Control of Non-Conforming Work

GUIDING PRINCIPLES AND SCOPE

Non-conforming work is any testing work which does not meet the Department of Forensic Biology's stated standards, either with respect to mode of execution or outcome. All non-conforming work must be addressed upon discovery so that the work can be appropriately evaluated, corrected as needed and prevented in the future.

This procedure describes the Department's process for evaluating non-conforming work, performing root cause analyses and taking appropriate follow-up action. Technical problems or difficulties can arise in all phases of Department operations. Listing each potential problem is impractical, therefore this topic is considered in general terms.

Apparently similar situations may result in different follow-up actions. This is because no two circumstances are exactly the same and the consequences of the particular non-conformity may be very different.

Identifying Non-Conforming Work

1. Any member of staff who discovers a technical, analytical or clerical error or realizes that there is *a technical, analytical or clerical problem that may compromise evidence integrity, the accuracy of casework analysis or results reported,* must address the issue immediately. The analyst assigned to write up the non-conformity becomes the ***principal investigator of the non-conformity.***

a. The Principle Investigator may be assigned by:

- Having been the person who discovered the non-conformity. This also applies to situations in which the analyst self-discovers the non-conformity.
- The person who discovers the non-conformity may assign the write-up of the non-conformity to the analyst who made the error.

All non-conformities must be reviewed by the direct supervisor of any analysts found to be directly involved in the non-conformity, the Quality Assurance Manager and the Technical Leader.

2. The principal investigator is tasked with investigating and evaluating the significance of the non-conforming work.

   a. **Technical problems related to the testing of a batch of samples** are reported to a supervisor. As multiple analysts and/or cases may be affected, corrective actions may be documented on the batch worksheets, via LIMS deviations or via emails to analysts' whose cases are affected.

      - Detection of exogenous DNA in negative controls is reported to a Quality Assurance Supervisor. **Note:** Determination of the source of exogenous DNA where less than 8 alleles are seen in at least 4 loci is difficult and may not be feasible.

   b. **Technical problems related to individual case samples** (e.g., possible sample mix-up) are reported to a supervisor, the analyst(s) assigned to the affected case(s), the supervisor(s) of the affected case(s) AND the Quality Assurance Manager.

   c. **Analytical or Clerical errors affecting reported results** (e.g., errors in conclusions drawn from analytical results or incorrect recording or transcribing of observational or analytical results) are to be reported to the case analysts' direct supervisor and/or Assistant Director as well as the Quality Assurance Manager.

   d. **Technical problems identified during routine quality control activities**, such as instrument performance checks, are reported to a Quality Assurance supervisor and are reported on the performance check worksheets.

Non-Conformity Reporting Form

Some non-conforming work can be easily corrected, such as by reanalysis. An example of this would be a sample that fails to give interpretable peaks in an electrophoresis run, but when re-injected an acceptable result is obtained. In such cases the action is documented on the batch worksheets, in case notes, or on performance check worksheets, as appropriate to the situation, but no further investigation is likely to be needed unless the incident was part of a pattern. In such cases, a **Non-Conformity Reporting Form does not need to be filled out**.

Some non-conforming work, such as contamination incidents or analyst errors in reporting case results require more investigation as to the scope and cause of the non-conformity. The incident and its evaluation are **documented on the Non-Conformity Reporting Form.**

- Should the cause of the non-conformity be attributed to an individual, the **Non-Conformity Reporting Form** must be completed by both the principal investigator and the immediate supervisor of the individual (if not already involved as the principal investigator).

When a non-conformity has been discovered, the investigation shall proceed in one of two ways. <u>It MUST first be determined by the principle investigator in which manner the non-conformity investigation shall proceed</u>. The two routes a non-conformity investigation may take are as follows:

1. It must be determined whether or not a **"Significant Event"** has occurred. Such "Significant Events" include:

   ●Intentional fabrication of work product, evidence examination, analysis or test results.

   ●Significant error(s) by an employee, or deficiency in a system or procedure that may have affected the accuracy of reported results of evidence examination or the accuracy of the reported results of analysis in one or more cases.

   ●Failure of an employee to follow protocol such that it may have affected the accuracy of reported results of evidence examination or the accuracy of the reported results of analysis in one or more cases.

   ●Statements made in the course of testimony by which an employee significantly misrepresents or misstates her/his education, experience, training or qualifications, or the reported results of any evidence examination or analysis.

<u>IF it has been determined by the principle investigator that a "Significant Event" has occurred, the non-conformity investigation must then proceed as follows:</u>

1. The principle investigator of the non-conformity **MUST IMMEDIATELY** inform the Quality Assurance Manager that a non-conformity on a "Significant Event" level has occurred. The Quality Assurance manager will assess the non-conformity to determine if indeed a "Significant Event" has occurred.

   a. If a "Significant Event" is found to have occurred, the Quality Assurance Manager **MUST IMMEDIATELY** inform the Office of Chief Medical

Examiners' Root-Cause Analysis Officer of the "Significant Event" and the principal investigator shall begin to document the non-conformity on the Non-Conformity Reporting Form.

b. If the Quality Assurance Manager has determined that a "Significant Event" has not occurred, the principal investigator may carry out a standard non-conformity investigation.

2. The Root Cause Analysis Officer shall follow the procedures mandated by New York City Legislation and the Root Cause Analysis Procedure of the Office of Chief Medical Examiner. This involves convening a Root Cause Analysis Committee to investigate the "Significant Event".

3. The Department of Forensic Biology shall ensure that the Office of Chief Medical Examiner issues the report of the Root Cause Analysis Committee to the following entities **within 7 days of the report being generated**:

■The NYC Mayor's Office/ NYC Council

■The NYS Commission on Forensic Science

■ASCLD/LAB

■Relevant District Attorney's Office

■Relevant Defense Council of record

If it has been determined by the principle investigator that a "Significant Event" has NOT occurred, the non-conformity investigation shall proceed in the following manner:

1. A Non-Conformity Reporting Form shall be completed. The principle investigator must determine several factors and document the results of their investigation in the Non-Conformity Reporting Form. Factors to be investigated include, but are not limited to, the following:

   a. The nature of the detected non-conformity.

   b. How the non-conformity was detected.

c. The cause of the non-conformity. **<u>This will require an in-depth Root- Cause Analysis of the situation.</u>**

d. How the non-conformity was resolved (immediate corrective actions taken).

e. Recommendations on future preventive actions to avoid the non-conformity from recurring.

f. Parties notified of the non-conformity.

Once the non-conformity investigation has been completed and the Non-Conformity Reporting Form has been filled out, the form must be given to the Quality Assurance Manager for review. The Quality Assurance Manager maintains the right to request further investigation into the non-conformity on an as-needed basis. Further investigation may be performed by the principle investigator, the Quality Assurance Manager, or another designated employee.

If a particular analyst is found to be the cause of the non-conformity, they must sign the Non-Conformity Reporting Form, as well as their direct supervisor. The direct supervisor shall track performance issues to ensure that repeated occurrences of similar issues are corrected through counseling, retraining, or other measures appropriate to the situation.

Any corrective actions taken to rectify the non-conformity are documented on the Non-Conformity Reporting Form and on the batch worksheets, in case notes or on performance check worksheets, as appropriate to the situation.

If the initial corrective action taken fails to correct the problem, the issue should then be referred to the Quality Assurance Manager for further investigation.

<u>Response to Non-Conformities (Corrective Actions)</u>

1. Based upon the initial investigation into the non-conformity by the principle investigator, the following may occur:

    ●The DNA Technical Leader(s) have the authority to suspend DNA analytical operations for the Department or an individual until such time as the technical issue has been resolved through corrective action.

- The Serology Technical Leader has the authority to suspend serology analytical operations for the Department or an individual until such time as the quality issue is resolved through corrective action.

- The Director, Deputy Director(s) and Assistant Directors are notified as soon as practicable when actions to suspend testing are proposed or taken.

2. If it has been determined by the principle investigator or, subsequently by the Root Cause Analysis Officer, that a "Significant Event" has not occurred, appropriate corrective actions may be implemented by the laboratory in order to ensure that the non-conformity does not recur.

3. Once the Root Cause Analysis Committee has issued their report concerning a "Significant Event", any recommendations they make concerning corrective actions may be implemented by the laboratory in order to ensure the non-conformity does not recur.

4. The Quality Assurance Team analyzes Non-Conformity Reporting Forms on a regular basis in order to track issues so that trends can be identified.

a. Non-Conformity Reporting Forms are assessed at least quarterly to determine if similar events occurred (such as those in the same area of testing or caused by the same individual) within an unreasonable timeframe.

b. The Quality Assurance Manager will determine if any trends pose additional concerns to the Management System of the laboratory.

CONTROL OF NON-CONFORMING WORK		
DATE EFFECTIVE 07/08/2016	APPROVING AUTHORITY QUALITY ASSURANCE MANAGER	PAGE 7 OF 7