluntarily implemented ANSI/ASB 023, *Training in Forensic DNA Isolation and Purification Methods*, they will at a minimum have been trained on the same specific topics, and stakeholders who receive such evidence can have some assurance about what it means to have been "trained" in DNA isolation and purification.

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[15] ANSI/ASB Standard 022, *Standard for Training in Forensic DNA Isolation and Purification Methods* (1st Ed. 2020), https://www.aafs.org/sites/default/files/media/documents/022_Std_e1.pdf.

[16] *Id.*

Voluntary Standards and Accreditation

In some circumstances, these standards, although voluntary, *can* be assessed in an accreditation audit, which involves both a review to see if a required policy or program exists, and, if so, whether it has been followed. As an initial matter, typically only those documents that set forth requirements, as opposed to those that make recommendations, can be assessed as a basis for accreditation. ANAB, for example, provides explicitly that "[a]dditional *requirement* documents that a CAB has incorporated into its management system or is subject to, either voluntarily, by law or by a regulatory body, will also be assessed" as part of accreditation.[17] In the example above, a laboratory that had incorporated ANSI/ASB Standard 023, *Standard for Training in Forensic DNA Isolation and Purification Methods*, into its "management system documents (e.g., policies, procedures, technical methods, training manuals, quality manual"[18]) as part of its accreditation requirements under ISO/IEC 17025 and then failed to provide training on cell lysis and separation of DNA from other materials could, if uncorrected, find its accreditation in jeopardy. This is a requirement of the standard, and the laboratory's choice to voluntarily incorporate it into their management system puts it under the purview of the accrediting body.

For another example, the Houston Forensic Science Center's Toxicology Section's *Analytical Manual- Standard Operating Procedures* (hereafter, Houston Toxicology Manual) requires that "[a]nalytical methods *shall* be validated to meet the requirements of ANSI/ASB

[17] ANAB, *Accreditation Manual for Forensic Laboratories, Forensic Inspection Bodies, and Property And Evidence Control Units*, MA 3033 (3/12/2024) at § 1.2, https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=7183 (emphasis added) (hereinafter, ANAB Accreditation Manual); *see also Manual and Style Guide for ASB Standards, Guidelines, Best Practice Recommendations, and Technical Reports,* § 1.1.2 (3d Ed. 2022) (hereinafter, ASB Manual) ("The requirements in a Standard are expressed as imperative sentences or stated in 'shall' language and can be assessed by one or more forms of conformity assessment procedures.").

[18] ANAB Accreditation Manual at § 3.5.

Standard 036, *Standard* Practices for Method Validation in Forensic Toxicology." (emphases added). Because the Houston Forensic Science Center has implemented this document as a requirement, the failure to validate analytical methods to its specifications plainly could lead to the laboratory being found in non-conformance and, if uncorrected, eventually jeopardize the laboratory's toxicology accreditation.[19]

The intersection of accreditation and recommendations documents is somewhat more complicated than those dealing with requirements. Recommendations, whether they are found embedded in requirements documents or stand alone, cannot serve themselves as the basis for accreditation, [20] so although recommendations are important for helping laboratories achieve consistent, reliable, and valid scientific practices and results, accreditation is not typically going to be the tool to enforce it.

Recommendations can, however, be incorporated into a laboratory's quality management system as a requirement. For example, the Houston Toxicology Manual provides "requirements" which set out the "acceptable extent and contents of expert opinions and testimony provided by a forensic analyst/toxicologist" in its lab based on ANSI/ASB Best Practice Recommendation 037, First Edition 2019: *Guidelines for Opinions and Testimony in Forensic Toxicology*."[21] Although this ANSI/ASB Best Practice Recommendation could not, on its own, serve as the basis for

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[19] Houston Forensic Science Center, *Toxicology Section, Analytical Manual- Standard Operating Procedures* (Version 4.0), § 7.3.2, https://records.hfscdiscovery.org/Published/Analytical%20Manual_v4.0_Eff%202024-03-04%20to%20Present.pdf#search=ansi%2Fasb

[20] *E.g.,* ASB Manual, *supra* note 17, § 1.2.2 ("A Guideline is written in 'should' language and is informative rather than directive. A Guideline in and of itself is not appropriate for conformity assessment.").

[21] *Id.* at § 32.1.1.

conformity assessment, the laboratory's choice to raise these recommendations to a requirement for its practitioners allows them to be considered in an accreditation audit.[22]

Ultimately, lawyers need to know what accreditation means— and doesn't. Accreditation alone does not and cannot guarantee good science. Given both the unregulated environment for forensic science in the United States and the broad dictates of ISO/IEC 17025 and 17020, more detailed voluntary consensus standards are critical to supporting the implementation of valid and reliable science that is consistent within and across laboratories. Any lawyer handling forensic evidence must do so with both an understanding of the relationship between accreditation and voluntary standards generally and, even more importantly, about whether and which voluntary standards are at issue in a particular case.

[22] Recommendations "can be used as part of an accreditation plan in conjunction with the standards or operation procedures included in the conformity assessment process,"[22], which in this case is ISO/IEC 17025.

Appendix A

Training Requirement Example

ISO/IEC 17025	The laboratory shall have procedure(s) and retain records for: . . . training of personnel.
ANAB, *Accreditation Requirements* F*or Forensic Testing And Calibration (2023)*, AR 3125, S. 6.2.2.2.	The training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include: a) the knowledge, skills, and abilities needed to perform work; b) general knowledge of forensic science; c) the application of ethical practices in forensic science; d) criminal law, civil law, and testimony; e) provisions for retraining; f) provisions for maintenance of skills and expertise: g) criteria for acceptable performance.
Quality Assurance Standards For Forensic DNA Testing Laboratories, Standard 6.1 (Effective July 1, 2020).	The laboratory shall have a training program documented in a training manual for qualifying analysts and technicians. The training program shall: 6.1.1 Address all DNA analytical, interpretation, and/or statistical procedures used in the laboratory. 6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in casework. 6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis. 6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review. 6.1.4 Include an assessment of oral communication skills and/or a mock court exercise. 6.1.5 Include requirements for competency testing.
ANSI/ASB Standard 023, *Standard for Training in*	At a minimum, the knowledge-based portion of the training program shall require review of the following:

Forensic DNA Isolation and Purification Methods (1st Ed. 2020).	a) Composition of DNA within cells, including: 1) cell and nuclear membrane structure; 2) structure of DNA and histone packaging of DNA into nucleosomes; 3) nucleases and other enzymes that can act on DNA in the cell. b) Impact of exposure to heat, humidity, mechanical breakage, and chemicals on DNA stability to include the mechanisms of DNA degradation. c) Cell lysis and separation of DNA from other materials: 1) function of chemicals, enzymes, and other reagents used in lysis and separation; 2) impact of pH, salt concentration, heat, molecular weight, and solubility; 3) use of DNA-preservation treated cards; 4) limitations of the technology. d) Methods for DNA isolation and purification used in the laboratory: 1) organic extraction (phenol:chloroform); 2) Chelex®b extraction; 3) solid phase-based purification; 4) differential lysis and extraction; 5) application of automation and robotic platforms; 6) other methods not described; 7) limitations of the above methodologies. e) Methods based on sample type used in the laboratory: 1) selection of suitable isolation method for sample type and condition and DNA test to be performed;

	2) pre-extraction cell separation (e.g., cell sorting, laser capture microdissection); 3) pre-extraction processing (e.g., soak, grinding, demineralization); 4) post-extraction processing (e.g., filtration, concentration, preservation conditions); 5) direct amplification without extraction; 6) other methods not described; 7) limitations of the above methodologies. f) DNA Yield: 1) sources of DNA loss during isolation and purification; 2) mechanisms to reduce DNA loss. g) PCR inhibitors: 1) sources (environmental, chemical); 2) mechanisms of interference with amplification; 3) methods to avoid or reduce effects on amplification. h) Contamination: 1) sources (environmental, procedural); 2) sample handling strategies and preventative methods; 3) decontamination procedures; 4) root cause analysis, corrective action when contamination occurs. i) Quality control in the DNA isolation and purification process to include, reagent blank control(s) and any other extraction controls.

	j) Storage, preservation, and retention of extracted DNA according to laboratory policy. k) Troubleshooting, including: a) forensic DNA isolation and purification errors; b) general equipment failure.