FORENSIC TOXICOLOGY LABORATORY
OFFICE OF THE CHIEF MEDICAL EXAMINER
CITY OF NEW YORK

NON-CONFORMING WORK PROCEDURE

PRINCIPLE

The scope is to identify and address non-conforming work that may occur during the course of toxicological analysis.

Non-conforming work is not complying with the laboratory standard operating procedures that could possibly affect the reliability of the final result. Technical problems and or difficulties can arise in all phases of the laboratory operations. It requires immediate corrective action to prevent future occurrences.

IDENTIFYING NON-CONFORMITY WORK

Any staff member who discovers a technical, analytical or clerical error that may compromise the evidence integrity and/or the accuracy of results must address the issue immediately. The analyst or supervisor who discovers the non-conformity becomes the principal investigator of the non-conforming work. The principal investigator will address and assess the significance of the non-conforming work and initiates and carries to completion the investigation. The following are examples of non-conforming work. It is impossible and impractical to list each potential problem; therefore this is a topic that will be considered in general terms.

Technical issues related to testing of a batch of samples (e.g., sample contamination) are reported to a supervisor. The issue will be documented on the batch sequence list.

Technical problems related to an individual case (e.g., possible sample mix-up) are reported to a supervisor and the analyst who handled the samples via email and documented in the case file.

Analytical errors affecting final results (e.g., errors in conclusion drawn from analytical results, errors in data review) are reported to a supervisor and the analyst whose work may have been affected via email and documented in the case file.

Clerical errors related to case work (e.g., incorrect recording of analytical results) are reported to a supervisor and the analyst whose work may have been affected via email and documented in the case file.

RECORDING AND INVESTIGATING THE NON–CONFORMITY

Non-conforming work must be thoroughly investigated. A root cause of the problem must be performed by the principal investigator.

The principal investigator must investigate the issue and completes a non-conformity reporting form. The investigation will entail a thorough review of the issue. Suitable corrective action should be included in finding the root cause and rectifying the problem. The non-conformity reporting form is reviewed by the section supervisor and the QA Manager.

Some non-conforming work (e.g., sample mix-up and sample contamination) can be easily corrected by reanalysis of the sample in question. The error and the next step must be documented on the batch sequence list. Once the next step has been completed, it will be compared to the first set of data and a conclusion drawn. This will be included in the case file and the non-conformity reporting form.

When a non-conforming work has been discovered, the investigation shall proceed in one or two ways. The principal investigator will determine in which manner the investigation will proceed. The two routes are as follows:

Determine whether or not a significant event has occurred as indicated on Chapter 2 of title 17 of the administrative code of the city of New York, section 17-207. Significant events may include:

> Intentional fabrication of work product, evidence examination, analysis or test results.
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> Significant error or errors 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.
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> Failure of an employee to follow protocol 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.
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> Statements made in the course of testimony by which an employee significantly misrepresents or misstates her or his education, experience, training or qualifications, or the reported results of any evidence examination or analysis.

If the principal investigator determines that a significant event has occurred, then the investigation of the non-conforming work must proceed as follows:

> The principal investigator of the non-conforming work must immediately inform the section supervisor, Quality Assurance Manager, Director, Assistant Director and Chief of Labs that a non-conformity that rises to a significant event level has occurred. The Quality Assurance Manager will assess the non-conformity to determine if indeed a significant event has occurred.

If a significant event is found to have occurred, the Quality Assurance Manager must immediately inform the Office of Chief Medical Examiner Root Cause Analysis Officer of the significant event and the principal investigator shall begin to document the issue on the non-conformity reporting form. The Root Cause Analysis Officer shall follow the procedures mandated by New York City legislation and convene a Root Cause Analysis Committee to investigate the significant event.

The Root Cause Analysis Officer shall ensure that the Root Cause Analysis Committee of the Office of Chief Medical Examiner releases a copy of the final report to the following entities:

Forensic Toxicology Laboratory customers

NYC Mayor's Office

NYC Council

NYS Commission on Forensic Science

American Board of Forensic Toxicology (ABFT)

Prosecutor office (as needed)

If the Quality Assurance Manager determines that a significant event has not occurred, the principal investigator will document the non-conformity in the case file and a copy of the non-conformity reporting form will be retained by the QA/QC group.

If the principal investigator determines that a significant event has not occurred, then the investigation of the non-conforming work will proceed as follows:

A non-conformity reporting form shall be completed. The principal investigator must determine the causes and contributing factors and document the results of the investigation on the non-conformity reporting form. Factors to be investigated include, but are not limited, to the following:

The nature of the detected non-conformity.

How the non-conformity was detected.

The cause of the non-conformity. This may require an in-depth root cause analysis of the issue.

How was it resolved and immediate corrective action(s).

Preventive measures for future reoccurring.

Who was notified of the non-conforming work.

Once the non-conforming work investigation has been completed and the non-conformity reporting form has been filled out, the form must be submitted to the Quality Assurance Manager for review.

The Quality Assurance Manager maintains the right to request further investigation into the non-conformity on as needed basis. Further investigation may be performed by Quality Manager or designated employee. QA Manager shall alert the Assistant Director and Director as needed. QA Manager, Assistant Director and Director have the right to suspend toxicological analysis as needed.

CORRECTIVE ACTION

The corrective action process shall include a one on one meeting with staff member(s) involved in the non-conforming work, retraining, monitoring and internal audits of the laboratory procedures to ensure that the operation is conforming to all of the requirements of the laboratory standard operating procedures and accrediting body guidelines.

Corrective actions taken to rectify the non-conforming work will be documented on the non-conforming work form.

REVISION HISTORY

Ver.08.18.2015	Implemented