

Nonconformity Summary



FM 2003

Authority: Vice President

Effective: 2015/02/25

Nonconformity Summary

Organization Name: Washington DC DFS

Assessment Dates: June 11/12, 2015

Lead Assessor: Frank Fitzpatrick

Standard: ISO 17025

NC #	Major/Minor /OFI	Repeat Finding?	Clause #	Description of Finding	Response Acceptable
DH-FA-15-1	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	4.8	ISO/IEC 17025 4.8 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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-2	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	4.11.1 and 4.11.2	ISO/IEC 17025 4.11.1 The problem identified by the USAO office concerning the statistical interpretations of mixture cases was not formal 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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-3	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	4.11.3 and 4.11.4	ISO/IEC 17025 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	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>

				action of this finding and the monitoring was not effective	
DH-FA-15-4	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	5.2, 5.2.1 and 5.2.5	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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-5	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	5.4.5.2	ISO/IEC 17025 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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-6	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	QAS standard, 8.4	FBI QAS standard, 8.4 Validations Has the analyst or examination team successfully	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>

				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.	
DH-FA-15-7	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	QAS standard, 5.2.3, 5.2.3.1 and 5.2.3.1.1	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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-8	Minor	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	QAS standard 9.1.1	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	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-9	Major	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	QAS standard 9.6, 9.6.4 and 9.6.4.c 9.6	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.	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
DH-FA-15-10	OFI	Y <input type="checkbox"/> N <input type="checkbox"/>		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	Y <input type="checkbox"/> N <input type="checkbox"/>

				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.	
	OFI	Y <input type="checkbox"/> N <input type="checkbox"/>	4.3.2.1	Some controlled documents have been authorized by staff who are no longer employed by the laboratory.	Y <input type="checkbox"/> N <input type="checkbox"/>
	OFI	Y <input type="checkbox"/> N <input type="checkbox"/>	4.13.2.3	QAM 4.13.2.11 permits the use of pencils in limited circumstances, however there is no provision for making these notes into a permanent record.	Y <input type="checkbox"/> N <input type="checkbox"/>
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