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. The evaluation of the potential for the non-conforming work to recur is completed through calculating a Overall Risk Mitigation Score via the risk mitigation assessment which occurs during the non-conforming work documentation. Based on the Overall Risk Mitigation Score, there are two possibilities:

1.5.1 An Overall Risk Mitigation Score less than 5 indicates that there is a low risk of recurrence and/or there is no doubt of the laboratory's conformance with its own management system. In these situations, the non-conformance **requires Correction only.** The non-conforming work must be documented via the Non-Conforming Work Workflow in Qualtrax

1.5.2 If the Overall Risk Mitigation Score is greater than or equal to 5, this indicates that there is a high risk of recurrence of the non-conforming work and/or there is doubt of the laboratory's conformance with its own management system, and **Corrective Action is employed**. Corrective Action is also employed in response to audit and assessment findings or non-

conformances. The non-conforming work must be documented via a Non-Conforming Work Workflow in Qualtrax which leads to a Corrective Action Workflow to document corrective actions taken.

1.5.2.1 Corrective Actions require follow-up by the Quality Assurance Manager to ensure that the actions taken were appropriate to prevent the non-conformity. These follow up actions will be documented through the Corrective Action Workflow in Qualtrax.

1.6 This procedure describes the Department's process for evaluating the significance of non-conforming work performing risk assessment and root cause analysis and taking appropriate follow up actions.

1.7 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.

2 Identifying Non-Conforming Work

2.1 Any member of staff who discovers or realizes that a technical or clerical error has occurred that may compromise evidence integrity, accuracy of casework analysis and/or results reported, must initiate the non-conforming work investigation.

2.1.1.1 Note: If the relevant manual section indicates a required action (i.e. indicated by "must/shall" language in the manual) that was not followed, then a non-conformance has occurred. If the relevant manual section indicates only a guideline/recommendation (i.e. "should/could/may" language) then a non-conformance has not occurred.

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

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

2.2.1 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.

2.2.2 The person who discovers the non-conforming work may assign the investigation to the analyst who caused the non-conforming work, whereby they become the Principal Investigator.

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

3 Investigating Non-Conforming Work

3.1 The PI is responsible for evaluating and investigating the significance of the non-conforming work. Such evaluation may include:

3.1.1 Why did the non-conformance occur?

3.1.2 Is further testing needed to identify the root cause of the non-conformance?

3.2 Non-Conforming work will be documented via the Non-Conforming Work Workflow in Qualtrax. (see Section 5).

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

3.4 The PI must make notifications to the Analyst(s) involved and their direct Supervisor(s) as to the outcome of the investigation and any actions taken. Notifications should be made to the Quality Assurance Manager and the Technical leader through the Non-Conforming Work Workflow in Qualtrax.

3.4.1 Note: If the issue is severe (it might constitute a Type III non-conformance or involve multiple reported cases, etc.), the principal investigator must involve the Quality Assurance Manager and Technical Leader in the investigation as soon as possible.

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

3.5 The PI must 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 obtained/reported.

3.5.1 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.

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

3.6 The PI will ensure that the non-conformance is/has been corrected by following laboratory standard operating procedures.

3.7 If the non-conformance requires the recall of previously reported data, the customer shall be notified, and this notification will be documented in the case communication log(s) of the affected case(s).

4 Determining the Level of Non-conforming work

4.1 The non-conforming work will be classified by the PI according to the following criteria:

4.1.1 Type I Non-Conformity

4.1.1.1 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.

4.1.1.1.1 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..

4.1.1.2 CODIS Type I non-conformity definition: CODIS errors are considered Type I non-conformities if the error does not impact external customers.

4.1.1.2.1 Example: A profile that was uploaded into CODIS with the incorrect allele assignment. The error is caught by the CODIS team (after upload, but before any DNA hits were generated with external agencies) and the CODIS team contacts the analyst to create a profile modification.

4.1.1.3 **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 NTC samples for Quantifiler Trio, electrophoresis failures due to instrument errors, and LIMS recognition errors for chain of custody). If the actions taken align with standard operations for troubleshooting and are documented in the appropriate batch paperwork, LIMS deviation, or STR Failure report, the non-conforming work process is not required.

4.1.1.4 If the non-conforming work event is classified as Type I, go to Section 5 for Documentation of Non-conforming work.

4.1.2 Type II Non-Conformity

4.1.2.1 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 will be considered a Type II event. In addition, if an error results in the complete loss of sample, this falls into the Type II non-conformity category.

4.1.2.1.1 Example: Likelihood ratio was reported for a suspect comparison. The exponential notation indicates 10e12 however the written likelihood explanation indicates 1 million, therefore conflicting with the exponential notation, making the actual likelihood ratio unknown to the customer. The report is easily amended to correct the error, however the error had no significant impact on the technical results reported.

4.1.2.2 Note: It is not required to correct clerical errors that did not affect reported results (e.g., Victim's name is spelled incorrectly.) If this correction is requested from an ADA, the clerical error can be corrected and an amended report issued, however no non-conforming work memo is needed.

4.1.2.3 CODIS Type II non conformity example: A profile is uploaded into CODIS with the incorrect allele assignment which affected the CODIS index (profile was uploaded to NDIS, when it was only eligible for LDIS). A report needs to be generated to reflect the change of index.

4.1.2.4 If the non-conforming work event is classified as Type II, go to Section 5 for Documentation of Non-conforming work.

4.1.3 Type III Non-Conformity

4.1.3.1 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.

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

4.1.3.2 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 should also be documented through the Non-Conforming Work Workflow in Qualtrax.

4.1.3.3 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.

4.1.3.4 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.

4.1.3.5 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 Workflow in Qualtrax . Refer to Section 5 for documentation process. The Quality Assurance Manager will also alert Laboratory executive management of the "Significant Event."

4.1.3.6 The Root Cause Analysis Officer shall follow the procedures mandated by New York City Administrative Code Section 17-207.When the non-conformity impacts DNA records into CODIS, the Workflow is also forwarded to the Casework CODIS Administrator for review.

4.1.3.7 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.

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

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

4.2.1 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.

4.2.2 As needed, 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.

4.2.3 As needed, 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.

4.2.4 As needed, 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.

4.2.5 As needed, 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.

4.2.5.1 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.

4.2.6 As needed, the CODIS Administrator has the authority to suspend an analyst's or laboratory's participation in CODIS

5 Documentation

5.1 All non-conforming work events will be documented and processed using the Non-Conforming Work workflow in Qualtrax. Through this workflow, analysts will document their investigation, including the following:

5.1.1 Principal Investigator

5.1.2 case numbers affected dates of occurrence

5.1.3 dates of discovery

5.1.4 description of non-conformity

5.1.5 level of non-conforming work

5.1.6 category of non-conformity

5.1.7 correction(s) made to rectify the non-conformity

5.1.8 analyst(s) involved and their supervisor (as applicable)

5.1.9 a root cause analysis summary

5.1.10 risk mitigation evaluation (see 5.1.12 below) including whether previous cases need to be reevaluated or work halted or recalled, and actions taken to prevent future non-conformities

5.1.11 Root Cause Analysis

5.1.11.1 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.

5.1.12 An overall Risk Mitigation Score will be determined to help identify when corrective action and further monitoring is required.

5.1.12.1 A Risk score is determined by assessing the chance of reoccurrence and the severity of the event using the grid below:

Risk

chance of reoccurrence	Severity: High	Severity: Medium	Severity: Low
High	10	8	6
Medium	8	6	4
low	6	4	2

5.1.12.2 A Mitigation score is determined by assessing the ability to detect the non-conformance and the ability to fix the non-conformance using the grid below:

Mitigation			
	Ability to Fix		
Ability to Detect	Easy	Moderate	Hard
Easy	6	5	4
Moderate	5	4	3
Hard	4	3	2

5.1.12.3 The Risk Score minus the Mitigation Score equals the Overall Risk Mitigation score.

5.1.12.3.1 If the Overall Risk Mitigation Score is less than 5, then corrections alone can be implemented to remediate the non-conformance.

5.1.12.3.2 If the Overall Risk Mitigation Score is 5 or greater, the Corrective Action is implemented to remediate the non-conformance. The Corrective Action process is documented in the Corrective Action workflow in Qualtrax which will follow the Non-Conforming work workflow.

5.1.13 Once an investigation is completed by the PI, the documentation is sent to the Quality Assurance Manager and appropriate technical leaders for review and determination of further actions.

5.1.13.1 The CODIS Manager will be notified if results have an impact on CODIS.

6 Corrections and Corrective Action

6.1 **Corrections** are those actions taken to identify and correct a nonconformity, where the Overall Risk Mitigation determined for a non-conformance is less than 5. Corrections may also be documented on batch worksheets and/or LIMS deviations.

6.2 **Corrective actions** are those actions taken to identify, correct, and/or prevent reoccurrence of a non-conformity, when possible, with a Overall Risk Mitigation of greater than or equal to 5.

6.2.1 Corrective actions can be implemented in response to certain nonconforming work events. When corrective action is employed, a plan is established with a set timeframe. The plan will be approved by the technical leader prior to implementation.

6.2.2 Corrective actions are documented using the Corrective Action Workflow in Qualtrax which opens following the Non-Conforming Work Workflow in Qualtrax. Within the workflow, the following is defined and documented:

6.2.2.1 Personnel responsible for implementing the corrective action

6.2.2.2 Information on the corrective action itself

6.2.2.3 The timeframe for follow up on the corrective action

6.2.2.4 What monitoring actions will be taken at the designated time.

6.3 If the initial correction(s) or corrective action(s) fail to correct the problem, the issue must be referred to the Quality Assurance Manager for further investigation.

7 Evaluating Non-Conforming Work Via QA/QC Group

7.1 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.

7.2 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.

7.3 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 in performance check records.

8 Quality Assurance Manager Assessment of 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.