LSD&FC

Non-Conformities and Corrective Actions

Purpose

The purpose of this procedure is to identify, track, investigate and correct nonconformities within the Biology/DNA Division at LSD&FC. This procedure provides instructions and assigns responsibilities for initiating, requesting, implementing, and verifying the effectiveness of corrective actions.

Scope

This SOP applies to all technical personnel at LSD&FC.

Guidelines & Requirements

- ISO/IEC 17025: 2017 (E) Standards
- R104 - A2LA General Requirements – ISO/IEC 17025:2017 Accreditation of Field Testing and Field Calibration Laboratories
- P113- A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies (CABs)
- P102a – A2LA Policy on Metrological Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies for all Calibrations and Verifications of Measurement and Test Equipment
- AABB's Guidelines "Guidance for Standards for Relationship Testing Laboratories", 12th Edition.

Reagents/Materials/Equipment

Corrective Action Report (Form QAC 008))
Corrective Action Report Log (Form QAC 010)
Incident Report (Form QAC 024)
Contamination Event Report (Form QAC 026)

Procedure

Nonconformity

1. Nonconformity is defined as a deviation from a standard, specification or an implied requirement of the Quality Management System. The deviation may occur in training/competency, processing, analysis or in reporting.
2. Deviations may occur with the following: reagent(s), equipment, procedure(s), laboratory results, staff work performance or a complaint from a submitting agency.
3. Should LSD&FC experience a nonconformance the impact on the quality of the work product and/or the integrity of the evidence will be determined.
4. The significance of the nonconformance will be evaluated when determining the course of the corrective action.
5. Non-conforming Work is classified as:

Level I (Critical) - This type of non-conforming work compromises the work product or the overall quality of the laboratory work product. These are non-conformities that are generally:

- Unexpected
- Require an inquiry to determine the root cause
- Require management involvement
- Raise immediate concern and may affect the overall quality of the laboratory work product
- Requires a Corrective Action Report

Examples of Level I non-conformities: missed identifications, false negatives or inconsistencies in proficiency test results, erroneous identifications, systemic quality issues.

Level II (Major) – This type of non-conforming work does not compromise the overall quality of the work and generally:

- Is discovered prior to case completion
- Is foreseeable
- Has a clear-cut immediate cause

- Has a defined remedial action, which shall be adequately documented by a simple entry on the examination documentation, or noted in the administrative or technical review form.
- May be corrected on the spot by the individual who discovers it or by the original examiner when administrative or technical review is returned.
- May be documented on an incident report or a contamination event report, as applicable.
- May require a Corrective Action Report.

Examples of level II non-conformities: administrative or transcription error, failure in a quality control check.

Note: a reoccurring level II non-conformity may escalate to a level I non-conformity.

Level III (Minor) – This type of non-conforming work does not compromise the overall quality of the work and generally:

- Easily discoverable
- Has a clear-cut immediate and identifiable cause.
- Can be easily remediated and documented.
- Can be corrected immediately by the individual who discovered it.
- May be documented on an incident report or a contamination event report, as applicable.
- Does not require a Corrective Action Report. But it should be documented in within the appropriate case file(s), if applicable.

Examples of level III non-conformities: error in illustration of a work flow.

How to Address a Non-conformity

The LSD&FC staff member who identifies a potential non-conformity will immediately inform the Section Director and/or Technical leader. The Section Director and/or Technical leader may select option 1 or option 2 listed below for further action.

Option 1: direct the staff member to do the following:

a) For administrative errors or transcription errors, the staff member will document the non-conforming work in the case file and provide the case file to the Section Director and/or technical leader for review.

b) For technical non-conforming work, the staff member will fill out an incident report form and forward it to the Technical leader for review. This form will then be forwarded to the Quality Manager to determine if a corrective action is needed.

c) For contamination issues, the contamination Event Report Form will be filled out and forwarded to the technical leader for evaluation. This form will then be forwarded to the Quality Manager to determine if a corrective action is needed.

Option 2:
Report the non-conformity to the Quality Manager if it is suspected that the non-conformity would affect any further work performed by the DNA/Biology Section and requires immediate evaluation by the Quality Manager.

Corrective Action

1. Corrective action is defined as an action that is taken to eliminate the cause(s) of a detected nonconformity, defect or other undesirable situation in order to prevent reoccurrence.

2. Corrective actions are administered by the Quality Manager.

3. The following procedure applies to all corrective actions:
   - The Quality Manager initiates the corrective action by assigning a CAR number.
   - The CAR shall follow numbering scheme: CAR-YYYY-# where the first 4 digits indicate the year followed by the next available sequential number.
   - The Quality Manager will assign an individual or an inquiry team to investigate the non-conformity.

- Over the course of the investigation, the individual assigned to the CAR or the inquiry team shall determine and document the following:
  - Events which identified the non-conformity
  - The non-conformity
  - Root-cause(s) of the non-conformity

4. Upon completion of the root-cause analysis of the non-conformity, a corrective action plan shall be developed by the investigator or the inquiry team and provided to the Quality Manager within 30 days. In the event that the team would need more time, an extension maybe granted by the Quality Manager.

5. Once a corrective action plan is accepted by the Quality Manager, section of 4 of the CAR shall be completed an implementation date selected.

6. After completion of the corrective action, the Quality Manager shall evaluate the success of the plan and complete Section 6 of the CAR.

7. The short-term effectiveness of the corrective action shall be evaluated by the Quality Manager and Section 7 of the CAR shall be completed.

8. If there is objective evidence that the actions are complete and effective, the Quality Manager shall close-out the CAR by signing and dating Section 9 of the CAR.

9. If the Quality Manager determines that the Corrective Action Plan has not adequately addressed the non-conformity, then sections 3 through 8 of the CAR shall be repeated.

10. If a staff member is removed from casework or if casework in a particular technical area has been suspended as a result of a CAR, then casework in that area or casework by the staff member shall not be allowed to resume until released by the Quality Manager and/or Technical Leader.

11. Data from the CAR will be used to populate the Corrective Action Report Log. This log will be used to track effectiveness of the corrective actions as well as trends.

12. The Quality Manager shall maintain all original documentation of incident reports, contamination event reports and corrective actions for a period of five years or a full accreditation cycle.

13. All of the aforementioned documents shall be part of the annual internal audit.

The Investigation & Root Cause Analysis Process

1. Root cause investigation determines the factor(s) which may have contributed to the nonconformity.
2. A deficiency that results in a nonconformity must be corrected to prevent reoccurrence of the same or similar nonconformity.
3. Root cause analysis may be difficult to define and must be carefully analyzed to determine the source of the deviation.
4. Potential causes may include but is not limited to the following:
    a. Customer requirement(s)
    b. Forensic sample(s)
    c. Incomplete or noncompliance with procedure(s)
    d. Staff member(s),
    e. Training
    f. Work load
    g. Equipment failure
    h. calibration
    i. Improper collection
    j. Improper storage
    k. Improper handling
    l. Calculation error
    m. Transcription Errors
    n. Resources
5. Once the root cause is determined a recommended course of corrective action will be scheduled to correct the problem.
6. If necessary, any follow-up activities will be scheduled

Types of Errors

Administrative Error

1. Any significant discrepancy in a forensic case that is determined to be the result of an administrative error such as clerical, documentation may be corrected as follows:
2. If the clerical error was found to be present on a report that has been issued to the client an amended report will be issued with the corrections noted in italicized font.
3. Minor documentation errors found on casework forms or worksheets will be corrected, crossed out initialed and dated.
4. Documentation errors that result in samples to be processed improperly should be further investigated to determine if the quality of the work product was compromised.

Systemic Error

1. Any significant discrepancy in a forensic case sample which is determined to be the result of a systemic error such as defects with equipment, supplies and materials or environment all casework completed since the last satisfactory proficiency will be reviewed.
2. Once the source of the error has been determined and corrected, all forensic personnel will be made aware of the issue and the corrective action that was taken so that the error does not occur again.

Technical Error

1. Any significant discrepancy in a Biology/DNA case sample that is determined to be due to incorrect processing, incorrect analysis or interpretation

Introduction of Exogenous DNA

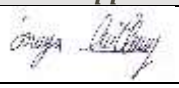
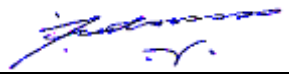
1. If exogenous DNA has been detected, the laboratory will attempt to determine the source of the DNA.

2. A Contamination Event Report shall be completed.

Retraining

1. If it is determined that there was a technical error in the processing of a case, the analyst who performed the error may need to be retrained in the area related to where the error occurred. Once it has been determined that the analyst understands the nature of the error, has corrected the problem and re-training has been satisfactorily completed the analyst at the discretion of the Technical Leader/Director and the Center Director will be allowed to resume analysis of casework specimens.

Procedure History

Procedure History		
Initial Version Created		
Author		***Date***
Shelley Johnson		September 1, 2017
Current Version		***Effective Date***
v3.0		December 6, 2018
Review & Approval History		
Date	***Reviewed & Approved by***	***Title***
12/06/2018		***Soraya McClung, MFS Director, DNA Technical Leader***
12/06/2018		***Richard I. Somiari, PhD Center Director***
Revision History		

Date	*Reason for Revision*	*Reviser*	*Version being changed*
11/22/2018	***Updated levels of non-conforming work*** ***Updated Guidelines and Requirements*** ***Added Incident Reports and Contamination Event Reports*** ***Updated Footer***	Soraya McClung	v1.0
12/6/2018	***Included Level III nonconforming work.*** ***Fixed Typos***	Dr Richard I. Somiari	v2.0

Review History		
Reviewed By	*Date*	*Version*