Control of Non-Conforming Work		
Status: Published		Document ID: 1191
DATE EFFECTIVE 10/24/2022	APPROVED BY Quality Assurance Manager	PAGE 1 OF 8

Control of Non-Conforming Work

1 Definitions, Guiding Principles, and Scope

1.1 A Non-Conformity (defined by the 2020 FBI Quality Assurance Standards) is "not meeting, implementing, maintaining, or complying with one or more of the requirements of these standards or a laboratory's procedures, policies or other quality system documents". Therefore, non-conformities occur when a standard of the FBI Quality Assurance Standard is not met during an FBI QAS audit as well as when technical work does not meet the Department of Forensic Biology's stated standards, either with respect to mode of execution or outcome. Non-conforming work events may also occur related to CODIS profile submissions.

1.2 The non-conformity definition is echoed in ISO 17025: 2017, which states in standard 7.10.1 that "the laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer."

1.3 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. There are multiple ways in which non-conforming work can be addressed and documented. Some investigations into non-conforming events will involve root cause analysis. Root cause analysis is the process of discovering the "why" something occurred so that appropriate solutions can be identified.

1.4 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 technical or clerical in nature relating to evidence examination, recorded sample information or reported results.

1.5 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.

1.6 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.

1.7 The Principal Investigator is the person who discovered the non-conforming work of another; or who self discovers his or her own non-conforming work. The Principal Investigator performs the investigation into the non-conformity.

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

1.7.2 If the assignment of the PI is unclear, consult the Quality Assurance Manager (QAM).

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 initiate the investigation.

2.2 Any questions regarding the identification of non-conformities should be addressed to the Quality Assurance Manager.

2.3 Once it is determined that non-conforming work has occurred, the Principal Investigator (PI) must be determined.

3 Investigating Non-Conforming Work – CASEWORK STAFF

3.1 The PI is responsible for evaluating and investigating the significance of the non- conforming work.

3.1.1 They must communicate directly with any Analyst(s)/ Supervisor(s)/ Manager(s) involved in the non-conforming work during the investigation.

3.1.2 They must also make notifications to the Analyst(s) involved, their direct Supervisor(s), the Quality Assurance Manager and the relevant Technical Leader (TL) as to the outcome of the investigation and any actions taken.

3.2 Once non-conforming work has been identified, the principal investigator needs to assess the non-conformance including the following points and must determine the type of non-conforming work that has occurred:

3.2.1 What part of the management system was not conformed with?

3.2.1.1 The PI should read the section the manual pertaining to the incident and determine whether the actions involved in the potential non-conformity was a required action (ie. indicated by “must/shall” language in the manual) or a guideline/recommendation (ie. “should/could/may” language)? If the manual section language is unclear indicating an action that “should/may/could” be done, a variance from this instruction is not a non-conformance.

3.2.2 Why did the non-conformance occur? Is further testing needed to identify the root cause of the non-conformance?

3.2.3 Evaluate the significance of the non-conforming work and any level of risk resulting from the non-conformance, including an impact analysis on previous results.

3.2.3.1 The PI needs to determine what impact the non-conformance had on cases involved in the said incident and what potential impact the non-conformity can have on future cases.

3.2.3.2 The PI could suggest improvements to the management system which will minimize risk of the non-conformity happening again.

3.2.4 The PI will ensure that the error has been corrected by following laboratory standard operating procedures.

3.2.5 Any questions that arise during the investigation or when documenting non- conformities should be addressed to the principal investigator's direct supervisor, manager or the Quality Assurance Manager.

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

3.3.1 Type I Non-Conformity

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

3.3.1.2 Example: (a) A profile that was uploaded into CODIS with the incorrect allele assignment. The error is caught by the CODIS team (after upload) and they contact the analyst to create a profile modification. (b) 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.

3.3.1.3 Documentation: Once the PI determines that a Type I non-conformity has occurred, the correction **MUST** be documented in one of the following ways: in LIMS on the test batch, a LIMS deviation, or via memorandum to be filed in the case record(s).

3.3.1.3.1 The memorandum shall contain the following information:

- The date the non-conforming work occurred.
- The affected case numbers.
- The nature of the detected non-conformity.
- The cause of the non-conformity.
- How the non-conformity was resolved.
- Documentation via LIMS test batches and/or LIMS deviations:

Note: Some standard operating procedures describe specific actions to be taken in order to resolve certain deviations from quality assurance/quality control requirements (such as failed control samples, electrophoresis failures, failure to meet calibration criteria, CODIS profile modifications, LIMS recognition errors for chain of custody). If prescribed actions are taken and the problem is successfully resolved and documented on the appropriate batch paperwork (if the entire batch is affected), deviation, failure report, or profile modification worksheet, then the non-conforming process described is not required. Documentation of the problem(s) and resolution must be retained appropriately in the LIMS as well as the relevant case records as required by the applicable operational procedure.

3.3.1.4 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 documentation of the non-conformity. If the non-conformity affects the entry of DNA records into CODIS, the CODIS administrator must also be verbally informed. This notification should occur regardless of how the non-conforming work event is documented.

3.3.1.5 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.

3.3.1.6 The Customer will be contacted as necessary. 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.

3.3.2 Type II Non-Conformity

3.3.2.1 Definition: Errors that are easily corrected but were not initially realized in the general course of daily quality system checks and those results were reported. 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.

3.3.2.2 Example: (a) A profile is uploaded into CODIS with the incorrect allele assignments affecting the CODIS index (LDIS, SDIS, NDIS). A report needs to be generated to reflect the change of index. (b) Suspect sample was typed in Fusion and had results at 21 loci. The issued report had a typographical error and indicated that a 22 locus profile was obtained. The 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).

3.3.2.3 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.

3.3.2.3.1 The form shall contain the following information:

- The date the non-conforming work occurred.
- The date the non-conforming work was detected.
- The affected case numbers.
- The nature of the detected non-conformity.
- How the non-conformity was detected.
- The cause of the non-conformity. This will require an in-depth Root Cause Analysis of the situation.
- How the non-conformity was resolved (immediate corrections or corrective actions taken).
- Recommendations to prevent the non-conformity from reoccurring.

3.3.2.4 Various Root Cause Analysis forms are available for use by the Principal Investigator to aid in performing a root cause analysis. Such forms include the Root Cause Analysis Worksheet- Chronological Map, Root Cause Analysis- 5 Whys form and the Root Cause Analysis- Fishbone Diagram form. Use of these forms is recommended but not required.

3.3.2.5 Once the non-conformity investigation is completed and the Non-Conforming Work Form has been filled out, the form is signed by the PI and 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. The form may also be reviewed by the QAM prior to signatures/acknowledgements (ie. digital recognition via email) being obtained.

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

3.3.2.7 Once the QAM has reviewed the non-conformity, the incident and corrections are reviewed by the appropriate Technical Leader.

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

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

3.3.2.10 The Customer will be contacted as necessary.

3.3.3 Type III Non-Conformity

3.3.3.1 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. 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.

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

3.3.3.3 Documentation: Such incidents are documented through an RCA Report by the OCME Root Cause Analysis Officer pursuant to NYC Administrative Code Section 17-207. The OCME Root Cause Analysis Guidelines outlines this process. The event may also be documented on the Non-Conforming Work Form.

3.3.3.4 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.

3.3.3.4.1 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.

3.3.3.4.2 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 may begin to document the non-conformity on the Non-Conforming Work Form. Refer to Section **3.3.2**. for documentation process. The Quality Assurance Manager will also alert Laboratory executive management of the "Significant Event."

3.3.3.4.2.1 The Root Cause Analysis Officer shall follow the procedures mandated by New York City Administrative Code Section 17-207.

3.3.3.5 The QAM will log the non-conformity in the Non-Conforming Work database.

3.3.3.6 When the non-conformity impacts DNA records into CODIS, the form is also forwarded to the Casework CODIS Administrator for review.

3.3.3.7 The RCA Report is distributed according to OCME procedure and filed in the associated case record(s).

3.3.3.8 The Customer will be contacted as appropriate.

4 Evaluating the Non-Conforming Work- QA/QC Staff

4.1 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.

4.2 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.

4.3 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.

5 Response to Non-Conformities

5.1 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.

5.2 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.

5.3 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.

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

5.4.1 The nuclear 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.

5.4.2 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.

5.4.3 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.

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

5.4.5 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.

6 Assessing Non-Conformity Trends

6.1 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.

6.2 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.

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