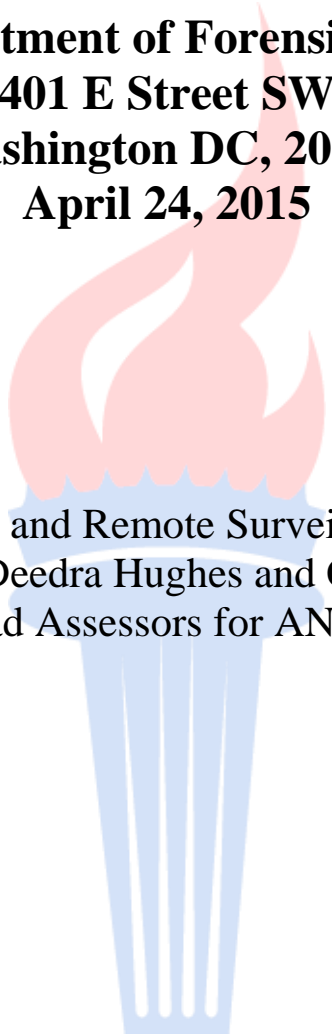




**DC Department of Forensic Sciences  
401 E Street SW  
Washington DC, 20024  
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**Surveillance and Remote Surveillance Audit  
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## **INTRODUCTION:**

The ANAB assessment team was tasked with the review of the mixture interpretation procedures previously used by the District of Columbia Department of Forensic Laboratory and the new procedures implemented in February 2015 after recent validations conducted by the laboratory. The ANAB assessment team also reviewed DNA mixture cases analyzed with the previous DNA mixture interpretation procedures as well as a thorough review of available DNA mixture cases analyzed with the new DNA mixture procedures implemented in February 2015. Analysts of the District of Columbia Department of Forensic laboratory were interviewed on the previous procedures, recent validations and new mixture interpretation procedures. Management of the laboratory was also interviewed during the onsite visit of the ANAB assessment team. This assessment was conducted under the authority of the District of Columbia Department of Forensic Laboratory's accreditation, at their request, to both ISO/IEC 17025 and the FBI QAS.

### **Activities performed by assessment team:**

**A. *Departmental Operations Manual***

Current departmental operations manuals were reviewed and found to be in compliance with the FBI Quality Assurance Standards and ISO/IEC 17025 guidelines.

**B. *FSL Quality Corrective Action Practices***

**C. Corrective actions for 2013 and 2014 were reviewed (ISO/IEC 17025). *FSL Laboratory Operations manuals, Quality Documents and training manuals***

The current FSL laboratory operations manual, quality documents and training manuals were reviewed by the assessment team.

**D. *FBU Quality control, reagent and standard operating procedures***

The current FBU quality control, reagent and standard operating procedures were reviewed by the assessment team. .

**E. *Previous two FBI QAS external audits***

**F. The external FBI QAS audits for 2013 and 2014 were reviewed. The FBI Quality Assurance Standards for DNA Testing Laboratories effective September 1, 2011 were used to evaluate the laboratory. *cDNA Mixture validation studies, training and interpretation***

The mixture validations, training and interpretation guidelines approved by the laboratory in February 2015 were reviewed by the assessment team.

**G. *Qualifying examinations and standard for analyst positions***

The competency testing of the analysts has not been completed. The completion date of the competency testing is set for July 2015.

**H. *Machine noise testing***

The analytical thresholds were evaluated by the assessment team.

**I. *Records of problems and remediation***

The corrective actions of the DNA sections and all remediation were reviewed by the assessment team.

**J. *Personnel files***

The personnel files of all analysts were reviewed.

**K. *Previous twelve months of documentation from meetings of management with personnel regarding policy and guidance regarding DNA typing***

This information was not provided to the assessment team.

**L. *Recent validations regarding new protocols and training***

The audit team has determined that the recent validations were conducted in accordance with the FBI Quality Assurance standards and the guidelines set forth by the Scientific Working Group of DNA Analysis and Methods regarding validations:

- I. *Quantifiler® Duo DNA Quantification Kit Using the ABI 7500 Real Time PCR Instrument validation was reviewed. The following studies were conducted by the laboratory: precision, reproducibility, accuracy, sensitivity and reproducibility, contamination, standard curve evaluation, mixture and NIST assessment.*
  - II. *Applied Biosystems® AmpFISTR® Identifiler® Plus PCR Amplification Kit Validation Using the Applied Biosystems® 3130xL Genetic Analyzer validation was reviewed. The following studies were conducted by the laboratory: precision, sensitivity (with 1ng and 0.5ng using 28 and 29 cycles), accuracy (with 1ng and 0.5ng using 28 and 29 cycles), reproducibility (with 1ng and 0.5ng using 28 and 29 cycles) and mixture (with 1ng and 0.5ng using 28 and 29 cycles). See recommendation #6.*
  - III. *Validation of the QIAGEN EZ1 Advanced XL workstation with the DNA Investigator DNA Extraction Kit was reviewed. The following studies were conducted by the laboratory: sensitivity study, reproducibility and precision study, accuracy and concordance study, contamination assessment, mixture study and mock evidence sample evaluation.*
  - IV. *Statistical Cut-off study using AmpFISTR ®Identifiler® Plus Amplification kit approved by the technical leader on February 1, 2015 was reviewed. The following studies were conducted by the laboratory: Random match probability study, combined probability of inclusion (CPI) study, mixture study, random match probability worksheet validation and combined probability inclusion worksheet validation. See Recommendation #5.*
  - V. *Reevaluation of AmpFISTR ®Identifiler® Plus internal validation, approved by the technical leader on February 3, 2015 was reviewed. The following studies were conducted by the laboratory: Threshold reassessment- analytical threshold and stochastic threshold were evaluated, peak height ratio, stutter study and different approaches for data analysis and profile interpretation were evaluated.*
- M. Sampling Review of casework and case files of all employees within the past 12**  
Case files were reviewed that were conducted with the old mixture interpretation procedures and the new mixture interpretation procedures.
- N. Review of cases work involving DNA mixtures and CPI calculations**  
The case files reviewed involved DNA mixtures and CPI calculations.
- O. Interview 8 – 10 FSL FBU scientists on casework, case flow, case processing, DNA mixture interpretation and training and case jacket reviews.**  
The following 10 analysts were interviewed: MacBean, Ciacco, Feiter, Zeffer, Larry, Mills, Curtis, Skillman, Johnson and Ferragut.
- P. Interview five (5) DFS manager**  
The District of Columbia Department of Forensic laboratory was interviewed on FBU casework, case flow, case management and management oversight.

Eight completed cases and two in progress cases were provide to the assessment team to review that were analyzed and interpreted under the new mixture interpretation procedures. The team determined that these cases did not give a full range of statistical calculations. The cases did not include any CPI calculations. It is noted that the lab has done a tremendous amount of work reevaluating their mixture interpretation procedures, analytical and stochastic thresholds including starting a process of determining major and minor contributors from mixtures, something that was not done in the past. The new procedures also lay out the

approach the analyst is required to take while interpreting. However, only a limited amount of cases from a limited amount of staff have used these procedures. A fair assessment of whether everyone understands the new concept and whether all factors of a mixture are being evaluated in the mixture interpretation has not been determined

### **The report contains identified Nonconformities listed as Major/Minor**

1. **Major Nonconformity:** A major nonconformity is the absence of or the failure to implement and maintain one or more of the accreditation checklist requirements or a situation which would, on the basis of available objective evidence, raise significant doubt as to operations or appropriateness of the results reported by the accreditation customer. The assessment team may judge numerous minor nonconformities against a single requirement to be a significant breakdown of the management system and thus a major nonconformity. Any minor nonconformity that is a repeat from the previous assessment will be considered a major nonconformity.
2. **Minor Nonconformity:** A minor nonconformity is any other nonconformity which seems to be an isolated occurrence and is normally easily corrected and verified.

Cited clause numbers refer to the International Standard ISO/IEC 17025 and/or the FBI QAS.

#### **Nonconformity #1 (Major)**

##### **ISO/IEC 17025, 4.8 Complaints**

Does the laboratory have a policy and procedure for resolution of complaints received from customers or other parties?

Are records maintained of all complaints and of investigations and corrective actions taken by the laboratory?

The complaint filed by the U.S Attorney's Office (USAO) with Department of Forensic Sciences was not addressed in accordance to the procedures defined in the Department of Forensic Sciences DOM07- Practices for Quality Corrective Action procedures. A corrective action in response to the complaint by the USAO office was not provided to the assessment team for review. The assessment team does not know if an official corrective action has been opened in response to the complaint filed by the USAO office.

#### **Nonconformity #2 (Major)**

##### **ISO/IEC 17025.4.11 Corrective Actions**

###### **Section 4.11.1 General**

Has the laboratory established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?

The problem identified by the USAO office concerning the statistical interpretations of mixture cases was not formally addressed by the Department of Forensic Lab in accordance with the laboratory's procedures, DOM07-Practices for Quality Corrective Action procedures.

###### **Section 4.11.2 Cause analysis**

Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?

The assessment team was not provided with a corrective action investigating the root cause of the problem regarding the statistical mixture interpretation complaint filed by the USAO office.

### **Nonconformity #3 (Major)**

#### **ISO/IEC 4.11 Corrective Action**

##### **Section 4.11.3** Selection and implementation of corrective actions

Where corrective action is needed, does the laboratory identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence? Are corrective actions to a degree appropriate to the magnitude and risk of the problem? Does the laboratory document and implement any required changes resulting from corrective action investigations?

##### **Section 4.11.4** Monitoring of corrective actions

Does the laboratory monitor the results to ensure that the corrective actions taken have been effective? In 2013 and 2014, the District of Columbia Department of Forensic Science laboratory had the some of the same findings identified in both years. It is apparent the corrective action plans that were put in place in 2013 were not effective since they occurred in 2014. The monitoring of the issues was not effective for the finding to occur again in 2014. In 2014 the laboratory also received a finding for not having a uniform procedure for reporting mixtures. The corrective action of this finding and the monitoring was not effective.

### **Nonconformity #4 (Major)**

#### **ISO/IEC 17025 5.2 Personnel**

**Section 5.2.1** The laboratory shall ensure the competence of all who operate specific equipment, perform tests, evaluate results and sign test reports.

**Section 5.2.2** The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.

**Section 5.2.5** The management shall authorize specific personnel to perform particular types of sampling, test, to issue test reports, to give opinions and interpretations and to operate particular types of equipment.

The laboratory did not ensure that all staff performing DNA mixture cases were competent to evaluate results. The laboratory did not provide training for all personnel involved with DNA mixture case interpretations. The laboratory allowed staff that was not competent or trained to perform DNA mixture cases.

The analysts were interviewed regarding their individual case files regarding case flow, case processing, DNA mixture interpretation, training, recent validations and training. The analysts were also asked questions concerning the lab's old procedures and mixture interpretation guidelines that were used on the case files reviewed by the assessors. It was apparent that the previous procedures lack guidance on mixture interpretation, how to determine the number of contributors, how to determine major and minor contributors, the proper application of Combined Probability of Inclusion (CPI) to mixture profiles and the guidelines on the review of DNA mixture cases. The analysts were not able to show when the loci were determined to be used for statistical purposes, if this occurs after the mixture was evaluated or after comparison to the known standards. The analysts were not able to demonstrate how inhibition, dropout was considered when evaluating mixtures. The recent internal validation of the Reevaluation of AmpFISTR®Identifiler® Plus and the Statistical Cut-off study using AmpFISTR®Identifiler® Plus Amplification kit was discussed with the analyst. Some of the analysts were able to explain the new procedures. However,

most of the analysts stated that they have not used these new procedures on casework and are still getting familiar with the procedures. It is apparent that the analysts need further training on the deconvolution of mixtures, determining major and minor profiles and the proper use of the Combined Probability of Inclusion (CPI) methods.

**Nonconformity #5 (Major)**

**ISO/IEC 5.4.5 Validation of Methods**

**Section 5.4.5.2** The laboratory shall validate non-standard methods, laboratory-designed/developed methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application.

The laboratory used procedures for the interpretation of DNA data that were insufficient or inadequate. The new procedures effective Feb 2015 addressed some of these issues. However not all potential issues were addressed and validated in these new procedures. For example, in the case files provided to the assessment team that contained mixtures interpreted under the new test methods did not contain a CPI calculation as part of the interpretation.

**Nonconformity #6 (Major)**

**FBI QAS standard, 8.4 Validations**

Has the analyst or examination team successfully completed a competency test using the DNA analysis procedure prior to its incorporation into casework applications?

The analysts have not completed a competency test on the new validated mixture interpretation procedures but are currently using the procedures on casework.

**Nonconformity #7 (Major)**

**FBI QAS standard, 5.2.3, 5.2.3.1 and 5.2.3.1.1 Personnel**

**5.2.3** Does the technical leader of the laboratory have responsibility for the following:

**5.2.3.1** Does the technical leader have the following general duties and authority:

**5.2.3.1.1** Oversee the technical operations of the laboratory?

There was no documentation that the technical was involved when the laboratory received the initial complaint regarding mixture interpretation. Therefore, the technical leader has not had oversight of the technical operations of the DNA laboratory.

**Nonconformity #8 (Minor)**

**FBI QAS standard 9.1.1**

Does the laboratory have a documented standard operating procedure for each analytical method used? The FSB 18 procedure 7.3.1.1.1 states that the use of 2P rule can be used but must be approved by the technical leader. During interviews and reviewed of the case files, it was determined that the technical leader did not approve the use of the 2P in statistical calculations. This procedure was not followed in the cases reviewed using the previous procedures where this was a requirement. However, the new procedures, FSB22, removed the requirement of the technical leader approval on 2P calculations. The new procedures do not provide a formula using the 2P calculations. See recommendation # 11.

**Nonconformity #9 (Major)**

**FBI QAS standard 9.6, 9.6.4 and 9.6.4.c**

- 9.6** Does the laboratory have and follow written guidelines for the interpretation of data?
- 9.6.4** Does the laboratory have and follow documented procedures for mixture interpretation to include the following:
- c. Policies for reporting results and statistics?

The laboratory's procedures FBS15ID+ and FBS18 which were used in the interpreting results on the cases the assessment team reviewed, lack guidelines on mixture interpretation and the proper use of statistical calculations. It was determined through the review of the cases files and interviews that the laboratory was not using the combined probability of inclusion calculation correctly. Cases reviewed by the assessment team demonstrated the inclusion of loci in the combined probability of inclusion calculation that had potential allelic drop out. SWGDAM Interpretation of DNA typing results for mixed samples published January 4, 2010 states the following: Section 4.6.3- When using CPE/CPI (with no assumptions of number of contributors) to calculate the probability that a randomly selected person would be excluded/included as a contributor to the mixture, loci with alleles below the stochastic threshold may not be used for statistical purposes to support an inclusion. In these instances, the potential for allelic dropout raises the possibility of contributors having genotypes not encompassed by the interpreted alleles. The laboratory was not following this recommendation in the cases reviewed by the assessment team.

**Laboratory Actions Required by ANAB:**

The laboratory's DNA section is not in compliance with the FBI QAS or the ISO/IEC 17025 standard. The non-compliance is in two general areas: technical and quality management system. For the technical area, staff were not competent (lack of completed training) and were using inadequate procedures (not fully validated and/or inadequately written). For the quality management system, there was a failure to address these issues before any casework was performed and a failure of not stopping casework when a compliant was received and/or when management including the DNA technical leader became aware of these issues.

DNA case work shall be suspended until all the nonconformities are successfully resolved. A completed assessment of whether everyone understands the new concept and whether all factors of mixture interpretation must be determined. This will include at a minimum the revalidation of test procedures, new interpretation guidelines based on these method validations for DNA mixture cases, creation of new procedures based on the interpretation guidelines, training of staff on the new procedures, competency testing of these new procedures, and authorizations of trained and competent DNA staff.

The laboratory will use its corrective action process to document these activities and to monitor the effectiveness of the new processes placed into service.

**The new process shall include at least the following:**

1. Update training manuals to include more detailed guidance on mixture interpretations.
2. A more detailed procedures on the review process involved in reviewing mixture cases.
3. Validations shall be conducted on three or more person's mixtures, since the laboratory has procedures to interpret three or more person mixtures without proper validation to support the procedures and lack of training for the analysts for three or more person mixtures.
4. The laboratory shall account stutter and dropout when conducting analytical threshold validations.
5. The analysts shall receive competency testing on the new procedures, and report writing training on the new procedures.

6. Reevaluation of the statistical cutoff study and the use of various analytical thresholds when applying to samples with apparent drop out.
7. A more detailed sensitivity study shall be conducted by the laboratory.
8. Statistical reevaluation of all the DNA cases that the assessment team reviewed, to include issuing amendment reports of any cases where the stats were applied incorrectly.
9. More detailed training with the analyst on the new validated procedures, mixture deconvolution, major and minor profiles, threshold evaluations and the proper use of the statistical method, Combined Probability of Inclusion, CPI.
10. Include a procedure for the correct use of significant figures in reporting statistics in case reports. This should include the proper method of rounding the statistical information.
11. The laboratory shall verify the ability to interpret the types of mixtures created from known standards that the interpretation protocols address.
12. Include a formula for 2P calculations. It should not be calculated just 2P, as that would not adjust for possible subpopulations and if it was actually a homozygous peak.

**CONCLUSION:**

DNA case work shall be suspended immediately until all the nonconformities are successfully resolved and all the required ANAB action items listed above are completed. The laboratory is required to respond to nonconformities in writing within 30 days of receipt of the assessment report. The response shall identify the corrective action taken, including root cause analysis, selection and implementation of corrective action, and any follow-up confirmation of effectiveness. It is recognized that some non-conformities may require more than 30 days for completion of the process of root cause analysis, selection and implementation of corrective action, and confirmation of effectiveness, and in such instances the 30 day response must include a description of action taken to date and a plan with milestones for completion of the corrective action. Once the nonconformities have been resolved and accepted by ANAB, an additional onsite visit is required. This additional visit will determine ANAB's subsequent course of action, which may include suspension, reduction of scope of accreditation, or withdrawal of accreditation. During this period no testing of DNA cases will be performed.

**COMMENDATIONS:**

The assessors and ANAB would like to thank the DC Department of Forensic Sciences for their openness and willingness to provide any requested materials necessary to conduct an efficient assessment during the audit.

Respectfully,

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