History and Project Scope

In 1997, New York became the first state to mandate accreditation for forensic laboratories funded by a unit of state or local government, that perform forensic testing on evidence in a criminal investigation or proceeding, or for purposes of identification.[1] The discipline of latent prints is not subject to the provisions of the article. New York has always required laboratories to be accredited by two entities: New York State, and either the American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB)[2] or the American Board of Forensic Toxicology (ABFT).[3] On April 22, 2016, ASCLD-LAB merged with the ANSI-ASQ National Accreditation Board (ANAB) and ANAB retained a forensic laboratory accreditation program for their laboratories. Currently, ABFT accreditation is limited to those laboratories that perform only toxicology testing. New York State accreditation is awarded by a majority vote of the New York State Commission on Forensic Science (CFS) after review of the accreditation documentation provided by either ANAB-ASCLD/LAB or ABFT. DNA laboratories also require a majority vote of the DNA Subcommittee before reaching the CFS.

In December 2014, the CFS requested a comprehensive review of the accreditation programs that utilize the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) 17025 standard (General Requirements for the competence of testing and calibration laboratories) and the program run by ABFT. Since only three ISO/IEC 17025 accreditation programs were in significant use within the United States for forensic laboratories, the CFS limited the ISO/IEC 17025 accreditation providers to: the American Association for Laboratory Accreditation (A2LA)[4], the ANSI-ASQ National Accreditation Board (ANAB)[5] and ASCLD/LAB (now ANAB) for this initial comparison.

As the administrative arm of the CFS, the Office of Forensic Services (OFS) obtained and reviewed this information. OFS examined each of the accreditation programs, as well as their supplemental and other program requirements. Information was collected from multiple sources, including from other ISO/IEC guides and standards. Documents were provided by the accreditation programs and information was gathered from the accreditation providers' websites and through communications (phone calls and e-mail exchanges) with representatives from the programs.

To facilitate the CFS review, a comparison table was created based on the ISO/IEC 17025 standard (hereinafter 17025). For A2LA, ANAB, and ASCLD/LAB which

[1] Article 49-B of the Executive Law (section 995, *et. seq*.), and majority vote of the Commission on June 11, 1996, required laboratories that met the definition in article 49-B to be accredited prior to July 1, 1997.
[2] www.anab.org/forensic-accreditation (Adopted by the Commission October 5, 1995)
[3] www.abft.org (Adopted by the Commission June 11, 1996); *see*, 9 NYCRR Part 6190.3(a)
[4] www.a2la.org
[5] www.anab.org

already conformed to 17025, any additional requirements (above the base requirements of 17025) were listed under the appropriate 17025 standard to which they applied. Since ABFT is not based on 17025, components of the ABFT program are similar, but not exactly the same, and were placed near the closely related 17025 standard and shaded in yellow.

In addition to the comparison table, an executive summary was provided to CFS members that provided an overview of accreditation. It described how the major components of a forensic accreditation program translate into increased quality and discussed other factors that influence the quality of forensic accreditation providers. Both documents were discussed at the April 15, 2015 CFS meeting, and the CFS requested that OFS continue to evaluate these accreditation programs. The merger of ANAB with ASCLD-LAB resulted in additional accreditation standards which became effective June 1, 2017. A new comparison table was prepared and accompanies this Executive Summary.

Overview of Accreditation

Accreditation is a process where an entity that performs a certain task seeks approval from an outside body known as an accreditation body (AB). The AB sets requirements with which the entity must comply and the AB has mechanisms in place to monitor compliance. More robust systems of accreditation undergo processes where they become recognized as ABs by other external organizations that cover greater geographical regions (regional cooperations) than the AB. Ultimately, the ABs generally seek recognition internationally.

Global trade has provided the most significant incentive to seek out accreditations recognized regionally and internationally. As supply chains become longer and longer, manufacturers are looking for mechanisms to ensure the quality of their products which are now made up from components from all over the world. They also seek accreditation to demonstrate to their customers that they meet an established level of quality to remain competitive.

While there is no trade advantage to accrediting forensic science laboratories, the international accreditations have become associated with best practices to ensure that results and reporting are comparable. Forensic laboratories around the world have started to migrate toward them from freestanding programs that were not externally recognized. These freestanding ABs were often discipline-specific and covered areas where there were no international standards.

The two external accreditation programs currently utilized by New York State began in this way. ABFT was formed in 1975 as an organization to certify forensic toxicologists who interpreted drug and alcohol test results. In the 1990s ABFT, in conjunction with the Society for Forensic Toxicology and the American Academy of

Forensic Sciences Toxicology section, developed an accreditation program for forensic toxicology laboratories performing postmortem toxicology and/or human performance testing. ABFT accredited its first laboratory in 1997.[6] On October 21, 2016, ANAB entered into an alliance with ABFT where ANAB would administer the ABFT accreditation program using the ABFT standards and assessors. ASCLD/LAB began as a committee on laboratory evaluation and standards of the American Society of Crime Laboratory Directors (ASCLD). After changing the Committee's name to the ASCLD Committee on Laboratory Accreditation, the first forensic accreditation program was approved by the ASCLD membership in 1980. In 1981, ASCLD/LAB was formed and began accrediting labs in 1982 under what has become known as their Legacy Program.[7]

Up until the late 1990s, there were no specific ISO or ISO/IEC standards for testing laboratories applicable to forensic laboratories. In 1978, ISO/IEC had developed Guide 25 which was a precursor to the 17025 standard. Some ABs used Guide 25 to develop programs for laboratory accreditation. A "guide" is the first step in the development of a "standard." While not as well developed at a standard, guides are necessary to get feedback from the relevant communities. Guide 25 was eventually replaced by 17025. In 1998, ISO/IEC 17020 (conformity assessment – requirements for the operation of various types of bodies performing inspection) was released, and was used by some as a standard for accrediting forensic disciplines such as crime scene since the discipline of crime scene involved inspection and collection. In 1999, ISO/IEC 17025 was released and offered the first opportunity for discipline specific programs that involve testing (e.g., forensic science disciplines) to conform to an international standard.

The National Forensic Science Technology Center (NFSTC) had a program that became FQS and is now a part of ANAB. FQS accredited the first public forensic lab in the United States using ISO/IEC 17025 in 2001.[8] In 2004, ASCLD/LAB began the ASCLD/LAB International Program, which was a combination of ISO/IEC 17025 and essential elements of the ASCLD/LAB Legacy Program. A2LA established forensic specific supplemental requirements for ISO/IEC 17025 in 2010; however, they previously accredited laboratories that perform forensic testing in other fields (i.e., chemical or biological testing). In April 2016, ANAB merged with ASCLD/LAB and released new accreditation requirements that became effective in June 2017.

Currently, there are ISO standards, guides and accreditation programs that are available to address important features of forensic operations such as reference material producers (ISO/CD 17034), general conformity requirements for proficiency providers (ISO/IEC 17043), and statistical methods for proficiency testing by inter-

[6] Email communication with Graham Jones, March 25, 2015 @ 7:45 pm
[7] Email communication with John Neuner, March 25, 2015 @ 5:04 pm
[8] Fitzpatrick, F., Ely, T., "Ensuring the Quality of Forensic Service Providers through Accreditation: The Illinois State Police Crime Scene Services Command Experience" The Police Chief, November 2007, vol. 74, no. 11.

laboratory comparisons (ISO/IEC 13528). These additional ISO standards add value to the ISO ABs which use these requirements to prove the competence of service providers.

Currently, A2LA and ANAB (which operates the ASCLD/LAB accreditation program) both conform to the ISO/IEC 17025 standard, have been recognized by regional cooperations, and are recognized internationally.

Major Components of a Forensic Accreditation Program that Translate into Enhanced Quality

Even though two of the three accreditation programs being evaluated follow the ISO/IEC 17025 standard, they differ from each other in their supplemental and program requirements. There are also significant differences between the current ISO ABs and ABFT. To aid Commission members as they evaluate the information that is being presented, below are accreditation concepts that directly relate to increased quality.

1) An Effective Management/Quality Management System

The management system constitutes an essential framework of a laboratory and includes both technical and administrative aspects. Quality Assurance Managers need to directly report to Laboratory Directors since both are ultimately responsible for ensuring the quality of the testing that is carried out in the laboratory. Beyond the organizational structure of the lab, an effective management system includes clearly delineated responsibilities, procedures, instructions, and the resources necessary to ensure quality. It also includes effective communication of laboratory management with, staff, customers and stakeholders. The laboratory also should ensure that any work that is subcontracted to another laboratory be sent to an equally competent (i.e., accredited) laboratory.

2) Document Control

Documents in use in the laboratory will be appropriately controlled to ensure that staff is aware of all currently approved procedures and that only authorized current versions of documents will be utilized. These documents need to be periodically reviewed for content and continued appropriateness.

3) Well-Trained and Competent Examiners

For a laboratory to perform quality work, examiners need to be sufficiently trained to ensure competence in the techniques that they perform. This includes appropriate education, training, experience and exposure to ethical issues that examiners may encounter in the laboratory. Training programs should be designed to ensure that examiners understand the science behind the testing they perform and that they can successfully convey the results of their analysis, both through written report and oral expression.

4) A Program of Proficiency Testing

Examiner proficiency should be monitored through a program of testing at periodic intervals through providers that meet recognized requirements (whenever possible). The frequency of such proficiency testing should be reasonable, but not burdensome.

5) Use of Appropriate Reference Standards and Material

The laboratory will take all appropriate steps to ensure that reference materials and standards are traceable to national and international standards/reference materials, whenever available. This is critical since the use of reference standards and materials allows for inter-laboratory comparison and reliability.

6) Instruments and Methods that Produce Consistent and Reliable Results

The instrumentation and methods used should be performance checked and validated to ensure that they are operating correctly, are fit for the intended use and produce consistent and reliable results. Appropriate controls must be included in all procedures.

7) Clear and Unambiguous Reports that Include Measurement Uncertainty, when Applicable

Policies should be in place to ensure clear and unambiguous results that have appropriate qualifying statements, as appropriate. Results and opinions should be clearly identified. There should be a sound policy for determining traceability and uncertainty of measurement. There also needs to be a policy for reporting uncertainty for critical measurements.

8) Case and Testimony Review

Completed case files should undergo administrative review prior to release and a percentage of completed case files should be subject to technical review. There should be a procedure where testimony is monitored to ensure that it is conveyed clearly, correctly and only within the confines of the expertise of the examiner, and that any associations get properly qualified.

9) A Continued System of Improvement through Internal Audits, Assessments, Surveillance Visits, Preventive Actions, and Corrective Action Procedures Involving Root Cause Analysis

For a laboratory to ensure quality, the laboratory must continue to improve its operations. This will initially occur through internal audits where laboratories continue to

evaluate themselves against their own management system, and against the standards and program requirements of their AB. It also will occur through external assessments/surveillance visits. Often this process of improvement will occur when non-conforming events are identified. It is essential that a timely root cause analysis be performed and the appropriate corrective and preventive actions be taken to avoid recurrence of non-conforming events.

10) Specific Policies for Disclosure to the Accrediting Body

There must be specific policies indicating what events and situations must be reported to the ABs, accompanied by clear time limits for reporting.

Other Factors that Influence the Quality of a Forensic Accreditation Program

While the ISO process establishes a base-line commonality between the two 17025 providers, there are differences in the programs that manifest themselves through the supplemental and additional program requirements. There also are subtle differences in how the information is conveyed. ABs with supplemental requirements that are clearly spelled out are more likely to be followed by a laboratory and evaluated during internal audits and external assessments, than those that direct the reader to other documents, or that are not clear in their content. The 17025 process allows for the ABs to either directly state, or have their requirements referred to another document, but clearly delineated supplemental and additional program requirements increase the chance of laboratory compliance and detection of non-compliance.

Another area where there can be differences, even among the ISO ABs, is in resources available to the ABs to carry out their mission. This is apparent in two main areas: the application/onsite assessment processes and the review of self-reported non-conformance events.

During on-site assessment or surveillance visits, the training and experience of the assessors (lead and other technical) is directly related to their ability to detect non-conformances. The number of assessors and the length of the assessment also contribute greatly towards increased chances of detecting non-conformances during assessments/surveillances.

The experience of an AB's staff is very important because staff make the final determinations regarding identified non-conformances and the appropriateness of laboratory corrective actions.

In addition to the tangible considerations that appear in the comparison chart, these intangible concepts need to be fully considered when comparing the various ABs. OFS obtained additional information from the three ABs regarding these concepts. A summary table appears in Appendix A of this executive summary and the AB's full responses appear in Appendix B.

Summary

At the request of the CFS, OFS collected a significant amount of information regarding the accreditation programs offered by A2LA, ABFT, and ANAB. A comprehensive table compares each of the ABs against ISO/IEC 17025, both in standards/program requirements and supplemental requirements. This chart does not consider other policy documents or requirements of the ABs which, in some instances, can be substantial. This Executive Summary is intended to provide historical/contextual information to assist Commission members in evaluating the data.