ANSI-ASQ National Accreditation Board

Department of Forensic Sciences
Consolidated Forensic Laboratory
401 E Street SW Washington, DC 20024

Pre-Assessment Review of District of Columbia Department of Forensic Sciences Consolidated Forensic Laboratory Quality Manuals and Forensic Biology, Firearms Examination, and Latent Fingerprint Units Standard Operating Procedures to ISO/IEC 17025:2005

Review Conducted May 2013

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INTRODUCTION

The pre-assessment was conducted against the standards of ISO 17020:2005 and supplemental requirements of FQS and *FRA-7 Forensic Requirements for Accreditation* by A. Robyn Quinn, Lead Assessor, David Grady, Technical Assessor, and James Gannalo, Technical Assessor.

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 laboratory and is for management purposes only.

This was a review of the District of Columbia Department of Forensic Sciences Forensic Science Laboratory Quality Assurance Manual, Latent Fingerprint Unit Quality Assurance Manual and Standard Operating Procedures, the Firearms Examination Unit Quality Assurance Manual and Standard Operating Procedures, and the Forensic Biology Unit Quality Assurance Manual and Standard Operating Procedures to ISO/IEC 17025:2005 for compliance to the ISO/IEC 17025 standard.

This review of DC Department of Forensic Sciences Consolidated Forensic Laboratory quality system covered the following documents:

1. DC DFS FSL Quality Assurance Manual (Revision 1)
2. DC DFS FSL DNA Quality Assurance Manual (Revision 2)
3. DC DFS FSL Firearms Quality Assurance Manual
4. DC DFS FSL Latent Quality Assurance Manual
5. DC DFS FSL Forensic Biology Unit Training Manual (Revision 1)
6. DC DFS FSL Latent Fingerprint Specialist Training Manual (Revision 1)
7. DC DFS FSL Fingerprint Analysis Section Administrative Guide (Revision 1)
8. DC DFS FSL Firearms Technician Training Manual (Revision 1)
9. DC DFS FSL Laboratory Operations Manual
10. DC DFS FSL Ancillary Manuals
11. DC DFS FSL Health and Safety Manual (Revision 1)

This report should not be taken as reflecting the quality of work product. The report is confidential to the agency and is for management purposes only.

FORMAT of REPORT

The report is in three sections:

Non-conformities: These are instances where there is objective evidence that a requirement described in any of the applicable standards is not being met.

Concerns: These are instances which, although not non-conformities, could have a negative impact on the validity of test results or the integrity of the agency's quality system or accreditation.

Comments: These are instances of commendable practice, or issues that could develop into concerns or non-conformities if not addressed. Commendations: These are recognition of good practice.

Cited clause numbers refer to the International Standard ISO/IEC 17025:2005, unless otherwise indicated**.**

Since this is a pre-assessment visit, the agency does not need to respond to non-conformities, concerns or comments; however, when addressed, non-conformities should be addressed using the agency's Corrective Action policy and procedures.

NON-CONFORMITIES

NC1

4.1 Organization and Management

4.1.5 The laboratory shall

j) appoint deputies for key managerial personnel (see Note).

The DC DFS FSL Quality Assurance Manual (Revision 1) page 27 of 81 states that "The FSL: j) As needed, executive management will appoint deputies for key managerial personnel."

NC2

4.3.2 Document approval and issue

Is a master list or an equivalent document control procedure identifying current revision status and distribution of documents in the management system established and readily available to preclude use of invalid and/or obsolete documents.

A master list identifying current revision status and distribution of documents in the management system was not included in the pre-assessment documentation.

NC3

4.7.2 Service to the Customer

4.7.2 Does evidence exist that the laboratory encourages feedback, both positive and negative, from customers or other parties?

DC DFS FSL Quality Assurance Manual (4.7) is inadequate in describing how the feedback would be solicited and what would be the actions arising from the feedback received.

NC4

4.13.2 Technical Records

4.13.2.1 F-1 FQS requi

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?

DC DFS LOM02 (5.2) does not include total number of pages.

NC5

4.14 Internal Audits

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?

Does the internal audit program address all elements of the management system, including the testing/calibration activities.

DC DFS DOM06 – Practices for Internal and External Audits does not include all elements of the management system (e.g., assessments by external bodies, client feedback, complaints, resources, personnel training).

NC6

Are such audits carried out by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited?

DC DFS DOM06 – Practices for Internal and External Audits does not define personnel trained/qualified to perform ISO 17025 internal audits.

NC7

4.14.1 F-5 FQS requirement
FQS Note: FQS defines annually as Jan 1st to Dec 31st. A predetermined schedule is defined as a schedule that at least designates the month of the scheduled function.

DC DFS DOM06 – Practices for Internal and External Audits does not designate the month of the scheduled function for the internal audit.

NC8

4.15 Management Reviews

4.15.1 F-6 FQS requirement
Is the management review performed at least annually?
Management review not included in documents for pre-assessment.

NC9

FQS Note: FQS defines annually as Jan 1st to Dec 31st. A predetermined schedule is defined as a schedule that at least designates the month of the scheduled function.
DC DFS FSL Quality Assurance Manual (4.15.1.1) states that management reviews will be conducted at least once per calendar year. The month of the scheduled function is not defined.

NC10

4.15.2 Are findings from management reviews and actions that arise from them recorded?
Management review not included in documents for pre-assessment.

NC11

Does management ensure that those actions are carried out within an appropriate/agreed timescale?
Management review not included in documents for pre-assessment.

NC12

5.2.4 Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests/calibrations?

The job description for DFS FSL DNA Forensic Scientist Manager (MS-401-14) is equivalent to DNA Technical Leader as defined in the FBI's Quality Assurance Standards. The following requirements (QAS) are not included:

5.2.3.2 Does the technical leader perform the following specific responsibilities:

5.2.3.2.2 Review and document the review of the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to their conducting independent casework analysis?

5.2.3.2.3 Approve the technical specifications for outsourcing agreements?

5.2.3.2.4 Review and document the review of internal and external DNA audit documents and, if applicable, approve corrective action(s).

5.2.3.2.5 Review annually the procedures of the laboratory and document such review?

5.2.3.2.6 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?

The DFS FSL DNA Quality Assurance Manual does not include the FBI's QAS requirement:

15.5 Have internal and external DNA audit documents and, if applicable, corrective action(s) been submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed?

NC13

5.4.2 F-22 FQS requirement
Are all critical reagents tested for their reliability before use?

The DFS FSL DNA Quality Assurance Manual does not define critical reagents currently in use.

NC14

5.4.7 Control of data

5.4.7.2 When computers or automated equipment are used for acquisition, processing, recording, reporting, storage, or retrieval of test/calibration data, does the laboratory ensure that:

Do such procedures include, as a minimum, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing?

Procedures for the use TBTG Qualtrax Compliance Software is not included in DC DFS FSL Quality Assurance Manual or Laboratory Operations Manuals.

NC15

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

The DC DFS FSL Quality Assurance Manual does not include a procedure for equipment requiring

calibration. A list of equipment requiring calibration including dates and calibration criteria was not included in the pre-assessment documentation.

NC16

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

The DC DFS FSL Quality Assurance Manual does not include a procedure for equipment requiring calibration. Therefore, evidence that the equipment does or does not go outside of the direct control of the laboratory could not be assessed. In addition, procedures do not exist defining the calibration status of the equipment as well as the calibration service performed. A list of equipment requiring calibration including dates and calibration criteria was not included in the pre-assessment documentation.

CONCERNS

CN1

Firearm Examination Unit – safety concerns:

Panic buttons are needed in the shooting tank room and indoor range.

Eye recognition overrides should be seriously considered in both the shooting tank room and the indoor range.

Additional safety training for all personnel assigned to intake.

Log books should be maintained for all calibrated instruments.

Calibration of instruments should be scheduled and the results logged.

COMMENTS

The assessor would like to thank the agency staff for their openness and willingness to provide any requested materials necessary to conduct an efficient pre-assessment. The agency is commended for having a clear commitment to quality, stemming from top management to all the staff. The quality manager, Karen Wiggins, is to be commended for her determination in bringing the DC DFS FSL into compliance with ISO17025:2005.

Several documents (e.g., DFS DOM06 and Forensic Scientist Manager (DNA) Job Description (MS-401-14)) cite ensuring compliance with requirements of the quality system and all associated quality standards pertaining to ASCLD/LAB-International 17025-based accreditation standards. Add FQS ANSI-ASQ Accreditation Board.

The DC DFS FSL quality system manuals refer to documents and records in a way that seems to overlap. A document is anything that tells your employees how to do their work (policies, procedures, required forms, plans, programs, manuals, instrument operating manuals, etc., etc.) while a record is anything with data on it (scientific data, name, results, anything that is added to an

approved document, etc.). ISO/IEC 17025:2005 lists documents under 4.3 and records under 4.13. A quality system may control both in the same process however there is a difference.

The agency will need to add a policy for either the use of the FQS symbol on all accredited test reports or include the following statement (edited as appropriate) on test reports, unless otherwise required by federal, state and/or local regulations:
"This test is accredited under the laboratory's ISO/IEC 17025 accreditation issued by ANSI-ASQ National Accreditation Board/FQS. Refer to certificate and scope of accreditation {insert accreditation number here]."

Several of the cases reviewed for the Firearms Examination Unit had photographs placed on the right side of the file folder, not the left.

PROFICIENCY TESTING, MANAGEMENT REVIEW, AND INTERNAL AUDIT

The agency has successfully completed proficiency tests and internal audits required by the International Standard.

A management review for 2012 was not received or reviewed.

NON-CONFORMITIES AND CONCERN FROM PRIOR REPORTS

There were no prior assessment reports.

CONCLUSIONS

The non-conformities identified are to serve as a guide for becoming compliant with the ISO 17025:2005 standards and FQS Forensic Requirements for Accreditation (FRA-7).

Respectfully Submitted,

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