DOM07 – Practices for Quality Corrective Action

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1. Background

1.1. A nonconformity is any action or event not conforming to the policies and/or procedures of the Department of Forensic Sciences (DFS) or the quality standards required by our accrediting bodies.

1.2. Quality corrective action shall be implemented when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified and evaluated for frequency and impact.

1.3. The purpose of quality corrective action is to bring about continuous improvement and is not considered punitive in nature. These practices specify steps and requirements to ensure a nonconformity is corrected and post-corrective action monitoring is performed to avoid recurrence. When quality corrective action is needed, a root cause analysis will be performed and select action steps will be implemented, in order to eliminate the problem and to prevent recurrence. Any required changes resulting from corrective action investigations shall be documented and implemented. These practices conform to the requirements of the Agency, government regulations, accreditation standards and the applicable supplemental standards.

2. Definitions

2.1. For the purposes of this document, the following terms shall have the designated meanings:

Directorate: Key managerial personnel consisting of Directors, Deputy Director, the Chief Operating Officer and General Counsel

DFS: Department of Forensic Sciences

DFS Quality: Team of Quality Assurance Specialists and Quality Staff

DOM: Departmental Operations Manual

Q-CAR: Quality Corrective Action Report

3. Scope

3.1. These practices are applicable to nonconformities identified by all DFS personnel, internal or external customers, internal or external auditors/assessors, or through feedback, casework and/or proficiency tests. These practices may not apply to maintenance issues or situations that are minor in nature and can be quickly and effectively dealt with within the affected unit.

4. Responsibilities

4.1. The **Unit Manager, Unit Supervisor, Unit Technical Lead and/or designee** will:

4.1.1. Receive/report a nonconformity, gathering all information related to the non-conformity.

4.1.2. Determine if the nonconformity is a significant condition adverse to quality; evaluating the frequency of occurrence and impact.

4.1.3. Perform a root cause analysis, if required.

4.1.4. Ensure an individual or team is assigned the responsibility of handling the corrective action.

4.1.5. Specify the response due date and the timeframe for the follow-up.

4.1.6. Ensure the adequacy of the quality corrective action plan.

4.1.7. Ensure the effectiveness of a quality corrective action is verified.

4.1.8. Inform laboratory staff and/or select analysts of completion of Q-CAR process.

4.1.9. Determine whether examinations are suspended and/or reports of examination(s) are withheld.

4.1.10. Authorize the resumption of work, if required.

4.2. The **Deputy Director and/or designated DFS Quality personnel** will:

4.2.1. Ensure the progress of a corrective action is monitored by confirming Parts A and B (Situation/Condition and Root Cause Analysis) are completed within 30 calendar days of Q-CAR issuance.

4.2.2. Establish the date of and ensure the effectiveness verification is performed as necessary within the established timeframe, where applicable.

4.2.3. Records shall be kept of all documentation related to a corrective action.

5. Practices

5.1. When a nonconformity occurs, an investigation of the situation or condition will be conducted to determine the impact and frequency of the nonconformity. Once the initial evaluation of the nonconformity is performed, a determination will be made if the nonconformity can be documented and corrected or if a root cause analysis will be initiated. If a root cause analysis will be performed, the nonconformity will be given a Q-CAR number for tracking purposes. The Q-CAR consists of four parts and any additional supporting documentation. The four main parts of the Q-CAR are Part A: Situation/Condition, Part B: Root Cause Analysis/Action Steps, Part C: Close Out, and Part D: Verification.

5.2. Part A: Situation/Condition

5.2.1. The Situation/Condition is a description of the background of the nonconformity. This will include all information regarding the event, parties involved, the frequency of occurrence, possible impacts, and any actions taken to address the nonconformity.

5.2.2. Part A (Situation/Condition) must be completed within 30 calendar days of a Q-CAR being issued.

5.3. Part B: Root Cause Analysis/Action Steps

5.3.1. Root cause analysis requires an in-depth investigation of the underlying causation factors rather than cursory symptom analysis. A process review to include technical procedures, instrumentation utilization and maintenance, controls and standards requirements and employee performance may be required.

5.3.2. The selection of action steps will be made by the team performing the root cause analysis, if possible. Action steps will be selected to ensure the nonconformance is resolved and does not occur again in the future.

5.3.3. Part B (Root Cause Analysis) must be completed within 30 calendar days of a Q-CAR being issued.

5.3.3.1. Case work may be suspended and/or Reports of Examination withheld during the corrective action process. Where appropriate, amended laboratory reports will be issued.

5.4. Part C: Close Out

5.4.1. When the completion of the action steps has been confirmed, the Unit Manager, Division Director or designee shall inform effected parties of

the completion of the process. Memoranda should be the method used to convey this information.

5.5. Part D: Verification

5.5.1. The laboratory shall monitor the result to ensure the corrective action(s) have been effective.

5.5.1.1. Once the effectiveness of the corrective action plan has been verified the final section of the Q-CAR will be completed.

5.5.1.2. If the verification determines the corrective action plan was not effective, the action steps implemented will be re-evaluated.

6. Documentation

6.1. The following records will be generated and retained for at least one accreditation cycle or five years, whichever is longer:

6.1.1. Q-CAR with the associated objective evidence.

7. References

7.1. ISO/IEC 17025– General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, (current revision)

7.2. ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).

7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4. Division-specific Quality Assurance Manuals, (current revisions).

7.5. Policy for Retention of Records.

7.6. CLIA 88, of the Code of Federal Regulations "Laboratory Requirements" (Current version)

7.7. H.R. 3448 – 107th Congress: Public Health Security and Bioterrorism Preparedness and Response Act of 2002.