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A quality assurance system for DNA testing

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ABSTRACT

Quality assurance is the combination of systematic actions which, when instituted properly, ensure quality. Quality control is the day-to-day implementation of the quality system. A complete quality system must address many issues, ranging from personnel requirements to facility management. This communication covers the Quality assurance process as it relates to the United States, and the standards set forth by the FBI and maintained by ASCLD/LAB accreditation.

Keywords: DNA, Quality Assurance, Quality Control, DAB, TWGDAM, SWGDAM, NRC I, NRC II, Proficiency Test, Certification, ASCLD/LAB, NFSTC, Accreditation, Audit

Introduction

In 1994, The United States Congress passed the DNA Identification Act which called for the formation of a DNA Advisory Board (DAB) [1]. Nominations for membership were submitted by the National Academy of Sciences (NAS), and other organizations, to the FBI for appointment to the DAB. The DAB was composed of distinguished professionals from the public and private sectors, each with individual expertise in a range of technical, judicial, and ethical areas. The DAB had an initial meeting in 1995 and setout to recommend quality assurance standards for DNA testing laboratories. The DAB combined critical elements of the TWGDAM (Technical Working Group on DNA Analysis Methods) guidelines with emerging contemporary issues. The DAB provided their recommendations to the Director of the FBI in 1997. The FBI Director subsequently issued the Quality Assurance Standards for Forensic DNA Testing Laboratories, effective October 1, 1998, with an additional formal (overlapping) set of standards for Convicted Offender DNA Testing Laboratories, effective April 1, 1999 [2].

With the National standards in place, the responsibility for maintaining and revising the standards is delegated to the Quality Assurance Working Group of SWGDAM (TWGDAM became SWGDAM - The Scientific Working Group on DNA Analysis Methods in a 1999 name change). Members of SWGDAM mirror the DAB, in that it includes distinguished professionals from both the public and private sectors. While the DAB recommended the adoption of National Standards to the FBI Director who issued the standards in a comprehensive document, the Audit Document, that is used to evaluate a laboratory's adherence to these standards, the National Standards are maintained and revised by the QA Working Group of SWGDAM.

NRC I

Prior to a formal set of QA standards recommended by the DAB, the National Academy of Sciences commissioned the National Research Council (NRC) to evaluate the reliability of DNA testing in the forensic arena. It was this first NRC Committee on DNA Technology in Forensic Science, chaired by Victor McKusick, that put forth the initial quality considerations in 1992. It was recommended that each forensic science laboratory engaged in DNA testing should have a formal, detailed, quality assurance and quality control program both at the individual and laboratory wide levels. The NRC suggested that QA programs within individual labo-

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ratories are insufficient to ensure adherence to higher standards, and that external mechanisms are needed within the forensic community to monitor a laboratory's practices [3,4].

NRC II

The second NRC report, NRC II, was the result of a second commission by the National Academy of Sciences. It was commissioned to address the evolving technology in forensic DNA analysis. The Evaluation of Forensic DNA Evidence published in 1996 by NRC II was the product of this commission, with Dr. James Crow chairing this committee. Much of NRC II addressed the use of statistics in forensic DNA typing, and refuted the use, previously suggested in NRC I, of the "ceiling principle" [3]. Any accurate estimation of laboratory "error rates" was also deemed irrelevant and highly discouraged [4,5]. With regard to quality assurance practices, NRC II recommended that laboratories adhere to high quality standards and should seek accreditation (recommendation 3.1) [5]. Additionally, proficiency tests should be administered and participated in regularly (recommendation 3.2) [5], and whenever feasible forensic samples should be divided into two or more parts at the earliest practical stage allowing for any unused portions of sample to be preserved for possible future testing and/or to permit additional testing (recommendation 3.3) [5].

Certification

Certification deals with the individual qualifications of a forensic scientist. Although certification in the United States is not legislatively mandated, there is a growing trend towards ascertaining individual certification. Currently, the American Board of Criminalistics (ABC) is actively certifying analysts working in DNA area, as well as other areas [6].

Individuals that are certified by the ABC may achieve Diplomate (D-ABC), Fellow (F-ABC), or Technical Specialist (S-ABC) status [6]. Diplomate status recognizes certification in all the general areas of the forensic sciences. Fellow status is achieved through further specialization in one of many disciplines offered. The Technical Specialist status certifies one in the technical aspects of DNA testing for a forensic laboratory (e.g., molecular biology or drug chemistry).

Accreditation

Accreditation deals directly with the ability of a laboratory to provide quality forensic science service. Currently, there are two laboratory-accrediting bodies in the United States: (a) ASCLD/LAB (American Society of Crime Laboratory Directors/Laboratory Accreditation Board); and (b) NFSTC (National Forensic Science and Technology Center). An audit precedes accreditation of the laboratory and is composed in an effort to assess if a laboratory is adhering to National Standards.

ASCLD/LAB is capable of accrediting all forensic disciplines, while NFSTC currently only accredits DNA laboratories also using the FBI National Standards. The laboratory audit performed by these organizations is an inspection used to evaluate, confirm, or verify activity that is directly related to quality as defined by the ASCLD/LAB document [4]. In order for a laboratory to be accredited it must adhere strictly to a quality assurance program and document compliance with applicable standards. ASCLD/LAB has adopted the FBI standards for accreditation within the DNA discipline.

Discussion

Quality Assurance

A quality assurance program includes the systematic actions necessary to demonstrate that a product or service meets specified requirements of quality. Quality control then is the day-to-day activities enacted to ensure quality. A complete quality system includes the organizational structure to implement and oversee the responsibilities, procedures, processes, and resources in a quality management program [4].

The FBI Director issued the Quality Assurance Standards for Forensic DNA Testing Laboratories October 1, 1998 [2]. The scope of the document defines the integrity of the testing process and competency of the laboratory. The definitions that follow define the details of the standards under examination [2]. Section 3 (Quality Assurance Program) deals directly with the quality system with standard 3.1.1 addressing the quality manual. It is this manual that defines the system and the procedures implemented by the laboratory to maintain the fundamental integrity of the process and the competency of the results. Standard 5 addresses DNA personnel requirements, as well as applicable sub-

categories, including: job descriptions (5.1.1); a documented training program (5.1.2); and continuing education (5.1.3). It is in these standards that the growing trend of individual certification will continue to increase. Standards 5.2 and 5.3 also directly address the minimum coursework, training, and experience standards for both examiner/analysts and the technical leader of a laboratory. [2]

Integral to the competency of the laboratory is the competency of the individuals working within the laboratory and performing the forensic examinations. In compliance with Standard 5, all DNA scientists must possess, at a minimum, a baccalaureate degree, either a BA or BS in a natural science, and possess six months of forensic DNA laboratory experience. A technical leader must possess a master's degree and have 3 years of forensic DNA laboratory experience in addition to the standards defined for a scientist. The core course requirements for examiner/analysts and technical leader include undergraduate or graduate course work in the following areas: biochemistry, genetics, molecular biology (molecular genetics, recombinant DNA technology. Training in statistics and/or population genetics is required of the examiner/analyst, whereas actual coursework in this area is required for the technical leader. [2]

Laboratory facilities are outlined as part of Standard 6. Access to the laboratory should be controlled and limited (6.1.1). Separate areas must exist for PCR amplification, evidence examination, DNA extractions, and/or PCR setup. [2]

Standard 7 addresses evidence control. An adequate evidence control system is essential to the maintenance of a laboratory's quality system. Evidence must be marked clearly for identification (7.1.1); a chain of custody maintained for all evidence (7.1.2); and laboratory procedures in place to minimize loss, contamination, or deleterious change to evidence items through secure areas for evidence storage (7.1.3 and 7.1.4). Whenever possible, it is recommended the laboratory retain a portion of the evidence sample or extract for possible future DNA testing in such a manner as to minimize degradation of the sample, such that as technology advances, the results can be verified or retested (7.2 and 7.2.1). [2]

All test methods in the DNA section of a laboratory must be validated prior to their use in casework (Standard 8). This validation includes both developmental validation (8.1.1) as well as internal validation (8.1.3). Methods that are not specified in the protocol, but are employed, need to be from reputable sources and appropriately validated prior to their use (8.1.4). [2]

Analytical procedures shall be approved by the laboratory management/technical leader according to Standard 9 (9.1) of the quality assurance document. Reagents must be properly identified, tested, and be of sound quality. Controls must be routinely used, such as quantitation standards, positive and negative amplification controls, reagent blanks, and allelic ladders within the PCR system (9.4.2). Standard 9.5 mandates that all DNA procedures shall be revised annually, or whenever a substantial change is made to the technology, against a NIST standard reference material (SRM). Standard 9.6 addresses laboratory guidelines for the interpretation of data. Controls must be verified, visual matches supported by a numerical match criterion, and statistics shall follow NRC II recommendations (9.6.1, 9.6.2, and 9.6.3). [2]

Equipment calibration and maintenance are the subjects of Standard 10. Instruments must be calibrated (10.2) and properly maintained (10.3). All calibration and maintenance records shall be documented and retained for future inspections. [2]

Standards 11 and 12 deal directly with the report writing and review process within DNA casework. Each laboratory should have written procedures for the process of taking case notes, and these notes should be maintained in the case file (11.1). Reports should include, although not be limited to: a case identifier, description of the evidence examined, a description of the methodology, locus, results and/or conclusions, a qualitative or quantitative interpretive statement, the date issued, disposition of the evidence, and a signature identifying the person writing the report (11.1.2). The report needs to undergo both an administrative and technical review prior to its issuance (12.1). An administrative review will include such items as (but not limited to): typing and/or grammatical errors, insuring that initials are on each page with the laboratories case identifier, and in the correct format. A technical review will be more thorough, addressing the technical procedures employed, and verifying that the results support the conclusions reached. The technical review process is essential in documenting the quality peer review process of a laboratory. [2]

Proficiency testing is the subject of Standard 13 of the quality assurance document. DNA examiners need to complete external proficiency testing every 183 days

(13.1), and records of those tests must be maintained (13.1.1). A laboratory should have a corrective action policy in the situation of an incorrect proficiency test result or poor casework performance (14.1), and documentation of that action must also be maintained, preferably in a quality manual (14.1.1). [2]

The quality assurance audit is the independent evaluation to document competency within a quality system. The DNA laboratory shall conduct audits annually (Standard 15). Audit procedures will cover all of the previously mentioned sections, as well as safety and previous audits. [2]

Conclusion

A sound quality assurance system is essential for a laboratory to consistently improve their laboratory practices. This system will help ensure, and support, the integrity of the results reported from a laboratory, and provide interested parties with information regarding the laboratory's credibility to perform the tests reported. If documentation is the cornerstone of a thorough quality system, then the quality assurance audit is the foundation upon which the system is built and repaired. It is through the implementation and documentation of a quality system that the integrity of the laboratory results are maintained, and competency proven. A laboratory that is not committed to a quality system jeopardizes not only their work product, but their integrity as well. Everyone using the laboratory services can be confident that the reported results are accurate, reliable, and reproducible with the use of a properly administered quality program. The DNA laboratory has justified its ability to accurately perform forensic DNA testing through a correctly documented and implemented quality assurance system.

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References

1. DNA Identification Act of 1994; Public Law 103-322 (United States).
2. Federal Bureau of Investigation, Quality Assurance Audit for Forensic DNA and Convicted Offender DNA Testing laboratories, Forensic Sci. Commun, 3(1), 2001. <http://www.fbi.gov/congress/congress02/forensicstd.htm> <http://www.fbi.gov/congress/congress02/datastd.htm>
3. National Research Council, DNA Technology in Forensic Science, National Academy Press, Washington, D.C., 1992.
4. Rudin, N., Inman, K., An Introduction to Forensic DNA Analysis, 2nd ed., CRC Press, Boca Raton, FL, 2002.
5. National Research Council, DNA Technology in Forensic Science, National Academy Press, Washington, D.C., 1996.
6. American Board of Criminalistics, Certification Examinations.<http://www.criminalistics.com/abc>