District of Columbia
Department of Forensic Sciences
Forensic Science Laboratory

401 E Street SW

Washington, DC 20024

Report on Conformance with

ISO/IEC 17025:2005

Accreditation Assessment Conducted on

September 16 - 18, 2013

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INTRODUCTION

The assessment was conducted against the standard of ISO/IEC 17025:2005 and any appropriate supplemental requirements. John G. Wegel, Jr. was Lead Assessor and technical assessor for biological screening and DNA. Robyn Quinn was technical assessor for biological screening and DNA. Pat Bencivenga was technical assessor for DNA. Domingo Villarreal was the technical assessor for latent prints. Greg Scala was the technical expert for firearms.

A Federal Bureau of Investigation, Quality Assurance Standards Casework DNA audit was performed as a supplemental audit. The report will be submitted separately.

The assessment was conducted at District of Columbia, Department of Forensic Sciences, Forensic Science Laboratory on September 16 - 18, 2013 by inspection of facilities; review of policies, procedures, and records; and by staff interviews.

Places where change is recommended reflect the requirements of program compliance and should not be taken as reflecting the quality of work product. The report is confidential to the customer and is for management purposes only.

The report contains identified non-conformances listed as major, minor, and opportunities for improvement. Each is defined below:

1. **Major Non-Conformances:** A major non-conformance 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 non-conformances against a single requirement to be a significant breakdown of the management system and thus a major non-conformance. Any minor non-conformance that is a repeat from the previous assessment will be considered a major non-conformance.
2. **Minor Non-Conformances:** A minor non-conformance is any other non-conformance which seems to be an isolated occurrence and is normally easily corrected and verified.
3. **Opportunities for Improvement:** An opportunity for improvement is not a non-conformance or finding. It is used to document items that may help a customer improve their operations.

Cited clause numbers refer to the International Standard ISO/IEC 17025, unless otherwise indicated**.**

The laboratory is required to respond to **non-conformities** 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.

All non-conformities will be verified at the next assessment or surveillance.

No response is required to opportunities for improvement.

All communication on non-conformities must be made through the Lead Assessor and/or the FQS Accreditation Manager.

This report contains the following information, as applicable:

- Non-Conformances
- Commendations
- Statement on Proficiency Testing, Management Review & Internal Audit
- Conclusions

NON-CONFORMITIES

Major Non-Conformances

4.3.2.3
Are management system documents generated by the lab uniquely identified?

The title page of the DOMs (Departmental Operations Manual), LOMs (Laboratory Operations Manual), Firearms and Latent Print Training Manual documents are uniquely identified. The remainder of the pages are not uniquely identified as required by the standard.

Does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?

With the exception of the title pages the remaining pages of the DOMs (Departmental Operations Manual), LOMs (Laboratory Operations Manual), Firearms and Latent Print Training Manual documents lack header information as required by DOM 02 Section 5.1.1. In addition the header information in the biology training manual is not complete as required by DOM 02 Section 5.1.1.

4.13.1.2
Are all records legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?

Are retention times of records established?

Retention times of records have not been established for training records, continuing education, and courtroom testimony in biology. (QAS 3.2)

4.13.2.1 F-1 FQS requirement
(f) Is each page of every document in the case record traceable to the analyst/examiner and where appropriate, to a uniquely identified case or exhibit. Is it clear from the case record who has performed all stages of the analysis/examination and when each stage of the analysis/examination was performed (e.g., relevant date(s))?

The administrative data contained in the case file is not traceable to the analyst because LOM 02 excludes these documents from this requirement. These are documents that are part of the case file records and as such are required to be traceable to the analyst/examiner.

4.13.2.1 F-1 FQS requirement
(g) Are laboratory generated examination records that are not part of a validated electronic computer system (e.g. LIMS) paginated using a page numbering system which indicates the total number of pages?

The administrative data contained in the case file is not included as part of the page numbering system used by the lab because LOM 02 excludes these documents from this requirement. These documents are part of the case file records and as such are required to be identified and included in the page numbering system the lab has established.

4.14.1
Does the lab periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with requirements of the management system and the International Standard?

The quality manual 4.14.1 states that Departmental Operations Manual 06 is to be followed for audits. DOM 06, section 5.1.2 only requires the Forensic Biology Unit auditors to assess the unit for the FBI QAS. There is no documented requirement to assess the biology unit to the ISO 17025 standards.

4.14.2
If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of the laboratory's test/calibration results, does the laboratory take timely corrective action and notify customers in writing if investigations show that the lab results may have been affected?

Corrective action(s) from external audits of the biology unit to the FBI Quality Assurance Standards have not been submitted to the Technical Leader for review to ensure that findings were appropriately addressed. (QAS 15.5)

4.14.3
Are the areas of activity audited, the audit findings, and corrective actions that arise from them recorded?

Corrective action(s) arising from external audits of the biology unit to the FBI Quality Assurance Standards have not been recorded. (QAS 15.5)

4.14.4
Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?

The biology unit did not record corrective actions from the previous external FBI QAS audit (2011). Therefore, follow-up audit activities are not being performed to verify and record the implementation and effectiveness of the corrective action taken.

5.4.2 F-19 FQS requirement
(a) Are all technical procedures used by a forensic science laboratory fully validated before being used on casework?

The following validation was evaluated in the biology unit during this audit: Applied Biosystems AmpFℓSTR® Identifiler® Plus PCR Amplification Kit (TL approval: 09/13/12). The internal validation studies included: Precision Study, Sensitivity and Stochastic Studies, Reproducibility Study, Accuracy Study, Mixture Study, Concordance, Inhibition, Degradation Studies, NIST Study. A contamination assessment was not included in the internal validation. (QAS 8.3.1.5)

5.4.2 F-24 FQS requirement
Are standard materials and reagents labeled with:
preparation date and/or expiry date?

FBR01 - Solution Preparation Guidelines (Issued: 4/15/2013 Revision: 2) does not include procedures for documenting commercial reagents. The Assessment Team noted several commercial reagents (dry chemicals) that were not labeled with an expiration date in the biology unit. (QAS 9.1.a)

5.8.1 F-40 FQS requirement
Is there a 'chain of custody' record maintained from the receipt of items/samples which details each person who takes possession of an item or alternatively the location of that item (e.g., if in storage)?

The chain of custody records in Latent Prints documents when items are delivered to

locked bins, tech review tray and finish work box. When items are removed from these locations the chain of custody records documents that the item is received from an individual instead of the above locations. Therefore, the chain of custody is not accurate.

5.8.2
Does the laboratory have a system for identifying test/calibration items?

The biology laboratory does not have a system for identifying test/calibration items. A procedure does not exist to ensure that items cannot be confused physically or when referred to in records or other documents. The system does not accommodate a sub-division of groups of items and the transfer of items within and from the laboratory. (QAS 7.1, 7.1.1 and 7.1.1.c)

5.10.1
Are results of each test/calibration (or series of tests/calibrations carried out by the lab) reported accurately, clearly, unambiguously, objectively, and in accordance with any specific instructions in the test/calibration methods?

The results on the Latent Print final reports do not clearly reflect the information documented on the Latent Analysis Worksheet.

Minor Non-Conformances

4.1.5
(j) Does the laboratory have deputies appointed for key managerial personnel?

Deputies for key managerial positions have not been identified/defined.

4.5.2
Subcontracting of tests
Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer (preferably in writing)?

The laboratory has not advised the customer or gained their approval prior to subcontracting DNA cases.

4.11.1
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?

FQS NOTE: A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal/external audits, management reviews, feedback from customers, or staff observations.

In the quality manual it is not addressed how or if a staff member can initiate a

corrective action when there are departures from policies, procedures or technical operations. The current corrective action procedure begins with management.

5.2.2 F-8
Are training programs relevant to the present and anticipated tasks of the lab?

In the Firearms Technician Training Manual under Instrumentation (Section 6, Unit 6) and under Serial Number Restoration (Section 16, Unit 13) there are references to film photography usage and techniques which are obsolete and no longer used in the FEU.

5.4.1
Does the laboratory use appropriate methods and procedures for all tests/calibrations within its scope?

In FEU05-SOP for Bullet Examinations and Comparisons, procedure 7.2, the definition of General Rifling Characteristics (GRC) omits "caliber" as an element of the GRC. A definition of Caliber is a critical element in GRC determination.

5.10.1
Are results of each test/calibration (or series of tests/calibrations carried out by the lab) reported accurately, clearly, unambiguously, objectively, and in accordance with any specific instructions in the test/calibration methods?

On a latent print report an identification was correctly linked to a left thumb. However, the Latent Examination Case Notes describe the identification as from a left index finger.

OPPORTUNITIES FOR IMPROVEMENT

4.1.5
(c) Does the laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?

The lab quality manual states it has policies and practices to protect confidential information. However, the quality manual does not address them nor does it point to where these policies and practices may be located.

4.2.2
Are the laboratory's management system policies defined in a quality manual (however named), including a quality policy statement?

The lab has a Quality Manual entitled FSL Quality Assurance Manual, document control number 1300. This is lab wide quality manual for goals, objectives, scope, management and technical requirements. Each of the three units has a quality manual. The

management section of all four manuals for the most part is identical. If a change is made to this shared section and not documented in all four manuals simultaneously there would then be conflicting information which could lead to a non conformity. One overall quality manual that addresses the management requirements and general technical requirements that cover the operation of the entire lab along with separate unit quality manuals that address unique unit quality issues or amplify the general technical requirements for that unit may be more manageable.

4.8
Does the laboratory have a policy and procedure for resolution of complaints received from customers or other parties?

When referring to the Quality Corrective Action Report which is a form (or any other form) to be used that is part of the quality system it would be advantageous to cite the form number along with the title of the form.

4.13.2.3
When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered alongside?

Are all such alterations to records signed or initialed by the person making the correction?

During the review of case files in the biology unit, the Assessment Team discovered that when mistakes occurred in records, the mistake was crossed out and were not initialed and dated by the person making the correction (as per laboratory policy). There were also mistakes that were obliterated when corrected.

5.3.4
Is access to and use of areas affecting the quality of the tests/calibrations controlled?

There are visitor sign-in logs in the biology, Latent Prints and Firearms units. The logs do not ask for the same information. It would be advisable that the section sign-in logs be identical throughout the lab.

5.4.1
Does the laboratory use appropriate methods and procedures for all tests/calibrations within its scope?

In FEU13-SOP Report of Results 7.4.1.2 "Fireable Condition)" is confusing and should be defined as to what "fireable" means in the context of an FEU report.

5.10.3.1
In addition to the requirements listed in 5.10.2, do test reports, where necessary for the interpretation of the test results, include the following:

(e) additional information which may be required by specific methods, customers or groups of customers?

Forensic Biology DNA Reports do not include a statement of eligibility for CODIS entry.

COMMENDATIONS

The assessor would like to thank Ms. Karen Wiggins for her efforts to gather all the information needed prior to the site visit and her cooperation during the assessment. Also, the agency staff is commended for their openness and willingness to provide any requested materials necessary to conduct an efficient assessment during the audit. The laboratory is commended for having a clear commitment to quality, stemming from top management to all the analysts and staff. The facilities were well maintained and demonstrated the staff's pride in their work place.

PROFICIENCY TESTING, MANAGEMENT REVIEW, AND INTERNAL AUDIT

The Laboratory has records for successful participation in Proficiency Testing in conformance with FQS requirements for initial assessment. In addition, the Laboratory has successfully conducted prior internal audits and management reviews in conformance with ISO/IEC 17025:2005.

CONCLUSIONS

The major and minor nonconformities identified should all be easy to remediate.

To appeal any non-conformity cited in this report, please submit your appeal according to the FQS appeals procedure, no later than ten (10) days following your receipt of this report from FQS. The justification for the appeal and the change that the laboratory is seeking must be clearly stated within 30 days of **Oct 26, 2013,** unless otherwise arranged.

Respectfully Submitted,

John G. Wegel, Jr.
Lead Assessor
ANSI-ASQ National Accreditation Board/FQS