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 the significance of non-conforming work, performing risk assessment and 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 the same and the consequences of the 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 or realizes that a technical or clerical error that may compromise evidence integrity, accuracy of casework analysis and/or results reported, must address the issue immediately.

2.2 **The first step is to determine the Principal Investigator (PI). See Section 3.**

2.3 The PI is tasked with evaluating and investigating the significance of the non-conforming work. They must ensure that they communicate directly with any Analyst(s) involved in the non-conforming work during the investigation. They must also make notifications to the Analyst(s) involved, their direct Supervisor(s), the Quality Assurance Manager (QAM) and the relevant Technical Leader (TL) as to the outcome of the investigation and any actions taken.

3 The Principal Investigator

3.1 The Principal Investigator is one of the following:

3.1.1 The person who discovered the non-conforming work of another; or

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

3.1.3 Note: The person who discovers the non-conforming work may assign the investigation to the analyst who caused the non-conforming work.

4 Assessing the Non-Conforming Work – CASEWORK STAFF

4.1 Non-conforming work can be of a technical nature relating to the testing of a batch of samples or individual samples. It can also be clerical in nature relating to evidence examination, recorded sample information or reported results.

4.2 Specific actions taken to address non-conforming work shall be directly proportional to the level of risk that the non-conforming work has in affecting samples, cases and/or the reported results. Corrections pertaining to non-conforming work may be documented on the batch worksheets and/or a LIMS deviation. Additionally, depending on the type of non-conforming work, it must be documented via a memorandum/ communication log, Non-Conforming Work Form, or RCA Report.

4.3 To address the different levels of risk, non-conforming work are to be classified by the PI according to the following criteria:

4.3.1 Type I Non-Conformity

4.3.1.1 Definition: Errors that are easily corrected, were discovered in the general course of daily quality system checks and have no significant impact on the affected samples, cases or reported results.

4.3.1.2 Example: Two samples are double loaded into the same STR plate well. The error is easily apparent during STR analysis and is easily fixed by re-loading the samples onto another STR plate.

4.3.1.3 Documentation: Once the PI determines that a Type I non-conformity has occurred, the correction **MUST** be documented via memorandum to be filed in the case record(s), and may also be documented in LIMS on the test batch and/or a LIMS deviation. The PI then verbally informs the Supervisor(s) of the Analyst(s) involved, the Quality Assurance Manager (QAM) and the relevant Technical Leader (TL) of the incident contemporaneously to the notice of the non-conformity.

4.3.2 Type II Non-Conformity

4.3.2.1 Definition: Errors that are easily corrected but were not initially realized in the general course of daily quality system checks. Type II non-conformities have no significant impact on affected samples, cases or reported results. Contamination

events, although detected in the general course of quality system checks, fall under this category of non-conforming work.

4.3.2.2 Example: Voucher number was incorrectly transcribed in case report and the report is issued. Report is easily amended to correct the error. However, the error had no significant impact on the technical results reported. Note: It is not required to correct clerical errors that did not affect reported results (e.g., Victim's name is spelled incorrectly).

4.3.2.3 Documentation: Once the PI has determined that a Type II non-conformity has occurred, the correction **MUST** be documented via the Non-Conforming Work Form to be filed in the case record(s), and may also be documented in LIMS on the test batch and/or a LIMS deviation. The form is signed by the PI, the Analyst(s) involved and the Analyst(s) Supervisor(s). The form is forwarded to the QAM and the relevant TL for review and entry into the Non-Conforming Work Database. When the non-conformity impacts DNA records entered into CODIS, the form is also forwarded to the Casework CODIS Administrator for review.

4.3.3 Type III Non-Conformity

4.3.3.1 Definition: Occurrence of a serious error in the processing or reporting of casework with a substantial likelihood that the error affected the accuracy, reliability and integrity of reported results, evidence examination or analysis. Type III non-conformities may not be easily corrected, may not be discovered in the general course of daily quality system checks, and are determined by QAM and the OCME Root Cause Analysis Officer to have had a significant impact on samples, cases, and reported results.

4.3.3.2 Example: DNA Hit issued containing incorrect information resulting in incorrect law enforcement follow-up.

4.3.3.3 Documentation: Type III non-conformities are events that constitute a "Significant Event" as outlined in the OCME Root Cause Analysis Guidelines under Agency Wide Documents in Qualtrax. Such incidents are documented through an RCA Report by the OCME Root Cause Analysis Officer pursuant to NYC Administrative Code Section 17-207. The event is documented on the Non-Conforming Work Form and is then entered by the QAM into the Non-Conforming Work Database. When the non-conformity impacts DNA records into CODIS, the form is also forwarded to the Casework CODIS Administrator for review The RCA Report is distributed according to OCME procedure and filed in the associated case record(s).

5 Assessing the Non-Conforming Work- QA/QC Staff

5.1 Laboratory members gather quality assurance metrics during daily laboratory work. Such metrics include, but are not limited to; rework, instrument issues, failed controls and detection of exogenous DNA.

5.2 The QA/QC Group reviews this information gathered during daily casework and assesses it for trends. As necessary, the QA/QC Group investigates and resolves such trends. Quality assurance metrics are assessed weekly, monthly, quarterly and yearly.

5.3 Technical problems identified during routine quality control activities, such as instrument performance checks, are not defined as non-conforming work. Such issues are brought to the attention of a Quality Assurance supervisor and are documented on performance check worksheets.

6 Determining the Type of Investigation Needed

6.1 When a non-conformity has been discovered, the PI must first determine the type of non-conforming work that has occurred. If a **Type I or Type II** non-conformity has occurred, the investigation may proceed as outlined in **Section 6.3**. If a **Type III** has occurred, the investigation must proceed as outlined in **Section 6.2.**

6.2 **TYPE III (SIGNIFICANT EVENT)**

6.2.1 If it is determined by the PI that a "Significant Event" may have occurred, the PI SHALL IMMEDIATELY inform the QAM that a non-conformity on a "Significant Event" level may have occurred. The QAM will assess the non-conformity to determine if indeed a "Significant Event" appears to have occurred.

6.2.1.1 If the Quality Assurance Manager determines that a "Significant Event" did not occur, the non-conformity will be returned to the PI to carry out a Type I or Type II non-conformity investigation.

6.2.1.2 If a "Significant Event" appears to have occurred, the QAM MUST IMMEDIATELY inform the OCME Root Cause Analysis Officer of the apparent "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 executive management of the "Significant Event."

6.2.1.3 The Root Cause Analysis Officer shall follow the procedures mandated by New York City Administrative Code Section 17-207. The OCME Root Cause Analysis Guidelines outlines this process.

6.3 **TYPE I or II NON-CONFORMITIES**

6.3.1 If it is determined by the PI or the QAM that a "Significant Event" has NOT occurred, the non-conformity investigation shall proceed in the following manner:

6.3.2 TYPE I NON-CONFORMITY

6.3.3 If the nature of the non-conformity is determined to be a Type I (an error that is easily corrected, caught by daily quality system checks and has no significant impact on samples, cases or reported results), the PI shall:

6.3.3.1 Ensure that the error has been corrected by following laboratory standard operating procedures. Typically, the Customer will not need to be alerted separately as there is no impact on samples, cases or reported results. The Type I non-conformity is documented in the casefile, which the customer will receive upon normal request.

6.3.3.2 The correction may be documented in LIMS on the test batch and/or a LIMS deviation but **MUST** be documented via memorandum to be filed in the case record(s). The memorandum shall contain the following information:

6.3.3.2.1 The date the non-conforming work occurred.

6.3.3.2.2 The affected case numbers.

6.3.3.2.3 The nature of the detected non-conformity.

6.3.3.2.4 The cause of the non-conformity.

6.3.3.2.5 How the non-conformity was resolved.

6.3.3.3 The Analyst(s) involved, their direct Supervisor(s), the QAM and the relevant TL shall be notified verbally by the PI of the non-conforming work incident and any corrections taken. This notification shall be documented on the memorandum to file.

6.3.3.4 The QAM 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.

6.3.4 TYPE II NON-CONFORMITY

6.3.5 If the nature of the non-conformity is determined to be a Type II (an error that is easily corrected, was not necessarily caught by daily quality system checks, and has no significant impact on samples, cases or reported results), the PI shall:

6.3.5.1 Ensure that the error has been corrected by following laboratory standard operating procedures. The Customer will be contacted as necessary.

6.3.5.2 The correction **MUST** be documented via the Non-Conforming Work Form to be filed in the case record(s), and may also be documented in LIMS on the test batch and/or a LIMS deviation. The form shall contain the following information:

6.3.5.2.1 The date the non-conforming work occurred.

6.3.5.2.2 The date the non-conforming work was detected.

6.3.5.2.3 The affected case numbers.

6.3.5.2.4 The nature of the detected non-conformity.

6.3.5.2.5 How the non-conformity was detected.

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

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

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

6.3.5.3 Various Root Cause Analysis forms are available for use by the Principal Investigator to aid 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.

6.3.5.4 Once the non-conformity investigation is completed and the Non-Conformity Reporting Form has been filled out, the form must be given to the Analyst(s) involved and their direct Supervisor(s) for review and signing. The form is then forwarded to the QAM for review.

6.3.5.4.1 The QAM may request further investigation into the non-conformity. Further investigation may be performed by the PI, the QAM, or another designated employee.

6.3.5.4.2 Once the QAM has reviewed the Non-Conformity, the incident and corrections are reviewed by the appropriate Technical Leader.

6.3.5.4.3 If the non-conformity affects the entry of DNA records into CODIS, the form will also be reviewed by the Casework CODIS Administrator.

6.3.5.5 Following the TL review and the Casework CODIS Administrator (if applicable) the form is filed in the case record(s). The QAM will log the non-conformity in the Non-Conforming Work database.

7 Response to Non-Conformities

7.1 If the PI, the QAM and/or the Root Cause Analysis Officer determines that a "Significant Event" has not occurred, appropriate corrections are implemented in order to ensure that the non-conformity is corrected and does not recur.

7.2 If there is a Significant event, after the Root Cause Analysis Committee issues the report concerning the "Significant Event," all Committee recommendations concerning corrective actions must be implemented once the relevant TL has approved the recommendations, to ensure the non-conformity is corrected and does not recur.

7.3 If the initial correction(s) (Type I and II non-conformities) or corrective action(s) (Type III non-conformities) fail to correct the problem, the issue must be referred to the Quality Assurance Manager for further investigation.

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

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

7.4.2 The mtDNA Technical Leader has the authority to suspend mitochondrial analytical operations for the Department or individual(s) until such time as the quality issue is resolved through corrective action.

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

7.4.4 The Director, Deputy Director(s) and Assistant Directors are notified by the relevant Technical Leader as soon as practicable when actions to suspend testing are proposed or taken. Additional notifications (OCME executive staff, accreditation bodies, etc.) are made as needed. C

8 Assessing Non-Conformity Trends

8.1 The QAM assesses the number of Non-Conformity Reporting Forms on a regular basis. Analyst work performance or general casework trends are assessed quarterly and yearly.

8.2 Supervisors are responsible for tracking non-conforming work pertaining to their direct reports. Non-conforming work must be discussed with direct reports periodically and during yearly performance evaluations. Should supervisors detect trends, they shall contact the QAM and/ or the relevant TL for follow-up as soon as practicable.

8.3 The QAM will determine if any trends pose additional concerns to the Management System of the laboratory.

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Status:Published | Document ID: 1191

DATE EFFECTIVE	APPROVED BY	PAGE
11/17/2020	Quality Assurance Manager	9 OF 9