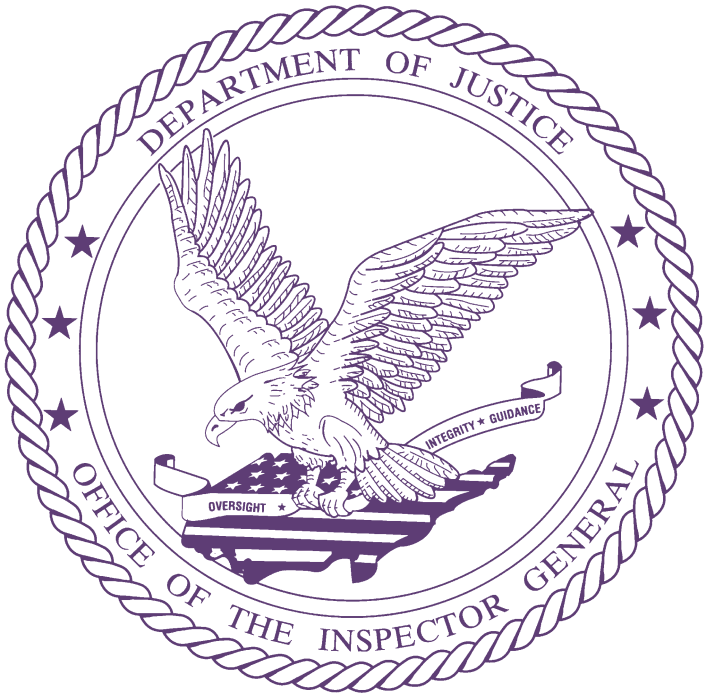
U.S. Department of Justice
Office of the Inspector General

The FBI DNA Laboratory: A Review of Protocol and Practice Vulnerabilities



Office of the Inspector General
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THE FBI DNA LABORATORY: A REVIEW OF PROTOCOL AND PRACTICE VULNERABILITIES

EXECUTIVE SUMMARY

I. BACKGROUND

Deoxyribonucleic acid, or DNA, is a molecule that contains the genetic code for living organisms. Within the last 15 years, researchers gained the ability to produce a computerized record containing a person's DNA characteristics (a DNA profile), a development with far-reaching forensic implications. Through comparison of DNA samples, investigators now reliably can conclude whether a particular suspect is or is not the source of DNA found at a crime scene. The Federal Bureau of Investigation's (FBI) Laboratory Division has played an important role in the development of DNA science to solve crimes.

From August 1988 to June 2002, Jacqueline M. Blake was employed in a DNA analysis unit of the FBI Laboratory. Starting in March 2000, she worked as a Polymerase Chain Reaction (PCR) Biologist and was responsible for performing tests on DNA from crime scenes and convicted offenders. Laboratory Examiners used her analyses to reach conclusions regarding the characteristics and sources of DNA profiles obtained from evidence items, and testified in court in reliance on the integrity of the procedures that she employed. During her tenure as a PCR Biologist, Blake performed analyses on evidence from crime scenes in slightly more than 100 cases.

An important step in the DNA testing procedures that Blake was obligated to follow is the processing of control samples that identify whether contamination has been introduced during the testing process, called negative control tests. Starting in the late stages of her training to become a PCR Biologist and for more than two years thereafter, Blake consistently failed to complete these control tests. Her omissions rendered her work scientifically invalid and unusable in court. Without proper processing of the negative controls, a Laboratory Examiner is not able to rule out the possibility that contamination, rather than the evidence under examination, is the source of the testing results. By itself, however, the failure to process the negative controls does not change the test results or lead to a particular testing outcome (e.g., creating a match between a known and unknown evidence sample). The retesting of evidence in Blake's cases to date indicates that, while she did not properly conduct the contamination testing, the DNA profiles that she generated were accurate.

In addition to omitting the negative control tests, Blake falsified her laboratory documentation to conceal the shortcut she was taking to generate

contamination-free testing results. Blake later told the Office of the Inspector General (OIG) investigators: "I knew that when I did not properly prepare the negative control samples for injection but initialed the related injection sheet anyway, I was misrepresenting that the negative control samples were properly prepared. . . ."

Blake generated more than two years' worth of testing results before her omissions were finally caught, and even then her discovery was accidental. In April 2002, a colleague of Blake was working late one evening after Blake had left the Laboratory for the day, and noticed that the testing results displayed on Blake's computer were inconsistent with the proper processing of the control samples. Further inquiry by Laboratory personnel led to the discovery that Blake had failed to complete the negative control testing in the vast majority of her cases. Blake later resigned from the Laboratory and was investigated by the Department of Justice (DOJ or Department) for her misconduct. On May 18, 2004, Blake pled guilty in the United States District Court for the District of Columbia to a misdemeanor charge of providing false statements in her laboratory reports.

Blake's actions have caused many problems. Although the FBI Laboratory has not identified a case where Blake's misconduct interfered with the content of a DNA profile, Blake's failure to process the negative controls rendered all of her DNA analyses scientifically invalid. We found that her actions caused substantial adverse effects in at least five respects. First, it required the removal of 29 DNA profiles from the national registry of DNA profiles, known as NDIS, 20 of which have yet to be restored as of March 2004.[1] Until these profiles are restored there will be an ongoing risk that an investigative agency will submit a DNA profile and not generate a match with a corresponding Blake profile because the Blake profile has been removed from NDIS. Past crimes thus may remain unsolved. Second, Blake's misconduct has delayed the delivery of reliable DNA reports to contributors of DNA evidence. Retesting in many of Blake's cases has taken upwards of two years to complete, leaving evidence contributors without information that they should have had long ago. Third, in a limited number of cases, Blake's faulty analysis is the only DNA information that is available. The previously submitted evidence was consumed in the testing process and new evidence samples cannot be obtained. Fourth, Blake's misconduct has adversely impacted the resources of the FBI and DOJ. The efforts that the FBI Laboratory and DOJ have had to expend on the corrective measures needed to address Blake's actions have been substantial. Both organizations have devoted thousands of hours of work to deal with the consequences of Blake's

[1] Of the 20 cases for which profiles have yet to be restored, no DNA remains for retesting in 2 cases, the Laboratory is awaiting the resubmission of evidence for reanalysis in 13 cases, and the Laboratory states it has completed reanalysis on an additional 4 cases. Reanalysis is being completed in one case.

failure to comply with the FBI Laboratory's DNA protocols, a cost that does not include the funding expended for contractor support to retest evidence. State and local investigators and prosecutors who were notified of Blake's misconduct and instituted corrective measures in their cases also have had to expend additional resources. And lastly, we believe that Blake's misconduct, and the Laboratory's failure to detect it for a period exceeding two years, has damaged intangibly the credibility of the FBI Laboratory. The Blake controversy has fed into a perception that the Laboratory has unresolved management and employee oversight issues.

The FBI's Office of Professional Responsibility notified the OIG approximately one month after the FBI discovered Blake's omission of the control tests. The OIG began an investigation of Blake and interviewed Laboratory staff members, analyzed documents, and met with representatives of the FBI's Office of General Counsel. The OIG investigation resulted in Blake signing an affidavit confessing to her misconduct. In addition, because the FBI Laboratory's application of its protocols did not lead to Blake's early detection, the OIG initiated this review of the FBI Laboratory's DNA protocols to assess whether the protocols were vulnerable to other abuse and instances of noncompliance.

This report describes the results of the OIG's review. Our objectives were twofold: 1) to analyze the vulnerability of the protocols in the FBI Laboratory's DNA Analysis Unit I (DNAUI) – the unit where Blake worked – to undetected inadvertent or willful noncompliance by DNAUI staff members; and 2) to assess the DNAUI's application of the protocols identified as vulnerable.[2] The report also examines and notes several areas of concern with regard to FBI management's response to Blake's misconduct.

II. METHODOLOGY OF THE OIG'S VULNERABILITY ASSESSMENT

The OIG's vulnerability assessment proceeded in two phases. In the first phase, the OIG team reviewed the DNAUI's protocols for vulnerabilities. The second phase consisted of OIG fieldwork at the DNAUI laboratory.

To facilitate our examination, particularly the review of the protocols, we recruited three scientists from the national DNA community to consult with our assessment team. OIG staff provided the scientists with the most current version of each of the written protocols governing DNAUI activities and requested that they identify any weaknesses in them that would render the Unit vulnerable to undetected wrongdoing by staff members. The scientists

[2] The DNAUI identifies and characterizes body fluids and body fluid stains recovered as evidence in crimes using traditional serological techniques and related biochemical analysis. It generates DNA profiles from the nuclei of cells recovered from such evidence.

reviewed the protocol documents and then met with the OIG assessment team to discuss the vulnerabilities identified.

With input from the scientists, OIG staff members then designed fieldwork to verify actual laboratory practices for the protocols deemed problematic, and to assess whether these practices served to mitigate any of the vulnerabilities identified. Our fieldwork consisted of interviews of more than 20 staff members within the DNAUI and the Laboratory Division and tours of the DNAUI facility, first at FBI Headquarters in Washington, D.C., and later at the new DNAUI facility in Quantico, Virginia. In addition to interviews, we also reviewed FBI documentation regarding: 1) the factors considered in the design of the new DNA facility; 2) the training curriculum and methods used within the DNAUI, along with various staff training records; and 3) the status of development of a computerized tracking system to be used by the Laboratory for evidence, samples, and other information. We also examined documents and interviewed personnel from the Laboratory, FBI OGC, and the Counterterrorism Section at the Department regarding FBI management's response to Blake's misconduct.

We compared the results of our fieldwork with the vulnerabilities detected by the scientists to determine whether any information gathered during fieldwork affected the extent and nature of the scientists' conclusions. We then discussed our results with the scientists. Generally, they did not make any changes to the areas they previously identified as vulnerabilities.

III. SUMMARY OF FINDINGS AND RECOMMENDATIONS

Our findings and recommendations focus on two general types of vulnerabilities that became apparent during our assessment: protocol vulnerabilities and practice or operational vulnerabilities.

A. Protocol Vulnerabilities

Our textual analysis of the FBI protocols that govern the DNAUI concluded that 31 out of 172 topical sections are significantly vulnerable to inadvertent or willful noncompliance by DNAUI staff members. One of four reasons typically accounted for each of the vulnerabilities: 1) the protocol lacks sufficient detail; 2) the protocol fails to inform the exercise of staff discretion; 3) the protocol fails to ensure the precision of manual note taking; and 4) the protocol is outdated. In addition, in the course of completing fieldwork that examined how staff members implement the protocols that we identified as problematic, we discovered operational vulnerabilities in the areas of team functions, training, information sharing, and evidence tracking. However, our review did not identify any protocol violations in the DNAUI regarding the failure to process negative control samples, other than the failure

of Jacqueline Blake. It also is important to note that our identification of a "vulnerability" should not be misconstrued as an invalidation of the science or techniques used by the DNAUI, or as an indication of the inadequacy of the entirety of DNAUI policies on a particular subject. Our use of the term "vulnerability" is limited to its definition as set forth in Chapter Five, Section I.C.

Approximately 20 percent of the written procedure and protocol sections we examined lacked the detail necessary for a technically qualified DNA scientist to reproduce all aspects of the analysis procedures in use in the DNAUI without the potential for variation. Protocols that lack essential detail can create a work environment that encourages use of disparate and unproven laboratory practices, can foster disregard for protocols, and can make it difficult for staff members and management to identify instances of protocol noncompliance. Accordingly, we recommend that DNAUI management ensure that the document sections we identified as vague describe completely and accurately management expectations, Unit procedures and policies, and "best practices" currently in use in the DNAUI.

Our review also identified protocols that do not describe adequately the decision criteria Laboratory staff should employ when their duties require them to exercise discretion in the testing process. Greater risk of abuse and error is present when testing procedures call upon the use of such judgment. If staff members are not equipped with sufficient guidance to exercise their discretion properly, they could prematurely halt the testing process when a probative DNA result might otherwise have been obtained. To address this deficiency, we believe that DNAUI management should add decision aids to its protocols, such as workflow diagrams and decision trees, that identify the factors that staff should consider when using judgment during the DNA testing process. These aids would help to structure decision-making and to ensure that staff members do not overlook relevant information.

We also determined that certain protocols lack comprehensive guidance on notetaking methods, even though compliance with the documentation requirements in those protocols depends heavily upon Laboratory staff implementing the methods properly. The DNAUI team structure makes it especially important that all staff members have a comprehensive and consistent understanding of how to record information as they complete their work, since Examiners draw their conclusions and testify in court based upon the work of the Serologists and PCR Biologists as reflected in the case file documentation. If staff members are allowed to delay recording observations and test results, their documentation of that information may not be fully accurate, may be unduly influenced by what they know should have occurred pursuant to the applicable protocols, and thus may compromise the accuracy of the resulting analytical conclusions. Therefore, we believe that the DNAUI should provide sufficient guidance to its employees to ensure that case

documentation meets quality assurance requirements, and it should also guarantee that the Unit's protocols provide comprehensive guidance on notetaking requirements.

Lastly, our review of protocol vulnerabilities identified several protocols that are outdated and no longer reflect current procedures in use in the DNAUI. By retaining outdated protocols, DNAUI management risks the chance that some staff members might not be aware of new requirements and rely inadvertently upon standards that have been superseded. While the staff we interviewed were aware of the new requirements, we recommend that these protocols be revised promptly.

We found that the work practices of the DNAUI's staff members served to mitigate, at least to some degree, the effects of the protocol vulnerabilities outlined above. In other words, the practices described to us by staff members indicated that they rely upon internal controls and an understanding of management expectations, not reflected in the protocols, that diminish the risks posed by the weaknesses in the written documents. However, we believe that until the DNAUI revises its protocols in accordance with the recommendations in this report, the Unit needlessly will remain subject to an increased risk of employee error and inadvertent protocol noncompliance. Because of the importance of the DNAUI's work, we believe this problem merits significant attention from the Laboratory and should be resolved promptly.

B. Practice Vulnerabilities

In terms of practice vulnerabilities, we recommend that the DNAUI should work to: 1) promote greater consistency in DNAUI team operations; 2) develop a comprehensive, written training curriculum; 3) improve management and staff communications; and 4) complete implementation of an information management system to improve efficiency and evidence tracking capabilities.

During our interviews with DNAUI staff members we received many comments that highlighted the need to ensure that the DNAUI's protocols are comprehensive and address all aspects of the Unit's operations. As the interviewees explained, variations exist in staff member work practices because the Unit's written guidance is silent on many subjects. These variations can diminish staff and management sensitivity to protocol noncompliance. Therefore, to promote greater consistency and accountability in DNAUI functions, we recommend that Laboratory management document and standardize the best practices of the Unit's teams and incorporate them in protocols.

Our review of DNAUI training revealed that the Unit lacks a comprehensive, written curriculum and that training consists largely of

individual discussions with a mentor and presentations given by various experienced staff members. Without a comprehensive, written curriculum, mentors and trainers can blur the distinction between team or individual preferences and the requirements of the protocols, leaving trainees unclear about which methods are mandatory and which are merely suggested. In our view, such an environment leaves the Unit vulnerable to inadvertent protocol noncompliance, since staff members may choose to alter their methods in ways that unwittingly contradict Unit requirements. To enhance the quality of its training program, we recommend that DNAUI management convert its "oral tradition" of training and other informal training methods into a comprehensive, written curriculum to ensure that trainees receive consistent instruction that comports with the Unit's protocols.

Further, our interviews revealed that the dissemination and solicitation of protocol-related information to and from DNAUI staff members are inconsistent and ineffective. Interview responses from staff members at all levels within the DNAUI revealed that the flow of information often is erratic and impeded by an incorrect management assumption that communications within the DNAUI, and between the DNAUI and Laboratory management, are functioning well. These types of communication weaknesses pose a risk to the efficiency and effectiveness of the Unit's operations and should be addressed. Consequently, we make several recommendations to Laboratory and DNAUI management that we believe will facilitate the exchange of protocol-related information.

During our review we also observed many DNAUI operations that could be made more efficient through use of a Laboratory Information Management System (LIMS). A LIMS is a computerized system of databases that track, organize, and link the information that must be maintained to document the receipt, handling, and disposition of each case and evidence item. The Laboratory currently lacks a LIMS, and therefore does not have the benefit of greater efficiency, increased detail and timeliness in documentation, and the reduced potential for human error or abuse. Accordingly, Laboratory management should ensure that a LIMS is implemented successfully and that its full utilization remains a top administrative priority of the Laboratory.

C. FBI Response to Blake's Misconduct

Finally, our review identified several issues of concern regarding the management response of the FBI to Blake's misconduct. These include: 1) the timeliness of the retesting of evidence and of written notifications to DNA contributors and prosecutors; 2) the sufficiency of the legal analysis provided by the FBI OGC in the months immediately following the discovery of Blake's misconduct; and 3) the scope of the Laboratory's remedial actions. We also believe that given Blake's prior work history and training experiences, the Laboratory should have paid more careful attention to her performance on her

initial PCR qualifying and proficiency tests and on the first several profiles she generated after she became a PCR Biologist.

As of February 2004, nearly two years after Blake's detection, of the 90 cases where Blake did not properly complete DNA testing, the FBI Laboratory had failed to provide direct, written notification to evidence contributors in 42 of those cases that Blake failed to process properly the evidence they submitted. Of this number, 20 contributors had received no notification at all concerning Blake's processing of their evidence.[3] We found that the FBI disregarded the views of the Department that written disclosures in these cases should have been completed much earlier. It also has taken nearly two years since the discovery of Blake's wrongdoing for the Laboratory to complete DNA retesting in her cases, with the result that some of these cases have languished at the Laboratory for more than four years. [4]

Our review further revealed that FBI OGC failed to ensure that its staff attorney assigned to the Blake matter through the fall of 2002: 1) conducted a comprehensive legal analysis of the Blake situation, and 2) fully assisted the Laboratory to provide sufficient notice to evidence contributors and prosecutors.

We also found that the Laboratory's remedial actions were too narrowly conceived in two respects. First, we believe that the Laboratory erred when it limited its review of Blake's work to the last 2 years of her 14-year career at the FBI. Second, the DNAUI should have taken steps soon after the discovery of

[3] According to the FBI, notification of these contributors can wait until evidence retesting is complete because, with two exceptions, the cases where notice has not been furnished are ones in which no report has issued from the DNAUI, a suspect has not been identified, and therefore there is no possibility that an evidence contributor would unwittingly rely upon Blake's invalid test results. We believe that this view overlooks the important interest that victims of crime have in the timely testing of evidence. All evidence contributors should have been notified directly in writing during the summer of 2002 that Blake had failed to process their evidence properly. At that juncture the evidence contributor would have had the ability to make an informed decision whether to resubmit new evidence or to seek testing services from another laboratory. Because 20 of these contributors were not informed, however, they were deprived of the opportunity to make this decision. We also believe that it is inappropriate for these contributors to learn about Blake's misconduct indirectly through public reports, rather than directly from the FBI. As explained in text below and in Chapter Six of this report, to avoid these problems in the future we recommend that, in circumstances where a protocol violation renders the Laboratory's testing results scientifically invalid, the Laboratory promptly notify the evidence contributor of the anticipated time needed to complete any necessary retesting.

[4] Of the 90 cases where Blake failed to process the negative controls, the FBI Laboratory, with the assistance of its contractors, intends to complete evidence retesting in 64 cases. In the remaining 26 cases, retesting has been deferred pending the resubmission of evidence from the original evidence contributor. As of February 2004, evidence retesting had been completed in only 27 cases.

her misconduct to reassess comprehensively its protocols for vulnerability to abuse.

In light of the management problems above, we recommend the following three corrective measures. First, the Laboratory should maintain basic case data and contact information for evidence contributors and associated prosecutors in an electronic format that can be shared conveniently as needed with other FBI components (such as FBI OPR and FBI OGC) and the Department. This step will facilitate prompt communications with evidence contributors and prosecutors in the event of future testing problems. Second, in circumstances where a protocol violation renders testing results scientifically invalid and a report from the Laboratory is not expected to issue within 180 days from the violation's discovery, the Laboratory should provide the evidence contributor with information about the violation, including whether any remedial measures have been instituted and the anticipated time to complete evidence retesting if necessary, within 90 days of the violation's detection. Lastly, the Laboratory should perform a file review of a sample of cases that Blake is known to have worked on prior to becoming a PCR Biologist to reconfirm that the procedures that were required in fact are documented as appropriate in the case files.

CHAPTER ONE
INTRODUCTION

The Federal Bureau of Investigation's (FBI) Laboratory Division has played an important role in the development of the use of deoxyribonucleic acid, or DNA, in the investigation of crimes. The DNA analysis units at the FBI Laboratory screen evidence from crime scenes for potential sources of DNA. When DNA is identified, FBI forensic scientists isolate and characterize the DNA to produce a profile that can be linked to a particular individual. The Laboratory relies upon written procedures and protocols to govern the testing techniques that are used to produce DNA profiles and to ensure that its DNA testing results are scientifically valid.[5]

The impetus for this review was the FBI's discovery that one of its DNA analysis unit staff members, Jacqueline Blake, disregarded an important step in the DNA testing process and produced dozens of DNA profiles that are scientifically invalid and unusable in court. Our review examines the vulnerability of the protocols in the unit where Blake worked – the DNA Analysis Unit I (DNAUI or Unit) – to undetected inadvertent or willful noncompliance by DNAUI staff members.[6]

Blake was employed in the DNAUI and its predecessor unit from August 1988 to June 2002. Starting in March 2000, she worked as a Polymerase Chain Reaction (PCR) Biologist and was responsible for performing tests on DNA from crime scenes and convicted offenders. Laboratory Examiners testified in court in reliance on the integrity of the procedures that she employed. During her tenure as a PCR Biologist, Blake performed analyses in slightly more than 100 cases.

Starting in the late stages of her training to become a PCR Biologist and for more than two years thereafter, Blake consistently failed to complete tests that identify whether contamination has been introduced during the DNA testing process, called negative control tests. Her failure called into question the integrity of the DNA profiles that her analyses generated, since it was not possible to confirm that her results were a true reflection of the evidence analyzed, unadulterated by contamination introduced in the Laboratory. Blake falsified her laboratory documentation to conceal the shortcut she was taking to generate contamination-free testing results.

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[5] Unless otherwise indicated, our references to the Laboratory's protocols also include its written procedures. The standards that govern DNA analysis at the FBI Laboratory are found in procedure manuals and protocol documents, as well as other sources. See discussion infra at Chapter Two, Section II and Chapter Three, Section II of this report.

[6] The DNAUI identifies and characterizes body fluids and body fluid stains recovered as evidence in crimes using traditional serological techniques and related biochemical analysis. It generates DNA profiles from the nuclei of cells recovered from such evidence.

Blake generated more than two years' worth of testing results before the FBI Laboratory realized that Blake had failed to complete the negative control testing in the vast majority of her cases. Blake later resigned from the Laboratory and currently is under criminal investigation by the Department of Justice (DOJ or Department) for her misconduct.

Blake's actions have rendered all of her DNA analyses for which she failed to complete the negative controls scientifically invalid. In addition, we found that her conduct caused substantial adverse effects in at least five respects: 1) it required the removal of 29 DNA profiles from NDIS, 20 of which have yet to be restored;[7] 2) it delayed the delivery of reliable DNA reports to contributors of DNA evidence in Blake's cases; 3) her testing consumed all the available DNA evidence in several cases, leaving only her suspect DNA profiles as a basis on which to draw conclusions; 4) the corrective action necessary to address Blake's misconduct has consumed substantial resources of the FBI Laboratory and DOJ, as well as the resources of state and local investigators and prosecutors who were notified of her misconduct and had to take corrective measures in their cases; and 5) the controversy surrounding Blake has caused some measure of credibility loss to the FBI Laboratory.

Following notification from the FBI's Office of Professional Responsibility (OPR), the OIG began an investigation of Blake and interviewed Laboratory staff members, analyzed documents, and met with representatives of the FBI's Office of General Counsel (OGC). The OIG investigation resulted in Blake signing an affidavit confessing to her misconduct. In addition, because the FBI Laboratory's application of its protocols did not lead to Blake's early detection, the OIG initiated this review of the FBI Laboratory's DNA protocols to assess whether the protocols were vulnerable to other abuse and instances of noncompliance.

This report describes the results of the OIG vulnerability assessment. Our primary objectives were twofold: 1) to analyze the vulnerability of the protocols in the DNAUI to undetected inadvertent or willful noncompliance by DNAUI staff members; and 2) to assess the DNAUI's application of the protocols identified as vulnerable. The report also notes several areas of concern with the management response of the FBI to Blake's misconduct.

The OIG's vulnerability assessment proceeded in two phases. In the first phase, the OIG team reviewed the most current version of each of the written protocols governing DNAUI activities for vulnerabilities. The second phase consisted of OIG fieldwork at the DNAUI laboratory.

To facilitate our examination, we recruited three scientists from the national DNA community to consult with our assessment team. The scientists

[7] DNA is not available for retesting for two of these profiles.

were responsible for reviewing the DNAUI protocols and identifying any weaknesses in them that would render the Unit vulnerable to undetected wrongdoing by staff members. The scientists also assisted OIG staff members in designing fieldwork to verify actual laboratory practices for the protocols deemed problematic, and in assessing whether these practices served to mitigate any of the vulnerabilities identified.

The fieldwork conducted by OIG staff consisted of interviews of more than 20 staff members within the DNAUI and the Laboratory Division and tours of the DNAUI facility, first at FBI Headquarters in Washington, D.C., and later at the new DNAUI facility in Quantico, Virginia. In addition to interviews, we also reviewed FBI documentation regarding: 1) the factors considered in the design of the new DNA facility; 2) the training curriculum and methods used within the DNAUI, along with various staff training records; and 3) the status of development of a computerized tracking system for evidence, samples, and other information. We then analyzed the DNAUI staff practices described during this fieldwork to identify whether vulnerabilities existed in staff practices, in addition to the protocol vulnerabilities already identified. Finally, we examined documents and interviewed personnel from the Laboratory, FBI OGC, and the Counterterrorism Section at the Department regarding the management response to Blake's misconduct.[8]

The report is divided into six chapters. Following this Chapter, we provide an overview in Chapter Two of the DNA testing process and the national standards that govern it. In Chapter Three we describe the FBI Laboratory, including operations in the DNAUI, and the FBI's protocols for DNA analysis. Chapter Four details Blake's misconduct and the FBI's response to it. In Chapter Five we describe the protocols and practices that we believe are vulnerable to abuse, and lastly, in Chapter Six we provide recommendations to enhance protocol compliance in the DNAUI.

[8] A more detailed explanation of our assessment methodology is provided in Chapter Five, Section I of this report.

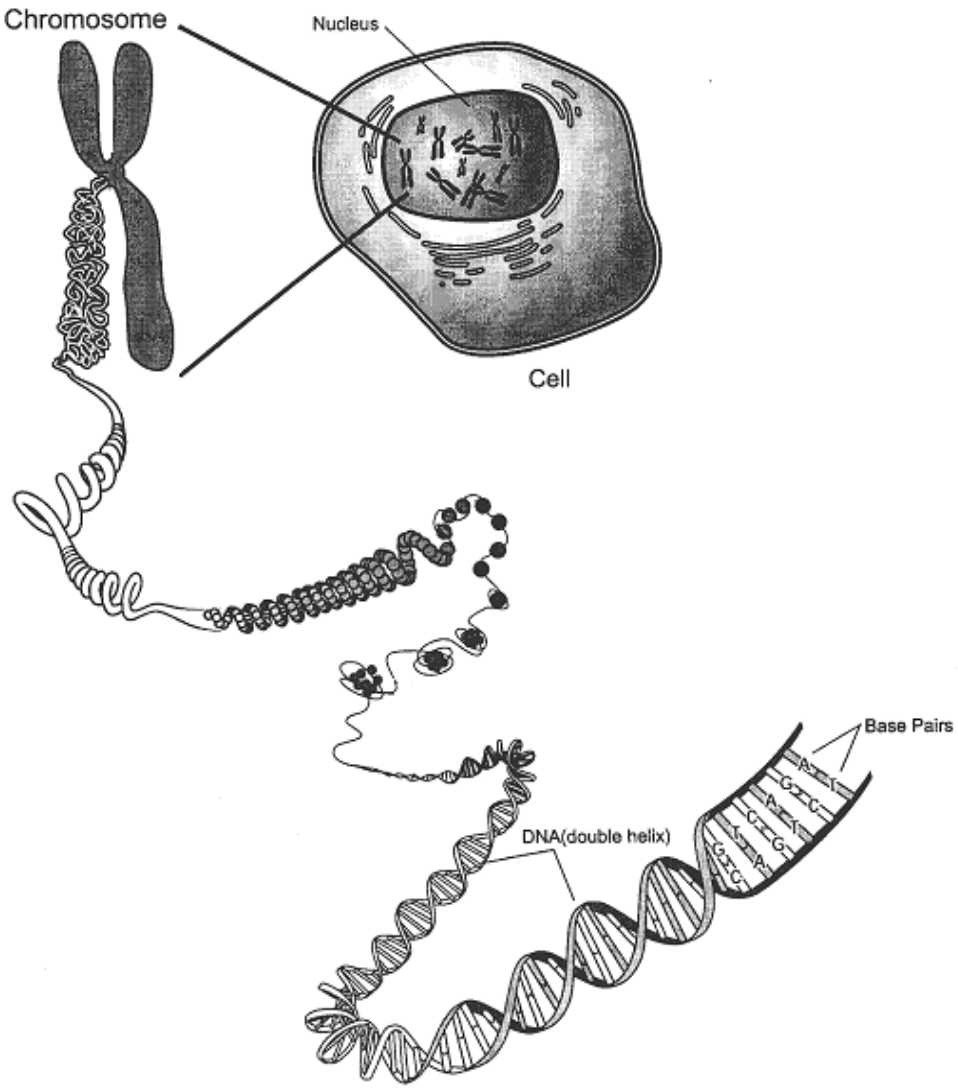
CHAPTER TWO
THE ANALYSIS OF DNA

In order to understand the nature of Blake's misconduct and the deficiencies this review identified in the FBI Laboratory's DNA protocols and practices, we first describe in this Chapter the basic characteristics of DNA and the work of forensic DNA scientists. We describe below the physical structure of DNA, testing methods, and the standards that govern DNA analysis.

I. GENERAL PRINCIPLES OF DNA ANALYSIS

A. The Structure of DNA

All living things are composed of cells, which typically have a nucleus that regulates metabolism, growth and/or reproduction. In human beings, the nucleus contains chromosomes composed of DNA that encode all of the information necessary to produce a complete human body. Chromosomes store information in the chemical structure of DNA much like a book or a compact disk. The nucleus contains 46 chromosomes, two copies of each of the 23 different human chromosomes. One copy of each chromosome is inherited from an individual's mother and one copy is inherited from an individual's father, giving a child DNA characteristics of both its mother and father.



Source: National Human Genome Research Institute, by artist Darryl Leja at www.accessexcellence.org/AB/GG/chromosome.html

Approximately 99.9 percent of human DNA is the same. Forensic DNA scientists are only interested in the 0.1 percent of the DNA that varies among people. The human traits that result from the variations in this part of the DNA can be obvious, like different eye color or different blood types, but may also be so subtle that only laboratory testing can detect them.

Each chromosome contains many genes, which are the portions of the chromosome that code for personally identifying characteristics, like hair color or eye color. The characteristics of a specific gene, or of a specific location on a DNA strand, is referred to as an allele. For example, if two people both have blue eyes, then they have the same alleles for their eye-color gene. It has been estimated that only 2 to 3 percent of the information in a chromosome is

organized into genes. While the function of the DNA between the genes is unknown, scientists currently believe that it does not code for anything. Since it varies widely among individuals, scientists examine the DNA located between the genes to determine a person's DNA profile. Examining this DNA allows scientists to determine an individual's unique DNA profile (except for identical twins), without that profile revealing personally identifying characteristics or medical conditions.

Even though forensic DNA scientists focus their analyses on specific chromosomal locations that vary widely between individuals, it is not necessary to examine every one of these locations to develop a unique DNA profile for an individual. Rather, scientists need only examine enough locations to virtually eliminate the possibility that two unrelated people have the same DNA profile purely by chance. Under current DNA standards applicable in the United States, an individual's DNA profile consists of the alleles present at 13 specified chromosomal locations. Scientists have determined that, in general, when DNA profiles consist of the alleles present at these locations the probability that two unrelated individuals will have the same DNA profile purely by chance is less than 1 in 200 billion. As a result, except for identical twins, examining the 13 locations produces a DNA profile that is essentially unique to an individual. See Appendix 1 (which contains an example of a complete DNA profile).

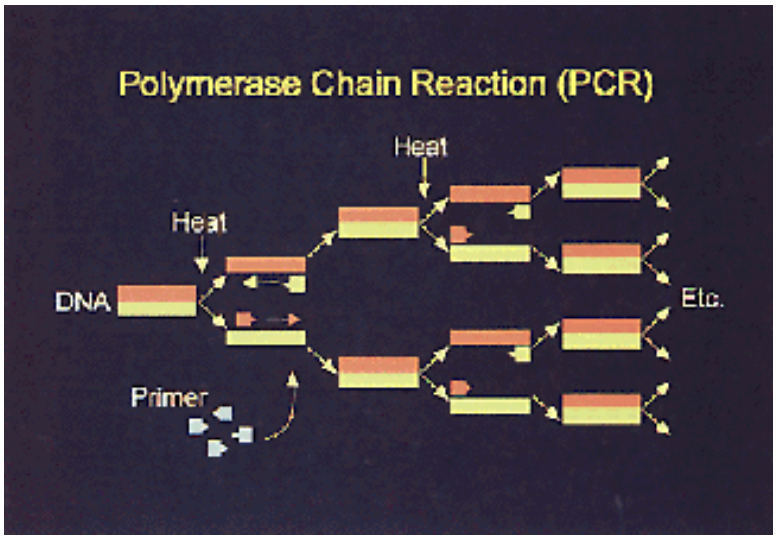
B. Overview of the DNA Testing Process

Law enforcement personnel who submit crime scene evidence for DNA analysis must package and seal the evidence and then arrange for its secure delivery to a DNA laboratory. Upon receipt of the evidence, forensic scientists first determine if the evidence might provide DNA by visually examining it for indications of body fluid stains, and then performing testing to determine whether specific body fluids that might contain DNA are present.

When possible, forensic scientists analyze only a portion of the stains on the evidence and save the remainder in case future testing is necessary. Generally, stains on fabric are cut out of the item and the DNA is extracted from the cuttings. If the stains are on a hard object, such as a knife, some of the dried body fluid is removed from the object with a cotton swab (known as swabbing an item) and the DNA is extracted from the cotton swab. The process used to extract the DNA varies depending on the organic source of the stain and the material containing the stain.

Once the DNA is extracted from the evidence, it undergoes a process known as polymerase chain reaction (PCR), which is also referred to as amplification. This process, often analogized as biological photocopying, allows scientists to make copies of specific chromosomal segments. The amplification process gives forensic scientists the ability to analyze minute DNA samples,

and has allowed DNA analysis to become a much more useful tool for forensic scientists. The diagram below illustrates the PCR process:

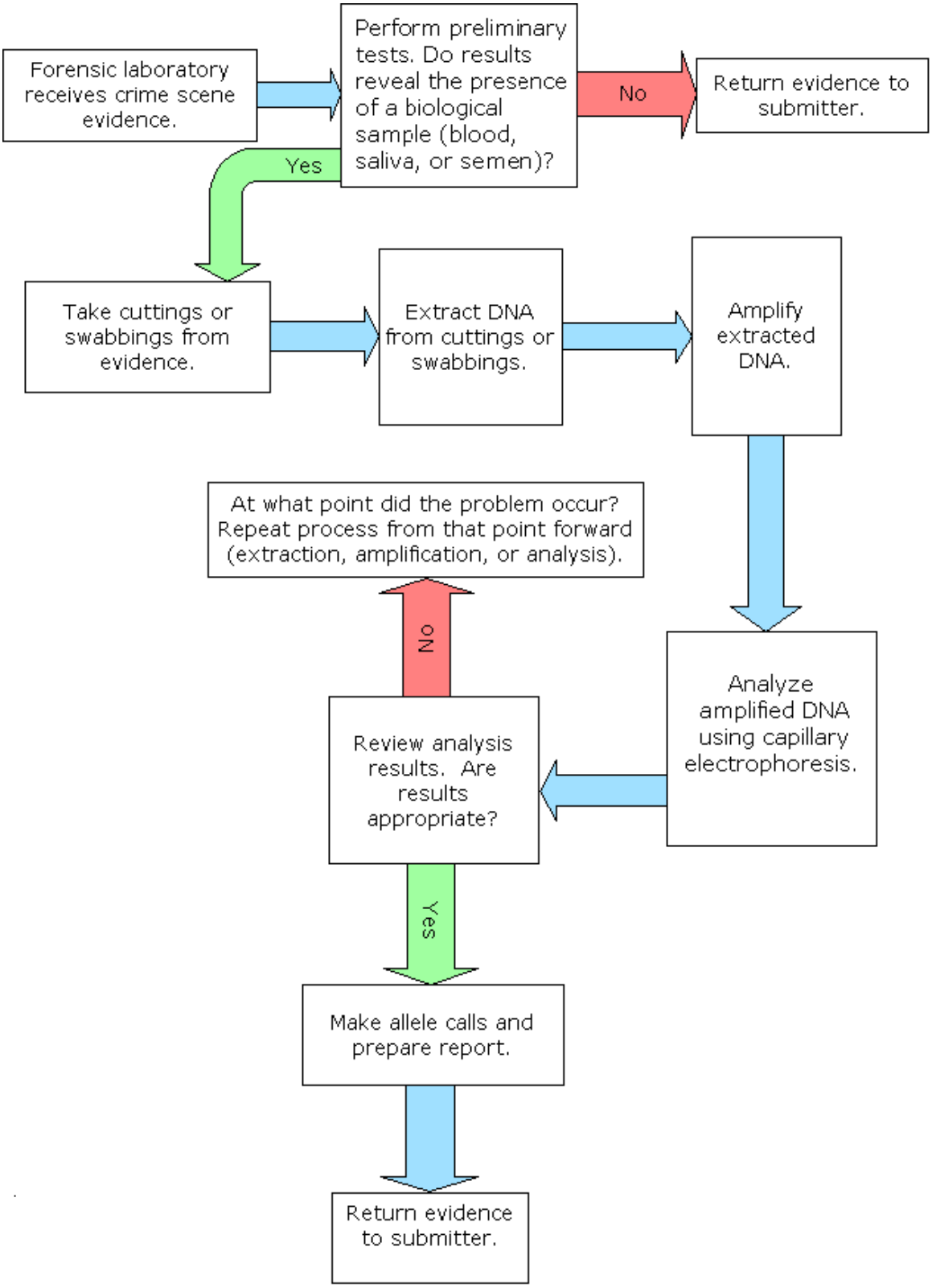


Source: Federation of American Societies for Experimental Biology at www.faseb.org/opar/bloodsupply/pcr.html

After amplification is complete, the DNA is analyzed using a machine that separates the DNA fragments present in the sample. This process is known as electrophoresis. Special software then measures the length of the DNA fragments, determines the alleles that correspond to the fragments, and compiles a DNA profile for the sample. The DNA testing process is summarized in the diagram on the following page.[9]

[9] Information concerning the final steps described in the diagram (i.e., data analysis and allele calls) is presented in Chapter Two, Section I.D of this report.

Steps in the Analysis of DNA



C. Short Tandem Repeat (STR) Analysis

As the name implies, short tandem repeat (STR) analysis is a method of determining an individual's DNA profile by counting the number of times a small DNA sequence (short tandem repeat unit) is repeated at a specific chromosomal location. STR analysis consists of three processes: amplification, electrophoresis, and interpretation.

In amplification, extracted DNA is added to chemical reagents and heated, causing the two strands that compose the DNA molecule (they resemble two sides of a "ladder," as seen in the graphic on page 5) to separate. Each of the two strands then can be used as a template to make (or synthesize) a new double-stranded DNA molecule.

The reagents in which the DNA is heated contain markers that identify the starting and ending points of the DNA fragment that is duplicated. The markers also are called primers because they prime (or stimulate) the synthesis reaction. Primers are short synthetic pieces of DNA designed to match the regions of human DNA which are highly variable. As the DNA and chemicals begin to cool, the primers attach to the single-stranded DNA. The primers contain fluorescent labels so that they may be detected by lasers later in the testing process.

Once the primers have bound to the beginning and end of the segment being copied, individual building blocks of DNA from the reagents fill in the rest of the empty spots on the single-strand. See diagram supra at page 7 describing the PCR process.

The heating and cooling of the DNA is accomplished by a machine called a thermal cycler, in which a tray of capped tubes containing the DNA and chemical reagents are placed. The thermal cycler can be programmed to heat and cool repeatedly for specific amounts of time. At the end of many repetitions, millions of copies of the original DNA section are created.

Any DNA present in a tube when the amplification process begins, whether from evidence or introduced through contamination, will be amplified.[10] To ensure that the DNA profile generated from the amplified DNA is representative of the DNA from the evidence sample and not from contamination, and to verify that the testing process is accurate, DNA protocols require forensic DNA scientists to analyze a series of control samples. For each batch of samples processed, at least one positive control, one negative control,

[10] DNA from contamination usually can be differentiated from crime scene DNA because it is miniscule in comparison to the amount of DNA that is present from the evidence. In other words, DNA from contamination typically will be "drowned out" by the DNA that is included from the evidence sample.

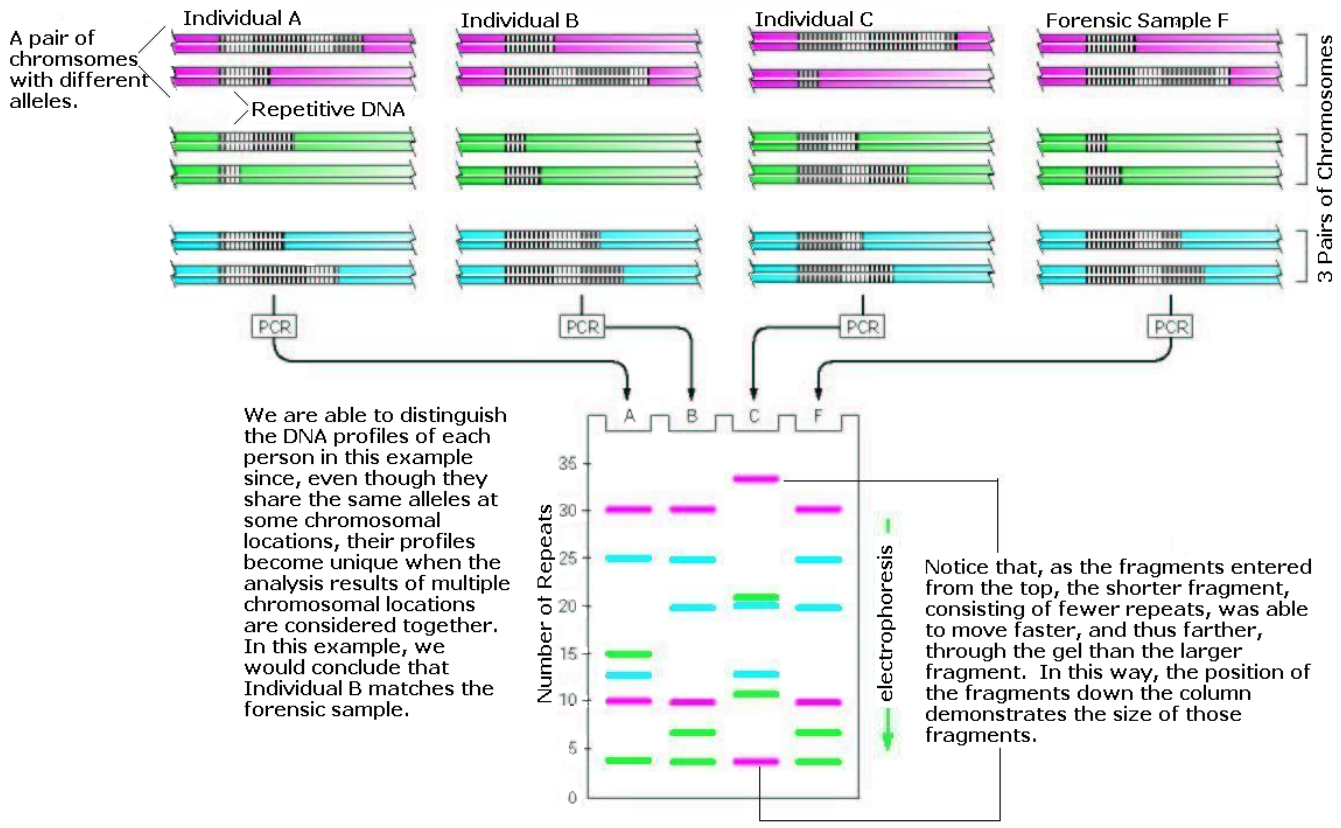
and one reagent blank are analyzed along with the DNA samples. The positive control tube contains the reagents necessary for amplification plus DNA from a source for which the DNA profile is known. Since the scientists know the correct test results for the positive control, it allows them to determine the accuracy and performance of the amplification and analysis processes. The negative control tube contains all of the reagents used for amplification. The reagent blank contains all of the reagents used to process an item of evidence from extraction through electrophoresis. DNA from the evidence is not added to these controls, though their contents are amplified. The purpose of the negative control and the reagent blank is to reveal any contamination that is present in the reagents or introduced during the testing process.[11]

TYPES OF DNA CONTROLS

	Positive Control	**Reagent Blank**	**Negative Control**
Material Tested	Amplification reagents and known DNA	All reagents	Amplification reagents
Reveals	Accuracy and performance of the amplification and analysis processes	Presence of contamination introduced at any point in the analysis process	Presence of contamination introduced during the amplification process

After the DNA has been amplified, the newly formed DNA fragments are sorted according to length (i.e., number of short tandem repeats) using electrophoresis. In general, electrophoresis is performed by adding DNA to one end of a piece of gelatinous material which contains tiny holes that allows the material to function as a molecular sieve. An electric current is applied across the material, causing the DNA fragments to move. Since it is easier for smaller fragments to move through the material, the smaller fragments move farther than the larger fragments. As a result, at the end of electrophoresis the DNA fragments are sorted by size. The size of the DNA fragments is determined by comparing the distance each fragment moved to the distances moved by the fragments of known size. The results of electrophoresis are illustrated in the following graphic.

[11] Unless otherwise noted, references to "negative controls" also include reagent blanks.



Source: www.accessexcellence.org/AB/GG/forensci_PCR.html ©1998 by Alberts, Bray, Johnson, Lewis, Raff, Roberts, Walter. Published by Garland Publishing, a member of the Taylor and Francis Group.

D. Capillary Electrophoresis

The principles described above also apply to capillary electrophoresis, a form of electrophoresis employed by the DNAUI. Its distinguishing characteristic is that the electrophoresis occurs inside a capillary tube (a very thin glass tube, comparable to a human hair) with a sieving material inside, rather than on a piece of gelatinous material. Capillary electrophoresis is an automated process that analyzes many DNA samples and requires minimal involvement by DNA scientists after the initial set-up procedures are completed. These procedures include cleaning and calibrating the electrophoresis machine and preparing the amplified DNA for analysis.

To prepare amplified DNA for capillary electrophoresis, the DNA scientist:

- Places a sufficient number of empty tubes in a rack;

- Adds water for dilution and internal size standard[12] to each of the empty tubes;

- Adds an appropriate amount of one of the following to the tubes containing the internal size standard:

  - amplified DNA from known samples, unknown or evidentiary samples, or the positive control;

  - amplified negative control or reagent blank; or

  - an allelic ladder,[13] which contains the more common alleles in the general population for specific chromosomal locations; and

- Seals the tubes with soft rubber caps.

Once the tubes are sealed, the rack is ready to be placed on the capillary electrophoresis machine. A sample list is prepared which identifies the location of each sample on the rack and makes it possible for the machine's computer to locate a specific sample. An injection list is also prepared which tells the computer the order in which the samples are to be analyzed. The capillary electrophoresis machine has a probe that punctures the soft rubber caps on the tubes and withdraws a specific amount of sample. The sample is drawn up into the capillary tube (referred to as injecting the sample) where the electrophoresis is completed.

As mentioned previously, the primers used during amplification contain fluorescent markers that allow the DNA fragments to be detected by lasers. The manufacturer of the capillary electrophoresis machine has developed proprietary software to display the test results and to aid in their interpretation. Using this software, the capillary electrophoresis machine determines the size of the DNA fragments in a sample based on the information detected by the lasers. The machine and the software then represent the lengths of the various fragments as peaks on a graph as illustrated on the following page:

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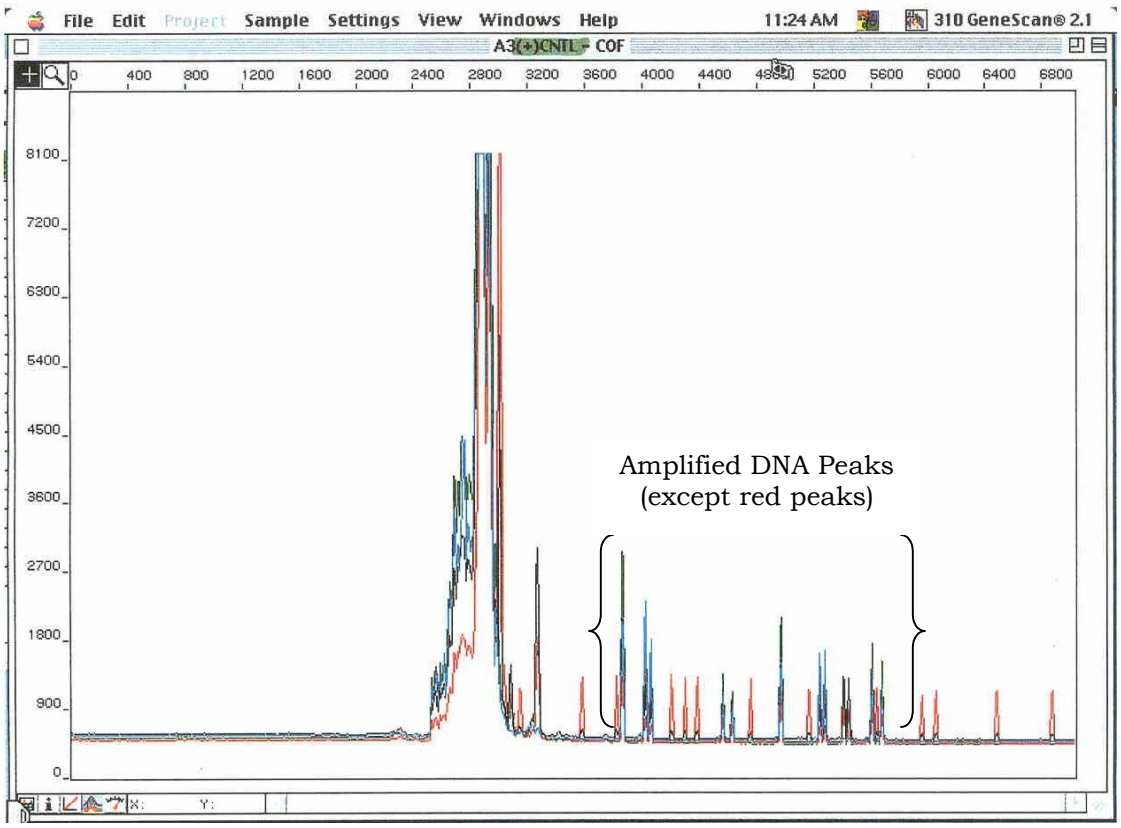
[12] The internal size standard contains DNA fragments of known sizes that provide reference points for determining the length of the sample's DNA fragments.

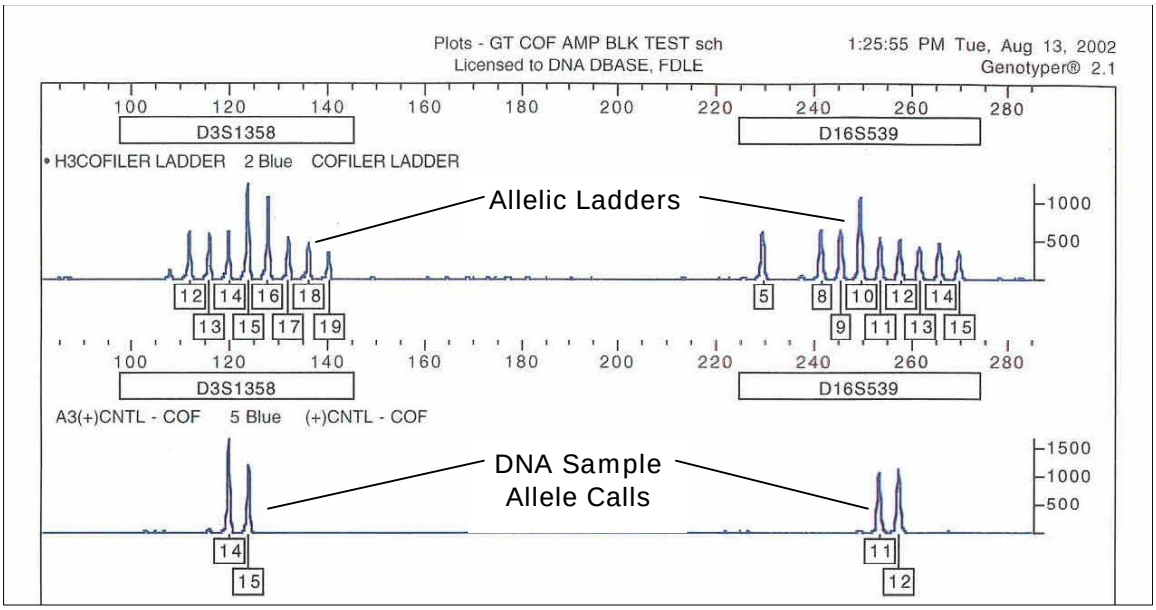
[13] Allelic ladders are used like molecular rulers to help "measure" the lengths of the fragments in the reference and evidentiary samples.



GeneScan® View: raw data for a Positive Control (9947A) prepared according to protocol. Peaks depicted in red originate from the internal size standard added to each sample.

The proprietary software has two components, GeneScan® and Genotyper®.[14] Data viewed in GeneScan®, as appears above, is the raw, unanalyzed, collection data that reflects everything the laser detects, including interference that is common in electrophoresis instruments (Genescan® data). Genotyper® allows forensic scientists to take GeneScan® data and display it in a format that conceals background noise and peripheral information, and to focus their review on the results of the control and evidence samples. An example of a Genotyper® display is presented on the following page:

[14] We provide additional information regarding this software in Appendix 2.



Genotyper® View: COFiler Ladder with Positive Control Allele call

Information collected during these analyses is used to assemble the DNA profile. As mentioned previously, two points of reference are used to help the software as it determines the lengths of the DNA fragments detected during electrophoresis: 1) the GeneScan® software uses the internal size standard, which contains DNA fragments of known sizes; and 2) the Genotyper® software uses allelic ladders as a point of comparison for the designation of the number of repeats in the DNA sample at particular chromosomal locations, since the peaks within the allelic ladder correspond to known fragment lengths at those locations. The DNA Examiner then works with the Genotyper® graphs, similar to the one above, looking for any peripheral information that should be considered. Unless contamination is detected or other complications disrupt the testing, the Examiner then documents what the allele values are at each of the chromosomal locations analyzed (usually 13 chromosomal locations are examined), which, once compiled, constitute a DNA profile. See Appendix 1 for an example of a complete DNA profile and the corresponding GeneScan® and Genotyper® graphs.

II. STANDARDS GOVERNING FORENSIC DNA ANALYSIS

The creation of national standards for DNA analysis played a pivotal role in establishing the integrity of the DNA testing process. In addition, by adhering to these standards, DNA laboratories, including the FBI's DNAUI, have been able to attest to the validity and reliability of their DNA testing results.

A. Sources of DNA Standards

Forensic DNA laboratories, particularly those participating in the FBI's Combined DNA Index System (CODIS),[15] have relied upon three primary sources of operational standards since the first forensic DNA laboratories were established in the late 1980's: 1) the Technical Working Group on DNA Analysis Methods (TWGDAM); 2) the DNA Advisory Board; and 3) the FBI's National DNA Index System (NDIS) program office.

TWGDAM was one of several technical working groups sponsored by the FBI. The goal of the working groups was to improve communication between the various scientific disciplines and to build consensus within the federal, state, and local forensic communities. TWGDAM was established in 1989 with representatives from 12 federal, state, and local laboratories, and focused specifically on the development of forensic DNA methods. Later that same year, TWGDAM developed and published in the *Crime Laboratory Digest*[16] a set of quality guidelines for forensic DNA laboratories.[17] TWGDAM expanded these guidelines in 1991 and in 1995.[18] In addition, TWGDAM worked with the National Institute of Standards and Technology (NIST) to develop model reference material that laboratories across the country could use to gauge the reliability of their equipment and DNA testing processes. In January 1999, TWGDAM was renamed the Scientific Working Group on DNA Analysis Methods (SWGDAM),[19] and in that capacity produced additional guidance for the forensic community, including guidelines for data interpretation, training, quality assurance, and health and safety audits.

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[15] For a description of CODIS, see discussion in Chapter Three, Section I.B.1. CODIS is a national DNA information repository that allows public laboratories across the country to store and compare DNA profiles from crime scene evidence, from convicted offenders, and from unidentified remains.

[16] The *Crime Laboratory Digest* was superseded by *Forensic Science Communications* in April 1999. *Forensic Science Communications* is a peer-reviewed forensic science journal published quarterly in January, April, July, and October by FBI Laboratory personnel.

[17] Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA restriction fragment length polymorphism analysis," *Crime Laboratory Digest*, Vol. 16, 1989, pp. 40–59.

[18] Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA analysis," *Crime Laboratory Digest*, Vol. 18, 1991, pp. 44-75; Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA analysis," *Crime Laboratory Digest*, Vol. 22, 1995, pp. 21–43.

[19] TWGDAM was renamed SWGDAM after the Department of Justice, Office of Justice Programs, created short-term technical working groups that began to be confused by members of the DNA community with the FBI's long-term technical working groups.

While no formal legal authority was granted to TWGDAM and SWGDAM, the guidelines they produced were accepted by the Laboratory Accreditation Board of the American Society of Crime Laboratory Directors as the benchmark for DNA laboratory accreditation. Further, when Congress authorized the creation of CODIS in the DNA Identification Act of 1994,[20] it provided that the guidelines issued by TWGDAM would be deemed to be national standards until the FBI issued its own standards pursuant to the Act.

The second source of DNA standards is the FBI DNA Advisory Board (Board). In the DNA Identification Act, Congress required that the FBI establish an advisory board to develop national quality assurance standards governing all CODIS participants.[21] As a result, the FBI established the Board, which was formally constituted on March 10, 1995.[22] Its members were appointed by the FBI Director based upon nominations from a variety of forensic and science organizations,[23] and included forensic scientists from state, local, and private forensic laboratories; molecular and population geneticists; a NIST scientist; a quality control specialist; an ethicist; and a judge. The Board's mission was to develop and revise, as necessary, standards for quality assurance, including proficiency testing standards for laboratories and analysts that examine DNA. The Board members acknowledged that TWGDAM had begun this work and that the Board should build upon it.

The Board fulfilled its mission with the submission to the FBI Director of quality assurance standards for two types of DNA laboratories:

- *Quality Assurance Standards for Forensic DNA Testing Laboratories* (Forensic Standards), effective October 1998.

- *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* (Offender Standards), effective April 1999.

Amendments to these standards must be approved by the FBI Director. Recommendations for changes can be requested through SWGDAM.

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[20] Section 210301 to 210306 of Title XXI of Pub. L. 103-322, September 13, 1994, 108 Stat. 2065.

[21] 42 U.S.C. 14131(a)(1).

[22] The Board was dissolved in December 2000 after a several month extension of its original charter of 5 years.

[23] These organizations included the American Academy of Forensic Scientists, the American Board of Criminalists, the American Society of Crime Laboratory Directors, and the National Academy of Sciences.

The third source of DNA standards is the FBI NDIS program office, currently within the Laboratory Division's CODIS Unit (see the organization chart on page 24 for the placement of the CODIS Unit within the Division). The NDIS office has issued programmatic rules that govern the exchange of information for NDIS participants and has established standards for the submission of DNA data, collectively referred to as NDIS Requirements.

B. Overview of Applicable DNA Standards

At present, three sets of standards govern the DNA activities of the DNAUI: 1) Quality Assurance Standards; 2) NDIS Requirements; and 3) Accreditation Standards. These standards are interrelated: to comply with the Quality Assurance Standards, a laboratory is supposed to pursue accreditation actively; to become accredited, a laboratory must demonstrate compliance with the Quality Assurance Standards; and to become a participant in NDIS, a laboratory must demonstrate compliance with both the Quality Assurance Standards and the NDIS Requirements. We describe each of the standards below.

1. Quality Assurance Standards

Quality Assurance Standards consist of two sets of standards: 1) Forensic Standards that govern the activities of DNA laboratories that analyze crime scene evidence, and 2) Offender Standards that govern the activities of DNA laboratories that analyze samples from convicted offenders. The Forensic Standards contain 155 requirements organized under 15 headings, and the Offender Standards contain 136 requirements also organized under 15 headings.[24] For complete versions of the Forensic and Offender Standards, see Appendix 3.

The key categories of requirements addressed in the two sets of Standards, which correspond to section headings in the Standards, are the following:

- Quality Assurance Program: written guidelines should be adopted and should contain the required categories of standards.

- Organization and Management: key roles and duties should be described in writing, as should the interrelation between the personnel involved in DNA analysis.

[24] A high degree of overlap exists between the two sets of standards. A total of 119 requirements are shared (identical or similar), 36 requirements are unique to the Forensic Standards, and 17 requirements are unique to the Offender Standards.

- Personnel: personnel filling key roles should be properly educated, trained, and should perform duties appropriate to their position.

- Facilities: the design of the laboratory should ensure security and minimize contamination.

- Evidence Control (Forensic Standards only) and Sample Control (Offender Standards only): to ensure the integrity of evidence and of offender samples, and their proper disposition, the laboratory should have a documented control system and adequate implementing procedures.

- Validation: the laboratory should demonstrate that its analysts are capable of using certain equipment and methods properly.

- Analytical Procedures: every procedure used by the laboratory in DNA analysis should be described in detail in writing and formally approved by laboratory management.

- Equipment Calibration and Maintenance: the laboratory should establish a written program for ensuring that equipment used for DNA analysis receives regular calibration and maintenance in accordance with recognized national standards.

- Reports: the laboratory should have written guidelines for maintaining documentation that supports reported conclusions regarding case evidence. Reports should describe with specificity the information collected and written policies should exist to govern the release of such information.

- Review: administrative and technical reviews should be conducted of all reports and supporting documentation for all evidence. The testimony of analysts in court should also be reviewed.

- Proficiency Testing: scientists performing DNA analysis should complete an external proficiency test (a test from an outside agency or commercial test provider that measures an analyst's skill in performing DNA analysis correctly) every 180 days, which should be reviewed and documented.

- Corrective Action: written procedures should exist governing a laboratory's documentation and resolution of errors made during proficiency testing and DNA analysis.

- Audits: the laboratory should undergo an audit every year, and at least every other year this audit should be conducted by an external entity.

- Safety: the laboratory should have and follow a written environmental health and safety plan.

- Subcontractor of Analytical Testing for Which Validated Procedures Exist: a laboratory making use of a subcontractor for any part of the DNA analysis process should establish certain specified controls to ensure the integrity of the subcontractor's work and results.

2. NDIS Requirements

NDIS Requirements are found in the Memorandum of Understanding (MOU) signed by the FBI and each NDIS participant. The MOU requires that signatories comply with general requirements already established (i.e., federal legislation, the Forensic and Offender Standards) as well as requirements specific to the national index that accompany the MOU in three appendices: NDIS Responsibilities (Appendix A); NDIS Data Acceptance Standards (Appendix B); and the NDIS Procedures Manual (Appendix C).[25]

3. Accreditation Requirements

The primary accreditation or certification entities for forensic and offender DNA laboratories are the American Society of Crime Laboratory Directors – Laboratory Accreditation Board (ASCLD-LAB) and the National Forensic Science Technology Center (NFSTC). Both groups draw upon the requirements set forth in the Forensic and Offender Standards for their evaluation of a public DNA laboratory's operations.

III. ACCREDITATION AND STANDARDS COMPLIANCE

While TWGDAM/SWGDAM and the Board were pivotal in creating standards for DNA laboratories, they lacked the means to enforce them. To compensate for this shortcoming, the Board adopted an "Accreditation Premise" which set forth the Board's expectation that standards compliance would be assured through the process of accreditation. Accrediting organizations would need to adopt and hold laboratories accountable for compliance with the Board's standards. The Board acknowledged that a weakness in this approach was the lack of any enforceable requirement that

[25] We provide a detailed description of these appendices in Appendix 4.

laboratories be accredited, even for CODIS participation. In an attempt to address this problem, the Board passed a resolution in February 1999 stating that unaccredited laboratories should seek accreditation "with all deliberate speed." In addition, this language was used in the preface to the Forensic and Offender Standards to emphasize the importance of accreditation.[26]

Compliance with DNA-related standards is an issue previously examined by the OIG. In 1999, the OIG performed an audit of CODIS to determine the extent of state and local CODIS participation and to verify compliance with the FBI's quality assurance standards and national index requirements.[27] In the report summarizing its findings,[28] the OIG explained that the FBI's practice at the time of audit fieldwork was to allow CODIS and NDIS participants to self-certify their compliance with the Quality Assurance Standards and with NDIS Requirements. Because the OIG believed this system of self-certification posed a high risk of undetected noncompliance, the OIG undertook compliance testing of various CODIS participants and subsequently identified multiple instances where the participants were not fully complying with national standards. In addition, while the OIG noted that all audited laboratories had complied with the Forensic and Offender Standards' annual audit requirement,[29] weaknesses were noted with some of the external audits: 1) audit findings were not binding on the laboratories (they could disregard them if they wanted); 2) although accreditation and certification agencies had the authority to ensure a laboratory took appropriate corrective action, accreditation or certification audits did not typically focus on compliance with the quality assurance standards; and 3) laboratory audits were not always performed consistently. From these observations, the OIG recommended that the FBI develop and implement a process that would ensure that laboratories resolve all deficiencies noted during the external audits.

In response to the OIG's findings and recommendations, the FBI developed a new operational procedure, called *National DNA Index System (NDIS) Review of External Audits*, which provides for the formation of several NDIS Audit Review Panels. Each panel consists of four qualified or previously qualified DNA examiners or analysts selected from the FBI and state or local laboratories, with the chief of the FBI Laboratory's Quality Assurance and

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[26] Despite these efforts, according to an FBI Laboratory study conducted in 1999, of 153 laboratories surveyed (64 local, 87 state, and 2 federal), only 87 were accredited. Of the accredited laboratories, 71 were accredited by ASCLD-LAB.

[27] CODIS is described in greater detail in Chapter Three, Section I.B.1.

[28] The OIG audit report, The Combined DNA Index System," Report No. 01-26, was issued in September 2001. See http://www.usdoj.gov/oig.

[29] The Forensic Standards and Offender Standards both require that laboratories undergo, every other year, a quality assurance audit conducted by external auditors. Internal audits conducted by in-house auditors are required during the alternating years.

Safety Unit serving as chairperson. All panelists are required to have completed successfully FBI quality assurance audit training. Under the new procedure, NDIS participating laboratories must forward to a review panel, via the custodian of the NDIS database, a copy of their external audit report, their response to the report, and corrective action plans that address the audit report recommendations. The panel reviews the audit report and related documents to determine if all findings and recommendations have been addressed adequately and/or resolved. If the audited laboratory does not respond to clarification requests by the panel, does not resolve an audit recommendation, or is determined to be non-compliant with the quality assurance standards, a corrective action and conflict resolution process can be invoked. A laboratory's failure to resolve a panel's concern can result in the termination of its access to NDIS.

In addition to these compliance procedures, the FBI created a standardized DNA audit guide (Guide) with input from the Board, ASCLD-LAB, and NFSTC to ensure that auditors of local, state, and federal DNA laboratories are thorough and interpret the Quality Assurance Standards consistently. The FBI offers Guide training for auditors, including those representing accrediting and certifying organizations such as ASCLD-LAB and NFSTC. For an audit to fulfill the Quality Assurance Standards' external audit requirement, it must be conducted in accordance with the Guide and by an auditor trained in its use. However, as this report details, even with these precautions, internal control weaknesses are not always uncovered in quality assurance audits. In fact, weaknesses in DNAUI procedures and protocols allowed a technician routinely to disregard required steps in the analysis of DNA, even while the Unit received clean audit reports from both internal and external auditors and while the Unit was accredited by ASCLD-LAB.

CHAPTER THREE
THE FBI'S DNA LABORATORY AND DNA PROTOCOLS

The FBI enforces over 200 federal laws and has jurisdiction to investigate all federal criminal violations not specifically assigned by Congress to another federal agency. Its investigations routinely address matters such as counterterrorism, foreign counterintelligence, organized crime, civil rights, and financial crime. As part of its law enforcement mission, the FBI also is authorized to provide other law enforcement agencies with cooperative services, such as fingerprint identification, laboratory examinations, and police training. Because the successful investigation and prosecution of crimes requires, in many cases, the collection, preservation, and forensic analysis of evidence, the FBI Laboratory Division and the forensic science specialties available to it are a central component of FBI operations.

I. THE FBI LABORATORY DIVISION

The FBI Laboratory provides leadership in the scientific analysis and prosecution of crimes throughout the United States. It is the only full-service federal forensic laboratory and is one of the largest forensic laboratories in the world. According to the FBI, Laboratory activities further three primary goals: 1) to provide forensic services to the FBI and other law enforcement agencies; 2) to deploy effective communications, collection, and surveillance capabilities to support investigative and intelligence priorities; and 3) to provide technical and forensic assistance through research, training, technology transfer, and access to information and forensic databases. The Laboratory seeks to meet these goals through forensic examinations, investigative operations support, research and development, application of information technology, and training.

Laboratory personnel conduct scientific examinations of evidence, free of charge, for federal, state, and local law enforcement organizations within the United States. As part of these examinations, Laboratory personnel may analyze physical evidence ranging from blood and other biological materials to explosives, drugs, and firearms. According to the FBI, the Laboratory conducts more than one million examinations each year.

In March 2003, the Laboratory moved to its new facility in Quantico, Virginia, resulting in the relocation of approximately 650 Laboratory employees. The design of the new facility is meant to provide for ideal security and evidence control. Offices and public areas are separated from the laboratory areas to avoid evidence contamination. Also, laboratory areas are

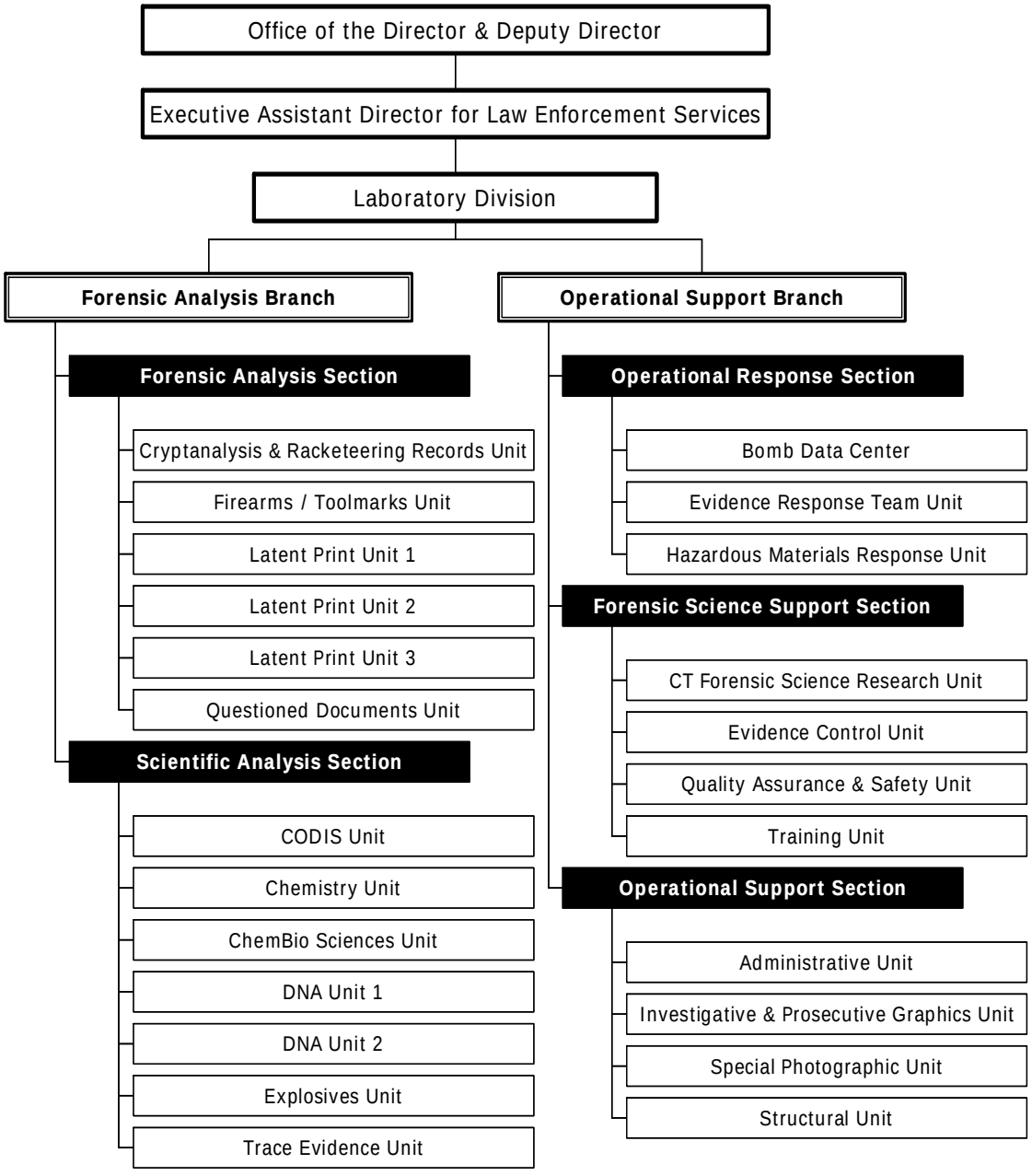
accessed through "biovestibules" that are meant to provide storage and serve as airlocks between laboratories and offices.[30]

A. Structure of the Laboratory Division

The Laboratory is located organizationally within the Law Enforcement Services Directorate of the FBI. It is comprised of various branches, divided into sections, which are further broken down into units. The subject of this review, the DNAUI, is part of the Scientific Analysis Section, as shown in the following Laboratory organizational structure:

[30] Additional information about our assessment of the DNA Analysis Unit I (DNAUI) portion of the new Laboratory building is contained in Chapter Five, Section II.B.1.a of this report.

Federal Bureau of Investigation



B. DNA Analysis Unit I

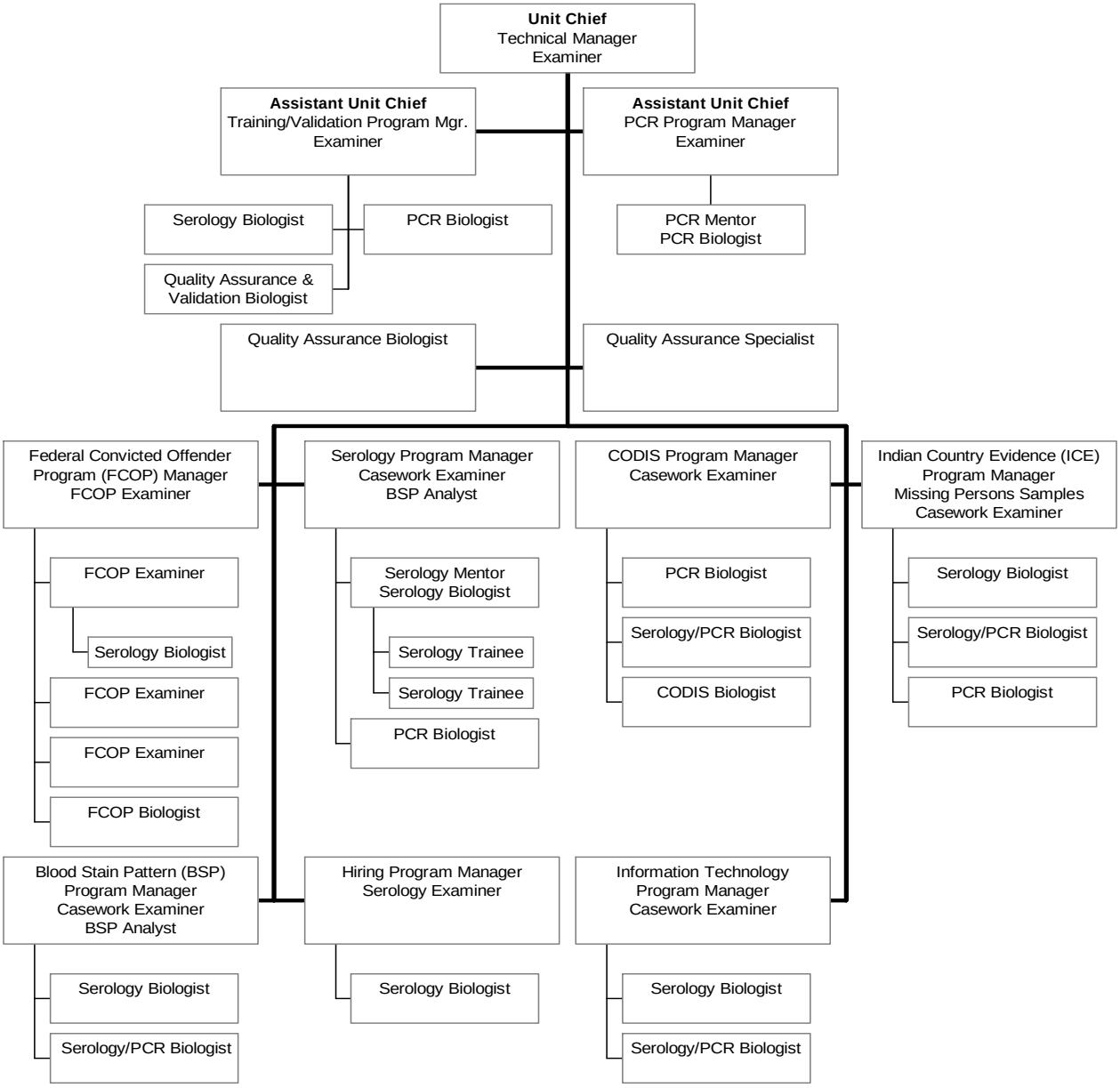
1. Organization and Functions

In 1988, a DNA Analysis Unit was established in the Laboratory. Prior to that time, body fluid examinations were performed by the Serology Unit. Although the DNA Analysis Unit was split into two units in 1993, they were re-joined in 1994. In 1998, the DNAUI and DNA Analysis Unit II (DNAUII) were formed. DNAUII was created when the Laboratory established a separate group to analyze a different type of DNA than is analyzed by the DNAUI.

The DNAUI analyzes nuclear DNA, or DNA found in the nucleus of a cell, while DNAUII analyzes mitochondrial DNA, or DNA found in the mitochondria of a cell. The mitochondria are about the size of bacteria and are scattered throughout a cell outside its nucleus. Since there are between 500 to 1,000 mitochondria in every cell, as opposed to one nucleus, mitochondrial DNA analysis affords a better chance of a DNA profile than nuclear DNA analysis in cases where a sample is decayed or degraded, such as skeletal remains that have been exposed to the elements for years. Consequently, the DNAUII receives and analyzes evidence samples and human remains that have not, or most likely will not, generate a traditional STR profile, such as teeth or pieces of bone that have no tissue attached. These types of evidence items are common in cases involving unidentified remains and missing persons. DNAUII receives evidence from across the country, since the specialized equipment, training, and facilities that are required for mitochondrial DNA analysis are usually beyond the resources of state and local laboratories. Further, because mitochondrial DNA analysis is more sensitive to trace amounts of DNA than STR analysis, it requires even greater safeguards in facilities and techniques to avoid contamination.

The DNAUI identifies and characterizes body fluids and body fluid stains recovered as evidence in crimes using traditional serological techniques and related biochemical analysis. These stains are analyzed and compared to results from the known body fluid samples submitted by the victim(s) and/or suspected perpetrator(s). This work is completed in the DNAUI in assembly-line fashion by teams of forensic scientists, which include a Serologist, a PCR Biologist, and an Examiner. The following chart represents the organization of the DNAUI:

DNA Analysis Unit I Organizational Chart *



***** Various personnel are cross-trained in both serology and PCR, and Examiners also serve as managers of various programs. See Chapter Three, Section I.B.2.b for additional information on team member roles and responsibilities.

The DNAUI participates in CODIS, which is administered by the CODIS Unit within the Laboratory. CODIS is a national DNA information repository that allows local, state, and federal crime laboratories to store and compare DNA profiles from crime scene evidence, from convicted offenders, and from unidentified remains. The FBI provides participating laboratories with special software that organizes and manages their DNA profiles and related information, including enabling participating laboratories to compare DNA

profiles. CODIS is organized as a hierarchy that encompasses national, state, and local indexes. DNA profiles are uploaded into the national index from the state indexes and into the state indexes from the local indexes. The forensic laboratories at each level of the CODIS hierarchy decide which DNA profiles will be uploaded to the next level, and conversely, the state and national levels determine, based upon applicable state and federal legislation, what profiles they will accept from the local and state indexes.

The DNAUI operates at the "state index" level, meaning that it uploads directly to the national database, or NDIS. The DNAUI has been uploading profiles to NDIS since September 1998. As of February 2004, the DNAUI had submitted approximately 1,602 forensic profiles (DNA profiles resulting from forensic or crime scene analysis work) to NDIS. According to DNAUI management, the Unit uploads approximately 30 forensic profiles per month to the CODIS database. In addition, the DNAUI oversees the Federal Convicted Offender Program, which involves analyzing known DNA samples from convicted felons in the federal system and uploading the resulting profiles to NDIS for comparison to crime scene evidence profiles from across the country. As of February 2004, the DNAUI had uploaded 213 offender profiles to NDIS.[31]

One of the goals of CODIS is to match DNA profiles from case evidence to other previously unrelated cases or to persons already convicted of other crimes. To determine the extent to which this goal is being met, the CODIS Unit has collected statistics from CODIS participants on the number of investigative leads that have been provided through CODIS' match capabilities. As of February 2004, the DNAUI reported a total of 187 investigations aided by CODIS.[32]

2. Operations

a) Flow of Evidence to DNAUI

At the time of our review, the Laboratory's Information and Evidence Management Unit, and specifically the Evidence Control Center (ECC) within that Unit, received all incoming evidence for the Laboratory.[33] The ECC staff

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[31] The DNAUII, also a CODIS participant, oversees the National Missing Persons DNA Database Program. Because missing persons' remains are frequently too deteriorated for nuclear DNA analysis, mitochondrial DNA analysis often is the only forensic option. The DNAUII also facilitates the collection and analysis of reference samples from relatives of missing persons for comparison to unidentified remains that are found as a means of determining their identity.

[32] CODIS's primary metric, the "Investigation Aided," is defined by the FBI as a case that CODIS assisted by producing a match between profiles (linking two cases together, or linking a case profile to an offender profile) that would not otherwise have been developed.

[33] By the date of this report, the ECC was reorganized into the Evidence Control Unit.

were responsible for ensuring that the evidence was sealed properly and that its receipt by the FBI was formally documented on a chain-of-custody form. The ECC staff would open the outer layer of packaging to retrieve the submission paperwork and the individually packaged sealed evidence containers. The ECC staff then would review the submission letter to determine the contents of the sealed container and what tests were requested. In addition, ECC staff labeled each evidence container with unique identifying numbers, as well as a Laboratory case number that would link it with other items received on the same case. Those identifiers, along with the information about the submitter and contents, were entered into the ECC's tracking system.

After all intake work was completed, the evidence was placed in secured storage where it would not deteriorate. The ECC then assigned the evidence to a specific unit within the Laboratory, termed the "primary unit." The primary unit was selected based upon an evaluation of the submission paperwork, from which ECC staff determined which unit would need to complete its work first to avoid contamination or deterioration of the evidence and/or would be conducting the most testing. Due to the nature of DNA evidence and its sensitivity to contamination, the DNAUI often served as the primary unit.

After the primary unit assignment was documented in the ECC system, the evidence was transferred to the designated unit and the necessary chain-of-custody documentation was completed. Within the primary unit, a coordinating Examiner was assigned to ensure that the evidence was routed in the proper order to all other units that will be performing tests on the various items of evidence.[34]

Throughout the analysis process, FBI policy requires that the chain-of-custody documentation be maintained to reflect all inter-unit transfers and to record which personnel processed the evidence. As part of this policy, after all laboratory analysis is completed, an inventory is performed to ensure that the evidence is accounted for. The evidence and all by-products of the analysis process are then repackaged and transferred back to the ECC for return to the submitter.

b) Team Structure

In those instances where the primary unit is the DNAUI, the coordinating Examiner works with a Serologist and PCR Biologist as a team to inventory

[34] During our fieldwork, we were notified by the DNAUI Unit Chief that new procedures were being drafted and tested. By the date of this report, staff of the Evidence Control Unit have taken the place of the coordinating Examiner and are responsible for the routing, tracking, and administration of evidence movement throughout the Laboratory.

evidence items, perform preliminary testing to identify and isolate sources of DNA on those items, and analyze any resulting DNA.

Teams in the DNAUI are divided into a form of assembly line, and each member of the team completes a portion of the analysis process and shares in the responsibility for that process. The three team members and their duties and responsibilities are as follows:

1) The Serologist assists with the initial and final evidence inventories and performs serology testing to determine what body fluids may be present in the evidence. Once body fluid screening is completed for a stain on an item of evidence, a portion of that stain is transferred to the PCR Biologist.

2) The PCR Biologist (the position held by Blake) is responsible for taking cuttings, swabs, or other material containing DNA from the Serologist and completing the PCR/STR process through the production of GeneScan® and Genotyper® data for the Examiner. Included in this process are the following activities:

- Extraction: the release or removal of DNA from evidence;
- Quantification: the measurement of the concentration of DNA in a sample;
- Amplification: the replication of extracted DNA so that the DNA can be detected by the analyzer or a capillary electrophoresis machine;
- Capillary electrophoresis: the use of a capillary electrophoresis machine to detect and measure the DNA fragments in a DNA sample; and
- Initial data review: the review of all data produced by the capillary electrophoresis instrument that is collected and analyzed by the Genescan® software.

3) The Examiner on each team serves as the first-line supervisor for the team members and are responsible for the work performed by them. Further, unless otherwise specified in written protocols and procedures, the Examiners are given sufficient autonomy to direct how the team will function. Examiners typically can assign work, structure communications, define the decision-making authority of other team members, and specify the level of direct involvement of the Examiner in the work of the other team members.

The Examiner on the team is supplied with all of the documentation from the Serologist and PCR Biologist, as well as the data produced from the capillary electrophoresis process (complete with sample lists, injection lists, and Genotyper® data). The Examiner is responsible for ensuring that:

- The decisions made by the Serologist (if not made in direct interaction with the Examiner) are sound, and that all evidence items are inventoried, examined, and transferred to the PCR Biologist properly;

- The decisions made by the PCR Biologist (if not made in direct interaction with the Examiner) are sound, and that DNA is extracted from all appropriate sources, quantification is completed correctly, batches of samples contain the required positive and negative controls and reagent blanks, and capillary electrophoresis is completed correctly;

- Chain-of-custody forms and case file documentation are completed properly; and

- The actions taken by the team members, as revealed by the written documentation supplied to the Examiner, are in accordance with DNAUI procedures and policies.

In addition, the Examiner is responsible for reviewing the filtered capillary electrophoresis data, or Genotyper® data, and drawing conclusions about the usability of that data based upon the control results. For this review, the sample and injection lists serve as a guide to show the order that the samples were analyzed and to indicate the presence of the appropriate control samples. Each Examiner decides whether to complete this data review from printouts or directly from the electronic data on the computer. If there are data quality problems, or control result problems, then the Examiner will work with the PCR Biologist to troubleshoot those issues. Otherwise, the Examiner proceeds to draw conclusions about the evidence based upon the data generated from the capillary electrophoresis. The Examiner then writes a report stating those conclusions and, if necessary, later testifies in court about them.

After the discovery of Blake's misconduct, the DNAUI changed its policies to require that the GeneScan® data be supplied to and reviewed by the Examiner, as well as the Genotyper® data, since it was the failure of Examiners to review GeneScan® data that allowed Blake to proceed undetected. See generally Chapter Four, Section II (describing the DNAUI GeneScan® review policy) and Chapter Four, Section V.C (describing the Laboratory's initial remedial actions after the discovery of Blake's misconduct).

c) Case Documentation and Review

DNAUI team members demonstrate compliance with the Laboratory's protocols primarily through the documentation that they produce as they perform their work. Although the Examiner can be involved at critical junctures in the DNA analysis process, the Examiner does not witness most of the work performed. Consequently, team members must thoroughly document their work in the case file to establish for the Examiner that they have followed the applicable protocols.

According to DNAUI personnel and the written procedures for case file documentation, a case file should include the following:

- Incoming submission letter;
- Acknowledgment letter (the letter that is sent to the submitter of the evidence to acknowledge receipt);
- Communication log;
- Chain-of-custody form;
- Search sheet (a sheet produced by the ECC advising unit staff whether previous submissions of evidence on that same case have been received, so that individual items can be sequentially and uniquely labeled throughout the case);
- Evidence inventories (listing of the items received, the submitter, and when the items were received);
- Task-specific case notes (includes a set of notes for serology work, PCR work, and examiner analysis);
- Capillary electrophoresis printouts;
- Population statistics calculations;
- Documentation of case file review;
- Administrative sheets (listing information specific to CODIS or DNAUI's new information management system); and
- The file copy of the final DNA report.

Both technical and administrative case file reviews are required for every DNAUI case. The initial technical review is performed by the team's Examiner. In addition, another Examiner who is not involved in the case performs an independent technical review or peer review of the case file. The peer reviewer draws his or her own conclusions from the supporting documentation without regard to the conclusions or report produced by the first Examiner. The results of these evaluations are then compared for consistency and any discrepancies resolved. Finally, the Unit Chief conducts an administrative review of the case file and examines the order and completion of the case file documents, report format, and other administrative items.

According to DNAUI personnel, a thorough technical or peer review generally involves checking:

- The incoming letter to verify the accuracy of the file worksheets, specifically confirming: 1) names; 2) exams requested; 3) evidentiary samples received (referred to as unknown or questioned samples); 4) DNA reference samples received (reference samples are provided by the victim and/or suspected perpetrator(s) for comparison purposes, and are often referred to as known samples); 5) case ID number; and 6) any other identifiers or miscellaneous information applicable to the case.

- The chain-of-custody documents to verify that they reflect the disposition of every item;

- Each page of laboratory documentation to verify that it is numbered (so it will be evident if any pages are misplaced) and that every page is initialed by the team member who produced it;[35]

- The serology paperwork to verify that: 1) all pertinent serology information is recorded and is correct; 2) the required serology controls were run; 3) appropriate serology testing was performed, and 4) the Examiner agrees that no more serology testing should be performed; and

- The PCR paperwork to verify that: 1) the questioned and known samples were processed at different times; 2) the Examiner agrees with the quantification results; 3) all samples selected were amplified; 4) the worksheet that summarizes the DNA profile results (also referred to as a call sheet) agrees with the Genotyper® printouts; and 5) the technical parameters used to interpret the data are consistent with protocol requirements.

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[35] See generally Chapter Four, Section II.B (discussing initialing requirement).

After the Examiner reviews these items, the Examiner (whether the initial Examiner or peer reviewer) determines what conclusions and statistics should be reflected in the report. For the peer reviewer, this determination is compared with the actual case report to verify that both Examiners agree. Finally, if the profile will be uploaded to CODIS, both reviewers confirm that the identifying paperwork listing the DNA profile is correct, and that the profile is appropriate for inclusion in the database.

II. THE FBI'S DNA PROTOCOLS

A. Overview of Existing Protocols

The activities of the DNAUI are governed not only by the Quality Assurance Standards that apply to all forensic DNA laboratories (as described in Chapter Two, Section II), but also by the FBI Laboratory's own procedures and protocols. These guidelines are contained in five FBI documents: 1) the FBI Laboratory Division Quality Assurance Manual; 2) the DNA Analysis Unit I Quality Assurance Manual; 3) the FBI Laboratory Division Caseworking Procedures Manual; 4) the Procedures for the Serological Identification of Biological Substances on Evidentiary Materials; and 5) the Short Tandem Repeat Analysis Protocol. As explained in Chapter Five, Section I (Assessment Foundation and Process), the OIG's assessment of vulnerabilities in the DNAUI's internal control structure focused on these protocols.[36] A brief description of each document is provided below:

1. FBI Laboratory Division Quality Assurance Manual

The FBI Laboratory Quality Assurance Manual addresses laboratory policies and operational practices. It is organized into 17 sections and identifies requirements and guidance for case documentation, evidence control, court testimony and testimony monitoring, authorization of deviations, corrective action, document control, calibration and maintenance, internal audits, laboratory security, proficiency testing, and conflict resolution. The document applies to all units in the Laboratory and therefore does not contain guidance specific to the DNAUI.

2. DNA Analysis Unit I Quality Assurance Manual

The DNAUI Quality Assurance Manual is organized into 20 sections and covers topics including:

[36] The FBI Laboratory also has published five resource documents that add explanation to the five manuals described above. These documents address issues such as calibration procedures and training programs for Biologists and Examiners.

- Organization, management, authority and accountability;
- Personnel qualifications, training, and continuing education;
- Facilities, security and evidence control;
- Case assignment, documentation and review;
- Reagents, equipment, and validation;
- Court testimony monitoring;
- Proficiency testing, audits, and corrective action; and
- Environmental health and safety.

3. FBI Laboratory Division Caseworking Procedures Manual

The Caseworking Procedures Manual provides guidance for all units within the Laboratory. It is divided into 12 sections, each covering a different aspect of the caseworking process. Topics include:

- Processing a request for examination;
- Inventorying, identifying, recording, acknowledging, examining, shipping, and transferring evidence;
- Formatting, content, review, and issuance of a "Report of Examination"; and
- Retaining case-related documentation.

4. Procedures for the Serological Identification of Biological Substances on Evidentiary Materials

This document is written specifically for DNAUI Serologists and identifies the methods and requirements for each of the serology procedures utilized by the DNAUI. It contains 72 sections, describes 6 routine and 8 non-routine serological procedures, and provides a general discussion of guidelines regulating laboratory set-up.

5. Short Tandem Repeat Analysis Protocol

The STR Protocol specifies the procedures and requirements for processing DNA evidence using short tandem repeat (STR) analysis. See generally Chapter Two, Section I.C (describing STR analysis). The document is

divided into 46 sections and covers the major processes involved in STR analysis, including extraction, quantification, amplification, electrophoresis, data evaluation and interpretation, and report writing. In addition, the Protocol provides information that applies generally to STR analysis, including guidelines for reagents, supplies, and equipment; special quality control considerations; and laboratory set-up instructions.

The protocols above implement the Quality Assurance Standards that apply to all forensic DNA laboratories. The national standards require laboratories to develop and adhere to operational standards that are tailored to their specific functions and circumstances. In general, these standards afford laboratories broad discretion regarding the content of their written procedures. See Section 9 "Analytical Procedures" in Appendix 3.

B. Protocols Designed to Protect the Integrity of the STR Process

Certain DNA protocols are specifically designed to protect the integrity of the STR process by helping to identify the presence of contamination and prevent its occurrence. They include: 1) the required use of quality controls; 2) on-going cleaning and decontamination; and 3) the systematic separation of sample sources and of stages in the analysis process.[37]

1. Quality Controls

As discussed in Chapter Two, Section I (General Principles of DNA Analysis) of this report, the use of positive and negative controls and reagent blanks serves as an indicator of contamination and whether the equipment and reagents functioned properly during the analysis process. The positive control allows the PCR Biologist and Examiner to determine the accuracy and consistency of the amplification and capillary electrophoresis processes each time DNA samples are analyzed. The negative control and the reagent blank reveal whether contamination was present in the reagents or whether contamination was introduced during the testing process. DNAUI procedures require the PCR Biologist to process positive and negative controls and reagent blanks with every batch of DNA samples analyzed. The Examiners, along with the PCR Biologists, analyze the control results to ensure that the data generated from the DNA samples meet the quality standards established for the resulting DNA profiles.

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[37] The descriptions below of these procedures reflect information collected during the course of our vulnerability assessment and are not necessarily found in the same level of detail in the DNAUI's protocols. This information was obtained during lengthy interviews with DNAUI staff members and management. Information regarding the weaknesses detected in the DNAUI protocols is found in Chapter Five, Section II of the report.

The failure to analyze properly the positive and negative controls and reagent blanks does not necessarily render DNA testing results inaccurate. Rather, it limits the conclusions that the DNAUI scientists may draw from the testing. Without properly analyzing the negative control and the reagent blank, DNAUI scientists cannot be sure that the only source of the test results is the DNA from the evidence under examination. The results could reflect impurities in the reagents or contamination introduced during the testing process. If the positive control is not analyzed properly, the DNAUI scientists cannot evaluate how well the amplification and capillary electrophoresis processes worked.

2. Cleaning and Decontamination

Adequate cleaning and decontamination procedures limit the possibility that forensic scientists will contaminate DNA samples during the testing process. Two types of contamination are of concern: 1) an evidence item or a DNA sample can be contaminated with DNA from a different case or from a different piece of evidence from the same case; and 2) the forensic scientist might also contaminate evidence with his or her own DNA.

The DNAUI cleaning and decontamination procedures can be summarized as follows:

- The Serologists and PCR Biologists clean their work surfaces and then cover those surfaces with clean brown paper each day before retrieving the evidence or samples from storage. The brown paper should be changed before each new evidence item is examined. The work surface always should be cleaned between cases and between the processing of items containing unknown DNA samples and those containing known DNA samples. If a piece of evidence is very messy, or if the item might have touched the work surface, the work surface should be cleaned before a new item is examined.

- Serologists and PCR Biologists wear gloves while examining evidence or processing samples. The gloves should be changed between items, or more often if necessary. When appropriate, the Serologists and PCR Biologists should wear facemasks when examining or testing evidence.

- Non-disposable utensils should be either cleaned or sterilized between use on separate evidence items. Pipette tips should be disposable and be changed for every use.

- Vacuum or fume hoods (hoods) should be small, enclosed work areas from which the air is vented to another location, often outside the building. When necessary, the air also should be

filtered to remove hazardous particles before it is released. The hoods should be decontaminated using ultra-violet light at the beginning and the end of the workday. The hoods should be cleaned on a weekly basis, or more often if necessary. For example, if something was spilled in the hood or a piece of evidence was extremely dirty, the hood would be cleaned immediately. PCR Biologists should cover their hood work-surface with disposable paper prior to beginning their work. This paper should be changed before each new item is processed. The PCR Biologists also should clean the hood between the processing of DNA samples from evidence and their processing of DNA samples from known sources (such as reference samples).

- Reagents should be decontaminated using ultra-violet light.

In addition, the DNAUI uses a contamination log to track occurrences of contamination. The log assists Unit management in identifying when staff members may need additional training or oversight, or in determining whether a procedure needs to be strengthened to avoid future incidents of contamination.

3. Separation of Sample Sources and of Stages in the DNA Analysis Process

The separation of the different types of samples and stages in the analysis process is important in reducing the possibility that DNA from one sample can contaminate another sample. For instance, samples from crime scene evidence (unknown samples) should be processed separately from samples submitted by suspects or other known individuals (known samples) to eliminate the risk of the suspect's DNA contaminating an unknown DNA sample. In the same way, it is also important to separate large and small samples of DNA to avoid the risk that the low quantity DNA will be contaminated by the high quantity DNA sample. Depending on the level of contamination, the DNA from the low quantity sample could be "drowned out" by the contamination, thus altering the test results for the low quantity sample.

The DNAUI Serologists and PCR Biologists attempt to limit such cross-contamination through the following procedures:

- Serologists work on one case at a time and examine only one piece of evidence at a time. The remaining evidence stays in storage until the first item is examined and returned to storage. PCR Biologists also work on cases sequentially and process samples from one item at a time. In addition, while adding samples and

reagents to test tubes, the PCR Biologists are supposed to have only one test tube open at a time. The test tubes remain capped until the Biologist adds something to the test tube.

- The Serologists and PCR Biologists always work on the crime scene evidence and unknown DNA samples before working on samples submitted by known individuals. To the extent possible, they also process low quantity DNA samples before working with the high quantity samples.

Several steps in the DNA testing process are performed in separate rooms in the DNAUI's new facility at Quantico, Virginia. The Serologists examine evidence and take cuttings or swabbings in one room. The PCR Biologists extract the DNA from the cuttings or swabbings in a second room under a hood. They also prepare the extracted DNA for amplification in that room. The actual amplification process takes place in a third room.

Once the DNA has been amplified, the DNAUI addresses the potential for amplification-related contamination as follows:

- Once employees work in the amplification room, they are not allowed to go back into a pre-amplification area for the remainder of the day. Employees must change lab coats and gloves before entering the amplification room, and again as they prepare to leave the amplification room. There are dedicated lab coats that are only worn in the amplification room.

- All equipment that is used in the amplification room stays there; the amplification room has dedicated instruments, equipment, and utensils. The tube racks used to transport the unamplified DNA to the amplification room are thoroughly cleaned before they are returned to use in the pre-amplification area.

- All amplified DNA stays in the amplification room until it is frozen and ready to be sent back to the submitter. The amplified DNA is packaged separately and sealed before it is packaged with the rest of the evidence being returned to the submitter.

The foregoing descriptions of the DNA analysis process, the standards and protocols that govern that process, and the structure and operations of the FBI Laboratory, particularly the DNAUI, provide context necessary to understand fully the findings and recommendations of our vulnerability assessment, as well as Blake's wrongdoing and how she exploited a loophole in the Laboratory's protocols to avoid detection. Before proceeding to address the results of our assessment, we describe below the events that precipitated the review, namely the discovery of Blake's disregard of protocols in the DNAUI.

CHAPTER FOUR
BLAKE'S MISCONDUCT

I. BLAKE'S CAREER WITH THE FBI

Jacqueline Blake was employed by the FBI in the DNAUI and its predecessor unit from August 8, 1988, until her resignation from the FBI on June 7, 2002. Blake has a Bachelor's of Science Degree in Biology from Benedict College in Columbia, South Carolina. She entered duty with the FBI as a Biological Laboratory Technician at the GS-5 grade level and was assigned to the Serology Unit of the Laboratory's Scientific Analysis Section. Her job responsibilities as a Serologist included inventorying and storing evidence and conducting routine evidence examinations to identify the presence of body fluids. Although her early performance appraisals noted that her training comprehension was slower than expected, she received fully successful evaluations or above from her initial appointment until 1994, and she reached the GS-10 grade level in 1991.

The first indications of problems with Blake occurred in 1991. In that year, Blake received an oral reprimand from the DNAUI Unit Chief for abusing her sick and annual leave accounts. She was advised in July 1991 that her leave balances were in deficit and that she could not take additional leave for the rest of the year. Blake nonetheless submitted a leave slip and failed to report to work for one day in November 1991 during an absence of the Unit Chief, even though she was aware that she had no accrued leave. She also took leave for a day in December 1991 without first seeking permission. These events prompted the DNAUI Unit Chief to audit her leave record, which revealed that 37 of her 46 sick leave days occurred either on a Friday, Monday, or the day following a holiday.

Blake's 1992 and 1993 performance appraisals rated her as "exceptional" on all critical elements. In June 1994, however, she received an overall job rating of unsatisfactory. Her performance appraisal stated that her "examinations are not performed according to acceptable laboratory practices," and that she generated false positive serology testing results during proficiency testing and "inaccurate documentation of examinations conducted for blood and semen." Following this evaluation Blake's conduct was monitored intensively for two months, during which time she passed a proficiency test and improved all of her job performance ratings to "fully successful."[38] By the end of 1994, Blake received an overall job rating of "superior," a level of performance that she maintained through 1996 when she was promoted to the GS-11 grade level.

[38] Around this time Blake also applied to become a Special Agent, but her application was rejected due to inadequate testing scores. She also withdrew from a lecture course for DNA Examiners because she was receiving failing marks.

Prior to her promotion in 1996, Blake indicated to DNAUI management that she wanted to transfer from serology to DNA analysis work. The Unit Chief at the time recalled that Blake seemed to have confidence problems and that she assigned an Examiner to work with her individually to help with the transition. Blake subsequently received training in the use of the DNAUI's preferred DNA testing methodology at the time, called restriction fragment length polymorphism (RFLP).[39] Blake's 1996 performance appraisal indicates that she demonstrated a "careful attitude" toward her RFLP work and adhered to the applicable protocol. Her 1997 performance appraisal rated her as "exceptional."

In April 1998, Blake was promoted to the position of GS-12 Biologist. In this capacity, she analyzed evidence following its examination by a Serologist and prepared detailed work notes for DNAUI Examiners describing the tests she performed and the results obtained. Over time Blake demonstrated good proficiency in the use of RFLP testing procedures and instructed other Laboratory employees in its use. Her performance appraisals in 1998 and 1999 gave her a summary rating of "exceptional."

In August 1999, Blake began training to become a PCR Biologist. The DNAUI was phasing out its use of RFLP and transitioning to PCR/STR technology. One Examiner, who had provided training to Blake when she was a Serologist, told the OIG that he advised the Unit Chief of DNAUI that Blake should not be allowed to become a PCR Biologist because she lacked the necessary skills. The Deputy Director of the Laboratory told the OIG that it can take up to two years to bring a new PCR Biologist on staff from outside the FBI. Under these circumstances, Laboratory management accepted Blake and thereby minimized a staffing shortage.

Blake took six months to complete the PCR training course, approximately two months longer than average, and her instructor noted that she seemed to have a difficult time with simple math.[40] Her PCR training required the completion of three training sets (one each for blood, saliva, and semen), and the processing of ten mock cases. The last mock case was considered a qualifying test for a later proficiency examination. On February 18, 2000, Blake worked on the eighth mock case and, undetected by the Laboratory, failed to process the negative controls. She made the same

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[39] RFLP is a technique that detects variation in a DNA sequence according to differences in the length of DNA fragments. These fragments are created using enzymes that cut the DNA strands at specific points. RFLP is a more restrictive technology than PCR/STR. It requires greater amounts of higher quality DNA to generate a profile, and takes considerably more time to complete. RFLP also is not as sensitive to contamination.

[40] According to one of Blake's Examiners, however, the instructor indicated to him during the training that Blake was performing satisfactorily and meeting the requirements of the training program.

undetected omission in both her qualifying and proficiency tests, which were administered on February 24, 2000, and March 14, 2000.

Thereafter, Blake assumed her duties as a PCR Biologist, which required her to take cuttings, swabs, or other material containing DNA from the Unit's Serologists and to complete the PCR/STR testing process (i.e., extraction, quantification, amplification, and capillary electrophoresis). Blake primarily worked on the examination team of Alan Giusti, although she also provided assistance to another Forensic Biologist Examiner, and the Manager of the DNAUII Federal Convicted Offender Program.

Blake's 2000 performance appraisal lacked the praise that characterized reviews of her RFLP work. Instead, the appraisal stated that Blake's work was "generally high" and that "she has required fairly extensive supervision to assist her in the decision-making processes that occur during the analysis." Her 2000 and 2001 performance appraisals graded her work as "fully satisfactory" and that she "meets expectations."

In fact, Blake's work in 2000 and 2001 was anything but satisfactory. Without the Laboratory's knowledge, from 2000 to 2002 she failed to process the negative controls in 90 out of 92 cases where DNA was detected on the evidence. Blake's misconduct was not discovered by the FBI until April 8, 2002, more than two years after she began work as a PCR Biologist. She initially denied omitting the negative controls when confronted by Richard Guerrieri, the DNAUI Unit Chief, on April 9, 2002. After that meeting, Blake did not report to the Laboratory again for work.

On May 10, 2002, Guerrieri notified Blake that she would be on leave without pay as of May 19. On June 7, Guerrieri and Joseph DiZinno, the Deputy Assistant Director of the FBI Laboratory (Deputy Director), went to Blake's residence to present a notification document from FBI OPR stating that her conduct had been referred for investigation. They also told her that the OIG was initiating a review of her actions. Blake said that she had thought about the matter and decided to resign. She turned over her credentials and building entry materials to Guerrieri. Blake composed a handwritten resignation letter, effective that day, which she gave to Guerrieri.

The FBI notified the OIG of Blake's misconduct in early May 2002. The OIG began an investigation, and over the next five weeks interviewed Laboratory staff, analyzed documents, and met with representatives of the FBI OGC. On July 11, 2002, an OIG attorney and investigator interviewed Blake at her home. Blake admitted to the OIG that she knew that she was not processing the negative controls that were required by the protocols. She also said she knew she was misrepresenting the status of the negative control samples when she did not properly prepare them for injection but initialed the related injection sheet anyway. On August 23, 2002, Blake executed an

affidavit attesting to these facts. The OIG referred the matter to the Department's Public Integrity Section for a prosecution decision. On May 18, 2004, Blake pled guilty in the United States District Court for the District of Columbia to a misdemeanor charge of providing false statements in her laboratory reports.

In her interview with the OIG, Blake explained that she wanted her cases to run smoothly and not to show contamination. Some Laboratory employees have speculated that the reason that she failed to process the negative controls was because she lacked confidence in her ability to master PCR/STR testing methods, which are far more sensitive to contamination than RFLP procedures.

Below we describe in detail Blake's wrongdoing, the impact of her conduct, why she was not detected sooner, and the adequacy of the FBI's response to the discovery that she had failed to process the negative controls in the vast majority of the cases that she handled.

II. BLAKE'S MISCONDUCT

A. Incompletely Processed Controls

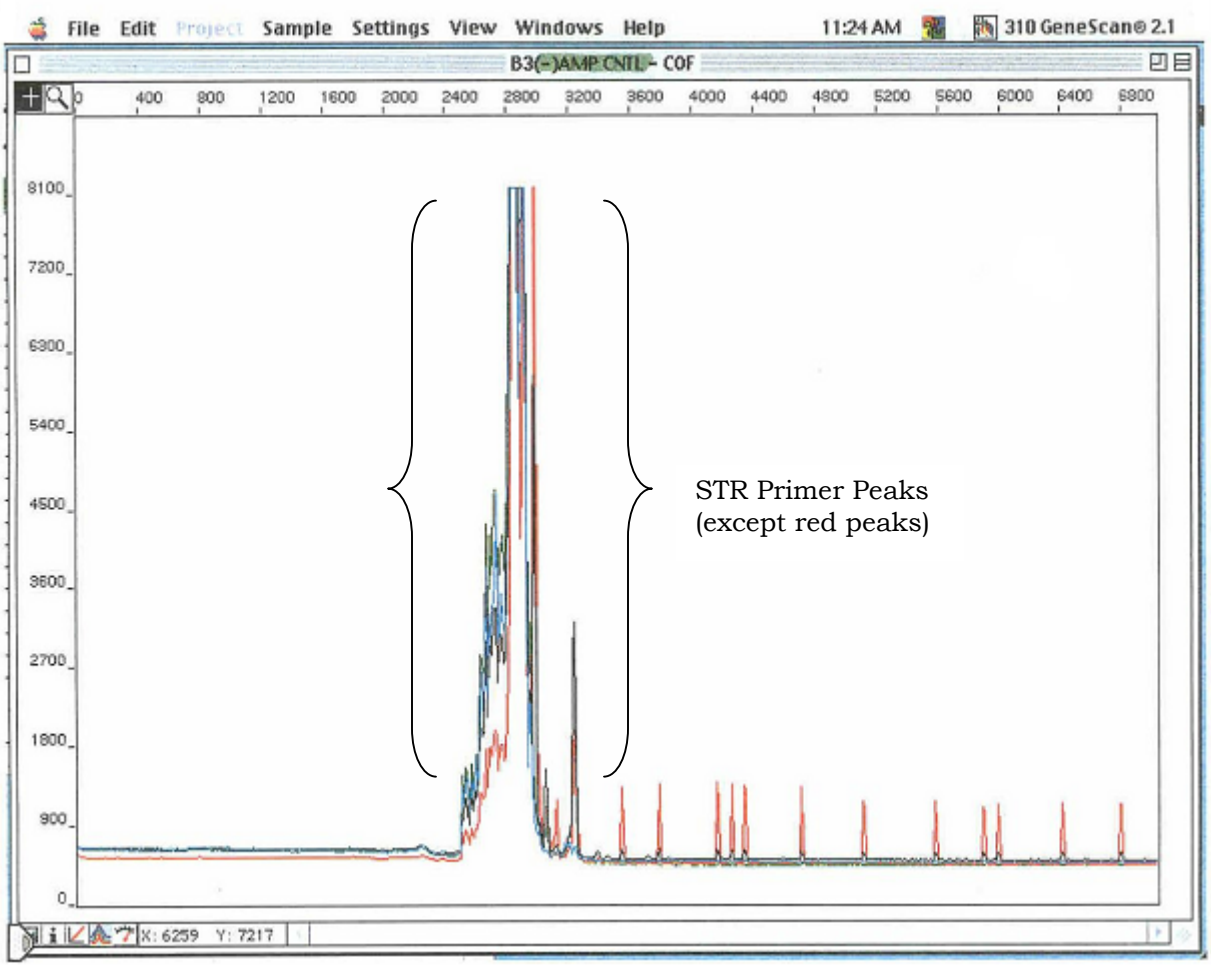
Blake's misconduct in the DNAUI resulted from her failure to process the negative controls and reagent blanks in accordance with DNAUI protocols. Although she properly prepared these two types of control samples for amplification, she failed to follow established procedures when preparing them for capillary electrophoresis. The effect of this omission has been to render nearly all of Blake's PCR work scientifically invalid.

As required during the extraction and amplification processes, Blake added all the amplification reagents to the negative control tubes and added all the extraction and amplification reagents to the reagent blank tubes. She also amplified the negative controls and reagent blanks as required.

As explained in Chapter Two, Section I.D (Capillary Electrophoresis) of this report, after amplification is complete the protocols require the PCR Biologist to add internal size standard to tubes. Prior to capillary electrophoresis, the PCR Biologist adds an appropriate amount of one of the following to the tubes containing the internal size standard: 1) amplified DNA from reference samples, evidentiary samples, or the positive control; 2) amplified negative control or reagent blank; or 3) an allelic ladder. After performing these steps, the DNA samples, positive control, negative control, reagent blank, and allelic ladders are ready for analysis using capillary electrophoresis.

Blake performed most of these steps as required. However, she failed to add a portion of the amplified negative controls and reagent blanks to the tubes containing the internal size standard. Therefore, the negative control and reagent blank samples that were analyzed through capillary electrophoresis consisted of only the internal size standard. As a result, the negative controls and reagent blanks were useless in detecting contamination that might have been introduced during the testing process. In order for these controls to detect contamination, the amplified contents of the negative controls and reagent blanks must go through capillary electrophoresis.

As illustrated below, GeneScan® printouts of the raw collection data for a properly completed negative control include everything detected during capillary electrophoresis, including the primer peaks that result from the reagents used during amplification.

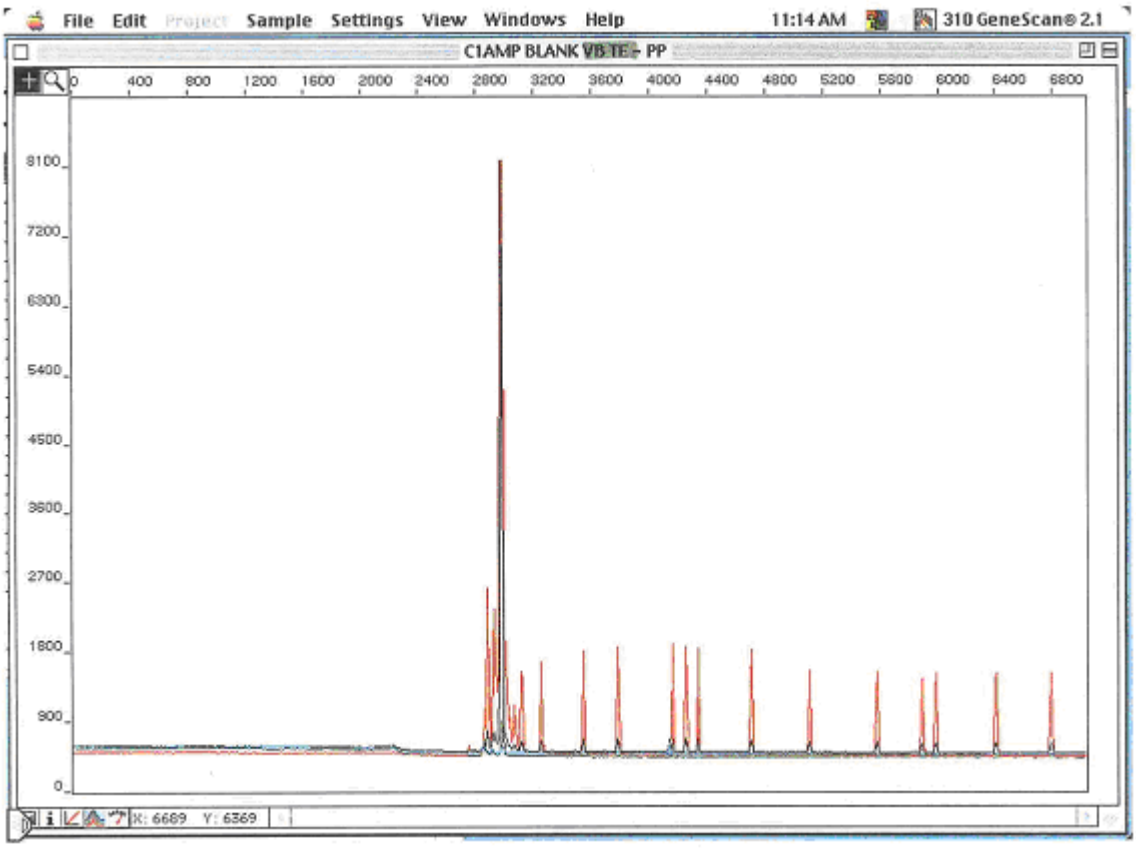


GeneScan® View: raw data for a Negative Control prepared according to protocol.
Peaks depicted in red originate from the internal size standard added to each sample.

When the negative controls and reagent blanks are prepared according to the DNAUI protocols, GeneScan® data will appear similar to the illustration above. During the amplification process, the primers are amplified along with

any other DNA in the tube (including any contamination that may have been introduced during the testing process), which allows the primers and the contamination to be detected during capillary electrophoresis.

If the PCR Biologist fails to add the appropriate portion of the amplified contents from the negative controls and reagent blanks to the tubes containing the internal size standard, those tubes will not contain any amplified DNA or unused primers, and only the internal size standard will be detected during capillary electrophoresis. Therefore, GeneScan® printouts of the raw collection data for the negative controls and the reagent blanks prepared by Blake do not show the primer peaks, as illustrated below. The red peaks shown on the printout represent only the internal size standard.



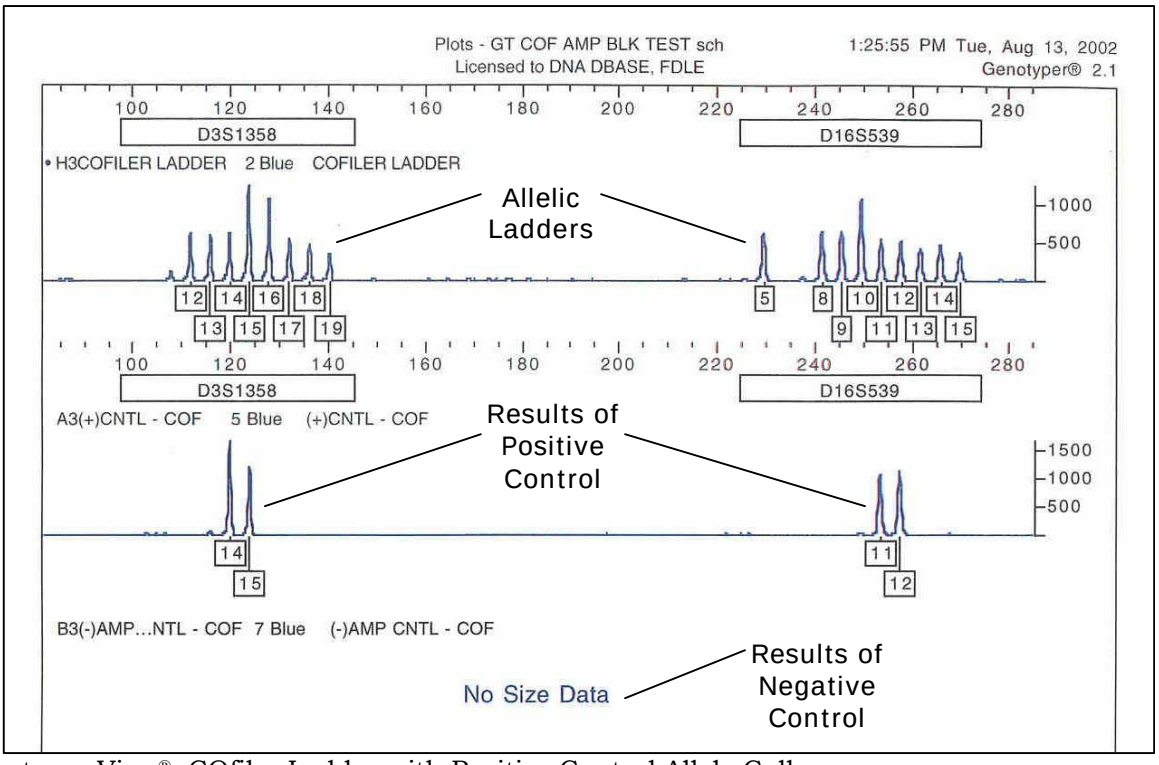
GeneScan® View: Negative Control without addition of amplified product

The differences between the graph on the previous page and the graph above are readily apparent. Reviewing GeneScan® data allows the Examiner to determine whether or not the PCR Biologist prepared the samples and controls for capillary electrophoresis in accordance with DNAUI protocols.

The consequence of Blake's omissions is that her testing results are scientifically invalid and cannot be relied upon. Without proper processing of the negative controls and reagent blanks, a Laboratory Examiner is not able to

rule out the possibility that contamination, rather than the evidence under examination, is the source of the testing results. By itself, however, the failure to process the negative controls does not change these results or lead to a particular testing outcome (e.g., creating a match between a known and unknown evidence sample). For this reason it is not possible to conclude that Blake intended to manipulate the testing process to implicate or to absolve individual defendants. The retesting of evidence in Blake's cases to date indicates that the DNA profiles that she generated were accurate.

Before Blake's misconduct was discovered, the DNAUI's policy called for Examiners to review only the Genotyper® printouts for the negative controls and reagent blanks to ensure contamination was not introduced during the testing process. This policy of not reviewing GeneScan® data allowed Blake's misconduct to continue undetected for approximately 25 months, since the Genotyper® data displays the message "No Size Data" [41] both for properly completed negative controls and reagent blanks that reflect no contamination (the desired result), as well as when no amplified product has been added (what Blake did). An example of this message appears in the following Genotyper® graph:



Genotyper View®: COfiler Ladder with Positive Control Allele Call

[41] The statement "No Size Data" is the message that the Genotyper® software displays when no DNA is detected in a sample (i.e., there is "no size data" because there were no DNA peaks for which Genotyper® could assign a size).

Thus, the only way to determine if the controls and samples are prepared properly for capillary electrophoresis is to review GeneScan® data that displays what the capillary electrophoresis detects. After Blake's misconduct was discovered, the DNAUI changed its policy to require Examiners to review GeneScan® data to ensure that the negative controls and reagent blanks are prepared properly.

B. Falsification of Laboratory Documents

In accordance with DNAUI protocols, Blake initialed each page of the case file documentation (including DNA analysis results) that she created. See generally Section 11.2.3 of the *DNA Analysis Unit I Quality Assurance Manual* (version. 7.28.00)(describing DNAUI initialing procedures).[42] A DNAUI employee's initials confirm his or her involvement in the processes and procedures described in the documentation. Id. Moreover, statements provided by Laboratory personnel, including Blake, indicate that DNAUI employees understood at the time of Blake's misconduct that an employee's initials at the bottom of a case file document signify that the work described is complete and accurate. By providing her initials in cases where she did not perform the requisite control testing, Blake falsified laboratory documents. As Blake has stated to OIG investigators, she knowingly misrepresented her work in Laboratory documents that she knew other DNAUI employees would rely upon to verify that she had complied with applicable procedures and protocols. According to Blake's signed, sworn statement to the OIG:

> During the OIG interview, I reviewed some documents that came from the file for Lab #991005047 GL FY. Included in those documents was an Injection List. The Injection List was prepared by me and lists the injections that the CE [capillary electrophoresis] machine was programmed to run in connection with the specific Lab Number. The Injection List that I reviewed was initialed by me in the lower left corner. These initials indicate that I generated the paper work and properly completed the preparation of the samples listed on the document for injection, including the negative controls. I knew that DNA Forensic Examiner Giusti, in this case, would have relied on this initialed Injection List as proof that all protocols were followed in processing the samples on the list. I knew that when I did not properly prepare the negative control samples for injection but initialed the related injection sheet anyway, I was misrepresenting that the negative control samples were properly prepared for injection and properly run on the CE machine. I also knew that no one routinely checked the raw data that would show the absence of the primer peaks for the negative controls.

[42] That section provides in pertinent part: "All technicians will typically document their involvement in the analytical processing of physical evidence by initialing the lower left corner of each page of the work product in which they were involved in generating."

Because she was not processing the negative control samples, Blake never had a need during her tenure in the DNAUI to record an entry in the Unit's contamination log. Yet, despite her prior training and performance problems, Blake's noteworthy and unusual record of contamination-free testing did not result in heightened scrutiny from Laboratory management.

C. The Impact of Blake's Misconduct

Our investigation of Blake's misconduct has not revealed any instances where Examiners from the FBI Laboratory presented erroneous DNA testing results in court based upon Blake's faulty STR analyses. Notwithstanding this fact, with the exception of 2 cases where she processed the negative controls and 11 cases where no DNA was found, Blake's misconduct has rendered over two years worth of her STR work scientifically invalid and unsuitable for use in court, requiring the FBI Laboratory to repeat DNA testing in her cases.[43]

Although the FBI Laboratory has yet to identify any cases where retesting did not confirm the accuracy of Blake's DNA profiles, we found that her actions caused significant adverse effects in at least five respects: 1) it required the removal of 29 DNA profiles from NDIS, 20 of which have yet to be restored;[44] 2) it delayed the delivery of reliable DNA reports to contributors of DNA evidence in Blake's cases; 3) her testing consumed all the available DNA evidence in several cases, leaving only her suspect DNA profiles as a basis on which to draw conclusions; 4) the corrective action necessary to address Blake's misconduct has consumed substantial resources of the FBI Laboratory and DOJ, as well as the resources of state and local investigators and prosecutors who were notified of her misconduct and had to take corrective measures in their cases; and 5) the controversy surrounding Blake has caused some measure of credibility loss to the FBI Laboratory.

After Blake's actions were discovered, the DNAUI notified the Forensic Science Systems Unit (FSSU)[45] within the Laboratory, which removed 29 profiles that Blake processed through STR analysis from NDIS. This work was completed by May 2002. As of March 2004, the Laboratory had retested and

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[43] As explained supra, while Blake's misconduct prevents the Laboratory from stating definitively that contamination did not distort her testing results, to date, reexamination of Blake's analyses, including retesting of evidence samples, has confirmed the accuracy of her work. As of February 2004, evidence in 27 of 90 cases where Blake failed to process the negative controls had been retested.

[44] DNA is not available for retesting for two of these profiles.

[45] In 2003, the FSSU was renamed the CODIS Unit.

restored nine profiles; no DNA remains for further analysis in two cases.[46] The Laboratory recently obtained contractor support to assist with evidence retesting in Blake's cases, and informed the OIG in October 2003 that it expected to restore the remaining profiles to NDIS by the end of March 2004. Until these profiles are restored there will be an ongoing risk that an investigative agency will submit a DNA profile and not generate a match with a corresponding Blake profile because the Blake profile has been removed from NDIS. Consequently, past crimes may remain unsolved.

Blake's misconduct also has delayed the delivery of reliable DNA reports to evidence contributors and wasted limited evidence samples. The Laboratory is attempting where feasible to obtain from contributors new evidence samples that Blake did not handle. In addition, in several cases Blake's faulty STR analysis is the only DNA information that is available. As with the two NDIS profiles described above, the earlier submitted evidence was consumed in the testing process and new evidence samples cannot be obtained.

Blake's misconduct also has adversely impacted the resources of the FBI and DOJ. The efforts that the FBI Laboratory and DOJ have had to expend on the corrective measures needed to address Blake's actions have been substantial. Both organizations have devoted thousands of hours of work to deal with the consequences of Blake's failure to comply with the DNAUI's protocols, a cost that does not include the funding expended for contractor support to retest evidence. The DNAUI Unit Chief estimated that in the year following the discovery of Blake's wrongdoing, he devoted more than half of his time working on Blake-related issues. The FBI's OGC and the DOJ's Counterterrorism Section have had to track legal proceedings in her cases and have issued dozens of notification letters to contributors explaining the possible ramifications of her actions. U.S. Attorney's Offices have had to respond as well. Blake's conduct has been put at issue in federal criminal

[46] According to the FBI, as of March 2004 the Laboratory was waiting for the resubmission of evidence in 13 out of the 29 cases for which NDIS profiles previously were removed. Reanalysis has been completed in an additional four cases, and currently is being completed in one case.

litigation through challenges to the admission of her work into evidence and to the integrity of DNA evidence generally.[47]

Lastly, we believe that Blake's misconduct, and the Laboratory's failure to detect it for a period exceeding two years, has damaged to some extent the credibility of the FBI Laboratory. Media reports of the Blake matter described her actions in the context of past and ongoing problems at the Laboratory.[48]

D. Why Blake Was Not Caught Earlier

1. The Detection of Blake's Misconduct

The discovery of Blake's misconduct was inadvertent. On Friday, April 5, 2002, a senior DNAUI Biologist and Blake's former PCR/STR instructor was waiting on her capillary electrophoresis machine to generate data when she happened to glance at Blake's machine, which was nearby. The Biologist noticed that the information displayed was not consistent with the proper processing of STR negative controls because the primer peaks were absent. She asked Blake the next time she saw her about the data stream that her machine had generated, and Blake provided a nonchalant response that heightened the Biologist's curiosity. She had expected Blake to explain that she had erred in her preparations for the electrophoresis; instead Blake indicated only that the configuration of the displayed data was not a problem.

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[47] In United States v. Smith, Criminal No. 2000-399(JCL) (D.N.J.), a civil rights action against five Orange, New Jersey, police officers for the death of a prisoner in their custody, the defense moved for a new trial after the Government disclosed that DNA test results that were admitted into evidence by stipulation had been generated by Blake without proper processing of the negative controls. After extensive submissions and argument, the court ultimately denied the defendants' motion, concluding that the introduction of the suspect evidence did not undermine confidence in the result of the trial. According to the DOJ Criminal Division, in the cases in which evidence that Blake handled was introduced, no defendant has successfully persuaded a court that Blake's protocol violation mandated a reversal of the conviction.

Challenges to exclude DNA evidence that was tested using STR technology also have been made in the Superior Court of the District of Columbia on grounds that the FBI's DNA protocols and quality assurance standards are neither minimally reliable nor generally accepted in the scientific community, and that Blake's conduct exemplifies the unreliability of the testing procedures. See United States v. Orlando Roberts, Crim. No. F-771-01, and United States v. David Veney, Crim. No. F-3986-00. The court in these cases denied the defendants' motions to exclude DNA evidence on these grounds. Blake did not analyze the DNA evidence in either case.

[48] See, e.g., "More Wrongdoing Found at FBI Crime Lab," Guardian Unlimited, April 16, 2003; "New Misconduct at FBI Lab Threatens Cases – Worker Lied at Trial; Other Accused of Shoddy Testing," The Baltimore Sun, April 16, 2003; see also "Voodoo Science and Another FBI Scandal," The Sunday Herald, April 20, 2003.

On Monday, April 8, 2003, the Biologist shared her concerns about Blake during lunch with a fellow Laboratory Biologist. Later that day, the first Biologist examined the underlying data for several of Blake's completed DNA profiles and discovered that the negative controls had not been processed. That evening, the Biologist telephoned her supervisor, the Unit Chief of DNAUI, Richard Guerrieri, at his home and told him of her findings. Guerrieri immediately recognized the potentially serious consequences if the Biologist's observations proved to be accurate.

Upon learning of the Biologist's concerns, Guerrieri contacted Blake's immediate supervisor, Forensic Biologist Examiner Alan Giusti. Guerrieri advised Giusti of the potential problem and directed him to conduct an "immediate and expeditious review" of multiple electronic raw data files for current cases to attempt to determine the nature and extent of the problem.

The next day Giusti identified several case files for review and examined them. He advised Guerrieri that there was "unacceptable performance of negative controls within the selected case files."[49] Guerrieri then reviewed the data collected by Giusti and concluded that there appeared to have been a systemic omission of the negative control within Blake's casework. With this finding, Guerrieri decided to notify then Acting Assistant Director of the Laboratory Division, Dwight Adams, of the situation.[50] Guerrieri did so the same day, April 9. Adams advised Guerrieri to pursue the matter as a "technical issue" unless circumstances warranted otherwise, and to interview Blake and attempt to ascertain the scope of the problem. According to Guerrieri, a "technical issue" is something that is not the result of a deliberate act. Guerrieri and Giusti also met with Blake on April 9 and she falsely stated that she had followed all required steps in processing her samples, though she may have made a few mistakes. Guerrieri informed Blake that until the technical issue was thoroughly evaluated and resolved, she was restricted from casework examinations and was not authorized to perform any further analyses.

2. How Blake Avoided Detection

We do not believe that Blake's success at escaping detection for over two years can be attributed to a lack of oversight by any one individual. Rather, Blake was not discovered earlier primarily for two reasons: 1) she was adept at lying to her supervisors; and 2) the DNAUI had in place a shortsighted policy that failed to require Unit Examiners to routinely scrutinize GeneScan® data.

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[49] Memorandum from FBI Laboratory, Scientific Analysis Section to FBI Director's Office, April 30, 2002 at p. 2.

[50] Adams has since become the Assistant Director of the Laboratory Division (hereafter "Laboratory Director").

Blake's willingness to lie to her supervisors coupled with the lack of review of GeneScan® data proved effective in concealing her failure to process the negative controls. Her affidavit to the OIG is clear that she knew exactly what she was doing when she initialed the CE injection sheet: she was misrepresenting to her supervisors that she had performed testing procedures that she in fact had omitted.

Blake also was fully aware that by not processing the negative controls and initialing the CE injection sheet she was taking advantage of a loophole in the Laboratory's procedures with respect to GeneScan® data. She told the OIG that she "knew that no one routinely checked the raw data." The DNAUI's standard operating procedures thus allowed Blake to carry out her misdeeds without discovery.

Moreover, the ease with which Blake escaped detection was facilitated by the Laboratory's failure to scrutinize her work in a manner that took into account her documented record of evidence handling problems and her prior training difficulties. Both during and after training to become a PCR Biologist, Blake received the same degree of oversight as a Biologist with an unblemished record. The Examiner for whom Blake worked most often, Alan Giusti, told the OIG that he was not aware of Blake's prior performance issues until after she was caught. He also did not know that one of his colleagues, who previously had trained Blake, had recommended that she not be permitted to become a PCR Biologist. The same individual refused to participate in her PCR training. Further, Blake's record of contamination-free testing for more than two years did not receive scrutiny. Laboratory personnel explained they thought that it was inconceivable that a fellow employee would not process the negative controls and therefore her failure to appear in the DNAUI's contamination log did not heighten scrutiny of her actions.

III. THE FBI'S RESPONSE

After the FBI Laboratory discovered Blake's omission of the negative controls, it worked quickly to determine the scope of the problem and to fashion a remedy to prevent its reoccurrence. The DNAUI isolated all of Blake's PCR/STR cases and performed case file reviews to determine if comparable misconduct had been committed by other DNAUI staff members. These initial remedial actions later were combined with efforts to repair the damage that Blake inflicted on the individual cases that she processed. We believe that, with some exceptions, the FBI's early response to Blake's misconduct was appropriate and timely. Our review revealed, however, that after the initial response, the pace of evidence retesting in the cases that Blake handled and of the Laboratory's notifications to evidence contributors and prosecutors has been problematic.

A. Initial Remedial Actions at the Laboratory

The Laboratory's initial remedial actions largely took place within the confines of DNAUI and were implemented under the supervision of Richard Guerrieri, the DNAUI Unit Chief. By April 15, 2002, Guerrieri was convinced that the lack of negative control data in Blake's work was not the result of equipment failure or other accident. Effective that day, he implemented a new policy requiring DNAUI STR case documentation to include hard copies of the electronic raw data files for all casework samples that depicted a negative result. In addition, the new policy provided that the STR documentation must be reviewed by the reporting Examiner and confirmed by a second Examiner. The decision also was made to limit the scope of the Laboratory's initial inquiry to the testing that Blake had performed as a PCR Biologist and not to examine her serology and RFLP examinations.[51] The DNAUI collected all the electronic raw data from Blake's STR tests and the training program files that she had completed.

By April 30, all of Blake's STR casework for Giusti and a second Examiner had been identified and was being categorized through the following priority system: reported inclusions (i.e., matches with known DNA samples), reported exclusions (i.e., elimination of match possibility with known DNA samples), and inconclusive results. This analysis led to the creation by early summer 2002 of a database of Blake's STR cases, which included information such as whether a DNA report had been issued from the DNAUI and the case status (i.e., phase of DNA testing). In all, Blake's STR analyses were identified

[51] In October 2003, the OIG asked the FBI what assessment the Laboratory had conducted of the risk that Blake had also committed misconduct while employed in the DNAUI as a Serologist and RFLP technician. The Laboratory replied that it was not prepared to offer a response at the time and thereafter interviewed Blake's former supervisors about her early work in the DNAUI. The same month the DOJ Criminal Division wrote to the Laboratory Director and recommended that the FBI "formulate a strategy to determine if Jacqueline Blake violated any protocols in her previous work assignments in the FBI laboratory," and that "[t]he FBI should work with the Criminal Division to design a plan for a preliminary inquiry . . . ." The Laboratory responded by letter dated January 28, 2004, that its risk assessment was completed and that it "is not aware of any outstanding technical issues that would potentially compromise the testing results previously generated by Ms. Blake in the areas of serology and RFLP analysis." The Laboratory reached this conclusion based on the facts that: 1) the analysis of her STR casework had not identified any "procedural departure[s]" other than her failure to process the negative controls; 2) the methodologies used in serology and RFLP work do not involve the use of amplified products from negative control samples; 3) any irregular control performance would have been detected through the quality assurance program and promptly addressed; and 4) the Laboratory's quality assurance controls, including proficiency testing programs and the direct supervision of Examiners, were in place when Blake was performing her serology and RFLP work. In short, the FBI Laboratory has expressed that it does not believe that an examination of Blake's work from August 1988 to March 2000 is warranted because Blake's primary failing was her aversion to processing STR negative controls – something that was not part of her serology and RFLP duties - and it is confident that its quality assurance controls would have caught her if she engaged in misconduct.

in 103 cases. Of these, no DNA had been identified in 11 cases, Blake failed to process the negative controls and reagent blanks in 90 cases, and she properly performed the tests in 2 cases. Out of the 90 cases in which Blake failed to process properly the controls, DNA analysis reports were sent to evidence contributors from the DNAUI in approximately 45 cases.

Guerrieri also developed a sampling plan to determine whether other biologists in the DNAUI failed to conduct the negative control tests. Ten active case files from each DNAUI PCR Biologist were scrutinized by the Unit's Examiners. All files, except those for Blake, indicated that the negative control specimens had been processed. Based on this evidence, the Laboratory concluded that the omissions in question were limited to Blake.

In addition to work within the DNAUI, Guerrieri promptly notified other units within the Laboratory of the Blake situation. On April 15, he spoke with John J. Behun, Chief of the FSSU and NDIS Manager. Behun concluded that all DNAUI specimens that Blake processed through STR analysis that were entered into NDIS should be identified and removed and placed into a temporary target batch file until the matter was resolved. This work was completed by early May 2002, and 29 profiles were removed from NDIS. DNAUI agreed to notify the FSSU of any confirmed NDIS matches involving DNA profiles generated by Blake and other NDIS contributors, to inform those contributors of the problem, and to attempt to reanalyze the negative control specimens and/or the remaining physical evidence. The DNAUI subsequently identified a single match through NDIS that had been generated by an external lab prior to the removal of Blake's profiles.[52]

Guerrieri also met with the DNAUII Unit Chief. In addition to her casework, Blake had performed STR analyses on some reference blood samples from incarcerated individuals within the Federal Convicted Offender Program managed by a DNAUII Examiner. Guerrieri and the DNAUII Unit Chief agreed

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[52] The NDIS match was generated from a convicted offender sample. The underlying criminal case involved an investigation of extortion, and the evidence tested was a letter. The FBI Laboratory, through the local FBI field office, requested a blood sample from the incarcerated offender to verify the match. After Blake's misconduct was discovered, the Laboratory also requested the return of the original evidence sample for retesting. The Laboratory never received the requested blood sample and the evidence was not returned for retesting. Follow-up contact by the Laboratory subsequently disclosed that prosecution was declined in the underlying criminal action. In another matter, the DNAUI generated a match in NDIS between one of Blake's profiles and an incarcerated offender. After Blake's misconduct was discovered, the profile was removed from NDIS and retesting performed. The newly generated profile matched the DNA profile of the same offender that previously was identified by NDIS. In addition, the Laboratory identified matches in a local DNA database from two of Blake's profiles. In one case, the FBI obtained resubmitted evidence and issued a new report. The profile from the retested evidence matched a profile in NDIS. The FBI is still waiting to receive evidence in the second case despite repeated requests to the contributor to resubmit its evidence.

that these samples should be located and retesting performed where appropriate.[53]

The Laboratory also sought guidance from FBI Headquarters, including the FBI's OPR and OGC. In mid-April, Adams met with Michael DeFeo, Assistant Director for OPR, and agreed that the Laboratory would forward documentation describing Blake's conduct to OPR for review. DeFeo advised Adams that the matter would have to be referred to the OIG. Guerrieri and DiZinno subsequently met with an OPR Unit Chief to brief him on the Blake matter. DiZinno said that the Laboratory hoped to receive guidance on what corrective actions should be implemented, including whether the Laboratory needed to evaluate Blake's serology and RFLP work. The OPR Unit Chief told them to furnish him with a written report outlining the misconduct allegations and the actions taken by the DNAUI in response to the discovery of the misconduct. On April 30, 2002, the Laboratory provided a 6-page memorandum to the FBI Director, with a copy to OPR, that described Blake's actions.

On May 7, 2002, OPR forwarded Guerrieri's April 30 Memorandum to the OIG, which began an investigation. As mentioned earlier, over the next five weeks OIG staff interviewed Laboratory personnel, examined documents, and met with representatives of FBI OGC. At a meeting on May 21, 2002, OGC explained that it would be heavily involved in the FBI's notifications to prosecutors, including providing legal guidance, and that the Laboratory would manage the Bureau's response to the Blake matter. The OGC and OIG agreed that the OIG would not be involved in managing the FBI's activities, though information would be shared to ensure that there was no interference with the OIG's investigation. The FBI OGC also explained that a management plan would be developed.

Following these developments, the DNAUI focused some attention on its operating procedures. In July 2002, as part of the Unit's annual review of its protocols, Guerrieri requested that DNAUI program managers take into account Blake's misconduct when formulating proposed protocol revisions. However, other than the requirement that GeneScan® data be included in the case file for review by the Examiners, Guerrieri did not receive any suggested modifications to the protocols from his staff. In addition, later that year Guerrieri initiated a project to map case processes in the DNAUI to facilitate communications and decision-making. See generally Chapter Five, Section III.A.2 (describing need for decision aids).

[53] Blake processed 105 offender samples. The Laboratory has retested 75 of these samples and expects to complete retesting of the remaining 30 by the end of March 2004. The Convicted Offender Program currently has a backlog of 24,000 samples waiting to be processed.

B. Identification and Processing of Cases That Required Corrective Action

After the FBI Laboratory took action to remedy the processing of negative controls in the DNAUI, its focus turned to correcting the damage that Blake caused in the cases she handled. This task has proved difficult for the Laboratory. For example, the majority of the evidence that required retesting in Blake's cases remained unevaluated over 23 months after her misconduct was detected and, in some cases, the Laboratory's testing has not been completed even though the evidence was submitted to the Laboratory over four years ago.[54] Moreover, as of March 2004, nearly half of the evidence contributors in cases where Blake failed to process the negative controls have not received written notification that Blake's misconduct impacted their evidence.

1. Early Reaction and Planning

One of the most pressing issues for the DNAUI after the discovery of Blake's misconduct was to identify the cases where an Examiner had relied on Blake's analyses and subsequently issued a report to a requesting party, and then to ascertain the status of legal proceedings in those cases. Completion of this work was not easy, however, because the Laboratory did not have a system to track legal proceedings after its findings were disseminated. As with many other issues, the formulation of the Laboratory's response to this problem was left to DNAUI Unit Chief Guerrieri and his staff. With Guerierri's oversight, the Laboratory established a database of Blake's cases in early summer 2002 to track its remedial work and to stay abreast of case developments.

Guerrieri met with an FBI Assistant General Counsel on April 10, 2002, two days after the discovery of Blake's actions, to inform her of the Blake problem.[55] From the outset OGC recognized the potential gravity of the situation. The OGC lawyer e-mailed her supervisor on April 15 and explained as follows:

> There is a major problem brewing in DNA Unit I that concerns a technician's work in preparing cases for the overall review of an examiner. They don't yet know the dimensions of the problem – it could be huge – implicating all of the cases of examiner Alan Giusti and other examiners as well, for years. They don't know if mistakes were purposeful or inadvertent, but they may threaten the integrity of our results across the board (Technicians do most of the underlying bench

[54] The FBI Laboratory has a goal for each unit to process its evidence within 60 days of receipt.

[55] At the time, the Assistant General Counsel was the primary OGC point of contact for the Laboratory.

work and examiners make the conclusions and write the reports). They are in the process of doing a review to try to ascertain the scope of the problem and whether it implicates other technicians as well (which they don't think it does). They have not yet notified OPR but they have taken the technician off cases immediately.

We may need a task force on this one – perhaps drawing from ASCLD-LAB expertise, and/or others out there in the forensic community. It's too early to tell anything just yet . . . .

Approximately one month later, OIG staff who were investigating Blake's actions met with OGC staff members and were told a management plan would be developed to guide the FBI's response to Blake's failure to conduct the required contamination testing and that it would be shared both with the OIG and the Office of the Deputy Attorney General. The OIG similarly was advised by the OGC Assistant General Counsel in May 2002 that "a policy will have to be arrived at in concert with the Lab." With the exception of the April 30, 2002, memorandum from the Laboratory to the FBI Director described supra, which the Laboratory explained to the OIG was its initial strategy, Laboratory management has acknowledged that no planning material was created to guide its remedial activities and to coordinate the work of the DOJ and FBI personnel working on the Blake matter.[56] Our review of documents furnished by the FBI, including e-mails, did not reveal any communications that outlined prospectively for the various participants what the FBI's response should entail, what the various participants were tasked to complete and, as appropriate, by when. In addition, in November 2002, the OGC Assistant General Counsel advised the OIG that no policy had been formulated for what she described then as a "fairly fluid" situation.

According to Laboratory employees, throughout the Spring and Summer of 2002 Laboratory management regularly discussed with the OGC how to proceed. The Laboratory Director explained that initially he held regular meetings with his staff to address Blake-related issues. The Department was not directly included in these meetings though, and the Laboratory Director explained that he has never spoken to the DOJ contact who the Criminal Division assigned to track developments in the Blake matter – Barry Sabin, the Chief of the Counterterrorism Section. According to Sabin, his role was to learn the facts of the Blake case, to identify any legal issues that required attention and advise the FBI accordingly, and to monitor the FBI's response on

[56] The April 30, 2002, memorandum described the Laboratory's early remedial actions, such as requiring inclusion of GeneScan® data in the casefile, the removal of Blake's profiles from NDIS, and the collection of Blake's STR data files.

behalf of DOJ.[57] The Laboratory Director further stated that he did not know what exactly the Counterterrorism Section was doing.[58] He also added that he has not asked anyone for an explanation of what the Counterterrorism Section's role is. He stated that he relies upon OGC to provide the Laboratory with pertinent guidance. Other Laboratory employees explained that they were surprised that there was not more direct contact with DOJ personnel. One senior FBI manager told the OIG that there was no leader overseeing the response of the FBI and DOJ to the problems caused by Blake's misconduct, and that was a problem because no one was in charge to coordinate activities.

2. Notifications

After the Laboratory determined that the failure to process the negative controls was limited to Blake and that her omissions were not the result of a technical defect, Laboratory management decided, with OGC assistance, to notify appropriate contributing agencies and/or prosecuting attorneys of the limitations regarding Blake's STR analyses. Additionally, Laboratory management decided that all trials in which Giusti had previously offered expert testimony regarding STR analyses based upon Blake's work would be identified, the resulting electronic data files reviewed, and appropriate officials notified if unacceptable performance of negative control specimens was

[57] In response to a draft of this report, the DOJ Criminal Division stated that the role of its attorneys in the Blake matter was limited to learning the pertinent facts, identifying legal issues related to criminal prosecutions that required attention, and monitoring to the extent necessary the FBI's response to these prosecution-related legal issues. The Criminal Division further explained that it was never asked to provide programmatic, scientific, or policy advice on issues related to Blake's misconduct. Our review found, however, that the work of the Criminal Division attorneys was not so limited, and the Counterterrorism Section in fact provided recommendations to the FBI on matters not specifically identified with criminal prosecutions. For example, in October 2003 Sabin wrote to the Director of the FBI Laboratory and stated that "[t]he FBI should formulate a strategy to determine if Jacqueline Blake violated any protocols in her previous work assignments in the FBI laboratory. The FBI should work with the Criminal Division to design a plan for a preliminary inquiry, and should keep the Criminal Division advised of any findings." We also were told that the Counterterrorism Section requested the FBI to provide prompt notifications to the evidence contributors who have not yet been told that Blake had processed their evidence improperly. These are cases where the Criminal Division believed that there are no prosecution-related legal issues (e.g., that Blake's work will not be relied upon to gain a conviction). Whether prosecution-related or not, we concluded that the advice of the Counterterrorism attorneys was appropriate.

[58] FBI personnel have expressed confusion over the work that Sabin was directed to perform. One FBI employee asserted that Sabin did not explain his role, while another employee said that he "did not know how DOJ management fits in." According to the Deputy Director of the FBI Laboratory, no meeting was ever held where the various FBI and DOJ participants identified their roles and responsibilities. Sabin told the OIG that he explained his role (as described in text above) to the OGC and to the Deputy Director of the Laboratory.

detected.[59] By April 30, 2002, the Laboratory had completed identification of Blake's STR analyses for Examiners Giusti and Garvey and had developed a priority notification scheme that accounted for various case considerations, including whether the DNAUI previously had provided testimony, trial status, terrorism linkages, and whether suspects had been identified. At approximately the same time Giusti began notifying evidence contributors by telephone of the situation; he also conferred with case prosecutors.

During May 2002, Guerrieri worked with OGC to create a notification letter for DNA contributors. Sabin began to assist the FBI with contributor notification and other issues at this time. He reviewed and provided input on the draft notification letter that Guerrieri and OGC had prepared.

On June 5, 2002, the first notification letters, signed by the Laboratory Director, were sent to 25 DNA contributors and prosecutors who had received a DNA report from the DNAUI. The letter stated cryptically that "some of the control samples were not processed to completion" during the DNA analysis and that the "DNA testing results reflected in [the issued report] should not be used for investigation or prosecution purposes until such control samples have been evaluated and determined to thoroughly satisfy established requirements." The letter requested that the contributor resubmit the evidence for additional analysis. The OIG subsequently raised concerns about these letters primarily because they failed to explain Blake's conduct adequately.

Additional notification letters signed by the Laboratory Director were sent in July and October 2002 to 44 contributors and prosecutors. These letters contained the same language used in the Laboratory's June letter, and were not sent consistently to associated prosecutors. According to one Laboratory employee, OGC became much more involved in notification and case tracking issues beginning in October 2002. A new OGC attorney was assigned that month to handle the Blake matter. The OIG was able to verify that OGC delivered 71 letters covering 56 cases to contributors and prosecutors in late November and December 2002,[60] many to the same contributors who received earlier notification from the Laboratory.[61] OGC's notification letters described

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[59] One matter that required immediate attention during the week of April 9, 2002, was Texas v. Berkley, a homicide case in El Paso, Texas. The Laboratory previously had issued a report based upon Blake's work and Giusti was scheduled to testify about his conclusions during the week of April 15, 2002. Guisti requested and received from authorities in El Paso a sample for retesting, completed the retesting, and issued a new report dated April 15, 2002, confirming the results of the original testing. Giusti testified in El Paso on April 17, 2002.

[60] OGC developed notification letter templates to cover cases in which: 1) there was no DNA to test, 2) Blake had followed the negative control protocols, and 3) a previous letter had been sent but more detailed guidance was necessary.

[61] OGC issued another five letters in January 2003, and the Laboratory sent four letters in August and September 2003.

Blake's misconduct, the function of negative controls, and the initiation of the OIG investigation. It also requested the addressee to resubmit evidence for testing and to share a copy of the notification letter with any prosecutors who were working on cases to which the previously submitted evidence related.

The Counterterrorism Section at DOJ also assisted the FBI to inform DNA contributors and prosecutors of the Blake matter by issuing letters supplementing the information contained in the FBI's notifications. Between July and September 2003, the Counterterrrorism Section sent out 27 letters to prosecutors and contributors and has issued another 2 since that time. Following discussions with prosecutors in Blake's cases, the Counterterrorism Section focused its notifications on matters where the possibility remained for Blake's DNA analyses to be relied upon in future investigative activities and/or court proceedings. The Counterterrorism Section prepared different letters depending on whether Blake's conduct previously had been disclosed to defense counsel. These letters emphasized disclosure obligations, that Blake had custody and control over the original submitted evidence that was used to conduct the initial DNA analysis, and that there was no indication that Blake failed to abide by any Laboratory protocols in the DNAUI other than those regarding the processing of control samples. The Executive Office for United States Attorneys also issued an 8-page guidance document regarding the Blake matter in June 2003 to all United States Attorney's Offices based on legal analysis performed by the Counterterrorism Section.[62] That document addressed a host of different legal issues implicated by Blake's conduct, including chain-of-custody and ethical considerations, and was included by the Counterterrorism Section in its correspondence to DNA contributors and prosecutors.

Despite these efforts, as of February 2004, DNA contributors in 42 cases still had not received written notification that Blake had failed to process properly the evidence they had submitted. Of this number, 20 contributors received no notification at all concerning Blake's handling of their evidence. Of the written notifications provided, in some situations as many as three letters have been sent to the same individual. See further discussion in Chapter Four, Section IV.

3. Evidence Retesting

In addition to its efforts to notify DNA contributors about the Blake problem, the Laboratory developed procedures to provide contributors with retesting of evidence. Initially Guerrieri, with the approval of Adams, opted to process only the negative controls that Blake had not completed. By late June or early July 2002, however, Guerrieri determined that full retesting of all

[62] This guidance is now being included with the Laboratory's reports that issue in Blake's cases.

samples in Blake's STR cases in which the negative controls had not been run was required to ensure technically valid results that could be used as evidence. Early testing of the uncompleted negative controls had resulted in the discovery of DNA contamination in some samples, while other analyses were missing a quantification step. Under these circumstances, and based on Guerrieri's recommendation, Adams opted for full retesting.[63] According to Guerrieri there was no discussion whether this decision had legal ramifications, and if so, what they might be.

The Laboratory also decided in Spring 2002 to perform the retesting itself rather than attempt to out-source the work to a contractor. According to one Laboratory employee, this decision was made within days of learning of Blake's misconduct. The decision also was made despite the fact that the Laboratory was faced with a substantial backlog of cases in the DNAUI. According to DiZinno, the Laboratory had, and continues to have, an unacceptable turnaround time processing evidence, especially in the DNAUI. By December 2002 the DNAUI recognized that it could not complete the retesting of Blake's cases in a timely manner. It thereafter reversed course and entered into contracts in September 2003 to have the evidence in Blake's cases retested by private laboratories. The Laboratory stated in early 2004 that it expected to have this work completed by the end of March 2004. DiZinno acknowledged to the OIG that the Laboratory underestimated the time it would take to retest Blake's evidence and that the pace of retesting has been problematic.[64] As of February 2004, evidence retesting had been completed in only 27 out of the 90 cases where Blake failed to process the negative controls, and 20 of the original 29 profiles removed from NDIS still have not been restored.[65]

IV. OIG ANALYSIS

Our examination of the FBI's response to Blake's misconduct revealed that the FBI Laboratory worked quickly to determine the cause of the negative control omissions in Blake's cases and whether other biologists in the DNAUI had experienced the same problem. After the Laboratory confirmed that the

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[63] As described by Guerrieri, full retesting entails completing all the duties of the Serologist, PCR Biologist, and Examiner described in Chapter Three, Section I.B.2.b of this report.

[64] The Criminal Division at DOJ has expressed the same sentiment. In a letter to the Laboratory Director dated October 28, 2003, the Counterterrorism Section recommended that "remedial measures [] be taken as soon as possible," and that "[r]etesting should be conducted in an expedited fashion."

[65] Of the 90 cases where Blake failed to process the negative controls, the FBI Laboratory, with the assistance of its contractors, intends to complete evidence retesting in 64 cases. In the remaining 26 cases, retesting has been deferred pending the resubmission of evidence from the original evidence contributor.

failure to process the negative controls was limited to Blake and not due to technical causes, such as equipment failure, it self-reported the facts and circumstances regarding her misconduct to the FBI OPR and sought guidance on how to fashion a proper response. OPR advised the OIG of the matter approximately one month later.[66] The DNAUI also promptly closed the loophole in its procedures that allowed Blake to escape detection for over two years: it required GeneScan® data to be included in the case file and reviewed by two Examiners. The effectiveness of the Laboratory's early response to Blake's wrongdoing was due largely to the efforts of the DNAUI Unit Chief, Richard Guerrieri, and his staff, who deserve credit for these actions.

However, our review identified other issues of concern regarding the FBI's response to Blake's misconduct. These include: 1) the timeliness of the retesting of evidence and of written notifications to DNA contributors and prosecutors; 2) the legal analysis provided by the FBI OGC in the months immediately following the discovery of Blake's misconduct; and 3) the scope of the Laboratory's remedial actions. We also believe that given Blake's prior work history and training experiences, the Laboratory should have paid more careful attention to her performance on her initial PCR qualifying and proficiency tests and on the first several profiles she generated after she became a PCR Biologist.

A. Timeliness of Evidence Retesting and Notifications

The retesting of evidence in Blake's cases has taken too long. The Laboratory's Deputy Director told us that he was not satisfied with the pace of the retesting, and the DOJ Criminal Division echoed the same concern in an October 2003 letter to the Laboratory Director that requested that evidence retesting "be conducted in an expedited fashion."[67] Given that the Laboratory has a goal of 60 days for each unit to process its evidence, and that the DNAUI has taken over 2 years to complete its reanalysis in many of Blake's cases (and in some matters over 4 years for the Laboratory to complete all requested analyses), we think it is self-evident that the pace of retesting has proceeded far too slowly.[68]

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[66] Under the OIG's Investigative Procedures Relating to FBI Employees, the FBI is required to report immediately to the OIG non-frivolous allegations against any employee or contractor which, if substantiated, would constitute a prosecutable offense.

[67] Letter from Barry Sabin, Chief, Counterterrorism Section, Criminal Division, Department of Justice to Dwight Adams, Assistant Director, FBI Laboratory, dated October 28, 2003, at 1.

[68] Laboratory Director Adams told the OIG that he was satisfied with the pace of retesting, a position we find hard to reconcile given the multi-year delays described above. The DNAUI Unit Chief stated that he wished he had had the staff to complete the retesting earlier but that he was satisfied with the procedures the Laboratory had employed to conduct the work. He emphasized that he would not sacrifice the quality of the retesting for time savings.

Several factors have contributed to the delays, including events beyond the Laboratory's control, such as the responsiveness of contributors to resubmit their evidence. The delays have been significantly exacerbated, however, by a decision the Laboratory made soon after Blake's detection. Although the DNAUI at the time had a substantial backlog of cases to analyze, and historically has been a bottleneck in the Laboratory's processing of evidence, Laboratory management opted not to seek contractor assistance with Blake's cases and instead attempted to complete the reexaminations itself. The result was that the Laboratory had less than ten cases retested by the end of 2002; it was only at that point that the decision was made to seek contractor support. The Laboratory entered into two contracts in September 2003 with private laboratories to retest the balance of evidence in Blake's cases.

We believe that the Laboratory failed to analyze properly whether it could absorb the additional retesting work and complete it in a timely fashion. The backlog of unprocessed DNA evidence and manpower constraints should have alerted the Laboratory to the need to seek outside assistance sooner than December 2002. The consequence of this decision is significant. The Laboratory's failure to seek the necessary resources promptly heightened the risk that a criminal would avoid identification because his or her DNA profile, which otherwise would be available but for Blake's misconduct, is not included in the appropriate DNA databases for law enforcement agencies to search.

Similarly, we are concerned with the time it took for the attorneys who worked on the Blake matter to generate a sufficient notification letter, and that nearly two years after the discovery of Blake's misconduct there were still 42 cases where evidence contributors had not received a letter notifying them that Blake had failed to process properly the evidence that they submitted. After the Laboratory issued its first letters in June 2002, which FBI OGC and the DOJ Counterterrorism Section worked on jointly, the OIG questioned the sufficiency of the notification. In our view, the June letter failed to describe adequately what Blake did. The Laboratory, however, continued to issue notification letters in July and October 2002 with the same language as the June letter.[69] FBI OGC began issuing its own notification letter to contributors and prosecutors in late November 2002 that described Blake's misconduct and was drafted largely by OGC supervisors. We believe that this letter was sufficient to alert evidence contributors and prosecutors to Blake's misconduct

[69] According to the Criminal Division, after the OIG voiced its objection to the June letter, the Criminal Division drafted a revised letter addressing all of the issues raised by the OIG and forwarded it to FBI OGC.

such that proper disclosures could be made.[70] We are concerned, however, that the Laboratory's letters were not sent or copied to all associated prosecutors.

Within the first two months following Blake's detection we believe that the OGC staff attorney assigned to the Laboratory should have prepared a notification letter comparable to the one that was sent by OGC in November and December 2002, and that the written notification should have been completed by mid-summer 2002 at the latest. These letters should have been delivered to all evidence contributors and their associated prosecutors. Although we did not find case-related prejudice resulting from the timing of the notifications, we believe that the Blake matter required earlier and more complete notification than was provided.

We also are concerned that nearly two years after Blake's detection, DNA contributors in 42 cases had not received written notification that Blake had failed to process properly the evidence they submitted, and 20 of these contributors received no notification at all concerning their evidence. According to the FBI, with two exceptions the cases where notice has not been furnished are ones in which no report was issued from the DNAUI and no

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[70] In response to a draft of this report, the FBI OGC took issue with our view that the letters issued in November 2002 by OGC differed significantly from the Laboratory's earlier letters, which made no mention of Blake's misconduct and stated simply that "[a] review of the data used to prepare the DNA analysis reports of examination . . . revealed that some of the control samples associated with these analyses were not processed to completion." In contrast, the OGC letters stated that "one biology technician in one of the FBI Laboratory's two DNA Units systematically and repeatedly violated the Laboratory's standard operating protocols by not processing negative control specimens to completion in approximately 100 cases over approximately a two-year period." In its response, the FBI OGC took the position that:

> the only substantive distinction between the initial and subsequent letter was the inclusion of Blake's misconduct as the cause of the flawed test results. It is a distinction without a difference (and certainly not a difference of any legal import) with respect to the sole purpose of the notice: to advise the contributor not to rely on the results.

We are concerned by this comment from OGC. As repeatedly explained to the OIG throughout the course of this review, both the FBI and DOJ issued notification letters to contributors and prosecutors so that Brady obligations could be satisfied. The purpose of the notification therefore was not simply to advise the contributor not to rely on the testing results. It also was to satisfy constitutional obligations. Impeachment evidence falls squarely within the dictates of the Brady rule. The Criminal Division's notification to federal prosecutors concerning Blake, which devotes several pages to an analysis of Brady obligations, further recognizes that whether information constitutes Brady material can depend upon the extent to which it could alter defense strategy. As explained in footnote 48, counsel have attempted in a limited number of cases, albeit without success, to use Blake's conduct to question the reliability of DNA testing procedures. In light of these considerations, we believe there is a distinction, indeed an important one, between failing to process negative controls due to an isolated event of equipment malfunction versus a laboratory employee who "systematically and repeatedly violated the Laboratory's standard operating protocol." We encourage the FBI to reevaluate this issue.

suspect has been identified. The FBI also has explained that the individuals who submitted the evidence in these cases have not contacted the Laboratory to inquire about the evidence, possibly indicating that the case in question is inactive. Although 11 of the 20 cases in which no notice was provided originated either from the Washington Field Office of the FBI or the Washington Metropolitan police, which received written notifications of Blake's wrongdoing in other cases as well as other communications about her misconduct,[71] we believe that all evidence contributors and associated prosecutors should have been notified directly in writing during the summer of 2002 that Blake had failed to process their evidence properly. At that juncture the evidence contributor would have had the ability to make an informed decision whether to resubmit new evidence or to seek testing services from another source. Because 20 of these contributors were not informed, however, they were deprived of the opportunity to make this decision. Moreover, we believe that the failure to provide these notifications by this date violated the spirit of the message that the Laboratory conveyed to the FBI Director and FBI OPR in its April 30, 2002, memorandum in which it explained that "[w]ith the assistance of the OGC, the LD [Laboratory Division] will notify all appropriate contributing agencies and/or prosecuting attorneys of the technical issue and potential limitations regarding the STR analyses conducted by Ms. Blake." The Counterterrorism Section also informed the OIG that it encouraged the FBI to make full and complete written notifications to all evidence contributors and associated prosecutors.

We further believe that the timeliness of the FBI's evidence retesting and notifications was hindered by the Laboratory's failure to maintain written planning materials and to disseminate them to officials who were assisting the Laboratory with the Blake problem. The FBI was unable to identify any document for us that set forth prospectively for Laboratory staff members the steps they should take to address Blake's misconduct and the timeframes contemplated to complete particular tasks. OPR asked for a written plan, and the Laboratory should have updated its April 30 memorandum as time progressed and shared it with others. FBI OGC explained to the OIG in May 2002 that a management plan would be created to guide the response over time and that it would be shared with the OIG and the Office of the Deputy Attorney General. Such a plan was never developed, and the consequence was unnecessary inefficiencies and delay.

We believe that had the Laboratory prepared a management plan, it would have diminished the likelihood that three entities – the Laboratory, FBI OGC, and the Counterterrorism Section – all would need to send out notification letters. It also may have triggered more careful analysis regarding

[71] The FBI Laboratory made a presentation for the United States Attorney's Office for the District of Columbia, and personnel from the Criminal Division, the FBI OGC, and the Laboratory briefed that office's management on the Blake matter.

the decision to keep the retesting of evidence within the Laboratory rather than seeking a contractor to assist with the work. This plan should have tasked the FBI OGC attorney assigned to the Laboratory with specific notification-related assignments and coordination responsibilities. It also should have identified milestones for the evidence retesting and triggers for the reevaluation of the need for contract support.

We are also troubled that Laboratory management at the highest levels seemed disinclined to seek out DOJ's views and to coordinate its planning activities with DOJ. Adams stated that the Laboratory Division at the FBI was "in charge" of the Blake situation, but at the same time he explained that he didn't know what the Counterterrorism Section was doing. We believe that if that were the case, the Laboratory Director should have reached out to DOJ to understand its views on the Blake problem, and if the Laboratory and DOJ had differing priorities, these should have been identified, discussed, and reconciled at the earliest possible moment. We believe that DOJ made it clear to FBI OGC that it wanted fuller disclosures and more information provided to contributors and prosecutors. DOJ pressed for more expedited evidence retesting. The Laboratory was slow to respond, with the result that two years after Blake's detection, evidence still is waiting to be retested and many evidence contributors still do not know that their evidence was improperly processed by Blake.

B. The Sufficiency of Legal Services Provided to the Laboratory in the Months Following Blake's Detection

We also question the relationship between the Laboratory and FBI OGC in the months following Blake's detection. Blake's misconduct required the Laboratory to address numerous issues, such as what the permissible uses are of Blake's corrupted profiles and how to conduct the retesting of evidence. Indeed, in the initial aftermath of Blake's discovery, the Laboratory needed assistance merely to determine what the issues were that needed to be evaluated and resolved.

The OIG's interviews with the Assistant General Counsel from OGC who handled the Blake matter from April to November 2002, and others have led us to conclude that the Laboratory did not receive the quality of legal services that one would expect from FBI OGC, and Laboratory management was not sufficiently assertive when soliciting legal advice. In our view, substantial effort was required at the outset of the Blake matter to: 1) learn the underlying facts, 2) identify and organize the legal issues that those facts implicated, 3) analyze and explain to the Laboratory the legal principles that were pertinent to the issues in question, 4) present the litigation risks and legal policy considerations associated with particular courses of action available to the Laboratory, and 5) highlight pitfalls or issues of special concern that warranted the Laboratory's attention.

Both the Laboratory and OGC explained that no meeting was ever held to brief the FBI Laboratory on the legal considerations described above or to present the findings and conclusions of any legal research. Indeed, the OGC attorney told us that she did not conduct any legal research. No memoranda were prepared for the Laboratory and our review of the Assistant General Counsel's case file did not reveal any documents, including e-mails or notes, that set forth substantive legal analysis or otherwise identified the issues and organized them in a way that would be comprehensible to the Laboratory. Disclosure issues were obvious from the outset, but there were others that should have been addressed in a meaningful way much earlier than they were, such as what was permissible with the off-loaded NDIS profiles and chain-of-custody issues. The Assistant General Counsel's response to our questions on several occasions was that we did not understand the way FBI OGC operated. She further explained that she is a traditional counselor at law who rendered advice based largely on past experience: someone posed a question and she provided an answer.

This approach was ill-suited to the complexities of the Blake matter, and we believe that her conduct had consequences for the response of the FBI and DOJ to Blake's misconduct. The deficit was readily apparent to the OIG in the first few months following Blake's detection, and in our view necessitated, for example, that her supervisors become extensively involved in the provision of notifications to contributors and prosecutors. We believe that a senior OGC staff attorney should have demonstrated the leadership to furnish comprehensive and timely legal support services for the Laboratory.

C. The Scope of the Laboratory's Remedial Actions

Our review concluded that the Laboratory's remedial actions were not comprehensive enough in two respects: 1) the scope of the Laboratory's self-generated protocol revisions were too narrowly focused; and 2) the assessment of Blake's work for protocol discrepancies failed to account for her work as a Serologist and RFLP technician, which together accounted for 12 of the 14 years that she was employed in the DNAUI.

As described earlier, after the Laboratory identified Blake's wrongdoing, the DNAUI promptly changed its operating procedures to require the inclusion of GeneScan® data in the case file and its review by two Examiners. Laboratory Deputy Director DiZinno explained that once the Laboratory understood exactly what Blake had done, the necessary changes in procedure occurred quickly. The DNAUI Unit Chief also requested that, as part of the Unit's annual protocol review, his program managers submit recommendations for protocol revisions that took into account Blake's wrongdoing. The only suggestion that was offered, however, was to institute what already had been done by that time: include GeneScan® data in the case file.

We believe that Blake's actions should have triggered an extensive reevaluation within the DNAUI of its protocols. DiZinno told the OIG that one of the lessons learned from the Blake situation is that the Laboratory could not count on the trustworthiness of all of its employees. Within the first two months of learning of Blake's wrongdoing, the Laboratory should have laid the groundwork for a comprehensive reevaluation of the DNAUI's protocols. Instead, the Laboratory seemed to focus on a far narrower issue – how do we spot someone who has developed an aversion to processing negative controls involving amplified DNA samples – and did not comprehensively examine its protocols, which is a clear deficiency.

We further believe that the Laboratory erred when it decided to limit its investigation of Blake to the last two years of her work, pending the discovery of additional incriminating evidence against her. The Laboratory did not even ask Blake's serology and RFLP supervisors whether they had noticed anything suspicious about her work until the OIG asked in October 2003 what assessment the Laboratory had conducted on Blake's work from 1988 through March 2000 concerning the risk that she had violated DNAUI protocols. The DOJ Criminal Division also raised this issue in a letter to the Laboratory at the end of October 2003.

The Laboratory has taken the position that no additional inquiry is warranted on the cases that Blake handled during her 12-year tenure as a serologist and RFLP technician primarily because it appears that Blake's major failing was limited to her aversion to running STR negative controls, there is no indication that she ever intended to manipulate test results, and the procedural controls in place in the DNAUI would have caught any misconduct. We think, however, that the message from the totality of circumstances surrounding Blake, including her 1994 performance appraisal and training history, is not so narrowly tailored: Blake was an untrustworthy employee who manipulated the DNAUI's procedures and lied about her conduct. The Laboratory's confidence in its serology and RFLP protocols to detect misconduct by Blake also must be considered in light of the fact that its STR protocols did not detect her misconduct.[72]

We have no evidence that Blake, in fact, violated DNAUI protocols while working as a Serologist or RFLP technician. We also have no indication that Blake's supervisors from 1988 to March 2000 failed to scrupulously evaluate her work and catch and correct every discrepancy that appeared in her casework. But we also believe that the Laboratory was not fully aware at the time of the kind of employee it was dealing with. Under these circumstances, a

[72] We say this fully aware that the procedures in STR and RFLP are completely different.

file review of a subset of Blake's early work, where identifiable, is appropriate taking into account what is now known about Blake's conduct.[73]

D. Oversight of Blake's PCR Qualification Testing and Early PCR Work

Although Blake's work and training performance was deficient at times, she did not receive additional scrutiny from the Laboratory, either during her qualifying testing to become a PCR Biologist or as she completed her first few examinations as a PCR Biologist. We believe that this was an error. Blake's record in the DNAUI was inconsistent enough to warrant additional scrutiny. The Examiner who oversaw most of Blake's work as a PCR Biologist was not made aware of her negative performance issues until after she was caught. Also, no one asked him to pay closer attention to Blake's work. Blake's supervisors should have had more information, consistent with applicable law and regulations, and should have been looking more closely for discrepancies in her work. Although it is not possible to say with certainty that Blake's misconduct would have been discovered earlier if her supervisors had had more complete information, we believe that the additional scrutiny would have increased the probability that she would have been detected prior to April 2002. Moreover, if her work had been analyzed during her initial qualifying and proficiency tests as a PCR Biologist, or during her first several tests as a PCR Biologist, her failure to run the negative control tests would likely have been detected by the summer of 2000 before she had processed many cases.

V. RECOMMENDATIONS

With regard to the FBI's response to Blake's misconduct, we recommend the following:

1) To facilitate prompt communications with evidence contributors and prosecutors in the event of future testing problems, the Laboratory should maintain the following information in an electronic format that can be shared conveniently with other FBI components (such as, FBI OPR and FBI OGC) and DOJ: all contributor contact and case information currently required for an evidence contributor to

[73] In this regard, we respectfully disagree with the conclusion of the United States District Court for the District of New Jersey. See generally United States v. Smith, Criminal No. 2000-399(JCL) (Memorandum Order, Jan. 12, 2004, D.N.J.) at 2 (denying motion for a new trial where Blake had performed DNA examination). Blake's conduct was not "unsophisti-cated," Smith, at 4; we believe that it was calculated and cunning. Blake exploited a loophole to her advantage that no one previously had recognized. She also was clever enough to experiment with her technique in the PCR training program, perhaps to see if anyone would notice. Its discovery at that point could have been discounted by the difficulty of having to learn complex test procedures.

request an evidence examination (see FBI Handbook of Forensic Services, (http://www.fbi.gov/hq/lab/handbook/intro2.htm); the e-mail address of the evidence contributor; and the name, title, agency, address, telephone number, and e-mail address of any associated prosecutor(s);

2) In circumstances where a protocol violation renders testing results scientifically invalid and a report from the Laboratory is not expected to issue within 180 days from the discovery of the violation, the Laboratory should notify the evidence contributor of the following information within 90 days of learning of the violation: the nature of protocol violation; how the violation occurred; the remedial measures that the Laboratory intends to implement in the case to generate scientifically valid testing results; and the time needed to complete the remedial measures and to issue a final report.

3) The FBI Laboratory should perform a file review of a sample of cases that Blake is known to have worked on prior to becoming a PCR Biologist to reconfirm that the procedures that were required in fact are documented as appropriate in the case files.

CHAPTER FIVE
OIG ASSESSMENT OF THE FBI'S DNA PROTOCOLS AND PRACTICES

Blake's misconduct occurred even while the DNAUI received satisfactory audit reports from both internal and external auditors. As described previously, Blake was able to conceal her actions for almost a 2-year period because of inadequate DNAUI internal controls.[74] As a result, the OIG undertook an assessment of the Laboratory's DNA protocols and practices to determine whether oversight vulnerabilities exist within the DNAUI.[75]

I. ASSESSMENT FOUNDATION AND PROCESS

A. Objectives

OIG staff designed the assessment to examine comprehensively the DNAUI's protocols and their application. Our objectives were to:

- analyze the vulnerability of DNAUI protocols to undetected inadvertent or willful noncompliance; and
- assess the DNAUI staff's application of the protocols identified as vulnerable above.

These objectives were accomplished in two phases. In the first phase, the OIG team reviewed the written DNAUI protocols for vulnerabilities. The second phase consisted of OIG fieldwork at the DNAUI laboratory.

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[74] The FBI stated in a response to a draft of this report that the DNAUI's success with accreditation and other inspections conducted by internal and external auditors is evidence of the adequacy of the DNAUI's internal controls. As explained elsewhere in this report, we concluded that Blake's ability to avoid detection, even though the Laboratory passed these inspections, is precisely why the additional measures set forth in Chapter Six are warranted. Accreditation inspections and quality assurance audits examine compliance with quality standards, but do not attempt to review a laboratory's operations for all needed management improvements. Our review identified numerous weaknesses that would not necessarily be evident in an accreditation or other peer review.

[75] Due to the significant differences between the analysis performed by the DNAUI and the DNAUII, including the performance of different techniques utilizing different pieces of equipment, and the fact that Blake did not work on cases in DNAUII, we limited our review to the protocols and practices of the DNAUI. However, we discuss infra the implications of potential vulnerabilities within the DNAUII posed by the conclusions of our DNAUI assessment, and recommend that the changes made in DNAUI procedures be applied to DNAUII where applicable. See Chapter Five, Section II.B.6.

B. Selection of Consulting Experts

To facilitate the assessment, particularly the review of the protocols, we recruited scientists from the national DNA community to assist the OIG. We selected the scientists by first soliciting recommendations from various contacts in the public and private DNA laboratory community, and then selecting three persons who could provide the team with varied experiences and a full understanding of the standards that govern forensic DNA laboratories. The scientists selected were crucial contributors to the OIG's work and brought to the assessment expertise in academic research and instruction; federal, state, and private DNA laboratory analysis and administration; and national DNA advisory committee participation.

The scientists we recruited were:

- Dr. Arthur J. Eisenberg, Associate Professor in the Department of Pathology and Director of the DNA Identity Laboratory, University of North Texas Health Science Center;

- Mr. William David Coffman, Crime Laboratory Analyst Supervisor, Florida Department of Law Enforcement, Tallahassee Regional Crime Laboratory; and

- Dr. John H. Ryan, Director of Forensic Programs at Myriad Genetic Laboratories Inc.

Each of these individuals has a distinguished record in the field of DNA analysis. Appendix 5 to this report contains brief biographies of the scientists.

C. Expert Introduction to the Work of the FBI Laboratory

To formalize the scientists' participation in the OIG's work, we conducted an orientation meeting in September 2002. At that time, OIG staff briefed the scientists on the circumstances surrounding the assessment, including Blake's misconduct.

During the orientation meeting, the FBI DNAUI Chief explained to the scientists the timeline of events and the actions taken by the FBI after their discovery of Blake's actions. The scientists and OIG staff also toured the DNAUI facilities – at that time housed at FBI Headquarters in Washington, D.C. – to gain an overview of the DNAUI's operations.

The OIG staff distributed to the scientists checklists and supplemental guidance designed to facilitate the scientists' review of the DNAUI protocols. The checklists and guidance contained key terms and definitions specific to our

assessment, and supplemented the verbal explanations provided by OIG staff describing what the scientists were to consider when determining whether a protocol is vulnerable. OIG staff structured the checklists so that they corresponded to the table of contents for each of the protocols reviewed to ensure that each section of the documents was assessed. See Appendix 6 (examples of the checklists and guidance provided to the OIG scientists).

For purposes of this assessment, we defined "vulnerability" as a function of "impact" and "risk" as follows:

- "Impact" is the measure of how essential a particular procedure or protocol is to the generation of a complete and accurate DNA profile, including ensuring that available DNA samples are efficiently and effectively processed for analysis.

- "Risk" is the measure of the sufficiency of existing internal controls to prevent, where possible, both inadvertent and willful noncompliance and to detect noncompliance when it occurs.

- "Willful noncompliance" is the intentional circumvention of applicable procedures and protocols.[76]

In addition to these definitions, categories of severity were defined so that numeric ratings could be generated. The scientists were given descriptions of the "impact" characteristics that a protocol or procedure would have if it fell into low, medium, or high impact categories.[77] They also were given similar descriptions for the low, medium-low, medium, medium-high, and high risk[78] categories.[79] These categories are further defined in the guidance contained in Appendix 6.

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[76] We applied this definition with the understanding that protocols alone cannot prevent malicious acts by staff members.

[77] In general terms, a low impact protocol is not required for the Laboratory to meet quality assurance requirements, and the procedures it sets forth have little or no impact on the production of a complete and accurate DNA profile. A protocol of high impact is one that is required by and governed by the quality assurance standards and is essential to obtain complete and accurate DNA results, and to preserve the integrity of the evidence and of the Laboratory's final conclusions.

[78] In general terms, a low risk protocol contains multiple mechanisms for management to ensure staff member compliance and to deter or detect noncompliance. A high risk protocol is one where no monitoring is being conducted to gauge staff compliance with the protocol, and the protocol contains no mechanisms to detect noncompliance.

[79] The OIG team divided the risk ratings into five categories, rather than the three categories used for impact, because the risk category definitions were nuanced enough to allow for additional distinctions. See Appendix 6.

Along with the checklists and guidance, OIG staff and the scientists reviewed the DNAUI protocols described below, which had been supplied to the OIG by the FBI. According to the FBI, these documents were the most current version of each of the protocols governing DNAUI activities at that time.

- DNA Analysis Unit I Quality Assurance Manual, issue date of July 28, 2000;
- DNA Analysis Unit I Examiner Training Program, issue date of January 30, 2001;
- DNA Analysis Unit I Procedure for One Point Thermometer Calibration, issue date of May 15, 2001;
- DNA Analysis Unit I Procedure for Pipette Calibration, issue date of September 28, 2001;
- Procedures for the Serological Identification of Biological Substances on Evidentiary Materials, issue date of October 31, 2001;
- Biologist Training Program & Requirements, DNA Analysis Unit I, issue date of January 2002;
- Short Tandem Repeat Analysis Protocol, FBI Laboratory, issue date of March 19, 2002;
- DNA Analysis Unit I Procedure for Monitoring Ultra-Violet Light Intensity, issue date of May 10, 2002;
- FBI Laboratory Division Caseworking Procedures Manual, issue date of July 15, 2002;
- FBI Laboratory Division Quality Assurance Manual, issue date of July 15, 2002; and
- DRAFT DNA Analysis Unit I Quality Assurance Manual, revision completed December 2002.[80]

[80] At the time of our review, the DNAUI Quality Assurance Manual was being updated. We were provided with the August 2002 version of the updated manual, clearly labeled as a "Draft" version. Upon review, the scientists found that the updated version was not materially different from the earlier version, and therefore the earlier version was used for the document review. The Draft version was not finalized until after the document review was completed by the scientists.

D. The Assessment Process

The OIG staff established guidelines for implementation of the assessment, including procedures that ensured that the scientists would document their conclusions on the checklists provided by the OIG. In addition, the scientists were instructed to base their conclusions solely on their analysis of the written materials above. In other words, when gauging vulnerability within the DNAUI, the scientists were to consider the contents of the protocols only, not factoring in any understanding they might have of the FBI's DNA methods or their observations and conversations with DNAUI staff members and management during the tour of the DNAUI. OIG staff intended the guidelines to enable the scientists to take a fresh look at subjects with which they were obviously familiar, so that they could find weaknesses in the internal controls that others may have missed.

The scientists reviewed the protocols in two sequential phases. OIG staff worked with the scientists to divide the document sections into two groups for review, referred to simply as Phase 1 and Phase 2. Phase 1 covered pre-analysis protocols; Phase 2 focused on the remaining protocols, including those related to the actual analysis of DNA samples. The checklists used by the scientists reflect the division that was made. See Appendix 6.

The scientists were given a period of time to review the protocol documents for each phase and then met with OIG staff to discuss and record the vulnerabilities identified. The meetings generated a consensus on the impact and risk ratings that should be assigned to each protocol section. In addition, the OIG recorded the underlying concerns for the agreed-upon ratings assigned by the scientists to ensure that the fieldwork conducted later and the conclusions and recommendations ultimately reported were an accurate reflection of the specific underlying weaknesses.

At the conclusion of the Phase 2 meeting, OIG staff asked the scientists to assist them in devising fieldwork to identify the actual work practices of DNAUI staff members. In preparation for fieldwork design, OIG staff summarized the protocol sections in which the scientists had identified key vulnerabilities, and analyzed the results to determine if any of the sections pertained to similar subject matter. In addition, we analyzed the comments voiced by the scientists for recurring themes and categorized them into key concern areas. From this analysis, we designed fieldwork to verify actual laboratory practices for protocols deemed vulnerable, and to assess whether these practices served to mitigate the vulnerabilities identified.

OIG staff conducted this fieldwork from March 12 through 21, 2003. The fieldwork generally was comprised of a tour of the new DNAUI facility in Quantico, Virginia, and a series of interviews of staff members from within the DNAUI and the Laboratory Division. Where possible, interview responses and

observations made during the tour were checked against supporting documentation for verification.

Fieldwork interviews served as our primary source of insight into the DNAUI's operations. We recognized that it would be important to collect information from a broad cross-section of personnel, since we intended to analyze their responses for consistency with the protocols, with others of the same operational position, and with respondents in different positions. Therefore we took the following steps to ensure variety in our sources of information.

Since the DNAUI staff function as teams, with each team generally consisting of a Serologist, a PCR Biologist, and an Examiner, we interviewed multiple staff members in each of these positions.

We also recognized that the amount of time that a person had held a position could affect his or her fluency in describing certain processes. Consequently, we interviewed the most senior and the most junior employees in each position, and judgmentally picked a third person in that same role. For the third Serologist and Biologist interviewees, we selected a staff member who was currently in training for a different team position and thus would have a level of familiarity with the duties performed in both roles.

This interviewing scheme was expanded to include a fourth interviewee from among the Examiners, so that our interviewees would include, in addition to the most senior and most junior Examiners, the Examiners who also supervised the key programs within the DNAUI: the Examiner-Supervisor of the Serology Program and the Examiner-Supervisor of the PCR (STR) Program.

Finally, we interviewed DNAUI management, including the Unit Chief, the Assistant Unit Chief, and the Quality Assurance Manager; and Laboratory Division management, including the Laboratory Director, the Deputy Director, and the Chief of the Scientific Analysis Section.

We also reviewed documentation and interviewed key personnel regarding: 1) the factors considered in the design of the new DNA facility; 2) the training curriculum and methods used within the DNAUI, along with various staff training records; and 3) the status of development of the Laboratory Information Management System (LIMS), a computerized tracking system for evidence, samples, and other information. However, we did not include in our fieldwork design an analysis of case file documentation for two reasons:

- Blake's misconduct persisted undetected due to the DNAUI's policy that GeneScan® data produced during electrophoresis did not need

to be included in the case file and therefore did not need to be reviewed by the Unit's Examiners. Consequently, a review of the case files would not shed additional light on Blake's misconduct, nor would we be able to detect similar misconduct by other staff members from a case file review.

- In April 2002, OIG auditors had reviewed approximately 150 DNAUI case files as part of an audit of the DNAUI and DNAUII's compliance with standards governing their CODIS participation.[81] We reviewed these case files to determine if the DNA profiles from each case, as reflected in NDIS, were complete and accurate.[82] Further, we reviewed the case files to determine if the profiles and supporting documentation complied with applicable Forensic Standards and NDIS Requirements.[83] This review identified no deviations from the applicable audit standards. While this work was performed prior to the OIG's knowledge of Blake's misconduct,[84] the review did serve as an indicator of the results we could expect from a case file review.

In addition, we relied upon the work performed by DNAUI management and staff members, as described in Chapter Four, Section III.A, to determine whether other DNAUI Biologists had failed to process the negative controls

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[81] To select case files for review, we first obtained a list of identification numbers for all of the profiles that the DNAUI had submitted to NDIS. The list was provided by the FBI Laboratory's FSSU, currently referred to as the CODIS Unit, which oversees the NDIS database. From this listing we selected a random sample of 142 profiles from a universe of 1,693 profiles, and requested that the DNAUI make available for our review the supporting case file documentation.

[82] A DNA profile was considered complete if all the analysis results obtained were reflected in the profile uploaded to NDIS. When the results in the uploaded profile matched those on the Examiner's worksheets, the profile was considered accurate.

[83] We considered the DNAUI case files and resulting profiles compliant with the Forensic QAS if the required steps in the analysis process were completed and documented, including the quantification of each sample's DNA, and if both technical and administrative reviews of the analysis work were performed. We concluded that the DNA profiles we reviewed complied with the NDIS requirements if the profile qualified for inclusion in NDIS. The NDIS requirements prohibit a laboratory from uploading profiles to NDIS that clearly match the DNA profile of the victim or another known person, unless the known person is a suspected perpetrator.

[84] We determined during our vulnerability assessment that one of the 142 cases included in our file review was identified by the FBI as a case on which Blake worked and failed to complete the negative controls. Our review could not have discerned Blake's misconduct from this case file because it did not include GeneScan® data per DNAUI policy. See discussion regarding how Blake's misconduct was detected in Chapter Four, Section II.D.

prior to the discovery of Blake's misconduct. That work determined that the controls were completed as required.

We analyzed the results of our fieldwork and compared them with the concerns voiced and vulnerabilities detected by the scientists to discern whether information gathered during fieldwork confirmed the extent and nature of the scientists' conclusions. We then conducted a follow-up meeting with the scientists to discuss the fieldwork results and to adjust, if necessary, their earlier conclusions that had been based strictly on the document review. The scientists made only a few minor updates to their earlier observations to reflect the information obtained during fieldwork. Generally, they did not change their conclusions regarding protocols previously identified as vulnerable.

II. DNA UNIT I PROTOCOLS AND PRACTICES IDENTIFIED AS VULNERABLE TO ABUSE

A. Types of Vulnerabilities Examined

During our assessment within the DNAUI, we examined two types of vulnerabilities: protocol vulnerabilities and practice or operational vulnerabilities. Our textual analysis of the FBI protocols that govern the DNAUI revealed various weaknesses, which are described in detail immediately below. In addition, in the course of completing field work that examined how staff members implemented the protocols that we identified as problematic, we discovered numerous practice vulnerabilities. These are described along with our analyses of the various protocols. The specific vulnerabilities we examined within the two general categories (protocol and practice) are presented in order of significance based upon the scope of the vulnerability (generally, the number of document sections associated with it or the pervasiveness of the problem across DNAUI functions) and its severity (generally, the extent to which the vulnerability could undermine the DNAUI mission).

B. Analysis of Protocol Vulnerabilities

As explained in Chapter Five, Section I.C of this report, our analysis of protocol vulnerabilities is based on a review of 5 FBI manuals and 5 instructional documents that collectively contain 172 topical sections.[85] See discussion supra at page 33. From this review we identified 31 sections as

[85] The manuals are: 1) the FBI Laboratory Division Quality Assurance Manual; 2) the DNA Analysis Unit I Quality Assurance Manual; 3) the FBI Laboratory Division Caseworking Procedures Manual; 4) the Procedures for the Serological Identification of Biological Substances on Evidentiary Materials; and 5) the Short Tandem Repeat Analysis Protocol. Of the five instructional documents, three specify procedures for equipment monitoring and calibration, and the remaining two address training programs for Biologists and Examiners.

significantly vulnerable[86] to inadvertent or willful noncompliance. It is important to note that our identification of a "vulnerability" should not be misconstrued as an invalidation of the science or techniques used by the DNAUI, or as an indication of the inadequacy of the entirety of DNAUI policies on a particular subject. Our use of the term "vulnerability" is limited to its definition as set forth in Chapter Five, Section I.C.

The sections we identified as significantly vulnerable to inadvertent or willful noncompliance are identified below, with the most vulnerable sections in bold italics:

- FBI Laboratory Division Quality Assurance Manual
  Of the 17 sections within this document, 2 are vulnerable:
  - ***Evidence Control Policy***
  - Case Documentation Policy
- DNA Analysis Unit I Quality Assurance Manual
  Of the 20 sections within this document, 5 are vulnerable:
  - Organization and Management
  - Authority and Accountability
  - ***Evidence Control***
  - Facilities (Security)
  - **Case Assignment, Documentation, and Review**
- FBI Laboratory Division Caseworking Procedures Manual
  Of the 12 sections within this document, 1 is vulnerable:
  - ***Procedures for the Examination of Evidence***
- Procedures for the Serological Identification of Biological Substances on Evidentiary Materials
  Of the 72 sections within this document, 4 are vulnerable:

[86] As explained in Chapter Five, Section I.C, we assigned categories of severity to the "impact" and "risk" ratings. We have included in our count of "significantly vulnerable" sections those that were categorized by the scientists as being in the "high" or "medium-high" impact and risk categories. We also limited our fieldwork testing to this same list of significantly vulnerable sections.

- ***Procedure for the Preparation of Dried Bloodstains from Coagulated Whole Blood***

- ***Procedure for the Preparation of Dried Bloodstains from Anticoagulated Whole Blood***

- Procedure for the Extraction of Suspected Semen Stains Prior to OneStep ABA Card PSA Test: Quality Control Procedures

- Procedure for the Extraction of Suspected Semen Stains Prior to OneStep ABA Card PSA Test: Questioned Stain Extraction Procedure

- Short Tandem Repeat Analysis Protocol
  Of the 46 sections within this document, 19 are vulnerable:

  - ***Guidelines for Control Samples***

  - Extraction (includes a total of 10 sections)

  - ***Amplification***

  - ***STR Typing: Setting up a Run***

  - GeneScan Analysis

  - Interpretation of Control Samples

  - ***Laboratory Set-up (includes a total of 4 sections)***

Although we identified 31 document sections as vulnerable, the causes of the vulnerabilities were few in number. In general, one or more of four reasons accounted for each of the vulnerability designations: 1) the protocol lacks sufficient detail; 2) the protocol fails to inform the exercise of staff discretion; 3) the protocol fails to ensure the precision of manual notetaking; and 4) the protocol is outdated.

The following chart depicts the categories of vulnerabilities and the document sections to which each category applies.

Protocol Vulnerabilities

Protocol Name and Section Title	Protocol Lacks Sufficient Detail	Protocol Lacks Guidance to Structure Decision-making	Protocol Fails to Ensure the Precision of Manual Notetaking	Protocol is Outdated
FBI Laboratory Division Quality Assurance Manual				
Evidence Control Policy	X			
Case Documentation Policy	X		X	
DNA Analysis Unit I Quality Assurance Manual				
Organization and Management	X			
Authority and Accountability	X			
Evidence Control	X		X	
Facilities (Security)	X			
Case Assignment, Documentation, and Review	X			X
FBI Laboratory Division Caseworking Procedures Manual				
Procedures for the Examination of Evidence	X		X	
Procedures for the Serological Identification of Biological Substances on Evidentiary Materials				
Procedure for...Bloodstains from Coagulated Whole Blood	X	X		
Procedure for … Bloodstains from Anticoagulated Whole Blood	X	X		
Suspected Semen Stains...: Quality Control Procedures	X			
Procedure for the Extraction of Suspected Semen Stains...: Questioned Stain Extraction	X	X		
Short Tandem Repeat Analysis Protocol				
Guidelines for Control Samples	X			
Extraction (total of 10 subsections)	X			
Amplification	X			X
STR Typing: Setting up a Run				X
Genescan Analysis		X		X
Interpretation of Control Samples	X	X		
Laboratory Set-up (total of 4 subsections)	X			

Given that each type of vulnerability was observed in multiple document sections, for ease of comprehension and to avoid repetition, we describe below each of the protocol vulnerabilities according to its cause rather than by individual document section.

1. Protocols That Lack Sufficient Detail

Our review of the DNAUI protocols revealed that 29 of 172 document sections lacked the detail necessary for a technically qualified DNA scientist to reproduce all aspects of the analysis procedures in use in the DNAUI without the potential for variation. In our view, a qualified DNA scientist should be

able to locate the DNAUI's essential testing requirements in its protocols and not have to resort to peripheral sources. Further, the protocols should contain guidance sufficient to ensure that qualified scientists are consistent in their interpretation of the testing requirements.

While the sections we have identified as lacking essential detail are a relatively small percentage of the total protocols examined in our review, we consider this vulnerability to be the most significant of the ones we identified and the most important indicator of the DNAUI's susceptibility to inadvertent noncompliance. Protocols that lack essential detail can create a work environment that encourages use of disparate and unproven laboratory practices. When laboratory staff members must rely on ad hoc verbal cues from their peers to complete their duties, the risk increases that they will deviate from the practices that are necessary to generate valid and reliable testing results. In addition, protocols that lack essential detail can foster a perception among staff members that the protocols are not authoritative and can be disregarded, even though they should serve as the DNAUI's primary source of instruction.

We describe below six sets of protocol sections that share similar deficiencies: 1) *Evidence Control*, *Facilities (Security)*, and *Procedures for the Examination of Evidence*; 2) *Extraction*, *Amplification*, and *Laboratory Set-Up*; 3) *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and *from Anticoagulated Whole Blood*; and *Procedures for the Extraction of Suspected Semen Stains*: *Quality Control Procedures* and *Questioned Stain Extraction Procedure*; 4) *Case Documentation Policy* and *Case Assignment, Documentation and Review*; 5) *Guidelines for Control Samples* and *Interpretation of Control Samples*; and 6) *Organization and Management* and *Authority and Accountability*.

a) *Evidence Control*, *Facilities (Security)*, and *Procedures for the Examination of Evidence*

Written Protocol

Forensic Standard 6.1 requires that laboratories have a facility that is designed to provide security and minimize contamination. This includes, as specified in subsection 6.1.1, controlling and limiting the access to the laboratory; and, as specified in subsection 6.1.2, separating by time or space evidence examinations, DNA extraction, PCR setup, and PCR amplification. Further, Forensic Standard 7.1 requires that DNA laboratories have and follow a documented evidence control system to ensure the integrity of physical evidence, including (as specified in subsection 7.1.4) secure areas for evidence storage.

While the DNAUI protocols address compliance with these standards in general terms, certain sections of the protocols lack the level of detail necessary to ensure that staff members understand and comply with management expectations regarding evidence control and security. We identified four sections as problematic: the *Evidence Control Policy* of the *FBI Laboratory Division Quality Assurance Manual*; the *Evidence Control* and *Facilities (Security)* sections of the *DNA Analysis Unit I Quality Assurance Manual*; and the *Procedures for the Examination of Evidence* section of the *FBI Laboratory Division Caseworking Procedures Manual*.

For example, the *Evidence Control Policy* requires in Section 3.2 that "Evidence will be labeled, stored, secured, and/or sealed to prevent loss, cross-transfer, contamination, or deleterious change." Additional guidance is not provided regarding how staff members should implement this protocol with respect to particular kinds of evidence. While this information may not be included within a laboratory-wide policy such as this one, we expected to find, and did not, a reference to other FBI manuals or protocols where more specific guidance can be obtained. Similar language is found in Section 3.5, which requires without elaboration the use of "universal precautions . . . to ensure the health and safety of personnel."

The *Evidence Control* Section of the *DNA Analysis Unit I Quality Assurance Manual* also includes vague provisions. For example, Section 7.6.1 states that "DNAUI will utilize documented standard operating procedures which minimize potential sample loss, contamination and/or deleterious change to the evidence." It does not, however, identify what those procedures are or reference another source where they are specified. Section 7.6.2 requires that "an attempt to limit the consumption of evidence should be made, when possible," and although three subpoints are provided explaining how storage should be used to limit consuming an evidence sample, the protocol does not clarify what is meant by "when possible" or address methods other than storage that can be used to ensure that a remnant of the evidence remains for future testing.

In addition, the proper handling of evidence during examinations is not addressed in the *Evidence Control* section. That section contains a discussion of chain-of-custody issues and the proper transfer, storage, and labeling of evidence, all of which are crucial to ensuring evidence integrity. Yet, if evidence is mishandled during the course of the examination itself, the benefits obtained from these precautions will be lost. While we were able to locate some examination evidence handling information in the *Short Tandem Repeat Analysis Protocol*, no reference was made to it in the evidence control policies, and the limited information provided in the STR protocol is no substitute for comprehensive guidance. We anticipated, for example, that the DNAUI protocols would specify that Serologists with workbenches in close proximity to

each other should not have case evidence open at the same time or that some type of "sign-up" sheet would be used to ensure that they do not use adjoining areas concurrently. Also, we expected to find a clear description of what it means to "separate" known and unknown DNA samples. Separation could mean that staff members clean between processing samples but use the same area, or alternatively that a different ventilation hood is used for the known and unknown samples. However, no such guidance on either issue is provided.

We also identified in the *Procedures for the Examination of Evidence* similar broad statements as those found in the *Evidence Control Policy*.[87] For example, although Section 4.1.3 directs staff members to "follow established unit precautions to preserve the integrity of the evidence," we were unable to locate a listing or explanation of the referenced "unit precautions." Also, Section 4.5.1 directs staff members to place evidence in a limited access secured area when they must leave it unattended and "protect the exposed areas of the evidence from loss, cross-transfer, and/or contamination." However, no explanation is provided regarding how staff members should implement this requirement, or what is intended by terms such as "protect" or "exposed areas." During an OIG tour of the DNAUI, staff members explained that evidence items under active examination can be left out while staff take breaks and that the evidence is marked with an "Evidence – Do Not Disturb" sign. Leaving evidence exposed poses unnecessary risks of evidence contamination, and the *Procedures for the Examination of Evidence* should be amended to require the proper storage of evidence when it is not being examined.[88]

In the *Facilities (Security)* Section of the *DNA Analysis Unit I Quality Assurance Manual*, the discussion of facility access limitations is not clear. For example, Section 6.1 specifies that "access to these areas [specific rooms that comprise DNAUI space are listed] are controlled by DNAUI personnel." However, no further explanation is provided for how DNAUI personnel are expected to accomplish this access control. Further, the Section states that "non-DNAUI personnel are permitted entry during normal working hours for

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[87] The Procedures for the Examination of Evidence section appears in the *FBI Laboratory Division Caseworking Procedures Manual*, while the Evidence Control Policy is found in the *FBI Laboratory Division Quality Assurance Manual*.

[88] Although not an issue that concerns protocol vagueness, we note that the evidence storage description in Section 6.4.3 of the *Facilities (Security)* Policy of the *DNA Analysis Unit I Quality Assurance Manual* permits large items needing room-temperature storage to be placed in a DNAUI room with an "Evidence – Do Not Disturb" sign displayed, if properly sealed in a tamper-evident manner, rather than requiring storage in a separately secured space such as an evidence vault. While this policy might have been necessitated by the limited storage available at the DNAUI's previous facility, its current facility allows for bulky evidence to be stored in a separately secured area and therefore the DNAUI should change its policy to the better practice of separately securing all evidence.

purposes relative to laboratory operations." Yet, no further explanation is provided concerning what restrictions should be imposed on non-DNAUI personnel (e.g., whether visitors must be escorted and in what areas they are permitted access). The Section seems to assume that DNAUI personnel already are aware of existing physical access restrictions, for the building and for the laboratory space, that serve as components of the Unit-specific access control. Instead, access control and physical security should be described (and other relevant sources referenced) in the *DNA Analysis Unit I Quality Assurance Manual*, and those descriptions should not assume an understanding of other physical access limitations.[89]

The overly broad or vague language used in the above evidence-control related protocols creates a number of problems. Staff members may not fully understand how they are expected to avoid loss, cross-transfer, or contamination of evidence, and may not realize that they are putting evidence at risk through the handling methods they have adopted. One item of evidence might be allowed to come too close to another item, and hairs, blood flakes, or fibers that become airborne might inadvertently be transferred to other evidence, possibly causing the analysis results to reflect improperly a connection between the cases or a DNA profile of someone not actually involved in the case.

Further, leaving evidence exposed and unattended poses a risk to the Examiner's ability to attest that team members maintained control over it. The importance assigned by DNAUI management to controlling access to evidence is apparent from other DNAUI protocols: 1) as a means of verifying limited access, evidence not under examination is stored sealed with tamper-evident material; and 2) evidence not under examination is secured in locked refrigerators, freezers, and bulky-storage space. It is difficult to reconcile these policies with protocols that contemplate that evidence will be left unattended and that fail to provide clear guidance for how it is to be protected.

Finally, there is a risk that evidence that is left unattended could suffer damage through an unforeseen event, such as fire-alarm sprinklers being set off in an emergency, or a plumbing leak that floods and compromises space below it. If that evidence were in a locked cabinet or refrigerator/freezer, it would be further protected in such events.

Interviews

In light of these potential risks, we conducted fieldwork to determine whether other factors diminished the risks we had detected during our

[89] In response to a draft of this report, FBI Laboratory management stated that the DNA Analysis Unit I Quality Assurance Manual has now been revised to include the information we cite as missing here.

document review. At the time of our fieldwork, the DNAUI had relocated from FBI Headquarters to a new laboratory building at Quantico, Virginia. We found that the change of facilities mitigated to some extent the impact of the lack of detail in several of the facility-related protocols. Specifically:

- The new facilities provide each Serologist and PCR Biologist with an ample evidence examination area that is not in close proximity to other examination areas. Further, each of the work areas is equipped with a vacuum hood to prevent the sharing of hoods that had been necessary at the previous location.

- Each work station is also equipped with individually securable storage for both case files and evidence items.[90] Each room is also equipped with a lock to which only the staff members with work areas in that room (and appropriate management officials) have a key, allowing them to secure their work area and evidence under examination if the room is left unoccupied.

- DNAUI now has the use of an evidence vault large enough for bulky, room-temperature evidence to be independently secured, and therefore the DNAUI should have no further need to store sealed room-temperature evidence in a DNAUI laboratory room.

- DNAUI also has a large evidence examination room for oversized items that allows them to be spread out unobstructed in a controlled setting. The room is separately securable to ensure that only the DNAUI staff members examining a large evidence item have access to that room if the evidence must be left unattended.

Our fieldwork also included interviewing staff members and management to determine whether their work practices offset any of the vulnerabilities created by weaknesses in the evidence control procedures and protocols.

We determined that there are several practices, primarily falling under the heading of cleaning and decontamination, that mitigate to some extent the protocol limitations. For example, we were informed by all staff members involved in evidence examinations that it is DNAUI practice to cover the work surface with paper prior to laying out an evidence item for examination. Such a step reduces the possibility for cross-transfer, since the paper that surrounds the item serves as a buffer between the item being examined by one member and another in close proximity. Also, we were informed that if an item

[90] The phrase "independently securable storage" refers to storage that can be secured independently of the security of the laboratory rooms in which the evidence might be placed, so that evidence control is not dependent entirely upon access limitations.

stretches beyond the parameters of the paper, then that portion of the work surface is decontaminated before moving on to another item. Further, staff members stated that work surfaces are decontaminated between cases, and utensils used in the examination of an item are decontaminated between items. Almost all staff members and management personnel interviewed regarding evidence handling issues reported working on one item at a time and one case at a time, separating evidence samples from known samples, using and changing gloves, cleaning and/or decontaminating work benches and hoods regularly, and changing work surfaces between items.[91] Also, the responses of staff members that were able to identify where in the protocols these requirements are found, as well as the responses provided by management, were consistent as to which protocols serve as the source of guidance on general evidence handling, cleaning, and decontamination.

However, not all of the staff members interviewed were able to identify where guidance on these topics could be located in the protocols. In addition, in spite of the consistency of the responses among those that did know where the guidance could be located, their responses indicated in other ways the need for greater clarity and detail in the written procedures and protocols. For example, several interviewees commented on the lack of general evidence handling guidance for serologists (additional deficiencies found in the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials* are addressed in the next section). In addition, when questioned regarding the separation of known and unknown samples, interview responses lacked a precise indication of the period of time or amount of space that meets the requirement for "separation." Consequently, it was not evident from the responses whether staff members have a clear understanding of the requirement to separate known and unknown samples.

Further, of all the staff members and management interviews we conducted, only one Laboratory employee, an Examiner, cited as a source of guidance the *FBI Laboratory Division Caseworking Procedures Manual.* This Manual provides the most detailed guidance available to DNAUI staff members on the subjects of inventorying, identifying, and examining evidence. In addition, it is the only protocol that addresses the issue of leaving evidence unattended during examinations, and the requirements (even though they are overly broad) for how that evidence is to be handled. One staff member, a senior PCR Biologist, claimed to have never seen the Manual before.

Many of the interviewees commented on the lack of written guidance concerning the routing sequence when evidence needs to be distributed to multiple units. These interviewees indicated that they know there is a definite

[91] The descriptions provided in Chapter Three, Sections II.B.2 & 3, supra, regarding cleaning and decontamination, separation of sample sources, and stages in the analysis process reflect the responses we typically received during the interviews.

order that evidence needs to follow to preserve each unit's ability to conduct testing. For example, the Latent Fingerprints Unit must test before the DNAUI tests, and the item cannot be stored in a refrigerator or freezer prior to the latent testing. One Examiner commented on the importance of this issue, emphasizing that the Serologists must be very conscious of the items that might need testing by other units, and work to preserve the evidence that is needed for this testing. The Examiner explained that when there is a question about how to route evidence, Serologists are expected to obtain input from the other unit. Yet, this guidance is not part of the DNAUI's serology procedures.

We also detected variance in responses regarding particular procedures in the protocols. While not every variance translates into a problem, diverging interpretations by staff members could indicate that they do not fully understand protocol requirements or are given a measure of flexibility that is not reflected in the protocol. The following examples illustrate these points:

- Drying of Samples: While most Serologists stated that known and unknown samples are dried at different times, one Serologist explained that they can dry at the same time.[92] The same Serologist did not believe there was a requirement for separating high and low quantity DNA samples, even though the specific requirement is contained in the *Short Tandem Repeat Analysis Protocol*. It is noteworthy that this protocol is one which Serologists, because of their duties, are not required to use or know. However, a senior Examiner also stated that there is not a specific requirement in the protocols for the separation of high and low quantity DNA samples, even though the Examiner is required to follow the *Short Tandem Repeat Analysis Protocol* that contains this requirement.

- Examiners' Understanding of the Biologists' Cleaning and Decontamination Practices: One Examiner stated that the PCR Biologists change gloves "whenever they are soiled" whereas another stated that they are changed between examination of items. One Examiner explained that a PCR Biologist might only change the work-surface paper between cases, while another stated that, in addition to changing the paper between cases, the hoods are cleaned. A third Examiner stated that, while he was uncertain, he thought that the hoods are decontaminated with ultra-violet light between cases; a fourth Examiner stated that the hoods are cleaned with bleach between processing evidence and known samples. The fact that each Examiner explained the

[92] Rather than using liquid blood from a tube for analysis, the practice in the DNAUI is to place a small amount of blood on a card, dry the card, and then use a portion of the dried stain for analysis.

cleaning and decontamination practices differently casts doubt on the clarity of their understanding. This is significant because Examiners may be required to describe those practices in court.

- Leaving Evidence Under Active Examination Exposed and Unattended During Staff Breaks: Staff members and managers who described this practice in their responses explained that the evidence is sealed and secured, and that an "Evidence – Do Not Disturb" sign is used (as explained in the written protocol). However, some staff members further described methods that exceed what is explicitly required. For example, an Examiner stated that when taking a break, one Serologist would cover the evidence with brown paper, and then place a sign over the evidence, or, if possible, return the evidence to its container and place a sign over the container. This Examiner was the only staff member to mention using paper to protect the evidence. Also, a senior PCR Biologist stated that for a quick break, his team uses a sign, and for longer breaks they return the evidence to its original package and use a sign. The Biologist added that with big items that had just been situated, staff members can leave the item out and tape off the area, placing a sign on the evidence. This Biologist was the only staff member to mention taping off the area where evidence was left out. Although these methods – using paper as a covering, returning the item to its original container, and taping the area off for larger items – serve to mitigate the risks associated with leaving evidence exposed and unattended, these methods are not reflected in the protocol. Therefore, there is no assurance that other staff members know and apply these methods, particularly since other respondents did not mention them.

During our fieldwork at the FBI's new laboratory, we inquired about facility security and were informed that access to DNAUI space is limited to DNAUI staff members, either by regular keys or by card keys. Although these practices seem sufficient, they are not evident from the text of the relevant protocol. In addition, after receiving interview comments that showed that some Laboratory personnel did not understand the importance of the protocols, we inquired whether staff members are required to certify that they have read and understand protocol revisions. According to the Unit Chief, staff members are required to attest to the receipt of new versions of the protocols. For notifications of changes that are made between revisions, no certification of receipt is required. The Unit Chief added that during training both trainees and trainers must attest to the trainee's understanding of the importance of adherence to protocols.

In light of the foregoing, we concluded that the potential risks posed by the lack of detail in the protocols described above, particularly the risks associated with facility limitations, have been mitigated somewhat by the following: 1) the DNAUI has moved to a new facility that no longer has the limitations we noted in the previous facility; 2) interview responses identified several methods and practices that exceed protocol requirements and that appear to protect the evidence; and 3) interview responses were largely consistent and in agreement with the protocols.

However, several interview responses we received revealed that some DNAUI staff members have an incomplete or inaccurate understanding of evidence handling and control requirements, and two persons we interviewed indicated that the protocols are not essential to their daily activities. We believe that staff members who do not understand or appreciate the importance of evidence handling and control procedures are susceptible to inadvertent noncompliance with the applicable protocols.

Recommendations

We recommend that DNAUI management:

4) Supplement the evidence handling and control protocols with sufficient detail so that they serve as a comprehensive source of guidance for staff members;

5) Cross-reference the DNAUI manuals, in specific sections where the subject matter warrants, with more detailed sources of guidance available to DNAUI staff members, such as the *FBI Laboratory Division Caseworking Procedures Manual* or the *Short Tandem Repeat Analysis Protocol*;

6) Revise policies for leaving the security of unattended evidence under examination dependent upon the facility access limitations, in light of the availability of independently securable storage for staff members at their workstations and of a bulky evidence examination room that is securable; and

7) Implement a policy that requires staff members to certify that they have read, understand, and will comply with each written protocol or procedure that governs DNAUI activities, including any approved deviations or other guidance issued that have not yet been formalized in a protocol.

b) *Extraction*, *Amplification*, and *Laboratory Set-up*

Written Protocol

Forensic Standard 9.1 requires that DNA laboratories follow written analytical procedures, including a standard operating protocol for each analytical technique employed.[93] Forensic Standard 9.1.2 requires that the procedures meeting these requirements address reagents, sample preparation, extraction, equipment, controls, and data interpretation. While the DNAUI meets these standards with the *Short Tandem Repeat Analysis Protocol*, we identified important information that is missing from its *Extraction, Amplification,* and *Laboratory Set-up* sections.

First, both the *Extraction* and *Amplification* sections fail to specify the requirements for the separation of known and unknown samples and of high- and low-quantity DNA samples. We believe that the *Extraction* section should specifically prohibit having two sample tubes open at once, and the *Amplification* section should require control samples to be processed last. The *Extraction* section also contains provisions that are overly broad: the incubation time given in Section 4.1.3 is listed as between 2 and 24 hours, and there are provisions in Sections 4.3-9 for staff members to perform additional organic extractions, if needed, without information provided regarding when and why those additional extractions would be appropriate. Finally, *Amplification* Section 6.7 fails to describe clearly the order in which sample tubes should be set up.

We recognize that some of the missing information cited in the previous paragraph is located within the *Laboratory Set-up* section, specifically the requirement for the separation of known and unknown samples and of high- and low-quantity DNA samples. The *Laboratory Set-up* section also clearly requires that the negative control samples be processed last as part of the amplification set-up, which is important for those samples to indicate contamination effectively. However, because the protocols function in part as a reference manual, the listing of these requirements in the *Laboratory Set-up* section does not diminish the need for them also to be presented in the protocol sections that address the stages in the analysis process (i.e., extraction and amplification) where an understanding of the requirements is most crucial. An employee who seeks guidance on an analytical step should find complete information in the relevant sections of the protocol and should not have to search elsewhere.

Moreover, the requirements described above that are included in the *Laboratory Set-up* section do not provide the level of specificity and clarity

[93] See Forensic Standard 9.1.1.

necessary for staff members to understand what is intended by the "separation" of the types of samples. For example, special precaution 3 under Section 12.2 states that "[i]t is important that the DNA extraction of questioned samples be performed at a separate time from the DNA extraction of known samples." Yet, the protocol does not explain what is meant by "separate time." It should state that all the unknown samples must be processed, capped, and removed from the immediate work-area before staff members begin to process the known samples. Also, special precaution 4 under Section 12.1 directs staff members to "[w]henever possible, extract samples containing high levels of DNA (whole blood) separately from samples containing low levels of DNA (stamps, small bloodstains, etc.) to minimize the potential for sample-to-sample contamination." Unfortunately, the qualifier "whenever possible" renders the protocol vague and open to differing interpretation.

Due to the importance of separating known and unknown samples, the risks posed by the lack of detail in the protocols described above are substantial. Without the requirement to process, cap, and set aside the unknown samples before processing the known samples, the risk of cross-contamination increases. In addition, without a clear requirement that separation be maintained during extraction and amplification, samples may be compromised later in the DNA analysis process. The implications of this particular aspect of a DNA laboratory's internal controls are far-reaching for the evidence tested and the presentation of the analysis results in court: adequate separation of known and unknown samples enables examiners to testify that the connection made between a suspect and the crime scene evidence analyzed is not the result of cross-contamination between the known sample from the suspected perpetrator(s) and the evidence items. If the known samples were to contaminate the evidence, the analysis results for the evidence profile would reflect the profile from a known sample as well as the profile obtained from the DNA present on the evidence item. In addition, the strength of the DNA in the known sample could serve to "drown out" the results of the DNA in the evidence, causing the resultant profile to reflect only faintly the DNA present in the evidence. Further, if the profile from a known sample were to appear in the analysis results for an evidence sample, an Examiner might wrongfully conclude that the contributor of that known sample is the potential source of the DNA on the evidence in the case being investigated.

Lastly, aside from sample separation, the lack of specific guidance in the protocols regarding incubation time and the use of additional organic extractions leaves Unit staff members at risk of deviating inadvertently from management expectations in those areas.

Interviews

In our interviews with DNAUI staff members regarding extraction, amplification, and laboratory set-up procedures, we asked them to comment

on: 1) the separation of sample types and the separation of the stages in the analysis process; 2) the exact incubation time used by staff members; 3) the use of the provision that governs additional organic extractions; and 4) the details of amplification set-up. Responses were virtually identical from the PCR Biologists and Laboratory management regarding the incubation time, the circumstances under which they would perform additional organic extractions, the separation of the stages in the analysis process, and the details of amplification set-up. In addition, written guidance had been disseminated to staff members restricting the incubation time to a more precise period.

Responses also were very similar regarding the separation of known and unknown samples during analysis. However, as previously described at page 86, the interview responses we received regarding sample separation did not reveal that staff members share a common understanding of the meaning of "separation," which would mitigate the risk resulting from the lack of clarity in the protocols. In addition, staff members and management generally indicated that the evidence and known samples are currently separated only through the completion of the extraction of the DNA from the samples. From that point forward the sample tubes from evidence and known sources can be on the same tray and can be set up for amplification at the same time. While such a policy limits the risk of contamination during the extraction process, it does not address possible contamination during amplification set-up. Therefore, evidence samples are still at risk for contamination prior to amplification.

With respect to separation of the analytical stages themselves, one area of vagueness surfaced when we interviewed the PCR Biologists about the amplification set-up process. Interviewees acknowledged that it is clear in the protocols that DNA extraction, PCR set-up, and amplification are to be conducted separately. Further, there is a requirement to have dedicated equipment for the pre-amplification areas of the Laboratory isolated from the dedicated equipment used in the amplification areas. We confirmed that these requirements are explained and referred to throughout the *Laboratory Set-up* section of the *Short Tandem Repeat Analysis Protocol*. However, we noted from the interview responses that the PCR Biologists have a practice of using a pre-amplification tray to carry tubes to the amplification room. The tubes are then placed into the thermal cycler and the "transport tray" returned to the pre-amplification area. Since the protocols do not address this practice or provide guidelines regarding the cleaning or decontamination steps that should be completed before that tray is put back in use, we could not compare the interviewee responses to written requirements. However, recognizing that some cleaning of the tray is necessary prior to future use, we inquired further with the PCR Biologists we had previously interviewed and were told that they understand the importance of cleaning these trays, and that they believe this to be true for all the PCR Biologists. Each of the interviewees described the cleaning method they use, whether a bleach wash, a UV light source, or both.

But the PCR Biologists acknowledged that there is no specific guidance on this aspect of the process in the protocols.

Finally, the DNAUI Chief explained that, in light of the foregoing risks, the Unit is making arrangements to have the known and unknown samples processed in different locations within the Unit. Thus, different staff members, equipment, and space will be used to analyze the known and unknown samples, mitigating any risk of cross-contamination due to the lack of separation.

Therefore, we concluded that the lack of guidance for Biologists on the use of transport trays was mitigated somewhat by Biologist cleaning practices. However, we find unmitigated the risks posed by: 1) the lack of clear delineation in the protocols or staff responses for what constitutes adequate separation of known and unknown samples; and 2) the failure to maintain that separation through amplification. While we acknowledge that DNAUI management's proposed solution of analyzing known and unknown samples in different sections of the Laboratory would address these risks, we base our conclusions and resultant recommendations on the protocols in place at the time of our review.

Recommendations

We recommend that:

8) DNAUI management amend the protocols to clarify what is required to "separate" known and evidence samples and to ensure that such separation occurs during examination, extraction, and amplification.

9) DNAUI management reflect in the protocols: (a) the current requirement for incubation time; (b) the procedures described by staff during interviews for the use of additional organic extractions; (c) the required order that samples are to be set up for amplification, as described by staff during interviews; and (d) explicit directions for the cleaning of the "transport trays" used by PCR biologists. This information, as well as the extraction and amplification evidence handling requirements found in the *Laboratory Set-up* section, should be reflected in the extraction and amplification sections of the *Short Tandem Repeat Analysis Protocol*, where that information is most pertinent to the surrounding information.

c) *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and *from Anticoagulated Whole Blood*; and *Procedures for the Extraction of Suspected Semen Stains: Quality Control Procedures* and *Questioned Stain Extraction Procedure*

Written Protocols

Our analysis of the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials*, which includes bloodstains, semen, quality control, and stain extraction protocols, revealed that it fails to provide adequate guidance on various evidence handling procedures. The following examples illustrate information gaps that DNAUI Serologists fill using unwritten standards.

- The *Procedures for the Extraction of Suspected Semen Stains: Quality Control Procedures* and *Procedures for the Extraction of Suspected Semen Stains: Questioned Stain Extraction Procedure*, do not address: 1) the amount of a swab to use for testing; 2) whether extracts and swabs are both sent to the Biologist for testing; 3) general precautionary steps to reduce contamination (such as the use of disposable paper); 4) the usable life of the positive semen control;[94] and 5) what should be done if the stain extraction procedure detects no semen.

- The *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and *Procedures for the Preparation of Dried Bloodstains from Anticoagulated Whole Blood* do not state that cotton sheeting used in the procedures should be pretested to ensure that it is sterile, and do not identify the quantity of blood to use when making bloodstains for drying.

A risk posed by the failure to establish comprehensive guidelines on the amount of evidence to use in testing (e.g., items 1 & 2 above for semen protocols) is that DNAUI staff members inadvertently may use too much of the available body fluid stain or exhaust the supply altogether, making future testing impossible. In circumstances where the first analysis run proves problematic, such waste could prevent acquisition of scientifically valid testing results since staff would not later have the option of reanalyzing a sufficient quantity of the evidence. In addition, the lack of general evidence handling guidance in these sections (e.g., items 3 & 4 above for semen protocols, and use of cotton sheeting in bloodstain protocol) poses an unnecessary risk of

[94] The DNAUI uses a positive semen control when testing potential semen stains during casework as a means of ensuring that the test functioned properly.

contamination, possibly hindering the production of a usable DNA profile. Further, the lack of a clear description of what should occur if a stain extraction procedure detects no semen (e.g., item 5 above for semen protocols), presents the risk that the analysis process could be prematurely halted rather than taking additional steps to determine if the evidence sample contains DNA. Further, although in isolation the remaining information missing from the protocols may have only a minor impact on DNAUI operations, the cumulative effect of failing to provide comprehensive guidance in the protocols is to allow a significant portion of the Unit's operations to be determined by the idiosyncrasies of individual staff member preferences. This in turn conveys the message that the written procedures and protocols are a peripheral source of instruction, and puts the DNAUI at greater risk for protocol noncompliance.

Interviews

During our fieldwork we interviewed DNAUI Serologists and Laboratory management regarding various information gaps in the serology protocols. Specifically, we asked them to describe: 1) the circumstances in which they would or would not perform each of the serology tests; 2) the factors they consider to determine how much evidence to test and how much to forward to the PCR Biologist; 3) their understanding of the usable life of the semen control; and 4) what steps are taken after testing if they obtain a negative result (indicating that no semen was detected). Serologist responses were generally similar on each of these issues and to the responses provided by management, indicating that staff members have acquired a clear understanding through training or peer input of management expectations.

Serologists offered mixed responses on only one issue: the useable life of the semen control. While they guessed what the expiration date might be (generally their guesses of one year were correct), they also stated that they look for a strong result from the control. If they do not obtain one, they simply retest a new batch of control sample.[95] Further, they commented that the semen control is used in significant enough volume that the expiration date is not an issue (each batch is used before the expiration date would be reached).

We reviewed the logs documenting the reagents used and confirmed that the last three batches of semen control were depleted prior to each batch's 1-year expiration date. In addition, we confirmed from the protocol that an expiration date is provided for staff members, but not within the *Procedures for the Extraction of Suspected Semen Stains* section of the protocol. Instead, the useable life of semen control samples is set forth in the *Procedure for the Presumptive Identification of Semen*. Consequently, we concluded that, while Serologists should be reminded of the control expiration dates, the Serologists'

[95] According to the protocol, Serologists test the control prior to processing the evidence samples so that a control failure does not jeopardize the analysis of the evidence.

unfamiliarity with that information does not pose a significant risk to the proper analysis of evidence samples.

In addition, we determined from the interview responses that staff member practices include various helpful internal controls that are not reflected in the protocols. Specifically, one member of management stated that the serology procedures do not reveal that a team's PCR Biologist also looks at and describes the evidence that the team's Serologist receives, and those descriptions can be compared for consistency. Staff member interviews also described a practice of performing a "general swabbing" of an item to ensure that no possible sources of DNA on that item have been missed. OIG team scientists stated that this is a valuable practice to ensure that staff members exhaust all options in finding potentially probative DNA sources.

Thus, our field work demonstrated that staff members generally possess a clear and consistent understanding of management expectations regarding serology procedures. We therefore conclude that the risk posed by the incomplete protocols has been mitigated in large part by communication of the necessary information through other means, such as training and peer guidance. Despite this fact, we believe that the better practice is for the DNAUI to revise its serology protocols to provide comprehensive guidance on all serology procedures in use in the Unit. The staff members and managers we interviewed agreed that many of the details they described about serology procedures are not found in the serology protocols. Further, one of the Serologists stated that the methods that staff members are supposed to employ to navigate an item through the serology process seems to be addressed only through training, and that the work of the Serologists is shaped by the preferences and idiosyncrasies of the person who trained them. One management interviewee acknowledged that the serology procedures do not contain information on administrative processes, such as proper storage of evidence, even though Examiners frequently are cross-examined on this topic in court.

Recommendation

10) We recommend that DNAUI management ensure that the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials* includes:

    a) Detailed guidance on proper evidence handling methods, similar in content to the guidance contained in the *Laboratory Set-up* section of the *Short Tandem Repeat Analysis Protocol*.

    b) In the *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and the *Procedures for the Preparation*

of Dried Bloodstains from Anticoagulated Whole Blood, a requirement to: (a) pretest the cotton sheeting to ensure that there is no DNA contamination; and (b) identify the amount of blood to use when making dried blood stains.

c) In the *Procedures for the Extraction of Suspected Semen Stains: Quality Control Procedures* and *Procedures for the Extraction of Suspected Semen Stains: Questioned Stain Extraction Procedure*, guidance regarding: (a) the amount of a swab to use for testing; (b) whether extracts and swabs are both sent to the Biologist for testing; (c) general precautionary steps to reduce contamination (such as the use of disposable paper and the pre-testing for sterility of cotton sheeting used to make dried blood stains); (d) the usable life of the positive semen control; and (e) what should be done if the stain extraction procedure detects no semen.

d) Unwritten internal controls that already are in use by DNAUI staff members and management, including (but not limited to): (a) the requirement for a team's PCR Biologist to record the characteristics of the evidence, supplementing the description generated by the Serologist; and (b) the requirement for Serologists to perform a "general swabbing" of an item to ensure that no possible sources of DNA on that item have been missed.

d) *Case Documentation Policy* and *Case Assignment, Documentation and Review*

Written Protocol

Forensic Standard 11.1 requires that DNA laboratories follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports. In addition, Forensic Standard 11.1.1 requires that DNA laboratories maintain, in a case report, all documentation generated by Examiners related to case analyses. While the DNAUI has implemented procedures and protocols for these broad standards, we determined that two of the protocol sections we reviewed lacked the kind of detailed guidance necessary to ensure that all staff members understand and comply with management expectations for case documentation and review. Specifically, these sections are the *Case Documentation Policy* section found within the *FBI Laboratory Division Quality Assurance Manual*, and the *Case Assignment, Documentation and Review* section found in the *DNA Analysis Unit I Quality Assurance Manual*.

Although the *Case Documentation Policy* section is a broad protocol that applies to all units within the Laboratory, we expected to find more detailed information on case documentation procedures. For example, the section currently fails to list the required contents of case files, including the basic forms and worksheets universal to all the units. In addition, it lacks a reference to the more detailed file content requirements found in each unit's case documentation and review protocol. Further, the section should contain general guidance on notetaking methods, with a reference to any additional detailed information contained in unit-specific protocols. See Chapter Five, Section II.B.3 for additional information on notetaking.

We identified similar deficiencies in the *Case Assignment, Documentation and Review* section in the *DNA Analysis Unit I Quality Assurance Manual*. That section lacks a detailed description of the requirements for a complete case file review, and fails to identify procedures to ensure that documentation of each key item within the case file is accounted for. Instead, we found general and overly broad guidance regarding review procedures. For example, Section 11.4.1.1 requires that case file reviews include an evaluation of all data, lumigrams, interpretations, conclusions, and other supporting materials contained in the case file packet. Although five subparts are included in this section that describe the type of information that is subject to these reviews, their terms are overly broad and open to interpretation. For example, subsection 11.4.1.1.4 requires a confirmation that "all conclusions reached by the examiner are consistent with the documented data and within the limits of the discipline." In addition, the section does not contain a precise description of notetaking methods and requirements for DNAUI staff members so that they are clear on how and when they should be taking notes. We did not find this information anywhere in the protocols. See Chapter Five, Section II.B.3 for additional information on notetaking.

Finally, the *Case Assignment, Documentation and Review* section fails to specify the procedures that should be followed to review and confirm case evidence profiles for entry into CODIS. A review of approximately 150 case files during OIG audit work conducted in April 2002 (prior to the OIG being notified of Blake's misconduct) provided an opportunity to confirm that the DNAUI has such procedures, and our examination of their use of those procedures found that the profiles were being processed correctly. See Chapter Five, Section I.D for further detail on this case file review. However, no information on these procedures was reflected in this *Case Assignment, Documentation and Review* protocol.

The risks regarding the lack of specificity in these protocol sections primarily are that staff members will not understand, and therefore may not comply with, management expectations for case file documentation and review. These risks are heightened in environments such as the DNAUI's, where work

is performed by teams and individual team members must rely upon the quality and thoroughness of their fellow team members' case file documentation for the completion of their own work. Therefore, without detailed guidance for case file documentation and review, the DNAUI is at risk of not having proper verification in each case that all necessary testing procedures were completed as required. For example, as the Blake matter reveals, had DNAUI protocols required the inclusion in the case file and review of GeneScan® data, Blake's supervisors readily could have detected her failure to complete the negative controls. Instead, Blake's misconduct escaped detection for more than two years. In addition, without a checklist to assist the review, a technically-qualified DNA scientist could miss an important part of the review process or fail to notice the omission of a vital document or piece of information. For example, an Examiner might be called away suddenly to assess analysis difficulties a staff member is experiencing and, upon returning to his or her case-file reviews, fail to remember what material had not been examined and thus overlook important information.

Interviews

To determine the extent to which the vulnerabilities we identified were mitigated or exacerbated by staff member work practices, we interviewed DNAUI staff members and management regarding their understanding of the requirements for case documentation and review. From those interviews we determined that the interviewees' comprehension of case file documentation requirements was largely consistent, both with other interviewees as well as with the general mandates provided in the protocols. The amount of detail in the answers varied among the interviewees; however, these variations were consistent with the duties and position of the interviewees. Most interviewees knew where case file documentation requirements were addressed in the protocols, and their answers often expanded upon the information given in the protocols.

Because our interviews with staff members focused on their duties that implement the protocols under scrutiny in our review, we interviewed only Unit management and Examiners regarding case file review. We found that their answers typically were similar, with the Examiners providing the level of detail that is consistent with their job responsibilities. We also found that the interviewee responses were consistent with the written case review protocol. We again noted that the answers, particularly from the Examiners, went beyond what is specified in the protocol, revealing that, while the protocol is lacking in detail, staff members appear to have gained an understanding of what constitutes a proper case file review through other means, such as training or peer guidance. Further, the OIG team scientists detected no additional risks posed by the methods attested to by staff members or management in the interview responses.

In conclusion, our fieldwork results revealed that staff members appear to understand management expectations regarding case file documentation and review, mitigating the risk posed by the lack of detail in the protocols. However, until the protocols adequately address the information gaps we previously identified, the risk of undetected noncompliance with management expectations will remain significant.

Recommendations

We recommend that DNAUI management:

11) Ensure that the *Case Documentation Policy* section found in the *FBI Laboratory Division Quality Assurance Manual* contains:

    a) A listing of the minimum contents for all unit case files, along with a reference to that part of each unit's case documentation and review protocol that addresses case file contents; and

    b) Guidance on notetaking methods and requirements common to all units, along with a reference to the corresponding unit-specific protocols.

12) Ensure that the *Case Assignment, Documentation, and Review* section found in the *DNA Analysis Unit I Quality Assurance Manual* contains:

    a) A detailed description of case file review procedures, including a checklist to facilitate the review and to document that the review accounts for each key item in the case file;

    b) Guidance on notetaking methods to ensure that DNAUI staff members understand how and when they should take notes; and

    c) A description of the procedures that must be followed to review and confirm case evidence profiles for entry into CODIS, or at a minimum, a reference to where those procedures are described in another policy document.

e) *Guidelines for Control Samples* and *Interpretation of Control Samples*

Written Protocol

Forensic Standard 9.4 requires that forensic DNA laboratories monitor their analytical procedures using appropriate controls and standards. Forensic

Standard 9.4.2 explains that, for PCR casework analysis, those controls and standards must include quantification standards, positive and negative amplification controls, reagent blanks, and allelic ladders. Further, Forensic Standard 9.6 requires that forensic DNA laboratories have and follow written guidelines for the interpretation of data, including (in Forensic Standard 9.6.1) verifying that all control results are within established tolerance limits. Although we found that the DNAUI analytical protocols require and describe the use of these various standards and controls, as well as provide general guidelines for their interpretation, we identified certain information that is missing from the *Guidelines for Control Samples* and *Interpretation of Control Samples* sections in the *Short Tandem Repeat Analysis Protocol* that should be included to ensure that staff members have a clear and consistent understanding of control sample requirements.

First, both the *Guidelines for Control Samples* and *Interpretation of Control Samples* sections lack comprehensive guidance regarding the material staff members should review when they examine control results. In addition, both sections fail to differentiate the review responsibilities of the PCR Biologists and Examiners. Such guidance could include a checklist or summary sheet that would enable reviewers to ensure the completeness of their examinations. Further, the guidance should describe the circumstances in which a control result would cause an analysis run to "fail" (meaning that those samples must be re-analyzed). The sections seem to assume that DNAUI staff members already understand fully from another source what it means to review the control results and know exactly what to do.

In addition, we questioned language in Section 10.3.3 of the *Interpretation of Control Samples* that allows DNAUI Examiners to use the results of an analysis to exclude a suspect in circumstances where the positive control has failed. The relevant provision states:

> If FSB [the DNAUI name for a positive control sample] does not exhibit the STR typing results listed above [the correct results are shown in a table above this statement], the following steps must be taken. 1) If there appears to be an injection or electrophoretic problem, reinject the FSB with a ladder. 2) If re-injection of the FSB does not resolve the problem, and may be due to amplification issues, all samples set-up and amplified with this control will be considered inconclusive for matching purposes, but can be used for purposes of exclusion. If sufficient DNA remains of samples co-amplified with a failed control, then it is appropriate to re-amplify them.

We questioned this provision primarily because it fails to identify precisely when staff members should apply it. Limited information is provided regarding the additional steps that might be attempted before reporting results.

Further, it is not clear what a report would state about the results in situations where this provision is employed. In circumstances where additional analysis has the potential to generate a dispositive result, the lack of detailed guidance in this protocol could result in the unnecessary provision of inconclusive information to law enforcement agencies.

In our view, the most significant vulnerability that results from the kinds of missing guidance on control results described above is that, similar to the previous protocol sections we have discussed that lack information, DNAUI management cannot ensure that staff members will know and comply consistently with their expectations. Also, when protocols are not comprehensive, staff members may become dismissive of them, enhancing the potential for inadvertent protocol noncompliance.

It is important to note that there does not appear to be a significant risk that testing results will be used improperly, given the requirement within the DNAUI (consistent with Forensic Standard 12.1) that all cases and analysis results be reviewed by a technically-qualified peer reviewer as well as by an administrative reviewer. In other words, if there is a misunderstanding on the part of a PCR Biologist and a supervising Examiner regarding the scrutiny that is to be applied to the control results, that misunderstanding would most likely be detected by the technical reviewer or the administrative reviewer (who, in the case of the DNAUI, is also the technical manager).

Interviews

To determine whether staff members' work practices serve to mitigate these risks, we interviewed PCR Biologists, Examiners, and management regarding: 1) how the responsibility to review control results is divided between the Biologists and Examiners; 2) what information staff members look for when they review the control results; 3) under what circumstances an analysis of samples would fail because of the control results; and 4) the rationale behind the policy of using an analysis of samples to exclude a suspect even though the positive control failed. Staff members and management responses on these issues revealed a high degree of consistency. Regarding the fourth issue, DNAUI management explained during our interviews that the practice of using a DNA analysis to exclude a suspect even though the positive control failed is employed only if the sample results are good but the positive control has some malfunction that causes it to fail applicable quality requirements, no remaining DNA exists for another test, and where the results clearly indicate that the suspect does not match the evidence samples. DNAUI managers stated that they believe DNAUI staff members understand these limitations and how they should represent pertinent results in a report. They further explained that this policy is based upon the belief that it would be inappropriate not to make available results that exclude a suspected perpetrator simply because of a technical issue on the positive control. While we understand the rationale for

the policy, we disagree that the parameters for the use of the policy are communicated fully. Information about the policy's usage is not represented in the protocol with the same level of clarity and comprehensiveness that was communicated to us through the interview responses.

The information we received during our interviews of staff members and management regarding the four issues above is not found in the protocols, but rather is communicated through other means, such as training and peer guidance. The high degree of agreement and shared understanding among DNAUI staff members serves to mitigate the potential risk to proper scrutiny of control results posed by the incomplete protocols.

Recommendation

13) To ensure that staff members maintain a complete and consistent understanding of the requirements in the *Guidelines for Control Samples* and *Interpretation of Control Samples* Sections in the *Short Tandem Repeat Analysis Protocol,* we recommend that the DNAUI remedy the above-described lack of detail in these Sections.

f) *Organization and Management* and *Authority and Accountability*

Written Protocol

Forensic Standard 4.1(c) requires that forensic DNA laboratories specify and document the responsibilities, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of DNA analyses. The *DNA Analysis Unit I Quality Assurance Manual* includes sections entitled *Organization and Management* and *Authority and Accountability* that, ostensibly, should satisfy the requirements of Standard 4.1(c). However, upon examination, we discovered that these sections do not provide an adequate description of the interrelation of the various members in the DNAUI team structure. We also did not find a clear indication that the Unit Chief, as technical leader, has the authority to halt operations if a significant problem is detected. Nor did we find a clear delineation of the responsibilities of each team member when responding to problems or improper staff member actions.

The lack of specificity in this protocol increases the likelihood that staff members will misunderstand lines of authority and accountability, particularly with teams that have been allowed to vary their operations from one another. As explained in Chapter Five, Section II.C.1, staff members cited many examples of teams adopting their own methods when the protocols are not specific, including defining the division of authority and responsibilities of team members. Although poor communication resulting from deficiencies in this

protocol would not necessarily jeopardize analysis results, it could hinder the efficient execution of laboratory duties. Further, misunderstandings could cause a delay in the response to significant problems if staff members do not understand the lines of authority.

Interviews

We conducted interviews to determine if staff members and management share an understanding of roles and responsibilities within teams and with respect to problem resolution. From the responses received we determined that, while staff members and management had the same general understanding, certain roles vary according to the team Examiner's preference. All interviewees agreed that team member roles and responsibilities, including those pertaining to problem resolution, are not clearly delineated in the protocols, although a few stated that position descriptions and performance plans provided some additional guidance. In addition, Laboratory management, Unit management, and staff member interviewees noted the lack of guidance concerning how staff members and management should respond in situations involving employee misconduct, such as the discovery of Blake's actions.

Due to the consistency of the interviewee answers from both staff members and management, we concluded that a clear understanding of general team member roles and responsibilities is provided through means other than the protocols, such as training and peer guidance. However, problem resolution guidance is lacking. Consequently, we concluded that the risk posed by the lack of comprehensive guidance in the protocols on team member roles is mitigated by the DNAUI's provision of that information to staff members through other means, while the risks associated with the lack of guidance on problem resolution remain unmitigated.

Recommendations

14) The above-referenced sections of the *DNA Analysis Unit I Quality Assurance Manual* should be revised to add comprehensive guidance regarding team member roles and responsibilities, particularly as it applies to problem resolution.

15) Include comprehensive guidance for problem response and resolution, similar to that contained in the *DNAUI Quality Assurance Manual*, in the *FBI Laboratory Division Quality Assurance Manual*.

2. Protocols That Fail to Inform the Exercise of Staff Discretion

Written Protocols

In addition to protocols that fail to identify in sufficient detail the procedures that DNAUI staff members should follow when they perform DNA analysis, we also identified protocols that suffer from a related defect: the failure to specify the decision criteria staff members should employ when their duties require them to exercise discretion in the testing process. See Chart at page 80. Greater risk of abuse and error is present when procedures call upon the proper exercise of discretion.

For example, the amplification set-up process requires DNAUI staff members to complete a series of objective steps where precise amounts of various substances are added to the amplification tubes. In contrast, Serologists are faced with a complex decision when, after completing preliminary testing and obtaining a negative result, they must determine what step to take next. Serologists must decide whether the presumptive test results should be followed or disregarded. In making that decision, they must consider, for example, whether other factors may have influenced the results, and whether a negative result automatically means that there is no detectable DNA on the evidence item. These questions and others like them must be answered and judgment applied to decide how the testing process should proceed. If staff members are not equipped with sufficient guidance to answer these questions, they could prematurely halt the serology process when a probative DNA result might otherwise have been obtained.

Consequently, in our view, the risks inherent in such decision-making should be offset by the provision to staff members of adequate evaluative tools and guidance to ensure that they are thorough and consistent in their consideration of options at each "crossroad" in the DNA testing process. We failed to find this type of guidance in five sections that address serology testing and electrophoresis data interpretation: the *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and *from Anticoagulated Whole Blood*; *Procedures for the Extraction of Suspected Semen Stains: Questioned Stain Extraction Procedure* from the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials;*[96] and the *GeneScan Analysis* and *Interpretation of Control Samples* sections from the *Short Tandem Repeat Analysis Protocol*.

[96] While only the above-mentioned serology procedures were specifically cited by the OIG team scientists, all the serology procedures would benefit from work-flow and decision-making guidance. See discussion at Chapter Five, Section III.A.2.

Interviews

To understand how staff members exercise discretion under these protocols, we interviewed Serologists and Unit management regarding: 1) the circumstances in which they do or do not perform each of the serology tests; and 2) the procedures they follow if they obtain a negative result (indicating that no DNA was detected). Serologist responses were generally very similar to each other and to the responses provided by management. For example, Serologists provided similar descriptions of the various factors that they consider when deciding how to process an evidence item – factors that are not explained in the protocols, and Serologists and managers (including the Examiners) provided comparable descriptions of the Examiners' role in serology decisions.

We also interviewed Examiners regarding the discretion they have when interpreting electrophoresis results. Specifically, we asked them to describe: 1) their responsibilities in the DNA analysis process; 2) what they specifically look for when reviewing GeneScan® data and control results; and 3) the circumstances in which they would decide to fail an analysis run based upon the control results. Their responses were generally consistent with one another and conveyed a level of detail not found in the protocols.

In light of the foregoing, we concluded that the work practices of DNAUI staff members serve to mitigate the risk posed by the lack of adequate evaluative tools and guidance in the protocols.

Recommendations

16) To minimize the potential for staff members to overlook relevant information or considerations when their duties require them to exercise discretion in the testing process, we recommend that DNAUI management supplement the above-described protocol sections with a work-flow diagram or decision tree. These aids would help to structure decision-making and better ensure that staff members are consistent in their evaluations.

17) Evaluate protocols beyond those listed above, including all of the serology procedures, for process descriptions that would benefit from work flow and decision diagrams.

3. Protocols That Fail to Ensure the Precision of Manual Notetaking

Written Protocols

Forensic Standard 11.1 requires that forensic DNA laboratories follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports. Further, Forensic Standard 11.1.1 requires that forensic DNA laboratories maintain, in a case record, all documentation generated by examiners related to case analyses. The DNAUI's protocols refer to these requirements and address, in a limited way, the documentation that should be present in a case file. However, we did not find comprehensive guidance on notetaking methods in three sections of the protocols where manual notetaking is identified as a significant part of staff member responsibilities. In addition, the sections lacked an explicit requirement for staff members to complete their notes contemporaneously with their work. The three sections are: 1) the *Case Documentation Policy* within the *FBI Laboratory Division Quality Assurance Manual*; 2) the *Evidence Control* section within the *DNA Analysis Unit I Quality Assurance Manual*; and 3) the *Procedures for the Examination of Evidence* within the *FBI Laboratory Division Caseworking Procedures Manual*.

The team structure in DNAUI makes it especially important that all staff members have a comprehensive and consistent understanding of how to record information as they complete their work. The case file documentation created by the Serologists and PCR Biologists serves a crucial role in communicating to the Examiner the results of the DNA analyses they have performed. The Examiner draws conclusions from this work and often testifies in court based in part on the documentation contained in the case file.

In addition, contemporaneous documentation is important to ensure that the case file accurately reflects the work performed on each evidence item that is tested. If staff members are allowed to delay recording observations and test results until after they have examined all the items for a case or have completed all of their work for the day, their documentation may not be fully accurate. Also, staff members may be unduly influenced by protocol requirements when relying on memory, and document what they know should have occurred when their recollection is vague. Such a situation could lead to difficulties when trouble-shooting testing problems. For example, a weak and unusable testing result might be caused by a sample with low quantities of DNA or by a technical problem in the analysis process. An Examiner reviewing such results may not be able to pinpoint how to generate a better outcome if he or she is provided with an incomplete record from a staff member who is documenting from memory.

Interviews

Because we could not find any requirement for contemporaneous documentation or comprehensive guidance on how staff members should take notes, we asked staff members and management what they believe the requirements are on this subject. We interviewed ten DNAUI staff and three members of DNAUI management.

DNAUI management cited a specific section of the protocols as the source of guidance on notetaking. However, the five staff members who cited the same section stated that the guidance in the protocols is very general and does not fully address the subject. Two staff members stated that notetaking is addressed in the protocols but did not cite a specific section. Three of the ten staff members stated that they did not think the protocols addressed the subject at all. Six of the ten staff members stated that documentation methods are learned during training.

Unit management stated that notes are taken contemporaneously as testing is performed. Staff members generally indicated that they take handwritten notes as they work and then transcribe the notes into the computer at a later time (typically on the day they are written). Further, staff members did not always give the same answers regarding the time when they take notes: one Serologist stated that staff members will process multiple items and then type up notes; another Serologist explained that staff members create notes immediately after processing each item; and a PCR Biologist stated that staff members would not "typically" put off transcribing their notes until the following day (indicating that there might be times when that does occur).

We also noted from interview responses that for those staff members who are taking contemporaneous notes on their computer during their work, there are no policies in place that require a protective covering (such as plastic wrap) to be used and changed at appropriate intervals to prevent contamination or cross-transfer as the staff person moves from handling an evidence item to typing on the computer keyboard. This issue is of greater concern now that the DNAUI has moved to its new facility. During our tour of the new Laboratory, the Unit Chief explained that the serology and PCR Biologist areas are equipped with a computer for each workstation to permit the immediate transfer of examination and analysis notes into the computer. He further stated that with the addition of these workstations staff members are expected to complete their notes contemporaneously with their work.

Given the disparities in staff member answers, we concluded that Laboratory management has not clearly articulated standards to govern notetaking, including handwritten notes that are later transferred to the computer. Further, it is evident from the Unit Chief's responses that while contemporaneous documentation previously was a goal, it now is an

expectation in the new facility. No written requirement has been published for staff members, however, setting forth comprehensive guidance on notetaking methods.

Recommendations

We recommend that Laboratory and DNAUI management:

18) Supplement documentation guidance found within the *Case Documentation Policy* in the *FBI Laboratory Division Quality Assurance Manual*, the *Evidence Control* section in the *DNA Analysis Unit I Quality Assurance Manual*, and the *Procedures for the Examination of Evidence* in the *FBI Laboratory Division Caseworking Procedures Manual*, to include comprehensive guidance on notetaking methods.

19) Require staff members to document contemporaneously the testing performed in each case.

20) Include in the Unit-specific protocols cleaning and decontamination techniques designed to reduce the risk of contamination or cross-transfer as staff members move back and forth between the evidence items they are examining and their computer keyboards to take notes.

4. Outdated Protocols

Our review of the DNAUI's protocols revealed that, at the time of our examination, four document sections had not yet been updated to reflect a new policy that had been implemented in the Unit as a consequence of Blake's misconduct. The new policy requires Examiners to review GeneScan® data for all samples that show no DNA peaks on the Genotyper® data, and should be reflected in: 1) the *Case Assignment, Documentation and Review* section of the *DNA Analysis Unit I Quality Assurance Manual*, and 2) the *Amplification*, *STR Typing: Setting up a Run*, and *GeneScan Analysis* sections of the *Short Tandem Repeat Analysis Protocol*. These sections of the protocols reflect the previous requirement for review of only the Genotyper® data by the Examiners, a practice that allowed Blake's actions to escape detection.

The risk posed by having outdated protocols is that some staff members might not be aware of new requirements and inadvertently rely upon standards that have been superseded. Unit management stated that their reason for delaying the updating of the protocol is two-fold: 1) they anticipated that the OIG vulnerability assessment would result in additional changes to their

protocols, and 2) because the protocol revision process is lengthy and time consuming, they wanted to wait and make all the revisions at one time.

We concluded from our fieldwork interviews that staff members involved in data review are aware of the new GeneScan® data review policy and understand that adherence to its terms is required. Further, in discussions on this subject with Unit management, they informed us that the policy change had been executed through an "electronic communication" in April 2002, a written format that is used to notify staff members of protocol changes that are implemented between formal revisions. OIG staff members were provided a copy of the electronic communication and confirmed that it describes the new data review requirements.

Recommendations

21) While we acknowledge that the risk posed by the lack of current information in the protocols was mitigated by DNAUI management's notification to staff members of the new data review policy, we recommend that Unit management update the protocol sections cited above.

22) Further, based upon the reasons given for delaying the updating of the protocols, we recommend that Laboratory management review the protocol-revision process to identify and implement methods to expedite that process. The revision of the protocols should not be so cumbersome that Laboratory management is deterred from keeping them current.

5. Summary of Protocol Vulnerabilities

In conclusion, the OIG team found 31 vulnerable sections in the 5 key manuals that govern the work of the DNAUI. In response to these findings, we examined the work practices of DNAUI staff members and management to determine whether those practices mitigated the vulnerabilities detected in the protocols. We found that the vulnerability risks posed by weaknesses in the protocols were mitigated to some extent by the work habits of the Unit's employees.

Although we did not conduct case file reviews throughout DNAUI, we did not identify through our interviews and fieldwork any instances of misconduct of the sort committed by Jacqueline Blake. Staff member and management responses conveyed a level of detail and consistency that reassured us that DNAUI employees are obtaining a clear understanding of the Unit's requirements through means other than the protocols, such as training or peer guidance. However, staff practice did not mitigate all of the protocol weaknesses, and interviewee responses confirmed the remaining protocol

vulnerabilities that we detected. Below we summarize whether the vulnerabilities identified in the document sections were mitigated or confirmed in accordance with the practice information provided by DNAUI staff members and management.

Protocol Vulnerability Status

Protocol Name and Section Title	Mitigated* Vulnerabilities	Unmitigated Vulnerabilities
FBI Laboratory Division Quality Assurance Manual		
Evidence Control Policy	X	
Case Documentation Policy	X	X
DNA Analysis Unit I Quality Assurance Manual		
Organization and Management	X	X
Authority and Accountability	X	X
Evidence Control	X	X
Facilities (Security)	X	
Case Assignment, Documentation, and Review	X	
FBI Laboratory Division Caseworking Procedures Manual		
Procedures for the Examination of Evidence	X	X
Procedures for the Serological Identification of Biological Substances on Evidentiary Materials		
Procedure for...Bloodstains from Coagulated Whole Blood	X	
Procedure for … Bloodstains from Anticoagulated Whole Blood	X	
Procedure for the Extraction of Suspected Semen Stains...: Quality Control Procedures	X	
Procedure for the Extraction of Suspected Semen Stains...: Questioned Stain Extraction Procedure	X	
Short Tandem Repeat Analysis Protocol		
Guidelines for Control Samples	X	
Extraction (total of 10 subsections)	X	X
Amplification	X	X
STR Typing: Setting up a Run	X	
Genescan Analysis	X	
Interpretation of Control Samples	X	
Laboratory Set-up (total of 4 subsections)	X	X

* The "Mitigated" column is marked for those protocols where interview responses indicated that:
1) staff members have a comprehensive understanding of the relevant protocol requirements, and
2) staff members attest that their personal methods comply with this understanding. Conversely, the "Unmitigated" column is marked for those protocols where interview responses indicated that either of these findings were not present. A mark in both columns indicates that some weaknesses were mitigated while others were not within the same protocol section.

Our recommendations to DNAUI management detailing the remedial actions that we believe are necessary to correct the identified protocol vulnerabilities are set forth in Section C below. We believe that until the DNAUI completes the actions prescribed in those recommendations, the DNAUI needlessly will remain subject to an increased risk of employee error and inadvertent protocol noncompliance.

6. Implications of DNAUI Protocol Vulnerabilities for DNAUII

While we did not conduct an assessment of DNAUII's protocols, we believe that our conclusions and recommendations regarding the DNAUI would also benefit the DNAUII in the following ways: 1) the changes made to the DNAUI's *Short Tandem Repeat Protocol* will improve STR work performed by or for DNAUII personnel; and 2) case file documentation and evidence storage and handling in the DNAUII will be improved by changes made to Laboratory-wide protocols, such as the *FBI Laboratory Division Quality Assurance Manual* and the *FBI Laboratory Division Caseworking Procedures Manual*.

However, based upon the extent of the vulnerabilities identified within DNAUI's protocols, we believe that the risk exists that DNAUII's protocols contain vulnerabilities of a similar nature, vulnerabilities that will not be remedied completely by the improvements made as a result of our preceding recommendations. Therefore, we make the following recommendation.

Recommendation

23) The recommendations in this report should be applied to DNAUII where applicable. In addition, DNAUII management should conduct a comprehensive vulnerability assessment of its own protocols and practices, similar in extent and focus to the assessment the OIG has conducted on the protocols and practices of the DNAUI, and remedy all vulnerabilities identified by that review. We believe that such an assessment will have a greater degree of success if DNAUII management solicits the participation of scientists outside the DNAUII, who can bring an unbiased perspective to the assessment.

C. Analysis of Practice Vulnerabilities

As explained earlier, the second type of vulnerability we identified during our review – practice vulnerabilities – was detected as we completed our fieldwork on the protocol vulnerabilities. These weaknesses result from the manner in which the DNAUI implements its protocols, leaving the Unit more susceptible to undetected inadvertent or willful protocol noncompliance. Our analysis is based largely upon the perceptions of DNAUI staff members, since each of the vulnerabilities was identified by multiple staff members and/or management during our interviews with them. Of special concern are the following: 1) variations in team operations; 2) the "oral tradition" of DNAUI guidelines and training; and 3) communication and operational inefficiencies. We describe each below.

1. Variations in Team Operations

During our interviews with DNAUI staff members, we regularly received comments regarding the degree of variation that exists in the operations of the DNAUI teams. For example, a PCR Biologist explained that various aspects of the work performed by staff members are not standardized. The Biologist further explained that while everyone follows the protocols (e.g., how samples are numbered, how to check in cases), the protocols are general and leave a lot of room for flexibility. The Biologist stated that, consequently, the teams often function very differently. The Biologist stated that this can be beneficial for someone who wants to devise and follow his own procedures, but when issues arise in the Unit, those variances also can pose a problem.

Another PCR Biologist provided similar comments, stating that even though the protocols are followed very strictly, there is a broad range of interpretative leeway for anything that the protocols do not specify. According to this Biologist, the practices of Biologists on the DNAUI teams vary, which can pose a problem if a Biologist ever has to do work for another team, since the supervising Examiner may not be comfortable with the Biologist's methods. In addition, the Biologist explained that since the Examiners testify based upon how their team operates, their testimony might not be precise if a Biologist from another team has provided assistance and employed another team's methods. The Biologist stated that there needs to be more uniformity between teams. The Biologist also explained that Examiners are probably unaware of the extent of these variations.

A Serologist commented that, due to the nature of the "oral tradition" of training (covered under the next section), many staff members have developed their own style, methods, and preferences for how they perform their work. Another Serologist referred to the variations in team operations and explained that they make it hard to train new staff members and to learn what is required.

Multiple staff members commented about the flexibilities afforded to teams due to the lack of detailed guidance on specific topics in the written procedures and protocols. Examples cited by staff members were: 1) how forms are filled out; 2) how case file documentation is transferred to the Examiner; 3) how responsibilities are divided between the PCR Biologist and the Examiner; 4) how much Examiners interact with their team members on decisions; 5) the work flow of the serology procedures; 6) notetaking; and 7) inter-Unit transfer of evidence.

One member of DNAUI management acknowledged that it would be advisable to standardize guidelines for team operations. He said that while he thought that the lack of uniformity had not yet caused a problem for the DNAUI, it could in the future. He stated, however, that there would probably

be resistance to standardizing team operations. He stated that even though there may be better ways to do things, staff members are accustomed to their own procedures and likely would resist standardization because they would not want to sacrifice their autonomy.

These interview comments highlight the need to ensure that protocols are comprehensive and address all aspects of the Unit's operations. See Chapter Five, Section II.B.1 (describing protocols that lack sufficient detail). As many interviewees mentioned, practice variations exist because the written guidance is silent on many subjects.

2. Training and the DNAUI's "Oral Tradition"

During our interviews with DNAUI staff members and management, we were informed that the Unit's training curriculum consists largely of individual discussions with a mentor and presentations given by various experienced staff members. Laboratory management was unable to furnish us with a single, comprehensive curriculum, though we were provided training program manuals for Biologists and Examiners, and PowerPoint slides used during training presentations. Also, we saw evidence in the training records that these presentations often relied upon other training materials, such as handouts and checklists. However, none of these materials has been collected and incorporated into a larger training program with a defined curriculum.

According to DNAUI staff members, this diffuse approach to training is founded upon the Unit's "oral tradition," since verbal instruction is the primary means of conveying training information. During interviews regarding Unit operations, several staff members explained their perspective on why the oral tradition, as a training philosophy, increases the Unit's vulnerability to inadvertent and willful noncompliance with applicable protocols.

For example, two staff members cited training as a key weakness in the Unit. They explained that when the Unit was created, training was better because everyone was "starting fresh and learning the same thing." However, over time people began to teach their own preferences as the only way to complete the Unit's work. In the view of these two individuals, the result is a staff that does not have an understanding of the "big picture" and that performs work in noticeably different ways. One of the staff members, a Serologist, explained that the weaknesses in training are exacerbated by the fact that, because many staff members have biology degrees, much is assumed about their basic understanding of laboratory operations, which may be unwarranted. The other staff member, a PCR Biologist, stated that some training improvements were being implemented under the current Unit leadership, and cited as examples the development of a written exam to assess candidate qualifications and increased stringency in the qualification requirements.

An Examiner who has served as the training coordinator for the DNAUI acknowledged that the oral tradition concerns him since it fosters "protocol drift" – something staff members described as the use of personalized testing procedures that deviate from and/or add to the letter of the protocols, though without jeopardizing the integrity of the testing results.[97] The Examiner identified several checks and balances on the training process that he felt counteracted the risks associated with an oral tradition. These included the constant involvement during training of a trainer/mentor and, following training, the oversight of an Examiner during casework duties who would notice whether something had been overlooked or improperly communicated during training. He added that key policies are reiterated throughout training, and that there are multiple ways to check to see if a person understands his or her duties. Yet, the Examiner acknowledged that in spite of these "checks and balances," protocol drift still occurs.

We note two considerations regarding the Examiner's comments. First, each of the checks on staff member behavior he identified requires another DNAUI staff member, rather than a written document in conjunction with staff guidance, to be the source of information and direction for the Unit's employees. Second, based upon the division of duties within DNAUI teams, particularly the division of duties and roles described by staff members, we are not convinced that the Examiners are sufficiently involved in the day-to-day activities of their team members to serve as one of the "checks and balances." This was illustrated by the fact that Blake's Examiner was unaware of her misconduct until Blake's colleague noticed her omissions.

In addition, when the distinction between staff member preference and protocols is unclear, trainees are left to draw their own conclusions regarding proper testing methods. In our view, such an environment leaves the Unit vulnerable to inadvertent noncompliance with Unit requirements, since staff members may choose to alter their methods in ways that unwittingly contradict Unit requirements.

A DNAUI Serologist, who also is involved in training activities, stated that management's failure to communicate the reasons behind the Unit's work requirements is a weakness and needs to be addressed during training. A PCR Biologist reiterated the point, stating that training has been a weakness in the Unit and that part of the problem is the failure to teach staff members why they are asked to do their work a certain way – the importance and history behind what they are doing – not just the actual procedural steps to perform.

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[97] For example, staff members have adopted methods for cleaning their transport trays that they believe are sufficient. These procedures are not specifically covered in the existing protocols; instead, they supplement requirements found in the Amplification and Laboratory Set-up protocols. Another example of protocol drift, a hypothetical provided by a DNAUI Biologist, would be using an incubation time of 1 hour, 55 minutes, when the protocol calls for an incubation time of 2 hours.

In conclusion, moving away from training that is based on the DNAUI's "oral tradition" will help to ensure that the other recommendations we present in this report reduce the DNAUI's vulnerability to undetected protocol non-compliance. A well-documented and comprehensive training curriculum should reinforce application of the revisions we have outlined to the Unit's protocols.

3. Communication and Operational Inefficiencies

We determined from our review of DNAUI operations and our analysis of interview responses that there are various communication and operational inefficiencies within the DNAUI.

a) Communications

During our interviews with DNAUI staff members and management, we inquired about the way that information is communicated within the Unit. This issue was of particular interest to us because of the importance of communication to the proper implementation and improvement of DNAUI protocols. We asked interviewees the following questions:

- How are staff members kept apprised of changes in work routine, procedures, and resources?

- What options are available to you if you were to have a recommendation, request, suggestion, or a critique regarding Unit operations or protocols?

We observed from interview responses that although members of upper management think that communication within the Unit, and between the Unit and Laboratory management, is functioning well, several staff members do not feel that they are kept informed about operational information and believe that communications are at times dysfunctional. Further, several comments we received indicate that some staff members do not believe that Laboratory management actively solicits and considers their input on issues that affect their work.

Management and staff members identified similar methods that are used to keep staff members updated on operational and protocol-related information, including e-mail and Unit or program meetings. However, it was clear from staff member responses that these methods are not consistently effective. Staff members explained that the dissemination of information, including protocol-related information, is erratic. Examiners made reference to this problem and said that some Examiners are better than others in passing along information, a point that also was noted by both a PCR Biologist and

Serologist. One Examiner stated that changes in technical operations that affect the quality of work are always passed on to staff members, but that Examiners may not pass on administrative information. However, we question whether Examiners are as consistent as this Examiner claims in conveying operational information, given the lack of a requirement that Examiners disseminate protocol-related information promptly and accurately to those under their supervision.

In addition, one Serologist added that even when decisions and other important information are communicated to staff members, the rationale behind them often is not explained, leaving staff members unclear on the goal that management is trying to achieve.[98] One Examiner said that he felt that information does not flow effectively up the hierarchy either, and identified a situation where the PCR Biologists decided to initiate a technical change in Unit procedures and failed to ensure that all the Examiners were made aware of it.

The types of communication weaknesses mentioned by staff members pose a risk to the efficiency and effectiveness of the Unit's operations and should be addressed. Of particular concern is the perception of Laboratory and Unit management that communication lines are functioning well, while many staff members describe a different perspective that questions whether they are being kept well informed of procedural changes and whether management properly considers technical input in operational matters.

b) Operations

During our review of protocol vulnerabilities, we observed many DNAUI operations that could be made more efficient through use of a Laboratory Information Management System (LIMS). A LIMS is a computerized system of databases that track, organize, and link the information that must be maintained to document the receipt, handling, and disposition of each case and evidence item. A LIMS allows a laboratory to:

- Reduce the incidents of human error associated with the manual entry of tracking information;

- Improve evidence handling efficiency, saving time particularly for those staff members who have numerous evidence processing and transfer responsibilities;

- Prevent the unauthorized alteration of tracking information;

[98] For additional discussion on this point, see supra at page 96.

- Allow management to trouble-shoot problems and to identify causes related to equipment, reagents, and personnel; and

- Document who has accessed and/or contributed to the information contained in the LIMS.

Because of these capabilities, we believe such a system would strengthen the Unit's internal controls and allow DNAUI staff members to be more efficient in their duties. As revealed in their interview responses, Laboratory and Unit management, as well as staff members, share this assessment and believe that acquisition of a LIMS is a priority for the Laboratory. We were informed that Laboratory management began to lay the groundwork for the implementation of a LIMS in 2002. During our March 2003 fieldwork, we met with personnel involved in LIMS development at the Laboratory and reviewed available documentation concerning the progress of implementation. From this information, we determined that the Laboratory had completed the bid process for a contractor who would design and implement the LIMS, and that all Unit Chiefs had been involved in determining the capabilities that the LIMS would need in order to suit the activities of their Unit.[99] In October 2003, we were informed that the LIMS had been procured and that the system should be on-line in December 2003 and functioning fully in the Laboratory by approximately March 2004. The Laboratory Director told us in March 2004 that he expected the LIMS to be fully operational this fiscal year, and that the Laboratory was waiting on security clearances for the staff of the LIMS contractor before commencing implementation of the system.

We recommend that the Laboratory's LIMS work remain one of its top priorities. Specifically, successful implementation requires that all appropriate personnel have ready access to the system, have received adequate training, and are afforded the resources needed to convert their current methods and operations to those that will maximize the capabilities of the LIMS. Further, we recommend that Laboratory management continue to set aside sufficient resources for the LIMS to ensure that it keeps pace with the changes and developments in technology that invariably will occur over time.

[99] We also were informed by the DNAUI Unit Chief that the DNAUI is implementing a unit-specific tracking system that will feed into the Laboratory-wide LIMS, called the Sample Tracking and Control System (STaCS). While initially STaCS has been used to track federal offender samples that are received as part of the Federal Convicted Offender Program (the federal database of convicted offender samples), management intends to expand STaCS for application to case evidence tracking.

CHAPTER SIX
OIG RECOMMENDATIONS

Jacqueline Blake's misconduct has required the FBI Laboratory to reassess its oversight of DNA testing in the DNAUI. The objective of this review was to identify ways to make the DNAUI less vulnerable to undetected inadvertent or willful noncompliance with the protocols that govern DNA analysis. Our recommendations focus on two general types of vulnerabilities: protocol vulnerabilities and practice vulnerabilities. In addition, we provide recommendations that we believe will address several of the issues of concern that we identified regarding the management response of the FBI and DOJ to Blake's misconduct. Our recommendations are listed below.

I. MANAGEMENT RESPONSE RECOMMENDATIONS

1) To facilitate prompt communications with evidence contributors and prosecutors in the event of future testing problems, the Laboratory should maintain the information below in an electronic format that can be shared conveniently with other FBI components (e.g., FBI OPR and FBI OGC) and the Department of Justice: all contributor contact and case information currently required for an evidence contributor to request an evidence examination (see FBI Handbook of Forensic Services, (http://www.fbi.gov/hq/lab/handbook/intro2.htm); the e-mail address of the evidence contributor; and the name, title, agency, address, telephone number, and e-mail address of any associated prosecutor(s);

2) In circumstances where a protocol violation renders testing results scientifically invalid and a report from the Laboratory is not expected to issue within 180 days from the discovery of the violation, the Laboratory should notify the evidence contributor of the following information within 90 days of learning of the violation: the nature of the protocol violation; how the violation occurred; the remedial measures that the Laboratory intends to implement in the case to generate scientifically valid testing results; and the time needed to complete the remedial measures and to issue a final report; and

3) The FBI Laboratory should perform a file review of a sample of cases that Blake is known to have worked on prior to becoming a PCR Biologist to reconfirm that the procedures that were required in fact are documented as appropriate in the case files.

II. REMEDY PROTOCOL VULNERABILITIES

Our analysis of the DNAUI's protocols revealed various weaknesses that leave the Unit vulnerable to employee error and wrongdoing. The recommendations we present below are designed to reduce the Unit's exposure to this vulnerability and fall in four general areas: 1) eliminate vague and ambiguous text from the protocols; 2) incorporate decision aids into the protocols; 3) enhance notetaking requirements; and 4) update the protocols.

A. Eliminate Text Vagueness

Approximately 20 percent of the protocol sections we examined lacked the detail necessary for a technically qualified DNA scientist to identify the testing methods that should be in use in the DNAUI. Accordingly, DNAUI management should ensure that the document sections identified as vague in Chapter Five of this report are corrected to describe completely and accurately management expectations, Unit procedures and policies, and "best practices" currently in use in the DNAUI. Specifically, DNAUI management should:

4) Ensure that the *Evidence Control Policy* of the *FBI Laboratory Division Quality Assurance Manual*, the *Evidence Control* and *Facilities (Security)* sections of the *DNA Analysis Unit I Quality Assurance Manual*, and the *Procedures for the Examination of Evidence* section of the *FBI Laboratory Division Caseworking Procedures Manual*, contain:

   a) Comprehensive guidance regarding the prevention of evidence contamination, loss, and destruction. At a minimum, this information should be included in *Evidence Control Policy* sections 3.2 and 3.5; *Evidence Control* sections 7.6.1 and 7.6.2; and *Procedures for the Examination of Evidence* sections 4.1.3 and 4.5.1.1. The Laboratory-wide sections should identify procedures that are applicable to all Units. Sections associated with a particular Unit should provide a complete listing of the evidence preservation methods in use in that Unit, even when those methods are identified elsewhere in the other Unit protocols.

   b) General guidance regarding DNA evidence handling procedures that is applicable to all Laboratory Units. This information should be provided in Laboratory-wide documents, including the *Evidence Control Policy* of the *FBI Laboratory Division Quality Assurance Manual,* and the *Procedures for the Examination of Evidence* section of the *FBI Laboratory Division Caseworking Procedures Manual,* and

should describe the requirements to process the evidence one case at a time, and to handle evidence one item at a time. The guidance also should identify procedures to ensure that one Unit does not compromise the ability of another Unit to test the same item of evidence.

c) Unit-specific guidance on DNA evidence handling procedures. This information should be included in the *Evidence Control* section of the *DNA Analysis Unit I Quality Assurance Manual*, and should contain all evidence handling, contamination-prevention, and evidence-preservation methods universal to all technical DNAUI staff.

d) An identification of facility access limitations, including a description of the context and limitations for access to DNAUI areas by non-DNAUI personnel. This information should be added to *Facilities (Security)* section 6.1.

5) Ensure that the *Evidence Control Policy* of the *FBI Laboratory Division Quality Assurance Manual*, the *Evidence Control* and *Facilities (Security)* sections of the *DNA Analysis Unit I Quality Assurance Manual*, and the *Procedures for the Examination of Evidence* section of the *FBI Laboratory Division Caseworking Procedures Manual* cross-reference other relevant guidance to ensure that staff members know whether additional information is located in other manuals.

6) Implement a policy that requires staff members to certify that they have read, understand, and will comply with each protocol that governs DNAUI operations, as well as any approved revisions that have not yet been incorporated into the protocols.

7) Revise policies for securing evidence under active examination to reflect the current availability of independently securable storage at staff member workstations, and of a securable bulky evidence examination room. The policies should require the use of these new facilities rather than leaving the security of unattended evidence under active examination dependent upon facility access limitations.

8) Ensure that the *Extraction* and *Amplification* sections of the *Short Tandem Repeat Analysis Protocol* include:

a) A requirement that the known and unknown (evidence) samples are processed separately during examination,

extraction, and amplification, including references to guidance that specifies the amount of time and space that meets the intent of the term "separation."

b) A requirement for the "separation" of high- and low-quantity DNA samples, as well as references to guidance that specifies the amount of time and space that meets the intent of the term "separation."

9) Ensure that the *Extraction, Amplification*, and *Laboratory Set-up* sections of the *Short Tandem Repeat Analysis Protocol* include:

a) Information on the use, cleaning, and decontamination of the "transport trays" used by PCR Biologists to move samples to the amplification area.

b) General evidence handling information.[100]

c) In the *Extraction* section, a prohibition on having two sample tubes open at once, clarification in section 4.1.3 regarding required incubation times, and further explanation concerning when the additional organic extractions permitted by section 4.3-9 are appropriate.

d) In the *Amplification* section, a requirement that control samples be processed last, and in section 6.7, the specification of the order in which sample tubes should be set up.

10) Ensure that the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials* includes:

a) Detailed guidance on proper evidence handling methods, similar in content to the guidance contained in the *Laboratory Set-up* section of the *Short Tandem Repeat Analysis Protocol*.

b) In the *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and the *Procedures for the Preparation of Dried Bloodstains from Anticoagulated Whole Blood*, a requirement to: 1) pretest the cotton sheeting to

[100] Currently, this information is included in the *Laboratory Set-up* section. We recommend that it be included in all sections of the *Short Tandem Repeat Analysis Protocol* that call for the handling of evidence, but at a minimum, in the *Extraction* and *Amplification* sections.

ensure that there is no DNA contamination; and 2) identify the amount of blood to use when making dried blood stains.

c) In the *Procedures for the Extraction of Suspected Semen Stains: Quality Control Procedures* and *Procedures for the Extraction of Suspected Semen Stains: Questioned Stain Extraction Procedure*, guidance regarding: 1) the usable life of the positive semen control; 2) the size of the swab to use for testing; 3) the need to use disposable paper to reduce the risk of contamination; 4) whether extracts and swabs are both sent to the Biologist for testing; and 5) what happens after the stain extraction procedure has been completed (i.e., what occurs if there is a negative or positive result).

d) Unwritten internal controls that already are in use by DNAUI staff members and management, including (but not limited to): (a) the requirement for a team's PCR Biologist to record the characteristics of the evidence, supplementing the description generated by the Serologist; and (b) the requirement for Serologists to perform a "general swabbing" of an item to ensure that no possible sources of DNA on that item have been missed.

11) Ensure that the *Case Documentation Policy* section found in the *FBI Laboratory Division Quality Assurance Manual* contains:

a) A listing of the minimum contents for all Unit case files, along with a reference to that part of each Unit's case documentation and review protocol that addresses case file contents; and

b) Guidance on notetaking methods and requirements common to all Units, along with a reference to the corresponding Unit-specific protocols.

12) Ensure that the *Case Assignment,* Documentation*, and Review* section found in the *DNA Analysis Unit I Quality Assurance Manual* contains:

a) A detailed description of case file review procedures, including a checklist to facilitate the review and to document that the review accounts for each key item in the case file;

b) Guidance on notetaking methods to ensure that DNAUI staff members understand how and when they should take notes; and

c) A description of the procedures that must be followed to review and confirm case evidence profiles for entry into CODIS, or at a minimum, a reference to where those procedures are described in another policy document.

13) Ensure that the *Guidelines for Control Samples* and *Interpretation of Control Samples* sections within the *Short Tandem Repeat Analysis Protocol* contain comprehensive guidance on each of the following: (a) the procedure to complete a case file review; (b) the difference between the review responsibilities of Examiners and of the PCR Biologists; (c) the circumstances in which a control result should cause an entire analysis run to "fail;" and (d) how and when staff members should use section 10.3.3 of the *Interpretation of Control Samples*. Further, these sections should contain a checklist or summary sheet to assist reviewers to verify the completeness of their work.

14) Ensure that the *Organization and Management* and *Authority and Accountability* sections of the *DNA Analysis Unit I Quality Assurance Manual* contain:

a) A complete description of the characteristics, responsibilities, interrelation, and limitations of each job position in the various DNAUI teams;

b) Problem-resolution guidance for each team member position that describes how to respond to operational and personnel problems (such as suspicion of protocol noncompliance), and that clearly delineates the options for resolution available to staff members; and

c) A clear statement identifying Laboratory personnel who have the authority to halt DNAUI operations if a significant problem is detected.

15) Include comprehensive guidance for problem response and resolution, similar to that contained in the *DNAUI Quality Assurance Manual*, in the *FBI Laboratory Division Quality Assurance Manual*.

B. Incorporate Decision Aids

In addition to protocols that fail to specify the procedures that DNAUI staff members should follow when they analyze DNA, our review identified protocols that do not describe adequately the decision criteria staff members should employ when their duties require them to exercise discretion in the testing process. To address this deficiency, we recommend that DNAUI management:

16) Add work-flow diagrams and decision trees to its protocols to assist staff members to exercise properly their judgment during the DNA testing process. These aids would help to structure decision-making and to ensure that staff members do not overlook relevant information. At a minimum, the following protocol sections should include decision-making aids:

    a) in the *Procedures for the Serological Identification of Biological Substances on Evidentiary Materials*: 1) the *Procedures for the Preparation of Dried Bloodstains from Coagulated Whole Blood* and *from Anticoagulated Whole Blood*; and 2) *Procedures for the Extraction of Suspected Semen Stains: Questioned Stain Extraction Procedure*;

    b) in the *Short Tandem Repeat Analysis Protocol*: 1) the *GeneScan Analysis* section, and 2) the *Interpretation of Control Samples* section.

17) Evaluate protocols beyond those listed above, including all of the serology procedures, for process descriptions that would benefit from work flow and decision diagrams.

C. Enhance Notetaking Requirements

During our review we identified three procedure and protocol sections that depend upon the precision of manual notetaking but that lack comprehensive guidance on notetaking methods. To address this deficiency, Laboratory and DNAUI management should:

18) Supplement documentation guidance found within the *Case Documentation Policy* in the *FBI Laboratory Division Quality Assurance Manual*, the *Evidence Control* section in the *DNA Analysis Unit I Quality Assurance Manual*, and the *Procedures for the Examination of Evidence* in the *FBI Laboratory Division Caseworking Procedures Manual*, to include comprehensive guidance on notetaking methods.

19) Require staff members to document contemporaneously the testing performed in each case.

20) Include in the Unit-specific protocols cleaning and decontamination techniques designed to reduce the risk of contamination or cross-transfer as staff members move back and forth between the evidence items they are examining and their computer keyboards to take notes.

D. Update Protocols

Our review identified several protocols that are outdated and no longer reflect current procedures in use in the DNAUI. To address this deficiency, DNAUI management should:

21) Revise the *Case Assignment, Documentation and Review* section of the *DNA Analysis Unit I Quality Assurance Manual*, and the *Amplification*, *STR Typing: Setting up a Run*, and *GeneScan Analysis* sections of the *Short Tandem Repeat Analysis Protocol* to include the current requirement that Examiners review GeneScan® data for all samples that show no DNA peaks on the Genotyper® print-out.

22) Review the protocol revision process and identify ways to expedite it. Protocols should not be so difficult to update that administrative burden justifies not keeping them current.

E. Implications for DNAUII

Based upon the extent of the vulnerabilities identified within DNAUI's protocols, we believe that the risk exists that DNAUII's protocols contain vulnerabilities of a similar nature, vulnerabilities that will not be remedied completely by the improvements made as a result of our preceding recommendations. Therefore, we make the following recommendation.

23) The recommendations in this report should be applied to DNAUII where applicable. In addition, DNAUII management should conduct a comprehensive vulnerability assessment of its own protocols and practices, similar in extent and focus to the assessment the OIG has conducted on the protocols and practices of the DNAUI, and remedy all vulnerabilities identified by that review. We believe that such an assessment will have a greater degree of success if DNAUII management solicits the participation of scientists outside the DNAUII, who can bring an unbiased perspective to the assessment.

III. REMEDY PRACTICE VULNERABILITIES

Our fieldwork focused on the DNAUI staff's application of the protocols we identified as deficient. The information we collected establishes that the DNAUI needs to: 1) promote greater consistency in DNAUI team operations; 2) develop a comprehensive, written training curriculum; 3) improve information dissemination; and 4) implement an information management system to improve evidence tracking capabilities and efficiency of operations.

A. Promote Greater Consistency in Team Operations

Our interviews of DNAUI staff members indicated that variation exists in the operations of the Unit's teams. Unwarranted flexibility in DNAUI operations can communicate to staff members that they are free to develop idiosyncratic work practices, which can create an environment with greater risk for inadvertent or willful noncompliance with protocols. To promote greater consistency and accountability in DNAUI functions, we recommend that Laboratory and DNAUI management:

24) Document and standardize the best practices of the Unit's teams and incorporate them in protocols.

25) To the extent practicable, minimize managerial flexibility permitted in team operations, even in areas considered to be of no "impact" to the analysis process (as we have defined the term for our assessment).

26) Document in the protocols those flexibilities that remain, with an explanation of the circumstances in which team members have leeway to exercise discretion and to vary testing methods. This documentation should provide staff members with clear guidance on the constraints placed by management on their discretion, so that they can be alert to practices that exceed those constraints. As part of this documentation, the protocols should include notations to staff where the precision of their actions can fall within an acceptable range (i.e., if the protocol calls for a 2-hour incubation time, but 1 hour and 50 minutes is acceptable, the protocol should reflect the range of time that is considered scientifically acceptable).

27) Ensure that protocols and training materials address the risks posed by protocol drift and protocol noncompliance, and prohibit individual staff or team variation from the protocols. This information should build upon the above-required analysis of team variations, the limitations placed upon existing flexibilities, and the delineation of those procedures where a scientifically acceptable

range of activity is permitted. In addition, in circumstances where DNAUI staff members deviate from the protocols, they should be encouraged to note the deviation and its degree in the case file.

B. Formalize Training

Our review of DNAUI training practices revealed that the Unit lacks a comprehensive curriculum and that training consists largely of individual discussions with a mentor and presentations given by various experienced staff members. To address this deficiency, DNAUI management should:

28) Convert this "oral tradition" of training into a comprehensive, written curriculum to ensure that trainees receive consistent instruction that comports with the protocols. As part of this process the Laboratory should:

    a) Collect the training materials that currently are in use and organize them into a coherent written course of study;

    b) Cross-reference the training materials to the protocols; and

    c) Ensure that the training materials reflect the standardized best practices and limited flexibilities established in recommendations 18-20.

29) Ensure that the training materials are kept current as the DNAUI protocols evolve.

C. Improve Information Dissemination

Laboratory/or DNAUI management (as appropriate to the recommendation) should:

30) Implement requirements that will ensure that managers within the Unit disseminate protocol-related information promptly and accurately to those under their supervision.

31) Ensure that serology and PCR program managers inform Unit management (including team supervisors) of changes to procedures employed in the DNAUI.

32) Solicit and evaluate technical input from staff members on significant changes that affect Unit procedures and protocols.

33) Develop and implement a communications plan that allows DNAUI staff members to provide feedback on the effectiveness of the Unit's protocols.

D. Implement a Laboratory Information Management System

We determined that Laboratory management had begun to lay the groundwork for the implementation of a Laboratory Information Management System (LIMS) in 2002, and has since made progress toward the implementation of a LIMS. However, given the benefits that a LIMS will bring to evidence tracking and chain-of-custody documentation, we recommend that Laboratory management:

34) Ensure that a LIMS is successfully implemented. To accomplish this, Laboratory management must provide to all appropriate personnel:

   a) Ready access to the system;

   b) Adequate training on the proper use of the system; and

   c) The resources needed to convert their current methods and operations to those that will maximize the capabilities of the LIMS.

35) Retain full utilization of the LIMS as one of the top administrative priorities of the Laboratory. To accomplish this, Laboratory management will need to devote sufficient resources to the LIMS to ensure that it keeps pace with the changes and developments in technology that will occur over time as the Laboratory evolves.

CONCLUSION

Our investigation was prompted by the misconduct of FBI Staff Biologist Jacqueline Blake. Because of her failure to follow DNAUI protocols, and the inadequacy of those protocols to expose her misconduct, we assessed the DNAUI's vulnerability to other inadvertent or willful protocol noncompliance by its employees.

Although our review did not identify other instances of misconduct by DNAUI staff members, we determined that certain DNAUI protocols and operations are vulnerable to abuse. Specifically, in approximately 20 percent of the protocol sections we reviewed we identified one or more of the following deficiencies: 1) the protocol lacks sufficient detail; 2) the protocol fails to inform the exercise of staff discretion; 3) the protocol fails to ensure the precision of manual notetaking; and 4) the protocol is outdated. While in most instances the work practices of the DNAUI's staff members served to mitigate the effects of these vulnerabilities, we believe that until the DNAUI's protocols are revised in accordance with the recommendations in this report, the DNAUI needlessly will remain subject to an increased risk of employee error and inadvertent protocol noncompliance. Because of the importance of the DNAUI's work, we believe the Laboratory should address these deficiencies expeditiously.

To remedy the protocol vulnerabilities that we identified, our report makes various recommendations to the FBI Laboratory and DNAUI management, such as: 1) replace vague sections of the protocols with comprehensive guidance and descriptions of the "best practices" currently in use; 2) add work flow and decision aids to the specific protocol sections we identified to assist staff members to exercise properly their judgment during the DNA testing process; 3) provide staff members with guidance sufficient to ensure that case documentation and case file reviews meet management expectations, and that protocols provide comprehensive guidance on notetaking requirements; and 4) update protocols to reflect current methods in use in the DNAUI.

Further, with regard to operations, our analysis revealed that the Laboratory and DNAUI management should: 1) promote greater consistency in DNAUI operations; 2) develop a comprehensive, written training curriculum; 3) improve management and staff information sharing; and 4) complete implementation of an information management system to improve efficiency and evidence tracking capabilities. Until significant progress is made in each of these areas, the DNAUI will remain vulnerable to a heightened risk of error.

Finally, during our review we identified a number of concerns with the FBI's management response to Blake's misconduct. We recommend that the

Laboratory maintain basic case data and contact information for evidence contributors and associated prosecutors in an electronic format that can be shared conveniently as needed with other FBI components (e.g., FBI OPR and FBI OGC) and the Department of Justice, provide prompt notification to evidence contributors of future protocol violations, and perform a file review of a sample of cases that Blake is known to have worked on prior to becoming a PCR Biologist to reconfirm that the procedures that were required in fact are documented as appropriate in the case files.

In sum, Jacqueline Blake's misconduct exposed weaknesses in the FBI DNA Laboratory's protocols and policies. We found that Blake was able to escape detection not only because she deceived her co-workers and her supervisors for two years, but also because the FBI failed to develop policies that subjected her work and the work of other DNA biologists to adequate scrutiny.

The FBI Laboratory cannot allow the integrity of its DNA testing results to rely solely on the trustworthiness of its employees. It must develop and enforce adequate quality assurance safeguards to identify staff errors and misconduct. Our assessment of the DNAUI's protocols to undetected inadvertent or willful noncompliance by DNAUI staff members revealed vulnerabilities. We believe that the recommendations contained in this report, if implemented fully and expeditiously, will help eliminate these weaknesses and significantly improve the FBI Laboratory's ability to detect promptly instances of protocol noncompliance in the DNAUI.

GLOSSARY OF TERMS AND ACRONYMS

Act: the DNA Identification Act of 1994 (Act) was the vehicle whereby Congress authorized the creation of CODIS, and directed the FBI to establish the Board. The Act also directed that the guidelines issued by TWGDAM would be deemed to be national standards until the FBI issued its own standards pursuant to the Act.

Allele: the characteristics of a single copy of a specific gene, or of a single copy of a specific location on a chromosome, is referred to as an allele. For example, one copy of a specific STR region might have 10 repeats, while the other copy might have 11 repeats. These would represent two alleles of that STR region.

Allelic ladder: contains the more common alleles in the general population for specific chromosomal locations. Allelic ladders are used like molecular rulers to help "measure" the lengths of the fragments in the reference and evidentiary samples. The Genotyper® software compares the peaks in the evidentiary or reference sample to the peaks in the allelic ladder at that same location.

Amplification: the replication of extracted DNA so that the DNA can be detected by an analyzer or a capillary electrophoresis machine. Amplification is the third of five stages in the PCR/STR analysis process.

ASCLD/LAB: the American Society of Crime Laboratory Directors/Laboratory Accreditation Board is one of the organizations that provides accreditation for labs. The organization performs a thorough inspection of the laboratory before it grants accreditation.

Board: the FBI established the DNA Advisory Board (Board), in response to a Congressional mandate within the Act, to develop national quality assurance standards that would ensure that the operations of CODIS participants met minimum quality standards. The Board was formally constituted on March 10, 1995, and was comprised of members of a variety of forensic and science organizations. The Board's mission was to develop quality assurance standards for laboratories and analysts that examine DNA.

Capillary electrophoresis: the form of electrophoresis employed by the DNAUI. Its distinguishing characteristic is that the electrophoresis occurs inside a capillary tube (a very thin glass tube) with a sieving material inside, rather than on a piece of gelatinous material. Capillary electrophoresis is an automated process that analyzes many DNA samples and requires minimal involvement by DNA scientists after the initial set-up procedures are completed.

Chromosomes: chromosomes store information in the chemical structure of DNA much like a book or a compact disk. The nucleus contains 46 chromosomes, two copies of each of the 23 different human chromosomes. One copy of each chromosome is inherited from an individual's mother and one copy is inherited from an individual's father, giving a child DNA characteristics of both its mother and father.

Combined DNA Index System (CODIS): provides a framework for storing, maintaining, tracking, and searching DNA specimen information. CODIS refers to the entire system of DNA databases (convicted offender database, forensic database, victim database, etc.) maintained at the national, state, and local levels. CODIS currently consists of three distinct levels: the National DNA Index System, State DNA Index System, and Local DNA Index System.

Deoxyribonucleic Acid (DNA): DNA is found in almost all living cells, and carries the encoded information necessary for building and maintaining life. This encoded information is what makes each person an individual. DNA consists of two strands of molecules that wrap around each other to resemble a twisted ladder whose sides are connected by rungs of chemicals called bases. There are four kinds of these chemical bases (also called nucleotides), and the order in which they are arranged is called the DNA sequence. It is this unique sequence that is determined when a DNA sample is typed.

DNA Profile: a set of DNA identification characteristics, i.e., the particular chemical bases at specific DNA locations, which permit the DNA of one person to be distinguishable from that of another person.

DNA Sample: a body tissue or fluid sample (blood, a skin cell sample, or semen, for example) that can be subjected to DNA analysis.

DNA Typing: the process by which a DNA sample is examined and a DNA profile is produced.

DNAUI: the DNA Analysis Unit I (DNAUI) identifies and characterizes body fluids and body fluid stains recovered as evidence in violent crimes using traditional serological techniques and related biochemical analysis. These stains are analyzed and compared to results from the known body fluid samples submitted by the victim(s) and/or suspected perpetrator(s).

Electrophoresis: a process whereby DNA fragments are sorted according to length (i.e., number of short tandem repeats). In general, the process involves: 1) Adding DNA to one end of a piece of gelatinous material which contains tiny holes that allows the material to function as a molecular sieve; 2) applying an electric current to the material, causing the DNA fragments to move; and 3) determining the size of the DNA fragments by comparing the distance each fragment moved to the distances moved by the fragments of known size. Since

it is easier for smaller fragments to move through the material, the smaller fragments move farther than the larger fragments. As a result, at the end of electrophoresis the DNA fragments are sorted by size. Electrophoresis is the fourth of five stages in the PCR/STR analysis process.

Examiner (Analyst): an individual who conducts or directs the analysis of forensic casework samples, interprets data, and reaches conclusions. In the context of the DNAUI, the Examiner collects supporting documentation from the Serologist and PCR Biologist for the work performed by each, interprets the data that resulted from that work, draws conclusions about those results, and writes a report describing those conclusions.

Extraction: a process whereby chemicals are used to release or remove DNA from evidence. Extraction is the first of five stages in the PCR/STR analysis process.

Forensic Database: consists of DNA profiles from persons whose identities are not known with certainty and who left DNA at the scene of a crime or whose DNA was carried away from it. For example, a DNA profile may be developed from a bloody knife found at a crime scene or found in a trash dumpster.

Genes: each chromosome contains many genes, which are the portions of the chromosome that code for personally identifying characteristics, like hair color or eye color. It has been estimated that only 2 to 3 percent of the information in a chromosome is organized into genes.

GeneScan®: a component of the proprietary software that accompanies the capillary electrophoresis machines used by the DNAUI. The GeneScan® software allows scientists to view and process the raw, unanalyzed data that documents everything the laser of the electrophoresis machine detects, including background noise that is common in electrophoresis instruments. GeneScan® is a registered trademark of Applied Biosystems.

Genotyper®: a component of the proprietary software that accompanies the capillary electrophoresis machines used by the DNAUI. Genotyper® allows the forensic scientist to take the processed GeneScan® data and display it in a format that applies allele designations to the profile fragments, and to focus his or her review on the results of the control and evidence samples. Genotyper® is a registered trademark of Applied Biosystems.

Guide: the FBI created a standardized DNA audit guide (Guide), with input from the Board, ASCLD-LAB, and NFSTC, to ensure that auditors of local, state, and federal DNA laboratories are thorough and interpret the quality assurance standards consistently. The FBI offers Guide training for auditors, including those representing accrediting and certifying organizations such as ASCLD-LAB and NFSTC. For an audit to fulfill the quality assurance

standards' external audit requirement, it must be conducted in accordance with the Guide and by an auditor trained in its use.

Internal Size Standard: contains DNA fragments of known sizes that provide reference points for determining the length of a sample's DNA fragments. GeneScan® software uses the internal size standard to help the software as it determines the lengths of the DNA fragments detected during electrophoresis.

Investigations Aided: the primary measuring unit that the FBI uses to quantify the success of CODIS. An investigation is aided when a DNA match through CODIS either identifies a potential suspect or links crimes together, but only when the DNA match provides new information that would not have been otherwise developed.

Known DNA sample: a DNA sample for which the source is known. These samples are generally obtained from the victim and/or suspected perpetrator of a crime, as well as from other persons whose DNA might be reflected when samples of the evidence are analyzed (could include a boyfriend, husband, or other third-party). These samples are also referred to as reference samples, since they serve as a reference to which the unknown DNA samples are compared with the goal of identifying the source of the unknown DNA samples.

Mitochondrial DNA: DNA found in the mitochondria of a cell. Mitochondria are about the size of bacteria and are scattered throughout a cell outside its nucleus. Since there are between 500 to 1,000 mitochondria in every cell, as opposed to one nucleus, mitochondrial DNA analysis affords a better chance of a DNA profile than nuclear DNA analysis in cases where a sample is decayed or degraded, such as skeletal remains that have been exposed to the elements for years.

National DNA Index System (NDIS): the FBI-maintained national component to CODIS. NDIS contains DNA profiles uploaded from approved SDIS laboratories.

NDIS Requirements: the NDIS office has issued programmatic rules that govern the exchange of information for NDIS participants and has established standards for the submission of DNA data, collectively referred to as NDIS Requirements. The NDIS requirements are found in the Memorandum of Understanding (MOU) that is established between the FBI and each NDIS participant. The MOU requires that signatories comply with general requirements already established (i.e., federal legislation, the Forensic and Offender Standards) as well as requirements specific to the national index that accompany the MOU in three appendices: NDIS Responsibilities (Appendix A); NDIS Data Acceptance Standards (Appendix B); and the NDIS Procedures Manual (Appendix C).

Negative Control: the negative control contains all of the reagents used for amplification. DNA from the evidence is not added to the negative control, though the contents are amplified. The purpose of the negative control is to reveal any contamination that is present in the reagents or introduced during the testing process.

NFSTC: the National Forensic Science Technology Center (NFSTC) is one of two primary accreditation or certification entities for forensic and offender DNA laboratories.

NIST: the National Institute of Standards and Technology.

Nuclear DNA: DNA found in the nucleus of a cell. The nucleus is the cell's control center. Nuclear DNA contains the entire genetic make-up of a person, including inherited traits such as eye color or height. There is only one group of nuclear DNA per cell, since each cell has only one nucleus. Since nuclear DNA is sensitive to environmental conditions, it can be difficult to obtain useable nuclear DNA from deteriorated and/or old crime scene samples. The alternative to nuclear DNA analysis is mitochondrial DNA analysis.

OGC: the FBI's Office of General Counsel.

OPR: the FBI's Office of Professional Responsibility.

PCR Biologist: in the context of the DNAUI, the PCR Biologist is the staff member responsible for completing the PCR analysis process and providing to an Examiner the results of that process from which they can draw conclusions and report results. Included within this process is the completion of extraction, quantification, amplification, and electrophoresis.

Polymerase Chain Reaction (PCR): a method used to replicate specific portions of the DNA strands. The DNA is heated, causing the two strands to separate like a zipper. The two DNA halves are then cooled and mixed with a special enzyme. The result of this process is the creation of two DNA strands identical to each other and to the original DNA strand. This process is repeated many times to replicate a desired DNA sequence millions of times in a matter of hours. PCR is especially valuable because it does not require high quality or large quantities of DNA. Also, this method lends itself to automation and less labor-intensive typing. The PCR/STR analysis process includes five stages, which are extraction, quantification, amplification, electrophoresis, and data interpretation.

Positive Control: the positive control contains the reagents necessary for amplification plus DNA from a source for which the DNA profile is known. Since the DNA scientists know the correct test results for the positive control, it

allows them to determine the accuracy and performance of the amplification and analysis processes.

Primers: short synthetic pieces of DNA designed to match places where human DNA is both repetitive and highly variable. Primers identify the starting and ending points of a DNA fragment that is to be duplicated with PCR. The primers also prime (or stimulate) the synthesis reaction when the DNA fragments are duplicated. The primers contain fluorescent labels so that they may be detected by lasers during electrophoresis.

Quantification: the process whereby the concentration of extracted DNA in a sample is measured, and the second of five stages in the PCR/STR analysis process.

Reagent: a substance that is used (as in detecting or measuring a component, in preparing a product, or in developing photographs) because of its chemical or biological activity.

Reagent Blank: the reagent blank contains all of the reagents used to process an item of evidence from extraction through electrophoresis. DNA from the evidence is not added to the reagent blanks, though their contents are amplified. The purpose of the reagent blank is to reveal any contamination that is present in the reagents or introduced during the testing process.

QAS: refers to the Quality Assurance Standards issued by the FBI Director upon the recommendation of the DNA Advisory Board. Quality Assurance refers to measures that are taken by labs to monitor, verify, and document performance. Two sets of QAS exist: QAS for Convicted Offender DNA Databasing Laboratories, effective April 1, 1999; and QAS for Forensic DNA Testing Laboratories, effective October 1, 1998.

SDIS: State DNA Index System containing the state-level DNA records uploaded from local laboratory sites within the state. SDIS is the state's repository of DNA identification records and is under the control of state authorities. The SDIS laboratory serves as the central point of contact for access to NDIS. The DNAUI serves as the SDIS laboratory for the FBI.

Serologist: a Serologist performs testing to determine what body fluids are present on the evidence and whether it is possible to extract DNA from it. In the DNAUI, the Serologist also assists with the initial and final evidence inventories, and is responsible for transferring to the PCR Biologist body-fluid stained evidence items and related case file documentation.

Short Tandem Repeats: short repeating units of identical chemical sequences arranged in direct succession in a particular region of the DNA.

Short Tandem Repeat Analysis (STR): refers to a DNA typing method that utilizes PCR technology to quickly amplify and analyze sections of DNA that contain short tandem repeats. This method allows a high level of discrimination, since 13 chromosomal locations are examined and subsequently compared with other samples.

SWGDAM: TWGDAM was renamed the Scientific Working Group on DNA Analysis Methods (SWGDAM) after the Office of Justice Programs created short-term technical working groups that began to be confused by members of the DNA community with the FBI's long-term technical working groups. Since being renamed, SWGDAM has produced additional guidance for the forensic community, including guidelines for data interpretation, training, quality assurance, and health and safety audits.

TWGDAM: the Technical Working Group on DNA Analysis Methods (TWGDAM) was the one of several technical working groups sponsored by the FBI to examine DNA's forensic science applications. TWGDAM was established in 1989 with representatives from 12 laboratories, and focused specifically on the development of forensic DNA methods. Later that same year, TWGDAM developed and published a set of quality guidelines for forensic DNA laboratories, and updated those guidelines in 1991 and in 1995.

Unknown DNA Sample: a sample of DNA for which the source is not known. Unknown DNA samples are also referred to as questioned samples. Unknown DNA samples are taken from evidence items submitted to a laboratory, that are analyzed by the laboratory and compared to a known DNA sample to determine whether the source of the unknown DNA sample can be identified.

COMPLETE DNA PROFILE

As noted in Chapter Two, Section I.D, the primers used during the amplification process contain different fluorescent labels, which allow the lasers in the capillary electrophoresis machine to detect and differentiate the various DNA fragments separated during capillary electrophoresis. The label on each primer determines the color in which the results are displayed on both computer monitors and printouts. At the present time, the fluorescent labels produce peaks that are blue, green, and yellow. The yellow peaks are usually displayed in black on the Genescan® and Genotyper® printouts, with the remaining peaks printed in the corresponding color. In addition, the internal lane standard peaks are always displayed in red.

At the present time, two amplification kits[1] are required for forensic scientists to test the 13 chromosomal locations that comprise a DNA profile. Scientists also test a 14th location, known as amelogenin, which indicates the sex of the DNA contributor. One amplification kit, Profiler Plus,™ contains the reagents necessary to test ten chromosomal locations. The fluorescent labels in this kit produce results that are shown in blue for three chromosomal locations, four locations are shown in green, and three locations are called yellow even though they display in black. The COfiler™ amplification kit displays the results for two chromosomal locations in blue, four locations are displayed in green, and one location representing the yellow peaks is displayed in black. Three chromosomal locations are tested with both the Profiler Plus™ and COfiler™ kits, which gives forensic scientists points of comparison to ensure the results are consistent between the two kits.

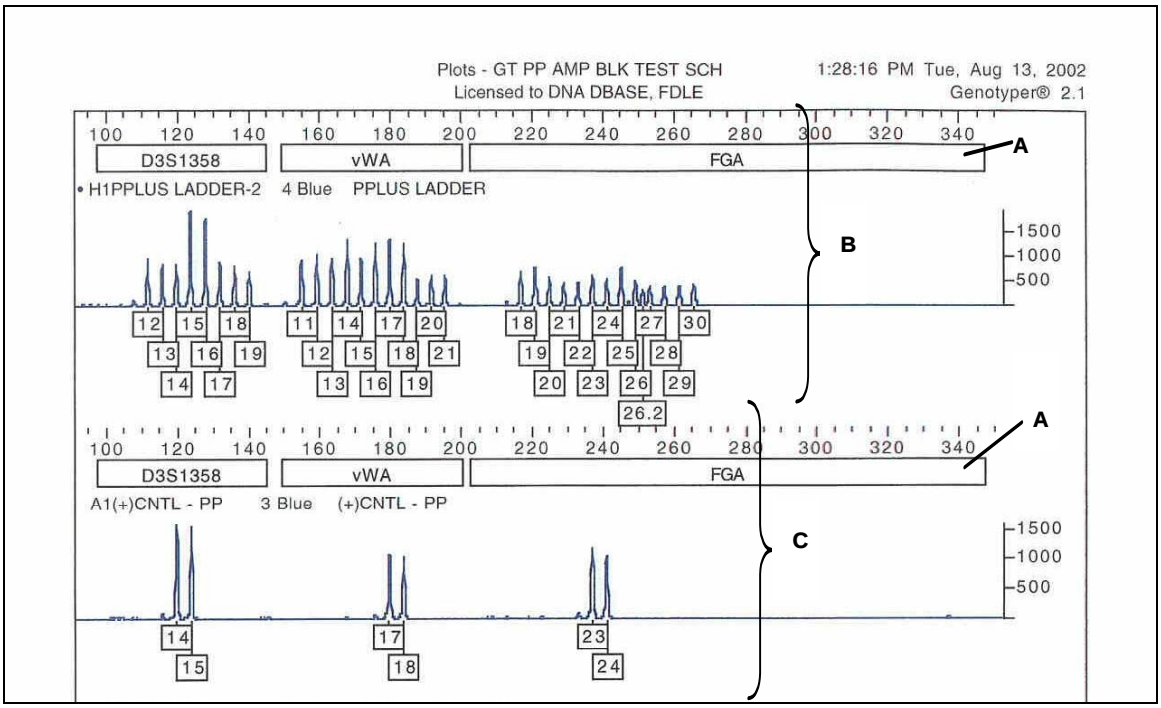
The Genescan® graphic for the positive control in Appendix 2 reflects the DNA profile of a sample used as a positive control by a CODIS participating laboratory. The following table represents the allele calls that correspond to the electrophoresis results shown in that graphic.

[1] In this report, we focus on the amplification kits manufactured by Applied Biosystems because they are used by the DNAUI. Some state and local DNA laboratories use kits manufactured by other companies. These kits examine the same chromosomal locations and produce the same type of data as the kits discussed here.

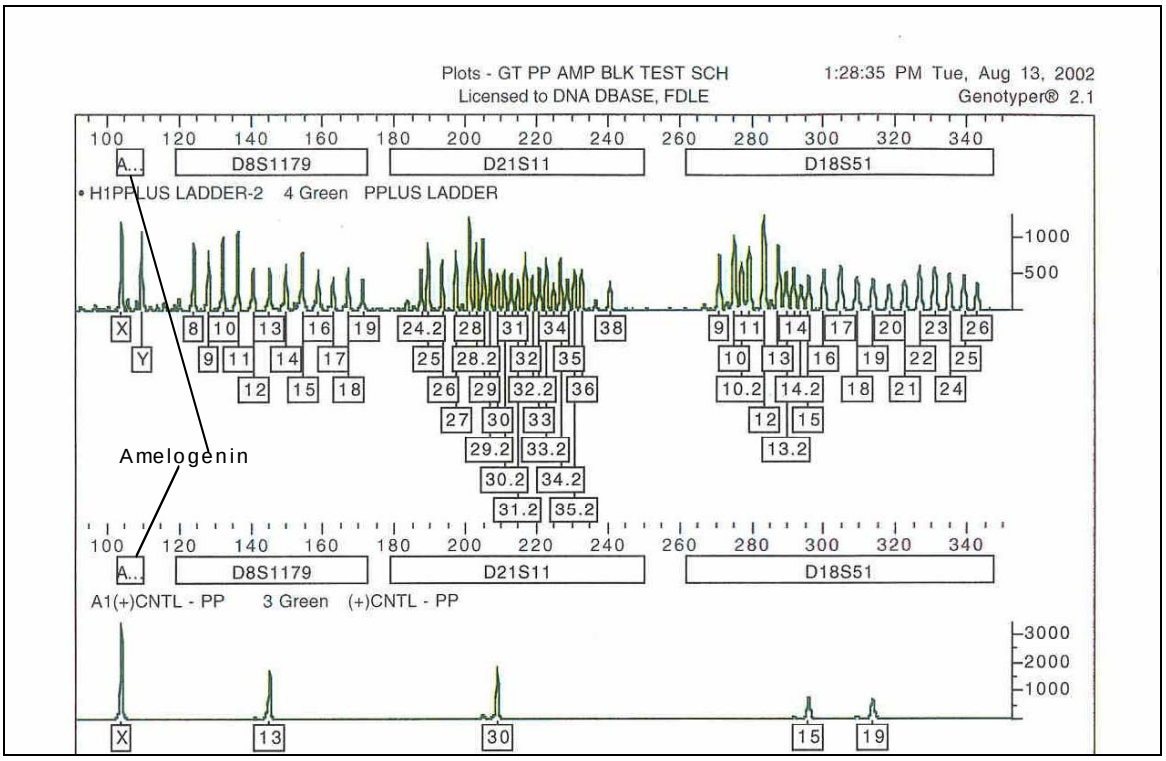
Example of a DNA Profile

Applied Biosystems Analysis Kit	Chromosomal Location	Alleles Present in DNA Sample	Genotyper® Printout
AmpFℓSTR® Profiler Plus™ PCR Amplification Kit	**D3S1358**	**14, 15**	Page 141
	VWA	17, 18	
	FGA	23, 24	
	Amelogenin	**X, X**	Page 141
	D8S1179	13, 13	
	D21S11	30, 30	
	D18S51	15, 19	
	D5S818	11, 11	Page 142
	D13S317	11, 11	
	D7S820	**10, 11**	
AmpFℓSTR® COfiler™ PCR Amplification Kit	**D3S1358**	**14, 15**	Page 142
	D16S539	11, 12	
	Amelogenin	**X, X**	Page 143
	THO1	8, 9.3	
	TPOX	8, 8	
	CSF1PO	10, 12	
	D7S820	**10, 11**	Page 143

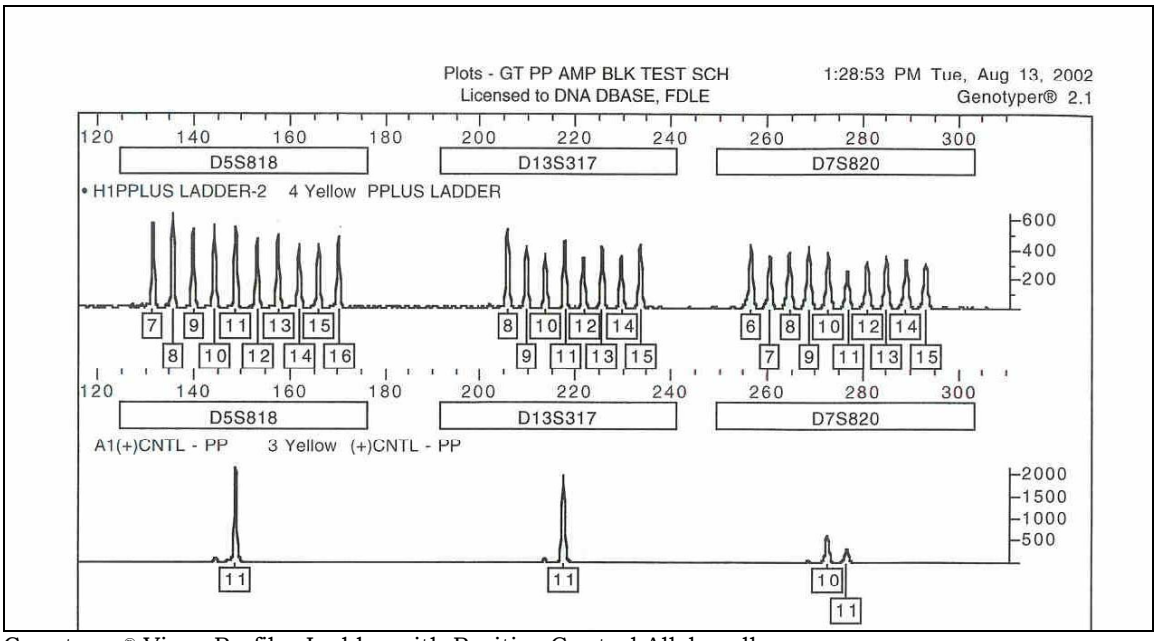
The following pages contain the Genotyper® printouts supporting the allelic values listed in the above chart. These printouts reflect the fact that Genotyper® reformats the Genescan® data and allows the forensic scientist that reviews the data to review only the specific peaks required for data interpretation, including (but not limited to) the specific peaks from the DNA sample and the allelic ladders. The background noise is filtered out in the Genotyper® view.



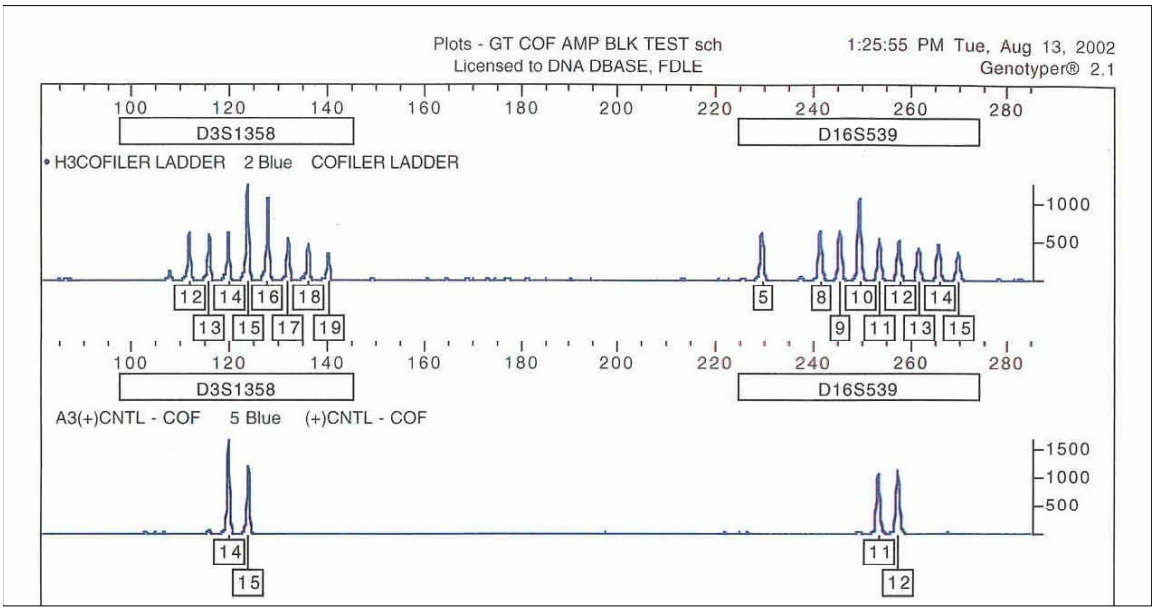
Genotyper® View: Profiler Ladder with Positive Control Allele call
A = Chromosomal Location, **B** = Allelic Ladder, **C** = Alleles present in DNA sample



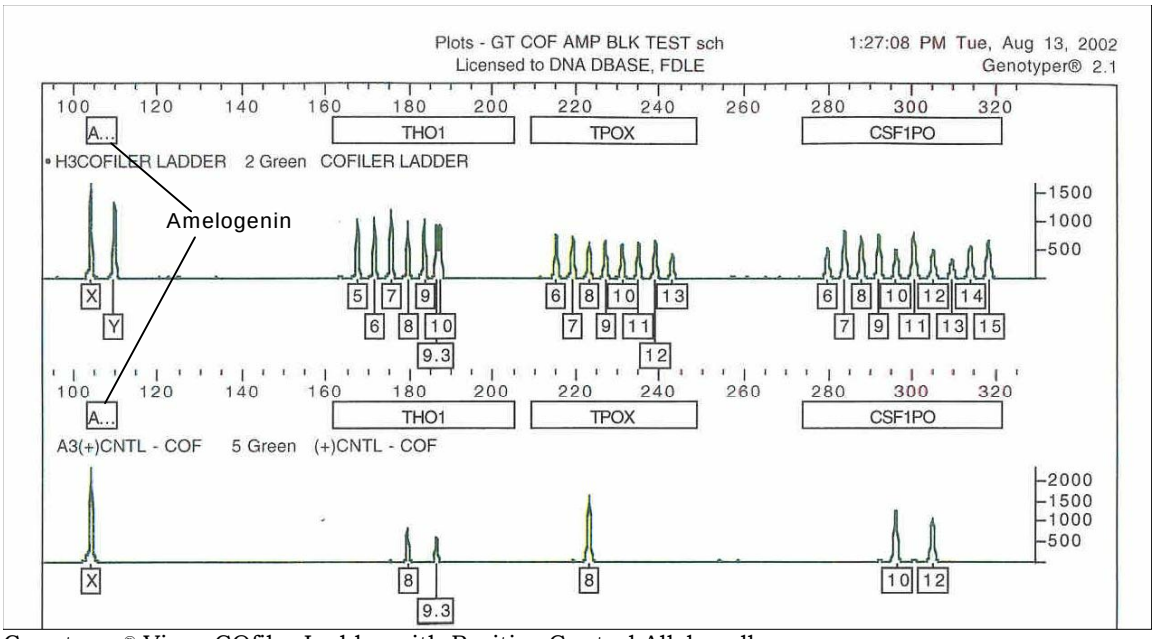
Genotyper® View: Profiler Ladder with Positive Control Allele call



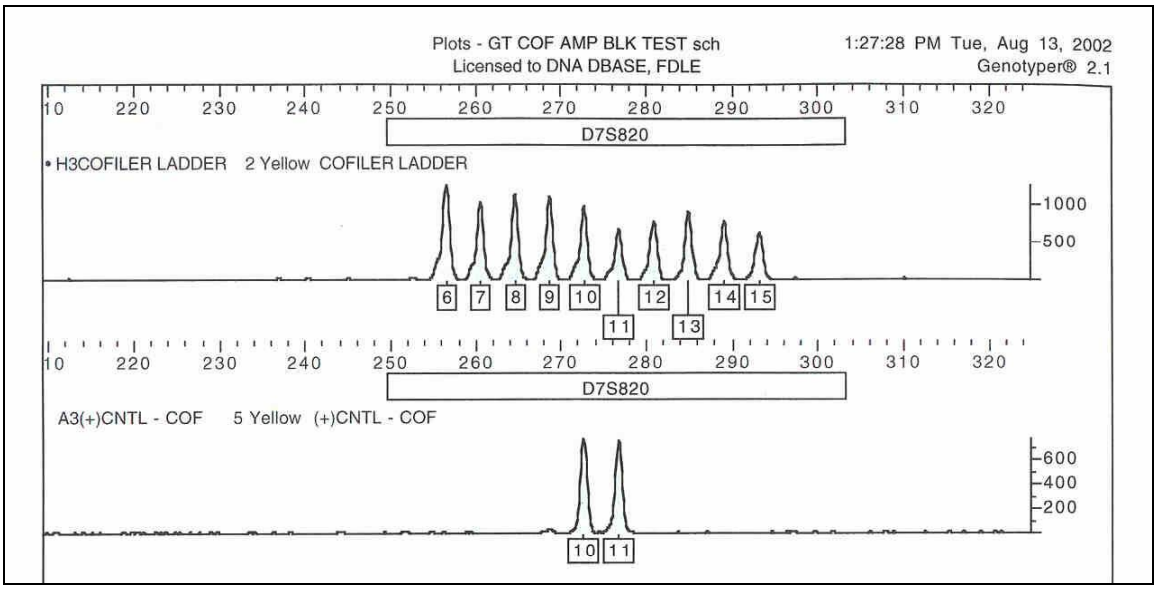
Genotyper® View: Profiler Ladder with Positive Control Allele call



Genotyper® View: COfiler Ladder with Positive Control Allele call



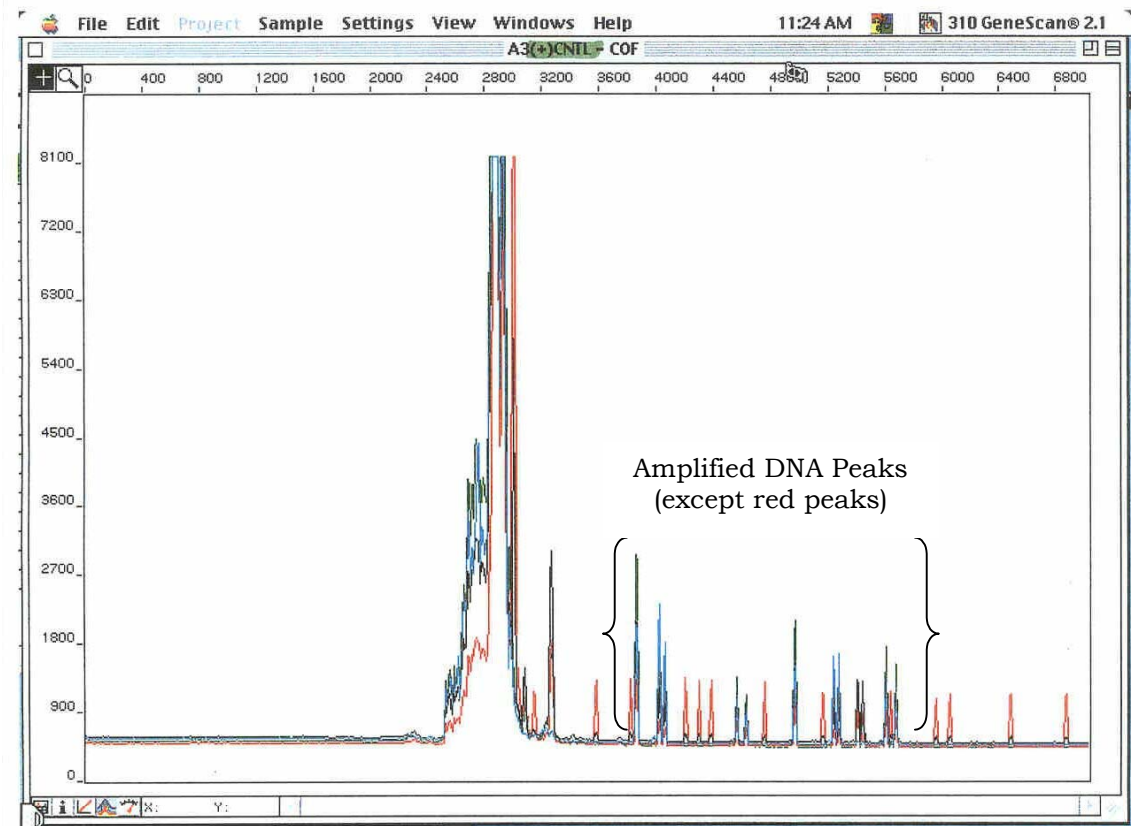
Genotyper® View: COfiler Ladder with Positive Control Allele call



Genotyper® View: COfiler Ladder with Positive Control Allele call

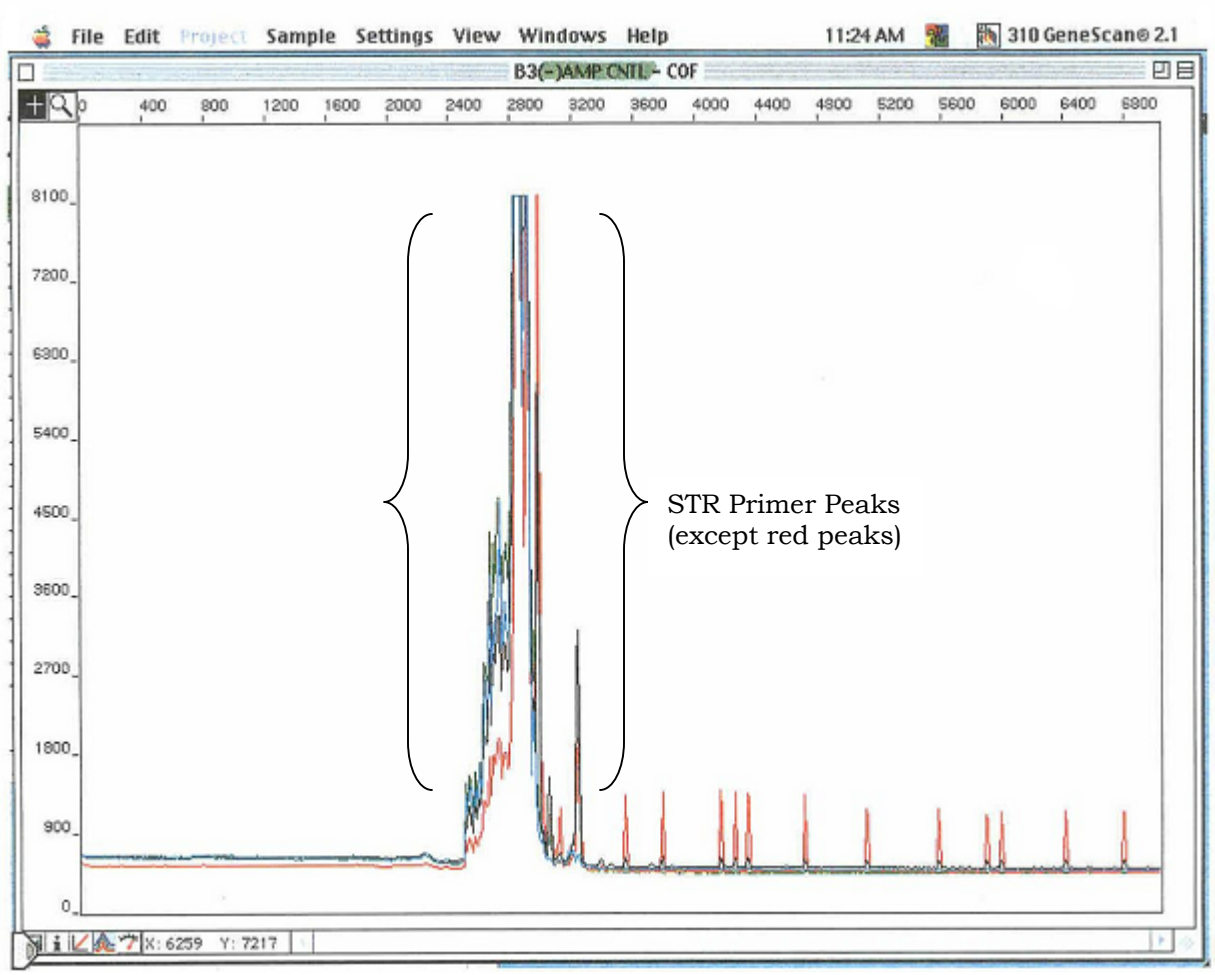
INTERPRETATION OF DNA ANALYSIS DATA

As mentioned in Chapter Two, Section I.D, the manufacturer of the capillary electrophoresis machine developed proprietary software to display the test results and to aid in their interpretation. The software has two components, GeneScan® and Genotyper.® Data viewed in Genescan®, as appears below, is the raw, unanalyzed, collection data that documents everything the laser detected, including the background noise that is common in these types of instruments. The following graphic illustrates the appearance and content of this data for a DNA sample.



Genescan® View: : raw data for a Positive Control (9947A) prepared according to protocol. Peaks depicted in red originate from the internal size standard added to each sample.

Genotyper® takes this same data and displays it in a different format. With Genotyper®, the forensic scientist selects which peaks are displayed, choosing among the internal lane standard, the primer peaks, specific peaks from the DNA sample, and the allelic ladders. The background noise is filtered out in the Genotyper® view. With the exception of the red peaks, the primer peaks are those located between the brackets on the following illustration.

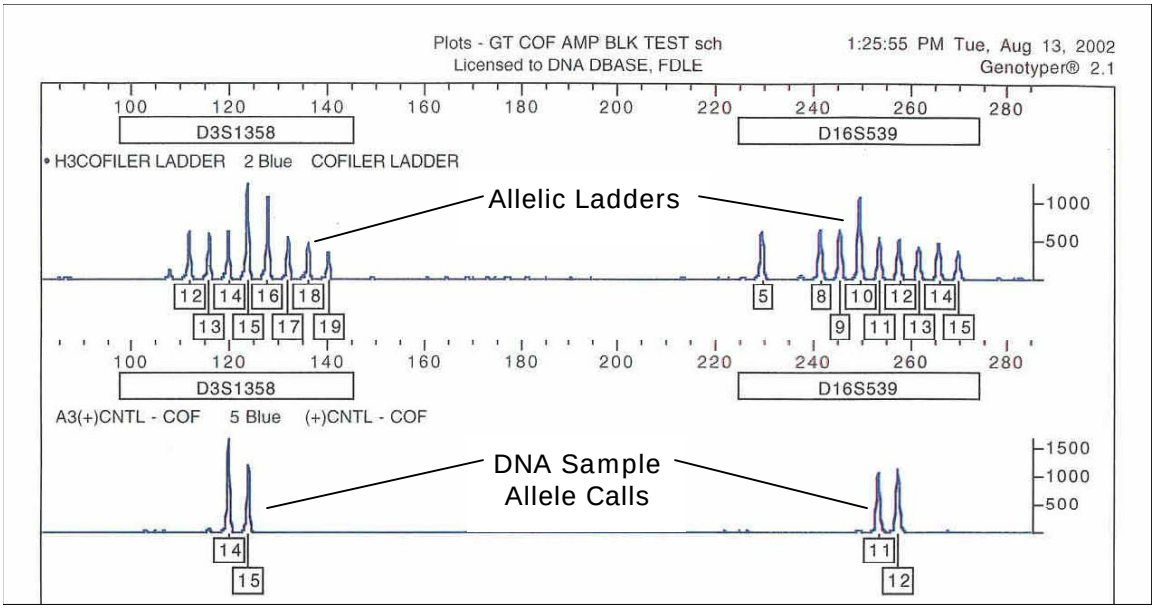


Genescan® View: raw data for a Negative Control prepared according to protocol.
Peaks depicted in red originate from the internal size standard added to each sample.

In order to determine accurately the length of the sample's DNA fragments, an internal size standard is added to each sample before it undergoes capillary electrophoresis. As mentioned earlier, the internal size standard contains DNA fragments of known sizes that provide reference points for the software to use when determining the length of the sample's DNA fragments. The peaks corresponding to the internal size standard are shown as red peaks in both the Genescan® and Genotyper® printouts.

The Genotyper® software uses allelic ladders to assign allele calls, (i.e., determine which alleles correspond to the lengths of the sample's DNA fragments as determined by Genescan®). There is an allelic ladder for each chromosomal location tested. These ladders contain the most common alleles in the general population at each location. The Genotyper® software compares the peaks in the evidentiary or reference sample to the peaks in the allelic ladder at that same location. Genotyper® then assigns the corresponding allele designation to the evidentiary or reference peaks. The number of repeats in the DNA fragment determines the allele designation. For example, an allele call of

15 means the DNA fragment contains 15 repeats. The following illustration contains both the allelic ladders and two allele calls for a DNA sample. The DNA profile at two chromosomal locations for the sample shown below is: alleles 14 and 15 at location D3S1358, and alleles 11 and 12 at location D16S539.



Genotyper® View: COFiler Ladder with Positive Control Allele call

FORENSIC AND OFFENDER QUALITY ASSURANCE STANDARDS

Standards For Forensic DNA Testing Laboratories

Preface

Throughout its deliberation concerning these quality standards, the DNA Advisory Board recognized the need for a mechanism to ensure compliance with the standards. An underlying premise for these discussions was that accreditation would be required to demonstrate compliance with the standards and therefore assure quality control and a quality program. Accordingly, the Board recommends that forensic laboratories performing DNA analysis seek such accreditation with all deliberate speed. Additionally, the Board strongly encourages the accrediting bodies to begin positioning themselves to accommodate the increasing demand for accreditation.

Proposed Mechanism To Recommend Changes To Standards

Once the Director of the FBI has issued standards for quality assurance for forensic DNA testing, the DNA Advisory Board may recommend revisions to such standards to the FBI Director, as necessary. In the event that the duration of the DNA Advisory Board is extended beyond March 10, 2000 by the FBI Director, the Board may continue to recommend revisions to such standards to the FBI Director. In the event that the DNA Advisory Board is not extended by the FBI Director after March 10, 2000, the Technical Working Group on DNA Analysis Methods [TWGDAM] may recommend revisions to such standards to the FBI Director, as necessary.

Effective Date

These standards shall take effect October 1, 1998.

INTRODUCTION

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

REFERENCES:

American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), ASCLD-LAB Accreditation Manual, January 1994, and January, 1997.

International Standards Organization (ISO)/International Electrotechnical Commission (IEC), ISO/IEC Guide 25-1990, (1990)
American National Standards Institute, New York, NY.

Technical Working Group on DNA Analysis Methods, "Guidelines for a Quality Assurance Program for DNA Analysis," Crime Laboratory Digest, April 1995, Volume 22, Number 2, pp. 21-43.

42 Code of Federal Regulations, Chapter IV (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.

1. SCOPE

The standards describe the quality assurance requirements that a laboratory, which is defined as a facility in which forensic DNA testing is performed, should follow to ensure the quality and integrity of the data and competency of the laboratory. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

(a) Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

(b) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

(c) Analytical procedure is an orderly step by step procedure designed to ensure operational uniformity and to minimize analytical drift.

(d) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

(e) Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

(f) Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary samples in order to prevent unnecessary loss of sample.

(g) Commercial test kit is a pre-assembled kit that allows the user to conduct a specific forensic DNA test.

(h) Examiner/analyst is an individual who conducts and/or directs the analysis of forensic casework samples, interprets data and reaches conclusions.

(i) Forensic DNA testing is the identification and evaluation of biological evidence in criminal matters using DNA technologies.

(j) Known samples are biological material whose identity or type is established.

(k) Laboratory is a facility in which forensic DNA testing is performed.

(l) Laboratory support personnel are individual(s) who perform laboratory duties and do not analyze evidence samples.

(m) NIST is the National Institute of Standards and Technology.

(n) Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of: 1) denaturation of the template; 2) annealing of primers to complementary sequences at an empirically determined temperature; and 3) extension of the bound primers by a DNA polymerase.

(o) Proficiency test sample is biological material whose DNA type has been previously characterized and which is used to monitor the quality performance of a laboratory or an individual.

(p) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

1) Internal proficiency test is one prepared and administered by the laboratory.

2) External proficiency test, which may be open or blind, is one which is obtained from a second agency.

(q) Qualifying test measures proficiency in both technical skills and knowledge.

(r) Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.

(s) Quality manual is a document stating the quality policy, quality system and quality practices of an organization.

(t) Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

(u) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

(v) Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(w) Restriction Fragment Length Polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.

(x) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

(y) Second agency is an entity or organization external to and independent of the laboratory and which performs forensic DNA analysis.

(z) Secure area is a locked space (for example, cabinet, vault or room) with access restricted to authorized personnel.

(aa) Subcontractor is an individual or entity having a transactional relationship with a laboratory.

(bb) Technical manager or leader (or equivalent position or title as designated by the laboratory system) is the individual who is accountable for the technical operations of the laboratory.

(cc) Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.

(dd) Technician is an individual who performs analytical techniques on evidence samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database. Technicians do not evaluate or reach conclusions on typing results or prepare final reports.

(ee) Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

(ff) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes:

1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.

2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1 The quality manual shall address at a minimum:

(a) Goals and objectives
(b) Organization and management
(c) Personnel Qualifications and Training
(d) Facilities
(e) Evidence control
(f) Validation
(g) Analytical procedures
(h) Calibration and maintenance
(i) Proficiency testing
(j) Corrective action
(k) Reports
(l) Review

(m) Safety
(n) Audits

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

(a) have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.
(b) have a technical manager or leader who is accountable for the technical operations.
(c) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided. The laboratory shall:

5.1.1 have a written job description for personnel to include responsibilities, duties and skills.

5.1.2 have a documented training program for qualifying all technical laboratory personnel.

5.1.3 have a documented program to ensure technical qualifications are maintained through continuing education.

5.1.3.1 Continuing education - the technical manager or leader and examiner/analyst(s) must stay abreast of developments within the field of DNA typing by reading current scientific literature and by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once a year.

5.1.4 maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical manager or leader shall have the following:

5.2.1 Degree requirements: The technical manager or leader of a laboratory shall have at a minimum a Master's degree in biology-, chemistry- or forensic science- related area and successfully completed a minimum of 12 semester or equivalent credit hours of a combination of

undergraduate and graduate course work covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology), or other subjects which provide a basic understanding of the foundation of forensic DNA analysis as well as statistics and/or population genetics as it applies to forensic DNA analysis.

5.2.1.1 The degree requirements of section 5.2.1 may be waived by the American Society of Crime Laboratory Directors (ASCLD) or other organization designated by the Director of the FBI in accordance with criteria approved by the Director of the FBI. This waiver shall be available for a period of two years from the effective date of these standards. The waiver shall be permanent and portable.

5.2.2 Experience requirements: A technical manager or leader of a laboratory must have a minimum of three years of forensic DNA laboratory experience.

5.2.3 Duty requirements:

5.2.3.1 General: manages the technical operations of the laboratory.

5.2.3.2 Specific duties

(a) Is responsible for evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.

(b) Is responsible for technical problem solving of analytical methods and for the oversight of training, quality assurance, safety and proficiency testing in the laboratory.

5.2.3.3 The technical manager or leader shall be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

STANDARD 5.3 Examiner/analyst shall have:

5.3.1 at a minimum a BA/BS degree or its equivalent degree in biology-, chemistry- or forensic science- related area and must have successfully completed college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA

analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis.

5.3.2 a minimum of six (6) months of forensic DNA laboratory experience, including the successful analysis of a range of samples typically encountered in forensic case work prior to independent case work analysis using DNA technology.

5.3.3 successfully completed a qualifying test before beginning independent casework responsibilities.

STANDARD 5.4 Technician shall have:

5.4.1 On the job training specific to their job function(s).

5.4.2 successfully completed a qualifying test before participating in forensic DNA typing responsibilities.

STANDARD 5.5 Laboratory support personnel shall have:

5.5.1 training, education and experience commensurate with their responsibilities as outlined in their job description.

6. FACILITIES

STANDARD 6.1 The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that:

6.1.1 Access to the laboratory is controlled and limited.

6.1.2 Prior to PCR amplification, evidence examinations, DNA extractions, and PCR setup are conducted at separate times or in separate spaces.

6.1.3 Amplified DNA product is generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas.

6.1.4 The laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.

7. EVIDENCE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented evidence control system to ensure the integrity of physical evidence. This system shall ensure that:

7.1.1 Evidence is marked for identification.

7.1.2 Chain of custody for all evidence is maintained.

7.1.3 The laboratory follows documented procedures that minimize loss, contamination, and/or deleterious change of evidence.

7.1.4 The laboratory has secure areas for evidence storage.

STANDARD 7.2 Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

7.2.1 The laboratory shall have a procedure requiring that evidence sample/extract(s) are stored in a manner that minimizes degradation.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods and procedures for forensic casework analyses.

8.1.1 Developmental validation that is conducted shall be appropriately documented.

8.1.2 Novel forensic DNA methodologies shall undergo developmental validation to ensure the accuracy, precision and reproducibility of the procedure. The developmental validation shall include the following:

8.1.2.1 Documentation exists and is available which defines and characterizes the locus.

8.1.2.2 Species specificity, sensitivity, stability and mixture studies are conducted.

8.1.2.3 Population distribution data are documented and available.

8.1.2.3.1 The population distribution data would include the allele and genotype distributions for the locus or loci obtained from relevant populations. Where appropriate, databases should be tested for independence expectations.

8.1.3 Internal validation shall be performed and documented by the laboratory.

8.1.3.1 The procedure shall be tested using known and non-probative evidence samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).

8.1.3.2 The laboratory shall establish and document match criteria based on empirical data.

8.1.3.3 Before the introduction of a procedure into forensic casework, the analyst or examination team shall successfully complete a qualifying test.

8.1.3.4 Material modifications made to analytical procedures shall be documented and subject to validation testing.

8.1.4 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or have been appropriately evaluated for a specific or unique application.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the laboratory management/technical manager.

9.1.1 The laboratory shall have a standard operating protocol for each analytical technique used.

9.1.2 The procedures shall include reagents, sample preparation, extraction, equipment, and controls which are standard for DNA analysis and data interpretation.

9.1.3 The laboratory shall have a procedure for differential extraction of stains that potentially contain semen.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.

9.2.2 Reagents shall be labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent.

9.2.3 The laboratory shall identify critical reagents and evaluate them prior to use in casework. These critical reagents include but are not limited to:

(a) Restriction enzyme
(b) Commercial kits for performing genetic typing
(c) Agarose for analytical RFLP gels
(d) Membranes for Southern blotting
(e) K562 DNA or other human DNA controls
(f) Molecular weight markers used as RFLP sizing standards
(g) Primer sets
(h)Thermostable DNA polymerase

STANDARD 9.3 The laboratory shall have and follow a procedure for evaluating the quantity of the human DNA in the sample where possible.

9.3.1 For casework RFLP samples, the presence of high molecular weight DNA should be determined.

STANDARD 9.4 The laboratory shall monitor the analytical procedures using appropriate controls and standards.

9.4.1 The following controls shall be used in RFLP casework analysis:

9.4.1.1 Quantitation standards for estimating the amount of DNA recovered by extraction.

9.4.1.2 K562 as a human DNA control. (In monitoring sizing data, a statistical quality control method for K562 cell line shall be maintained.)

9.4.1.3 Molecular weight size markers to bracket known and evidence samples.

9.4.1.4 Procedure to monitor the completeness of restriction enzyme digestion.

9.4.2 The following controls shall be used for PCR casework analysis:

9.4.2.1 Quantitation standards which estimate the amount of human nuclear DNA recovered by extraction.

9.4.2.2 Positive and negative amplification controls.

9.4.2.3 Reagent blanks.

9.4.2.4 Allelic ladders and/or internal size makers for variable number tandem repeat sequence PCR based systems.

STANDARD 9.5 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.6 The laboratory shall have and follow written general guidelines for the interpretation of data.

9.6.1 The laboratory shall verify that all control results are within established tolerance limits.

9.6.2 Where appropriate, visual matches shall be supported by a numerical match criterion.

9.6.3 For a given population(s) and/or hypothesis of relatedness, the statistical interpretation shall be made following the recommendations 4.1, 4.2 or 4.3 as deemed applicable of the National Research Council report entitled "The Evaluation of Forensic DNA Evidence" (1996) and/or court directed method. These calculations shall be derived from a documented population database appropriate for the calculation.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall have a documented program for calibration of instruments and equipment.

10.2.1 Where available and appropriate, standards traceable to national or international standards shall be used for the calibration.

10.2.1.1 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results.

10.2.2 The frequency of the calibration shall be documented for each instrument requiring calibration. Such documentation shall be retained in accordance with applicable Federal or state law.

STANDARD 10.3 The laboratory shall have and follow a documented program to ensure that instruments and equipment are properly maintained.

10.3.1 New instruments and equipment, or instruments and equipment that have undergone repair or maintenance, shall be calibrated before being used in casework analysis.

10.3.2 Written records or logs shall be maintained for maintenance service performed on instruments and equipment. Such documentation shall be retained in accordance with applicable Federal or state law.

11. REPORTS

STANDARD 11.1 The laboratory shall have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports.

11.1.1 The laboratory shall maintain, in a case record, all documentation generated by examiners related to case analyses.

11.1.2 Reports according to written guidelines shall include:

(a) Case identifier
(b) Description of evidence examined
(c) A description of the methodology
(d) Locus
(e) Results and/or conclusions
(f) An interpretative statement (either quantitative or qualitative)
(g) Date issued
(h) Disposition of evidence
(i) A signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report.

11.1.3 The laboratory shall have written procedures for the release of case report information.

12. REVIEW

STANDARD 12.1 The laboratory shall conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

12.1.1 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.2 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each examiner.

13. PROFICIENCY TESTING

STANDARD 13.1 Examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis shall undergo, at regular intervals of not to exceed 180 days, external proficiency testing in accordance with these standards. Such external proficiency testing shall be an open proficiency testing program.

13.1.1 The laboratory shall maintain the following records for proficiency tests:

(a) The test set identifier.
(b) Identity of the examiner.
(c) Date of analysis and completion.
(d) Copies of all data and notes supporting the conclusions.
(e) The proficiency test results.
(f) Any discrepancies noted.
(g) Corrective actions taken. Such documentation shall be retained in accordance with applicable Federal or state law.

13.1.2 The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

(a) All reported inclusions are correct or incorrect.
(b) All reported exclusions are correct or incorrect.
(c) All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.
(d) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.
(e) All discrepancies/errors and subsequent corrective actions must be documented.
(f) All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.
(g) All proficiency test participants shall be informed of the final test results.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow procedures for corrective action whenever proficiency testing discrepancies and/or casework errors are detected.

14.1.1 The laboratory shall maintain documentation for the corrective action. Such documentation shall be retained in accordance with applicable Federal or state law.

15. AUDITS

STANDARD 15.1 The laboratory shall conduct audits annually in accordance with the standards outlined herein.

15.1.1 Audit procedures shall address at a minimum:

(a) Quality assurance program
(b) Organization and management
(c) Personnel
(d) Facilities
(e) Evidence control
(f) Validation
(g) Analytical procedures
(h) Calibration and maintenance
(i) Proficiency testing
(j) Corrective action
(k) Reports
(l) Review
(m) Safety
(n) Previous audits

15.1.2 The laboratory shall retain all documentation pertaining to audits in accordance with relevant legal and agency requirements.

STANDARD 15.2 Once every two years, a second agency shall participate in the annual audit.

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program.

17. SUBCONTRACTOR OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST

STANDARD 17.1 A laboratory operating under the scope of these standards will require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory.

17.1.1 The laboratory will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor.

Standards For Convicted Offender DNA Databasing Laboratories

Preface

Throughout its deliberation concerning these quality standards, the DNA Advisory Board recognized the need for a mechanism to ensure compliance with the standards. An underlying premise for these discussions was that accreditation would be required to demonstrate compliance with the standards and therefore assure quality control and a quality program. Accordingly, the Board recommends that forensic laboratories performing DNA analysis seek such accreditation with all deliberate speed. Additionally, the Board strongly encourages the accrediting bodies to begin positioning themselves to accommodate the increasing demand for accreditation.

Introduction

Forensic DNA identification analysis currently involves forensic casework and convicted offender analyses. These complementary functions demand adherence to the highest analytical standards possible to protect both public safety and individual rights. Separate standards have been drafted for laboratories performing these functions. This separation is an acknowledgment of the differences in the nature or type of sample, the typical sample quantity and potential for reanalysis, and specialization that may exist in a laboratory. Standards for convicted offender laboratories, in some instances, are less stringent than for those performing forensic casework analyses, but in no case should the two documents be interpreted as conflicting. This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

Mechanism To Recommend Changes To Standards

Once the Director of the Federal Bureau of Investigation (FBI) has issued standards for quality assurance for convicted offender DNA testing, the DNA Advisory Board may recommend revisions to such standards to the FBI Director, as necessary. In the event that the duration of the DNA Advisory Board is extended beyond March 10, 2000, by the FBI Director, the Board may continue to recommend revisions to such standards to the FBI Director. In the event that the DNA Advisory Board is not extended by the FBI Director after March 10, 2000, the Technical Working Group on DNA Analysis Methods (TWGDAM) may recommend revisions to such standards to the FBI Director, as necessary.

Effective Date

These Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories take effect April 1, 1999.

REFERENCES:

American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), ASCLD-LAB Accreditation Manual, January 1994, and January, 1997.

International Standards Organization (ISO)/International Electrotechnical Commission (IEC), ISO/IEC Guide 25-1990, (1990)
American National Standards Institute, New York, NY.

Technical Working Group on DNA Analysis Methods, "Guidelines for a Quality Assurance Program for DNA Analysis," Crime Laboratory Digest, April 1995, Volume 22, Number 2, pp. 21-43.

42 Code of Federal Regulations, Chapter IV (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.

1. SCOPE

The standards describe the quality assurance requirements that a government laboratory which is defined as a facility in which convicted offender DNA testing is regularly performed should follow to ensure the quality and integrity of the data and competency of the laboratory. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

(a) Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

(b) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

(c) Analytical procedure is an orderly step by step procedure designed to ensure operational uniformity and to minimize analytical drift.

(d) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

(e) Batch is a group of samples analyzed at the same time.

(f) Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material and the corresponding known values of a measurement.

(g) CODIS is the Combined DNA Index System administered by the FBI. It houses DNA profiles from convicted offenders, forensic specimens, population samples and other specimen types.

(h) Commercial test kit is a preassembled kit that allows the user to conduct a specific DNA identification test.

(i) Convicted offender is an individual who is required by statute to submit a standard sample for DNA databasing.

(j) Convicted offender database (CODIS) manager or custodian (or equivalent role, position, or title as designated by the laboratory director) is the person responsible for administration and security of the laboratory's CODIS.

(k) Convicted offender standard sample is biological material collected from an individual for DNA analysis and inclusion into CODIS. See also database sample.

(l) Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter.

(m) Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample.

(n) Database sample is a known blood or standard sample obtained from an individual whose DNA profile will be included in a computerized database and searched against other DNA profiles.

(o) Examiner/analyst (or equivalent role, position, or title as designated by the laboratory director) is an individual who conducts and/or directs the analysis of samples, interprets data and reaches conclusions.

(p) Known samples are biological material whose identity or type is established.

(q) Laboratory is a government facility in which convicted offender DNA testing is performed or a government facility who contracts with a second entity for such testing.

(r) Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are individual(s) who perform laboratory duties and do not analyze samples.

(s) NIST is the National Institute of Standards and Technology.

(t) Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of: 1) denaturation of the template; 2) annealing of primers to complementary sequences at an empirically determined temperature; and 3) extension of the bound primers by a DNA polymerase.

(u) Proficiency test sample is biological material whose DNA type has been previously characterized and which is used to monitor the quality performance of a laboratory or an individual.

(v) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as: 1) Internal proficiency test is one prepared and administered by the laboratory. 2) External proficiency test, which may be open or blind, is one which is obtained from a second agency.

(w) A Qualifying test measures proficiency in both technical skills and knowledge.

(x) Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.

(y) A quality manual is a document stating the quality policy, quality system and quality practices of an organization.

(z) Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

(aa) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

(bb) Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(cc) Restriction Fragment Length Polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.

(dd) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

(ee) Second agency is an entity or organization external to and independent of the laboratory and which performs DNA identification analysis.

(ff) Secure area is a locked space (for example, cabinet, vault or room) with access restricted to authorized personnel.

(gg) Subcontractor is an individual or entity having a transactional relationship with a laboratory.

(hh) Technical manager or leader (or equivalent position or title as designated by the laboratory director) is the individual who is accountable for the technical operations of the laboratory.

(ii) Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.

(jj) Technician (or equivalent role, position, or title as designated by the laboratory director) is an individual who performs analytical techniques on samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database.

(kk) Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

(ll) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA analysis and includes: 1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on samples. 2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1 The quality manual shall address at a minimum:
- (a) Goals and objectives
- (b) Organization and management
- (c) Personnel qualifications and training
- (d) Facilities
- (e) Sample control
- (f) Validation
- (g) Analytical procedures
- (h) Calibration and maintenance
- (i) Proficiency testing
- (j) Corrective action
- (k) Documentation
- (l) Review
- (m) Safety
- (n) Audits

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:
- (a) have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.
- (b) have a technical manager or leader who is accountable for the technical operations.
- (c) have a CODIS manager or custodian who is accountable for CODIS operations.
- (d) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided. The laboratory shall:

5.1.1 have a written job description for personnel to include responsibilities, duties and skills.

5.1.2 have a documented training program for qualifying all technical laboratory personnel.

5.1.3 have a documented program to ensure technical qualifications are maintained through continuing education.

5.1.3.1 Continuing education - the technical manager or leader, CODIS manager or custodian, and examiner-analyst(s) must stay abreast of developments within the field of DNA typing by reading current scientific literature and by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once a year.

5.1.4 maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical manager or leader shall have the following:

5.2.1 Degree requirements: The technical manager or leader of a laboratory shall have, at a minimum, a Master's degree in biology-, chemistry-, or forensic science-related area and successfully completed a minimum of 12 semester or equivalent credit hours of a combination of undergraduate and graduate course work covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology), or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as statistics and/or population genetics as it applies to forensic DNA analysis.

5.2.1.1 The degree requirements of section 5.2.1 may be waived by the American Society of Crime Laboratory Directors (ASCLD) or other organizations designated by the Director of the FBI in accordance with criteria approved by the Director of the FBI. This waiver shall be available for a period of two years from the effective date of the standards. The waiver shall be permanent and portable.

5.2.2 Experience requirements: A technical manager or leader of a laboratory shall have a minimum of three years of relevant problem solving or related analytical laboratory experience.

5.2.3 Duty requirements:

5.2.3.1 General: manages the technical operations of the laboratory.

5.2.3.2 Specific duties:

(a) Is responsible for evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.

(b) Is responsible for technical problem solving of analytical methods and for the oversight of training, quality assurance, safety and proficiency testing in the laboratory.

5.2.3.3 The technical manager or leader shall be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

STANDARD 5.3 CODIS manager or custodian shall have the following:

5.3.1 Degree requirements: A CODIS manager or custodian shall have, at a minimum, a Bachelor's degree in a natural science or computer science.

5.3.2 Experience requirements: A CODIS manager or custodian shall have a working knowledge of computers, computer networks, and computer database management, with an understanding of DNA profile interpretation.

5.3.3 Duty requirements:

(a) Is the system administrator of the laboratory's CODIS network and is responsible for the security of DNA profile data stored in CODIS.
(b) Is responsible for oversight of CODIS computer training and quality assurance of data.
(c) Has the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured. The state CODIS manager or custodian has this authority over all CODIS sites under his/her jurisdiction.

STANDARD 5.4 Examiner/analyst shall have the following:

5.4.1 Degree requirements: An examiner/analyst shall have, at a minimum, a Bachelors degree or its equivalent degree in biology-, chemistry-, or forensic science-related area and must have successfully completed college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis.

5.4.2 Experience requirements: An examiner/analyst shall have a minimum of six (6) months of DNA laboratory experience, including

the successful analysis of a range of samples typically encountered in convicted offender analysis prior to independent work using DNA technology.

5.4.3 An examiner/analyst shall have successfully completed a qualifying test before beginning independent work responsibilities.

STANDARD 5.5 Technician shall have:

5.5.1 on-the-job training specific to their job function(s).

5.5.2 successfully completed a qualifying test before participating in DNA typing responsibilities.

STANDARD 5.6 Laboratory support personnel shall have:

5.6.1 training, education and experience commensurate with their responsibilities as outlined in their job description.

6. FACILITIES

STANDARD 6.1 The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that:

6.1.1 Access to the laboratory is controlled and limited.

6.1.2 Prior to PCR amplification, evidence examinations, liquid sample examinations, DNA extractions, and PCR setup are conducted at separate times or in separate spaces.

6.1.3 Amplified DNA product is generated, processed and maintained in a room(s) separate from the evidence examination, liquid blood examinations, DNA extractions and PCR setup areas.

6.1.4 A robotic work station may be used to carry out DNA extraction and amplification in a single room, provided it can be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms.

6.1.5 The laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.

7. SAMPLE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented sample inventory control system. This system shall ensure that:

7.1.1 Offender samples are marked for identification.

7.1.2 Documentation of sample identity, collection, receipt, storage, and disposition is maintained.

7.1.3 The laboratory follows documented procedures that minimize sample loss, contamination, and/or deleterious change.

7.1.4 The laboratory has secure areas for sample storage including environmental control consistent with the form or nature of the sample.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods and procedures for DNA analyses.

8.1.1 Developmental validation that is conducted shall be appropriately documented.

8.1.2 Novel database DNA methodologies shall undergo developmental validation to ensure the accuracy, precision and reproducibility of the procedure.

8.1.2.1 Documentation shall be available which defines and characterizes the locus.

8.1.3 Internal validation shall be performed and documented by the laboratory.

8.1.3.1 The procedure shall be tested using known samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).

8.1.3.2 Before the introduction of a procedure into database sample analysis, the analyst or examination team shall successfully complete a qualifying test.

8.1.3.3 Material modifications made to analytical procedures shall be documented and subject to validation testing.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the laboratory management/technical manager.

9.1.1 The laboratory shall have a standard operating protocol for each analytical technique used.

9.1.2 The procedures shall include reagents, sample preparation, extraction, equipment and controls which are standard for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.

9.2.2 Reagents shall be labeled with the identity of the reagent, the date of preparation and expiration, and the identity of the individual preparing the reagent.

9.2.3 The laboratory shall identify critical reagents, if any, and evaluate them prior to use.

STANDARD 9.3 The laboratory shall monitor the analytical procedures using appropriate controls and standards.

9.3.1 The following controls shall be used in RFLP analysis:

9.3.1.1 When required by the analytical procedure, standards for estimating the amount of DNA recovered by extraction shall be used.

9.3.1.2 K562 as a human DNA control.

9.3.1.3 Molecular weight size markers to bracket samples on an analytical gel. No more than five lanes shall exist between marker lanes.

9.3.1.4 A procedure shall be available to monitor the completeness of restriction enzyme digestion. Interpretation of the autorad/lumigraph is the ultimate method of assessment but a test gel or other method may be used as necessary.

9.3.2 The following controls shall be used for PCR database analysis:

9.3.2.1 When required by the analytical procedure, standards which estimate the amount of human nuclear DNA recovered by extraction shall be used.

9.3.2.2 Positive and negative amplification controls.

9.3.2.3 Contamination controls.

9.3.2.3.1 Samples extracted prior to the effective date of these standards without reagent blanks are acceptable as long as other samples analyzed in the batch do not demonstrate contamination.

9.3.2.4 Allelic ladders for variable number tandem repeat sequence PCR-based systems.

STANDARD 9.4 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.5 The laboratory shall have and follow written general guidelines for the interpretation of data.

9.5.1 The laboratory shall verify that all control results are within established tolerance limits.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall identify critical equipment and shall have a documented program for calibration of instruments and equipment.

10.2.1 Where available and appropriate, standards traceable to national or international standards shall be used for calibration.

10.2.1.1 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results.

10.2.2 The frequency of the calibration shall be documented for each instrument requiring calibration. Such documentation shall be retained in accordance with federal or state law.

STANDARD 10.3 The laboratory shall have and follow a documented program to ensure that instruments and equipment are properly maintained.

10.3.1 New critical instruments and equipment, or critical instruments and equipment that have undergone repair or maintenance, shall be calibrated before use.

10.3.2 Written records or logs shall be maintained for maintenance service performed on instruments and equipment. Such documentation shall be retained in accordance with federal or state law.

11. REPORTS

STANDARD 11.1 The laboratory shall have and follow written procedures for generating and maintaining documentation for database samples.

11.1.1 The laboratory shall have written procedures for the release of database sample information.

12. REVIEW

STANDARD 12.1 The laboratory shall have and follow written procedures for reviewing database sample information, results, and matches.

12.1.1 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.2 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of laboratory personnel.

13. PROFICIENCY TESTING

STANDARD 13.1 Examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis shall undergo, at regular intervals of not to exceed 180 days, external proficiency testing in accordance with these standards. Such external proficiency testing shall be an open proficiency testing program.

13.1.1 The laboratory shall maintain the following records for proficiency tests:

(a) The test set identifier.
(b) Identity of the examiner.
(c) Date of analysis and completion.
(d) Copies of all data and notes supporting the conclusions.
(e) The proficiency test results.
(f) Any discrepancies noted.

(g) Corrective actions taken. Such documentation shall be retained in accordance with applicable federal or state law.

13.1.2 The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

(a) All reported inclusions are correct or incorrect.
(b) All reported exclusions are correct or incorrect.
(c) All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.
(d) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.
(e) All discrepancies/errors and subsequent corrective actions must be documented.
(f) All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.
(g) All proficiency test participants shall be informed of the final test results.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow procedures for corrective action whenever proficiency testing discrepancies and/or analytical errors are detected.

14.1.1 The laboratory shall maintain documentation for the corrective action. Such documentation shall be retained in accordance with federal or state law.

15. AUDITS

STANDARD 15.1 The laboratory shall conduct audits annually in accordance with the standards outlined herein.

15.1.1 Audit procedures shall address at a minimum:

(a) Quality assurance program
(b) Organization and management
(c) Personnel
(d) Facilities
(e) Sample control
(f) Validation

(g) Analytical procedures
(h) Calibration and maintenance
(i) Proficiency testing
(j) Corrective action
(k) Documentation
(l) Review
(m) Safety
(n) Previous audits

15.1.2 The laboratory shall retain all documentation pertaining to audits in accordance with relevant legal and agency requirements.

STANDARD 15.2 Once every two years, a second agency shall participate in the annual audit.

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program.

17. SUBCONTRACTOR OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST

STANDARD 17.1 A laboratory operating under the scope of these standards will require certification of compliance with these standards when a subcontractor performs convicted offender DNA analyses for the laboratory.

17.1.1 The laboratory will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor including but not limited to:

(a) Random reanalysis of samples.
(b) Visual inspection and evaluation of results/data.
(c) Inclusion of QC samples.
(d) On-site visits.

NDIS REQUIREMENTS

The NDIS Requirements are found in the Memorandum of Understanding (MOU) signed by the FBI and each NDIS participant. The MOU requires that signatories comply with general requirements already established (i.e., federal legislation, the Forensic and Offender Standards), as well as requirements specific to the national index that accompany the MOU in three appendices: NDIS Responsibilities (Appendix A); NDIS Data Acceptance Standards (Appendix B); and the NDIS Procedures Manual (Appendix C). While the Appendices include a multitude of individual requirements, we include in the following examples from among the more significant of those requirements.

Appendix A, NDIS Responsibilities, mandates that laboratories:

- Comply with FBI requirements for physically and electronically safeguarding CODIS against unauthorized use, including providing an appropriate and secure site for the NDIS system.

- Designate one agency within each state to be responsible for ensuring that conditions and standards for participation in the national index are met.

- Designate one CODIS liaison within the state agency to handle communications with the FBI.

- Ensure that appropriate personnel are provided copies of, understand, and abide by the NDIS Procedures Manual.

- Identify in writing, in prescribed form, personnel approved to access CODIS and ensure that access to CODIS is limited to approved personnel.

- Maintain records on personnel approved to access CODIS, including proficiency testing records and any other report required by the FBI, for a period of 10 years.

- Conduct background investigations of personnel designated to input data to or access the national index.

- Maintain a system of controls to ensure that DNA records are kept as long as they are substantiated by the laboratory's internal records and are allowed to be retained by federal or state law, by judicial decree or by consent, and used in local, state, and national indexes in accordance with the Act, applicable state law, and for the national index, in accordance with the Privacy Act of 1974. This is the only NDIS

requirement that pertains to the convicted offender profile sample as well as the forensic profile sample.

- Report on a monthly basis confirmed national index matches to the FBI in a form prescribed by the FBI.

- Provide to the FBI a written report of deletions/modifications within 10 business days of discovering a DNA record requires deletion/modification.

Appendix B, NDIS Data Acceptance Standards, requires that:

- Laboratories using STR technology must use an FBI-approved STR kits.

- Laboratories must attempt analysis of all 13 STR chromosomal locations that constitute a complete DNA profile (see Appendix 3 for an example of a complete DNA profile that includes each of these 13 chromosomal locations) and must obtain results for a minimum of 10 of those locations for a forensic profile to be considered "complete" and be included in the national index. An STR convicted offender profile will not be included in the national index unless the laboratory tests and obtains results for all 13 chromosomal locations.

- Only forensic profiles derived from crime scene evidence matching the suspected perpetrator(s) or an unknown individual can be uploaded to the national index. Profiles clearly matching the victim or any known person other than the suspected perpetrator(s) cannot be uploaded to the national index. However, if the forensic profile is a mixture that cannot be clearly separated into a portion matching the victim or other known person and the portion matching the suspected perpetrator, such a profile would be accepted.

Appendix C, NDIS Procedures Manual, provides (among other information) procedures for confirming and documenting potential matches found in the CODIS databases, both for case-to-case matches as well as case-to-offender matches. These procedures require that:

- Potential or "candidate" matches be refuted or confirmed within 30 business days.

- In circumstances where a match is confirmed between two cases, the laboratory must notify, at a minimum, the law enforcement agencies investigating the cases.

- A report must be generated and filed for each confirmed candidate match, including, at a minimum, the prescribed forms and information delineated in the procedures.

SCIENTIST BIOGRAPHIES

Dr. Arthur J. Eisenberg

Dr. Eisenberg received a Ph.D. in Molecular Biology from the State University of New York at Albany in 1984. He has worked in the field of DNA identification testing for the past 20 years, and has helped in the development of many of the reagents and methodologies used in the field. He currently serves as an Associate Professor in the Department of Pathology and as the Director of the DNA Identity Laboratory at the University of North Texas Health Science Center, Fort Worth, Texas. The DNA Identity Laboratory, in addition to performing parentage and DNA forensic testing, was designated by the Texas Legislature in its 2001 legislative session to serve as the site for the state's Missing Person Database.

Dr. Eisenberg has been a member of the FBI's Scientific Working Group on DNA Analysis Methodologies for the past 14 years. He is also a member of the College of American Pathologists/American Association of Blood Banks Parentage Testing Proficiency Committee, and is a former member of the American Association of Blood Banks Parentage Testing Standards Committee. He was appointed to the United States DNA Advisory Board, an oversight group created as a result of the DNA Identification Act of 1994, in the position of Molecular Biologist and was later named Chairman.

Mr. William David Coffman

Mr. Coffman received his Bachelor of Science degree in Chemistry from the University of Houston in 1982, and later completed additional coursework in the subjects of Molecular Biology, Genetics, and Biochemistry. Mr. Coffman's professional career began with a serology position at the Houston Police Department Crime Laboratory in 1984. After a variety of DNA experiences, Mr. Coffman accepted in 1987 a position as a forensic biologist with the Florida Department of Law Enforcement Tallahassee Regional Crime Laboratory. In 1990 Mr. Coffman was asked to establish the state of Florida's DNA Investigative Support Database and in 1994 was promoted to his current position as Crime Laboratory Analyst Supervisor, overseeing Florida's DNA Investigative Support Database Program.

Mr. Coffman has served as an expert witness in the field of Forensic Biology in the states of Florida, Texas, New Hampshire, and Wisconsin approximately 150 times, and has testified or given depositions on the subject of Forensic DNA and cases related to DNA Databasing approximately 15 times.

Mr. Coffman has served in a variety of positions in the national professional DNA community, including: Vice Chairman, Scientific Working Group of DNA

Analysis Methods; Combined DNA Index System Subcommittee Chairman, Scientific Working Group of DNA Analysis Methods; member of the FBI's Quality Assurance Standards Audit Review Panel; member of the Laboratory Funding Working Group that functions as part of the National Commission on the Future of DNA Evidence; member of the FBI's DNA Advisory Board from March 1997 to March 2000; member of the National DNA Database Pilot Program conducted for the Combined DNA Index System administered by the FBI; member of the American Academy of Forensic Scientists; member of the Southern Association of Forensic Scientists; member of the Florida Sex Crimes Investigators Association, and a Special Subcommittee member for the Missing and Exploited Children Information Clearinghouse.

Dr. John H. Ryan

Dr. Ryan received his Ph.D. in Genetics in 1995 from the State University of New York at Stony Brook. Dr. Ryan's professional experience began in 1995 when he accepted a position as a DNA technician at the Armed Forces DNA Identification Laboratory (AFDIL). AFDIL provides worldwide scientific consultation, research, and education services in the field of forensic DNA analysis to the Department of Defense (DoD) and other agencies. During his 5-year tenure at AFDIL, Dr. Ryan progressed to the position of Technical Leader of the mitochondrial DNA section. Dr. Ryan accepted his current position as the Director of Forensic Programs at Myriad Genetic Laboratories, Inc., in June of 2000. The Forensic Programs at Myriad Genetic Laboratories provides highly automated processing of DNA samples. In addition, Dr. Ryan currently serves as a DNA Expert on the Scientific Advisory Board for the International Commission on Missing Persons (ICMP) for the former Yugoslavia. The ICMP, works to bring resolution to the families of those missing from the conflicts in the former Yugoslavia.

Dr. Ryan has held a variety of positions in the national professional DNA community, including President of the Human Identity Trade Association, a member of the Mid-Atlantic Association of Forensic Scientists, a provisional member of the American Academy of Forensic Scientists, and a Diplomat of the American Board of Criminalistics.

CHECKLISTS AND GUIDANCE FOR SCIENTISTS

This Appendix contains the definition of terms, guidance, and forms that were used by the assessment team to determine which portions of the FBI DNAUI written procedures and protocols were vulnerable to undetected inadvertent or willful noncompliance.

The document sections in the checklists track directly to the table of contents of the various documents listed. Separate tables were completed for both impact rankings and risk rankings, even though the following documents show impact and risk on the same checklist.

FBI DNA Laboratory Vulnerability Assessment
Instructions for Numeric Ratings of Impact

Impact is defined as the measure of how scientifically essential a particular procedure or protocol is to producing a complete and accurate DNA profile. Producing a complete DNA profile includes ensuring that available DNA samples are efficiently and effectively processed for analysis. This definition does not include a consideration of whether a procedure or protocol is essential to the legal utility of a DNA profile.

Descriptions of Rating Criteria

Low Impact (Value = 1-3) A procedure or protocol falling into this category is optional, and while it may be beneficial, it is not in any way required. The details of this procedure or protocol, and even whether it is adhered to, have little to no impact on the production of a complete and accurate profile. The general focus of the procedure or protocol is adherence to organization-specific guidelines, or to maintain efficient and consistent operations. Non-adherence has no direct impact on the integrity of the overall evidence or final conclusions.

Medium Impact (Value = 4-7) A procedure or protocol falling into this category is required by quality standards, and certain aspects of what it includes are specified by quality standards. Failure to fully adhere to the procedure or protocol could compromise the obtaining of complete and accurate DNA results, and could compromise the integrity of the overall evidence or final conclusions, but not necessarily.

High Impact (Value= 8-10) A procedure or protocol falling into this category, as well as many of its specific contents, are specifically required by quality standards. Proper adherence to the procedure or protocol is essential to obtaining complete and accurate DNA results, as well as preserving the integrity of the overall evidence and the final conclusions.

FBI DNA Laboratory Vulnerability Assessment
Instructions for Numeric Rating of Risk

Risk is the measure of the sufficiency of existing controls to prevent both inadvertent and willful noncompliance and to detect noncompliance when it occurs. Willful noncompliance, in the context of this assessment, is defined as the intentional circumvention of applicable procedures and protocols. We applied this definition with the understanding that protocols alone cannot prevent in the first instance malicious acts by staff members.

Descriptions of Rating Criteria

Low Risk (Value = 1-2)	A procedure or protocol falling into this category has several mechanisms in place both to ensure staff compliance and to deter and detect noncompliance. Mechanisms could include hard-wired computerized controls, threshholds or sign-offs; checklists; forms; witnesses or reviews; separation of duties; random checks, etc. Mechanisms would almost exclusively be those in which the process is forced to stop until the procedure or protocol is properly adhered to, and would be very difficult to bypass without the deliberate collusion of staff.
Medium-Low Risk (Value = 3-4)	A procedure or protocol falling into this category has several mechanisms in place to ensure staff compliance and to detect noncompliance. Mechanisms will generally be those that halt the process until the procedure or protocol is properly adhered to, but could also be based somewhat on faith in staff compliance. These mechanisms most likely could not be bypassed by a single individual unless there is negligence by other staff.
Medium Risk (Value = 5-6)	A procedure or protocol falling into this category has a few mechanisms that serve to ensure staff compliance or to detect noncompliance. However, the mechanisms generally rely on faith in staff compliance, and would not halt the process if not complied with. Mechanisms could be bypassed for a short time by a single individual if other unknowing staff are not consistently thorough in their oversight responsibilities.

Medium-High Risk (Value = 7-8)	A procedure or protocol falling into this category has minimal mechanisms to ensure staff compliance or to detect noncompliance. Mechanisms that are in place rely on faith in staff to perform as expected without monitoring to detect otherwise, and could be bypassed for a lengthy time by a single individual, even if other staff are being thorough in their oversight responsibilities.
High Risk (Value= 9-10)	A procedure or protocol falling into this category is not being monitored and has no mechanisms to detect noncompliance. Staff are left to themselves to adhere to the procedure or protocol, and noncompliance could exist indefinitely unless another staff member happens to discover and disclose the noncompliance to management.

Impact/Risk Assessment Forms, Phase 1

= Lab Wide = Unit Specific

Instructions: rate each of the following major sections for impact and risk. The rating should reflect the highest level of impact or risk of procedures/protocols contained within the section. Put N/A if the section is informational only. If the sections listed below contain subsections that cover too broad an impact or risk range to be assessed as a whole (>3 values), an itemized assessment of each subsection should be completed.

# of Sections	**FBI Laboratory Division Quality Assurance Manual**											
	Laboratory Policies	1	2	3	4	5	6	7	8	9	10	N/A
1	Statements of Policy											
2	Case Documentation Policy											
3	Evidence Control Policy											
	Operational Practices	1	2	3	4	5	6	7	8	9	10	N/A
4	Practices for Authorizing Deviations											

Notes:

	DNA Analysis Unit I Quality Assurance Manual											
		1	2	3	4	5	6	7	8	9	10	N/A
5	Evidence Control											

Notes:

	FBI Laboratory Division Caseworking Procedures Manual											
		1	2	3	4	5	6	7	8	9	10	N/A
6	Procedures for Processing a Request for Examination											
7	Procedures for Case Assignment											
8	Procedures for Inventorying & Identifying Evidence											
9	Procedures for Recording & Acknowledging Evidence											
10	Procedures for the Examination of Evidence											
11	Procedures for the Formatting and Content of a Report of Examination											
12	Procedures for Reviewing a Report of Examination											
13	Procedures for Issuing a Report of Examination											
14	Procedures for Shipping Evidence											
15	Procedures for Transferring Evidence											
16	Procedures for Retaining Case-Related Documentation											
17	Procedures for Handling Drug and Valuable Evidence											

Notes:

Procedures for the Serological Identification of Biological Substances on Evidentiary Materials

Routine Procedures

	Procedure for the Presumptive Identification of Blood	1	2	3	4	5	6	7	8	9	10	N/A
18	Reagents and Supplies											
19	Quality Control Procedures											
20	Test Procedure											
21	References											

	Procedure for the Confirmatory Identification of Blood	1	2	3	4	5	6	7	8	9	10	N/A
22	Reagents and Supplies											
23	Quality Control Procedures											
24	Test Procedure											
25	References											

	Procedure for the Preparation of Dried Bloodstains	1	2	3	4	5	6	7	8	9	10	N/A
26	Reagents and Supplies											
27	Quality Control Procedures											
28	Preparation of Dried Bloodstains from Coagulated Whole Blood											
29	Preparation of Dried Bloodstains from Anticoagulated Whole Blood											
30	Reference											

	Procedure for the Presumptive Identification of Semen	1	2	3	4	5	6	7	8	9	10	N/A
31	Reagents and Supplies											
32	Quality Control Procedures											
33	Test Procedure											
34	References											

	Procedure for the Extraction of Suspected Semen Stains Prior to OneStep ABACard PSA Test	1	2	3	4	5	6	7	8	9	10	N/A
35	Reagents and Supplies											
36	Quality Control Procedures											
37	Questioned Stain Extraction Procedure											
38	Reference											

	Procedure for Human Semen Identification by the OneStep ABACard PSA Test	1	2	3	4	5	6	7	8	9	10	N/A
39	Reagents and Supplies											
40	Quality Control Procedures											
41	Test Procedure											

42	Interpretation of Results											
43	Disposal											
44	References											

Non-Routine Procedures

	Procedure for the Origin Determination of Stains	1	2	3	4	5	6	7	8	9	10	N/A
45	Reagents and Supplies											
46	Quality Control Procedures											
47	Test Procedure											
48	Interpretation of Results											
49	Disposal											
50	References											

	Procedure for Evaluating the Specificity of Anti-Species Antisera	1	2	3	4	5	6	7	8	9	10	N/A
51	Reagents and Supplies											
52	Quality Control Procedures											
53	Test Procedures											
54	Interpretation of Results											
55	References											

	Procedure for the Presumptive Identification of Blood Using Luminol	1	2	3	4	5	6	7	8	9	10	N/A
56	Reagents and Supplies											
57	Quality Control Procedures											
58	Test Procedure											
59	Interpretation of Results											
60	References											

	Procedure for the Calibration of OneStep ABACard Tests for the Detection of p30	1	2	3	4	5	6	7	8	9	10	N/A
61	Detection of p30											
62	Reagents and Supplies											
63	Preparation of p30 Standard Solutions											
64	Tests of the p30 Standard Solutions											
65	Interpretation of Results											
66	Reference											

	Procedure for the Microscopic Identification of Spermatozoa	1	2	3	4	5	6	7	8	9	10	N/A
67	Reagents and Supplies											
68	Quality Control Procedures											
69	Test Procedures											
70	References											

	Procedure for the Staining of Smear Slides with Kernechtrotpicroindigocarmine for the Microscopic Identification of Spermatozoa	1	2	3	4	5	6	7	8	9	10	N/A
71	Reagents and Supplies											
72	Quality Control Procedures											
73	Test Procedures											
74	References											

	Procedures for the Detection of Amylase in Saliva Stains	1	2	3	4	5	6	7	8	9	10	N/A
75	Reagents and Supplies											
76	Quality Control Procedures											
77	Test Procedures											
78	Interpretation of Results											
79	References											
80	Radial Diffusion Template											

	Procedure for the Detection of Urea in Urine Stains	1	2	3	4	5	6	7	8	9	10	N/A
81	Reagents and Supplies											
82	Quality Control Procedures											
83	Test Procedures											
84	Interpretation of Results											
85	References											
86	Radial Diffusion Template											

	Laboratory Setup	1	2	3	4	5	6	7	8	9	10	N/A
87	Dedicated Equipment and Supply Items											
88	Dedicated Laboratory Space											
89	Equipment Calibration											

Notes:

Impact/Risk Assessment Forms, Phase 2

= Lab Wide = Unit Specific

Instructions: rate each of the following major sections for impact and risk. The rating should reflect the highest level of impact or risk of procedures/protocols contained within the section. Put N/A if the section is informational only. If the sections listed below contain subsections that cover too broad an impact or risk range to be assessed as a whole (>3 values), an itemized assessment of each subsection should be completed.

# of Sections	**FBI Laboratory Division Quality Assurance Manual**	1	2	3	4	5	6	7	8	9	10	N/A
1	Authorization and Approval Hierarchy											
2	Laboratory Quality System											
	Laboratory Policies	1	2	3	4	5	6	7	8	9	10	N/A
3	Court Testimony Policy											
	Operational Practices	1	2	3	4	5	6	7	8	9	10	N/A
4	Practices for Corrective Action											
5	Practices for Court Testimony Monitoring											
6	Practices for Document Control											
7	Practices for Instrument Calibration and Maintenance											
8	Practices for Internal Audits											
9	Practices for Laboratory Security											
10	Practices for Open Proficiency Testing											
11	Practices for Scientific or Technical Casework Conflict Resolution											
12	Practices for Validating Technical Procedures											
13	Practices for Writing Standard Operating Procedures											

Notes:

	DNA Analysis Unit I Quality Assurance Manual	1	2	3	4	5	6	7	8	9	10	N/A
14	Mission Statement											
15	Goals and Objectives											
16	Organization and Management											
17	Authority and Accountability											
18	Job Descriptions, Personnel Qualifications and Training/Continuing Education											

		1	2	3	4	5	6	7	8	9	10	N/A
19	Facilities (Security)											
20	Documentation System											
21	Standard Operating Procedures											
22	Report Writing											
23	Case Assignment, Documentation and Review											
24	Quality Control of Reagents and Materials											
25	Instrument Calibration and Maintenance											
26	Validation											
27	Court Testimony Monitoring											
28	Addressing Complaints											
29	Proficiency Testing											
30	Audits											
31	Corrective Action											
32	Environmental Health and Safety											

Notes:

Short Tandem Repeat Analysis Protocol

		1	2	3	4	5	6	7	8	9	10	N/A
33	Scope: Principles of Forensic STR Typing Tests											
34	Reagents and Supplies and Equipment											
35	Reagents and Supplies for Extraction											
36	Reagents and Supplies for Quantitation											
37	Reagents and Supplies for Profiler Plus / Cofiler Amplification and Detection by ABI Prism 310											
38	Equipment											
39	Special Quality Control Measures											
40	Guidelines for Control Samples											
41	Equipment											
42	Quality Control of Critical Supplies and Reagents											
43	Extraction											
44	Whole Blood or Bloodstains											
45	Vaginal Swabs or Semen Stains											
46	Saliva Stains											
47	Envelope Flaps or Stamps											
48	Cigarette Butts											
49	Tissues											
50	Hairs											

		1	2	3	4	5	6	7	8	9	10	N/A
51	Bone											
52	Teeth											
53	Quantification by Quantiblot											
54	Amplification											
55	STR Typing by Capillary Gel Electrophoresis											
56	Setting up the Instrument											
57	Setting up a Run											
58	Genescan Analysis											
59	Genotyper Analysis											
60	Before Applying Genotyper											
61	Using a template file											
62	Examining data											
63	Interpretation											
64	Designation of Profiler Plus ID and Cofiler Alleles											
65	Preliminary Evaluation of Data											
66	Interpretation of Control Samples											
67	Interpretation of Specimens											
68	Application of Population Frequency Data to Profiler Plus ID and Cofiler Typing Results											
69	Source Attribution											
70	Minimum Allele Frequency											
71	Allele Frequencies											
72	Report Writing											
73	Laboratory Set-up											
74	DNA Extraction and Non-amplified DNA Laboratory											
75	PCR Set-up											
76	Amplified DNA Analysis											
77	References											
78	Safety											

Notes:

Miscellaneous Procedures

		1	2	3	4	5	6	7	8	9	10	N/A
79	Procedure for Monitoring Ultra-Violet Light Intensity											
80	Procedure for Pipette Calibration											
81	Procedure for One Point Thermometer Calibration											

Notes: