Control of Non-Conforming Work		
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Control of Non-Conforming Work

1 Guiding Principles and Scope

1.1 Non-conforming work is any technical 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.

1.2 This procedure describes the Department's process for evaluating non-conforming work, performing root cause analyses and taking appropriate follow-up actions. 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.

1.3 Some situations, which may appear to be similar at the outset, may result in the implementation of 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. Some follow-up actions may involve simple corrections, whereas others may require more extensive corrective actions.

2 Identifying Non-Conforming Work

2.1 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 first step is to assign a staff member to become the Principal Investigator.

2.2 The Principal Investigator is tasked with investigating and evaluating the significance of the non-conforming work, as well as making any notifications to the relevant analyst or supervisor as described in section 4 of this document.

3 The Principal Investigator may be:

3.1 The person who discovered the non-conforming work of another.

3.2 The person who self discovers his or her own non-conforming work.

3.3 The person who discovers the non-conforming work may assign the investigation to the analyst who created the non-conforming work.

4 Assessing the Non-Conforming Work

4.1 **Technical problems related to the testing of a batch** of samples are brought to the attention of a supervisor. As multiple analysts and/or cases may be affected, corrections may be documented in one of three ways; on the batch worksheets, via LIMS deviations or via emails to analysts' (subsequently saved to the relevant LIMS case file(s)) whose cases are affected.

4.1.1 Detection of exogenous DNA in negative controls is to be brought to the attention of the Quality Assurance Group.

4.1.2 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.

4.2 **Technical problems related to individual case samples** (e.g., possible sample mix-up) are brought to the attention of a supervisor, the analyst(s) assigned to the affected case(s) and the supervisor(s) of the affected case(s).

4.3 **Clerical errors affecting reported results** (e.g., incorrect recording or transcribing of observational or analytical results) are to be brought to the attention of the case analyst, their direct supervisor and/or Assistant Director.

4.3.1 It is not required to correct clerical errors that did not affect reported results (e.g., Victim's name is spelled incorrectly).

4.4 **Technical problems identified during routine quality control activities**, such as instrument performance checks, are brought to the attention of a Quality Assurance supervisor and are documented on performance check worksheets.

5 Non-Conformity Reporting Form

5.1 Some non-conforming work can be easily corrected following laboratory standard operating procedures. Examples include issuing an amended report to make a minor correction of a non-technical nature or performing rework (e.g., failing to run a positive control on an STR plate. This is easily corrected by re-running all the samples associated with that STR plate with a positive control). In such cases, the non-conformity **does NOT need to be documented on the Non-Conformity Reporting Form.**

5.2 Some non-conforming work cannot be corrected by following laboratory standard operating procedures, such as contamination incidents or technical errors (non-typographical) in reporting case results. Such non-conforming work requires more investigation as to the scope and root cause of the non-conformity. The incident and its evaluation are **documented on the Non-Conformity Reporting Form.**

6 Determining the Type of Non-Conforming Work Investigation Needed

6.1 When a non-conformity has been discovered, the Principal Investigator must first determine in which manner the non-conformity investigation shall proceed (see flowchart on page 8).

6.1.1 The Principal Investigator must first determine whether or not a potential "**Significant Event**" has occurred. Events that constitute a "Significant Event" are outlined in the OCME Root Cause Analysis Guidelines under Agency Wide Documents in Qualtrax.

6.2 **IF it is determined by the Principal Investigator that a "Significant Event" has occurred, the non-conformity investigation shall then proceed as follows:**

6.3 The Principal Investigator of the non-conformity SHALL 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.

6.3.1 If the Quality Assurance Manager has determined that a "Significant Event" has not occurred, the non-conformity will be returned to the Principal Investigator to carry out a standard non-conformity investigation.

6.3.2 If a "Significant Event" is found to have occurred, the Quality Assurance Manager MUST IMMEDIATELY informs 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. The Quality Assurance Manager will also alert Laboratory upper management of the "Significant Event".

6.3.3 The Root Cause Analysis Officer shall follow the procedures mandated by New York City Legislation. The OCME Root Cause Analysis Guidelines outlines this process.

6.4 **If it is determined by the Principal Investigator that a "Significant Event" has NOT occurred, the non-conformity investigation shall proceed in the following manner:**

6.4.1 If the nature of the non-conforming work can be corrected by following Laboratory Standard Operating Procedures with no impact to the affected case sample(s) and/or case(s) (eg. amplification performed without a positive control, all samples re-amplified) the Principal Investigator shall:

6.4.1.1 Ensure that the error has been corrected by following laboratory standard operating procedures.

6.4.1.2 Document the correction as appropriate (eg. via LIMS on the test batch, via memorandum to file in the LIMS records, via case contacts).

6.4.1.3 A summary email of the non-conforming work incident shall be sent to the analyst(s) to whom the non-conforming work has been attributed, as well as their direct supervisor(s), the Quality Assurance Manager and the relevant Technical Leader with the following information:

6.4.1.3.1 The nature of the detected non-conformity.

6.4.1.3.2 How the non-conformity was detected.

6.4.1.3.3 The cause of the non-conformity. This may require an in-depth Root Cause Analysis of the situation.

6.4.1.3.4 How the non-conformity was resolved (immediate corrections or corrective actions taken to resolve the issue).

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

6.4.1.3.6 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 Principal Investigator, the Quality Assurance Manager, or another designated employee.

6.4.1.3.7 **No Non-Conformity Reporting Form needs to be filled out in such instances.** The Quality Assurance Manager will ensure that the email pertaining to the non-conforming work incident is appropriately filed in the associated analyst(s) electronic non-conforming work folder. This folder is maintained by the Quality Assurance Manager. Supervisors shall track performance issues by maintaining non-conforming work documentation (emails and/or forms) pertaining to their direct reports to ensure that repeated occurrences of similar issues are corrected through counseling, retraining, or other measures appropriate to the situation.

6.4.2 If the nature of the non-conforming work has had an impact on the affected case sample(s) and/or case(s) (eg. statistical relevance of reported results is incorrect but has not had an impact on case proceedings, contaminated extraction negative control renders DNA results from consumed samples unusable), the Principal Investigator shall:

6.4.2.1.1 Determine the relevant 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:

6.4.2.1.2 The nature of the detected non-conformity.

6.4.2.1.3 How the non-conformity was detected.

6.4.2.1.4 The cause of the non-conformity. This will require an in-depth Root Cause Analysis of the situation.

6.4.2.1.5 How the non-conformity was resolved (immediate corrections or corrective actions taken).

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

6.4.2.1.7 All relevant Parties shall be notified of the non-conformity.

6.4.2.1.8 **Note**: Various Root Cause Analysis forms are available for use by the Principal Investigator to aide in performing a root cause analysis. These forms may be found within Qualtrax via the following path: Forms Manual/ Quality Assurance Control Forms/ Control of Non-Conforming Work. Use of these forms is recommended but not required.

6.4.2.1.9 Once the non-conformity investigation is 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. Once the Quality Assurance Manager has reviewed the Non-Conformity, the incident is reviewed and corrections are reviewed by the appropriate Technical Leader.

6.4.2.1.10 If a non-conformity is attributed to a particular analyst or analysts, they must sign the Non-Conformity Reporting Form, as well as their direct supervisor(s). The Quality Assurance Manager will file the nonconforming Work Form in hard copy and electronic format. 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.

6.4.2.1.11 Any corrections or 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.

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

7 Response to Non-Conformities

7.1 If it has been determined by the Principal Investigator, the Quality Assurance Manager and/or the Root Cause Analysis Officer, that a "Significant Event" has not occurred, appropriate corrections may be implemented by the laboratory in order to ensure that the non-conformity does not recur.

7.2 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.

7.3 Based upon the severity of the non-conformity the following may occur:

7.3.1 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.

7.3.2 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.

7.3.3 The Director, Deputy Director(s) and Assistant Directors are notified as soon as practicable when actions to suspend testing are proposed or taken. Additional notifications (accreditation bodies, etc) will be made as needed.

8 Assessing Non-Conformity Trends

8.1 The Quality Assurance Manager assesses the number of Non-Conformity Reporting Forms and related emails on a regular basis in order to ensure that trends pertaining to analyst work performance or equipment/ reagent performance can be identified. Non-Conformity Reporting Forms and related emails are assessed to determine if similar events (such as those in the same area of testing or caused by the same individual) have occurred within a narrow timeframe.

8.2 Laboratory members should email the Quality Assurance/ Quality Control Group when non-conforming work trends pertaining to equipment/ reagents are seen in the laboratory. The QA/QC Group investigates and resolves such non-conforming work and documents it in the QA Incident Folder on the Forensic Biology Main Drive.

8.3 Supervisors are responsible for tracking non-conforming work by maintaining non-conforming work documentation (emails and/or forms) pertaining to their direct reports.

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

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