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# ROOT CAUSE ANALYSIS REPORT
# RCA# 2017-01
# May 30, 2017

## Executive Summary

On February 27, 2017, the Office of the Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error relating to the postmortem testing process of the Forensic Toxicology Laboratory (Forensic Toxicology). This error resulted in an incorrect result reported by Forensic Toxicology. After careful review, the QA Director determined that this was a "significant event" within the meaning of Title 17, Chapter 2, Section 17-207 of the Administrative Code of the City of New York. On May 4, 2017, OCME assembled a Root Cause Analysis (RCA) Committee to identify the causal factors and corrective actions to be taken for this event, which was identified as RCA# 2017-01.

The RCA Committee met and reviewed the Forensic Toxicology Laboratory's postmortem testing process and identified areas for improvement. The root cause for this event was identified as a data entry error which incorrectly associated a laboratory specimen to the incorrect case. As discussed below, the RCA Committee recommends that the laboratory enhance their ability to detect and prevent this type of error by reinforcing existing quality control steps, developing standard operating procedures for clerical staff, and improving workload distribution for directors who are managing critical laboratory functions alone. As discussed below, the Committee also recommends that the laboratory consider utilizing technology to reduce manual data entry and to automatically generate laboratory reports.

## Background

The primary mission of the OCME Forensic Toxicology Laboratory includes conducting post mortem analysis to determine the absence or presence of drugs and their metabolites, or other toxic substances in human body fluids and tissues. Results of Forensic Toxicology testing are used by medical examiners to help determine cause and manner of death.

After the medical examiner completes an autopsy, samples may be collected and submitted to Forensic Toxicology for testing. The samples are received and accessioned by laboratory staff. Analysts will then prepare the samples to be tested, type the sequence list (sample list), load the sample vials onto the instrument, and test the samples. Results are then processed utilizing software and submitted to directors for review and approval. Following director approval, the clerical staff will draft the laboratory report and lab directors will review the complete case file and results. After the report is signed out, the clerical staff will perform a final administrative review before uploading the report to the Case Management System (CMS).

See Appendix A for a diagram of the workflow.

**Event Description**
On January 5, 2017, a medical examiner case was transported to the Queens mortuary. The case involved an elderly man found deceased in his locked apartment.

On January 6, 2017, a medical examiner performed the autopsy and submitted decomposition fluid, liver and vitreous humour samples to Forensic Toxicology for testing. Three days later, the laboratory received and accessioned the samples.

On January 12, 2017, the laboratory began testing the samples. While typing the sequence list for volatile analysis, an analyst unintentionally associated a bile specimen belonging to another case with this case.

On February 13, 2017, the laboratory completed testing and issued a laboratory report. The laboratory report included results for decomposition fluid, bile and vitreous humour. Upon receipt of the laboratory report, the medical examiner emailed the laboratory and inquired about the significance of the bile result.

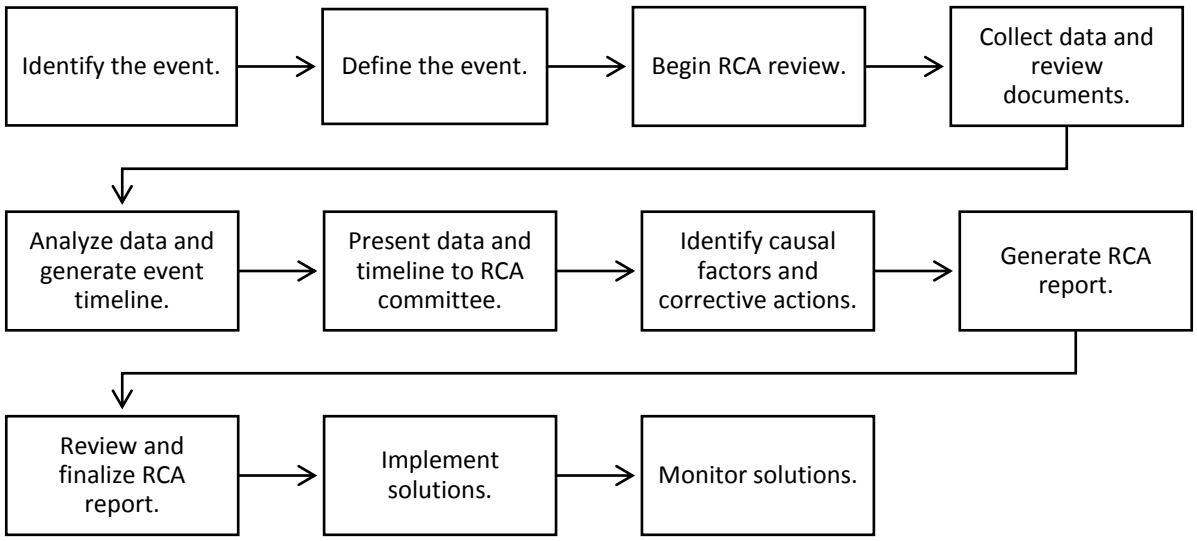
On February 14, 2017, laboratory staff reviewed the case and discovered that a bile specimen was not received by the laboratory and should not have been reported. The laboratory notified the medical examiner of the error and amended the Forensic Toxicology report the next day. The medical examiner confirmed that there was no impact to the case.

See Appendix B for a detailed chronology of events.

**Composition of RCA Committee**
The RCA Committee is a multidisciplinary team of professionals assembled in accordance with criteria defined by Title 17, Chapter 2, Section 17-207 of the City's Administrative Code. The RCA committee includes OCME employees and an external expert who serves in a medical or scientific research field. The members of this RCA committee include the following:

- The root cause analysis officer.
- A laboratory employee who is knowledgeable in the area relating to the event.
- A member of the OCME executive management.
- Two employees from OCME departments that are not implicated by the event.
- An outside expert with risk management experience in the medical field.

**OCME Root Cause Analysis Process**
Root Cause Analysis (RCA) is a structured methodology used to study and learn from events. The goal of the RCA is to understand what happened, identify why it happened and recommend solutions to prevent recurrence. The process used is as follows:




**Review of Remedial Actions Taken By Forensic Toxicology**

Following a review of the Forensic Toxicology postmortem workflow and the event timeline, the RCA committee reviewed the immediate remedial actions taken by the laboratory after being informed of the error. The actions taken are listed below:

- Forensic Toxicology immediately notified the medical examiner of the error and amended the laboratory report.
- The laboratory conducted an investigation as part of its nonconformity management process.
- A retrospective study was conducted to determine if similar data entry errors occurred when entering the sequence lists for volatile analysis. The review included 205 sequence lists entered between October 2016 and April 2017. Additional data entry errors were not found.
- A second retrospective study was conducted to verify the accuracy of the Forensic Toxicology reports. This review included 723 reports generated between October 2016 and March 2017. Additional data entry errors were not found.

The RCA committee found the actions and retrospective studies taken by the laboratory to be appropriate.

**Causes and Contributing Factors**

The RCA committee further examined the workflow and employed cause and effect analysis to identify causes and contributing factors for incorrectly associating the bile sample to this case. Using this methodology, the RCA committee identified the following causal factors:

1. *Analyst 1 unintentionally associated a bile specimen to the case while typing the sequence list and did not catch the error during self check.*

   Evidence: The RCA committee reviewed the laboratory's workflow and the process used to enter a sequence list for volatile analysis on the head space sampler. In addition, the Root Cause Analysis officer reviewed the standard operating procedure describing this workflow.

   During the review of the lab's process, the RCA committee learned that after sample preparation, two analysts are involved in setting up the analysis. Analyst 1 enters the sequence list (the list of samples to be tested) and loads the sample vials onto the appropriate autosampler positions. Analyst 1 then verifies that the correct sample vials were loaded onto the correct autosampler positions as indicated on the sequence list. Analyst 2 is then called to double check and verify the vials and vial placement against the sequence list.

   The committee noted that entering a sequence list involved significant manual data entry. A sequence list may include between 50 – 100 samples. If 60 samples are to be tested, then the analyst would need to type 60 samples names, resulting in 60 lines of text. The "sample name" that is typed into the sequence list includes the laboratory number, the aliquot number, the specimen source, and the dilution. In this case, the sequence list included 81 samples resulting in 81 lines of typed text.

   During an interview, Analyst 1 stated that he "may have been rushing a little" so that he could continue with other tasks. Rushing is known to contribute to errors, and in this case, may have contributed to the analyst making the data entry error and not catching the error during verification and sample unloading. The RCA committee discussed the analyst's past performance and the workload volume. No issues with the analyst's past performance were found and the workload volume was considered typical for the day.

   Manual data entry is a time consuming task that is prone to human error. The manual data entry involved in typing the sequence list and the rushing of the analyst were determined to be two of the root causes which led to the bile specimen being incorrectly associated with the case and Analyst 1 not identifying the data entry error during verification.

2. *Analyst 2 did not identify the data entry error during double check due to a slip.*

   Evidence: After Analyst 1 has typed the sequence, loaded the samples, and checked their work, Analyst 2 is responsible for performing a double check and verifying that the vials and vial placement match the sequence list. This type of double checking is known as an "independent double check" because Analyst 2 independently checks Analyst 1's work.

   The committee determined that the data entry error was likely missed by Analyst 2 due to a slip. A slip is a classification of human error which is defined as an action that is not carried out as intended. Slips usually occur when an individual is familiar with the task and can perform it without much conscious attention resulting in "auto processing". In

this case, the slip occurred because Analyst 2 was an experienced analyst who missed the data entry error while performing a manual inspection. In addition, the analyst did not report any distractions or unusual circumstances that may have contributed to the oversight. The RCA committee also discussed Analyst 2's past performance and the workload volume. No issues with the analyst's past performance were found and the workload volume was considered typical for the day.

The RCA committee noted that the laboratory's standard operating procedure did not describe the double check procedure or how it should be performed. Also, a review of best practices in healthcare indicated that double checking may be implemented in different ways, some more effective than others. According to research, there are more effective double checking procedures than the independent double check procedure used by the laboratory. This is explained in more detail in the "Corrective Action Plan" section below.

The failure to catch the error during the double check process was identified as a root cause which resulted in the incorrect association of the bile specimen to the case.

*3. The assistant director was managing an increased workload.*

Evidence: After the samples were tested, the incorrectly associated bile specimen should have been identified during the sequence approval and case review steps. During sequence approval, the director reviews the sequence for accuracy before it is added to the case file. During case review, the director reviews the results and case history before signing the report. Both steps are performed by either one of the two assistant directors or the laboratory director.

The committee learned that during the week of February 13, 2017, both the laboratory director and an assistant director were off-site attending different meetings. This left one assistant director to manage multiple responsibilities in their absence for one week. These tasks included scheduling tests, approving sequence lists, reviewing cases, and signing out reports. At the time the error occurred, the laboratory did not have other personnel trained that could assist with any of these tasks. It was determined that the increased responsibilities and workload contributed to the assistant director missing the error.

*4. Clerical staff had little experience drafting and reviewing Forensic Toxicology reports.*

Evidence: A review of the workflow indicated that there were two opportunities for clerical staff to catch the error. The error should have been caught during the drafting of the report and during the final administrative review before the report was uploaded to CMS. The Forensic Toxicology report has a "Specimens Received" and a "Results" section. Clerical staff should have noted the discrepancy between the submitted specimens and the reported results.

The RCA committee learned that the Forensic Toxicology clerical unit is staffed by two individuals. Beginning the week the error occurred, the senior member of the clerical team was on medical leave. In order to make sure that the laboratory had sufficient coverage, a member from the Forensic Biology administrative unit was assigned to support the Forensic Toxicology clerical unit. The staff member from the Forensic Biology administrative unit was trained for three days on how to review Forensic Toxicology reports and how to upload reports to CMS. Training primarily consisted of observing how the work was done and then performing the work herself. The committee noted that Forensic Toxicology did not have any checklists or written standard operating procedures for clerical staff to refer to.

The RCA committee also discussed how report drafts are generated. The committee learned that laboratory reports are not automatically generated by the laboratory information management system (LIMS). Clerical staff must review and type the report based on the information written on the Case Record Sheet. The Case Record Sheet is a paper document which analysts use to record all tests completed for a case. In general, 400-500 reports are manually typed by the Forensic Toxicology clerical team every month.

As stated earlier, manual data entry is known to be a time consuming task that is prone to human error. The manual data entry required to draft reports, the lack of written standard operating procedures for clerical staff to refer to, and the lack of experience of the staff contributed to the clerical staff not correcting the error.

See Appendix C for the cause and effect analysis.

**Corrective Action Plan**

Before the RCA committee met, Forensic Toxicology had already taken steps and implemented the following corrective actions:

- The LIMS work list, which is a printout of the sequence list from LIMS, is now included as part of the documentation for sequence approval. Directors are now required to review the work list as part of their review.

- The double check has been modified from an independent double check to double checking with a peer. Instead of two analysts checking the work independently, one analyst will call the vial position number and details and the second analyst will verify the information against the sequence list. This double check is similar to a "read back" where individuals work together to verify work. Double checking with a peer and automated double checks have been shown to be more effective than independent double checks.

The RCA committee reviewed the above corrective actions and found them to be appropriate. These corrective actions improve the laboratory's ability to prevent and to detect the error.

In addition to the actions already implemented by Forensic Toxicology, the RCA committee recommends the following actions to address the identified causal factors:

1. Forensic Toxicology should identify appropriate senior personnel and train them so that they can assist with director responsibilities. This will help to improve the distribution of work when a director must manage the laboratory alone.

2. Forensic Toxicology must develop checklists or written standard operating procedures for the administrative review performed by the clerical staff. The procedures should describe the fields clerical staff must review and the actions that must be taken for identified errors.

3. Forensic Toxicology should enhance training for individuals providing coverage for clerical staff. This should include a review of the new standard operating procedures and more hands on experience.

See Appendix D for a cause map with identified corrective actions.

Lastly, the RCA committee recommends that the agency consider the following:

- Upgrade the laboratory technology in order to reduce reliance on manual data entry and manual inspection. Bar code technology and an integrated LIMS system will help to prevent errors and improve efficiency. To minimize manual data entry, a committee member suggested that the laboratory explore the possibility of exporting the sequence list from LIMS as a .txt or .csv file, and then uploading the file to their analytical instruments.

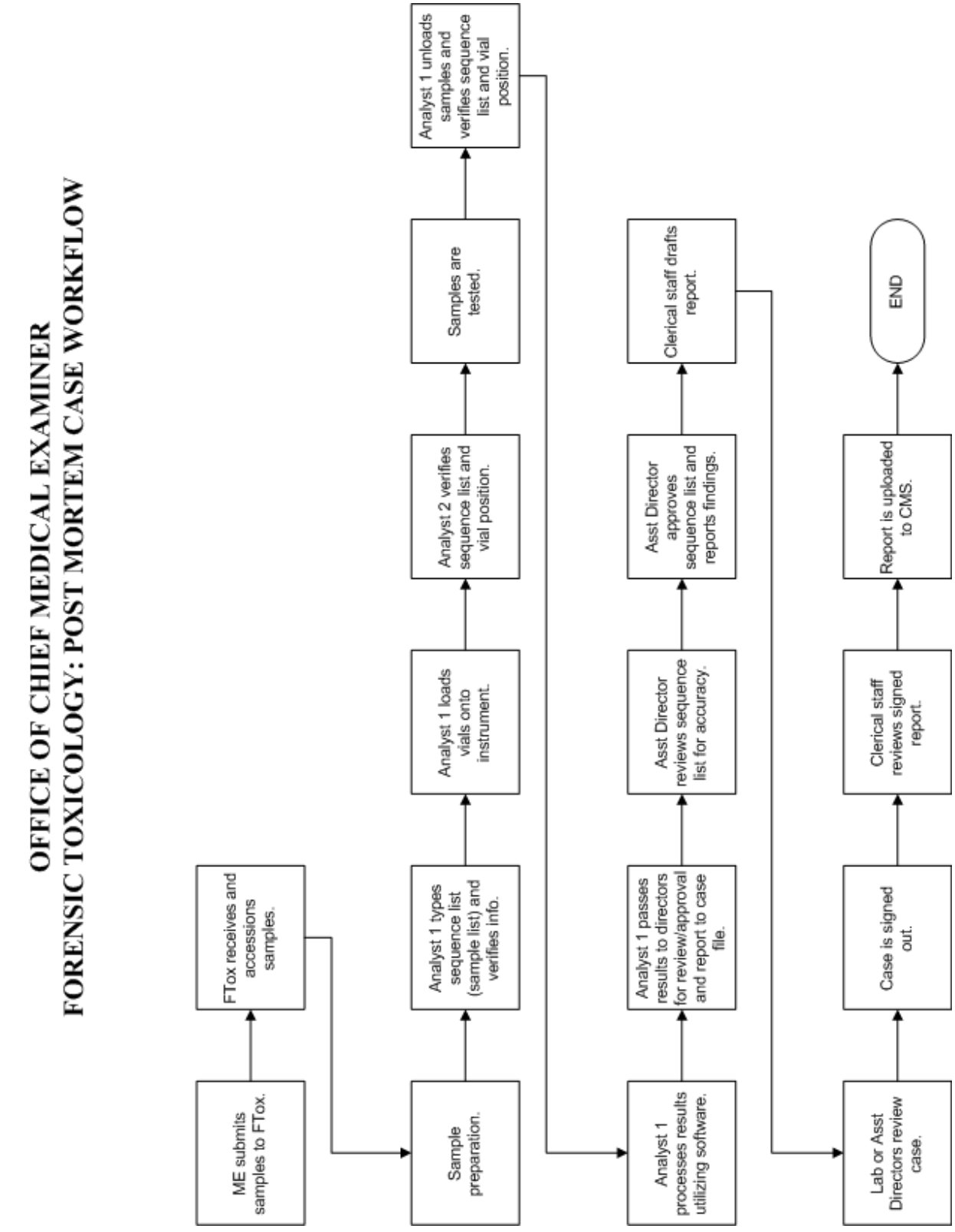
- Develop a general laboratory report format for OCME laboratories in order to improve clerical support and prevent errors. Standardization of the report template will help to reduce the learning curve for clerical staff from other departments.

**Summary of Corrective Actions**

| Causal Factor | Corrective Action | Recommended Completion Date |
|---|---|---|
| Analyst 1 unintentionally associated a bile specimen to the case while typing the sequence list and did not catch the error during self check. | 1. The LIMS work list is now included as part of the documentation for sequence approval.<br><br>2. The double check has been modified from an independent double check to double checking with a peer. | Completed on 3/17/17 |
| Analyst 2 did not catch the data entry error during double check due to a slip. | 1. The double check has been modified from an independent double check to double checking with a peer. | Completed on 3/7/17 |
| The assistant director was managing an increased workload. | Forensic Toxicology should identify appropriate senior personnel and train them so that they can assist with director responsibilities. | 8/31/17 |
| Clerical staff had little experience drafting and reviewing Forensic Toxicology reports. | 1. Forensic Toxicology must develop checklists or written standard operating procedures for clerical staff.<br><br>2. Forensic Toxicology should enhance training for individuals providing coverage for clerical staff. | 8/31/17 |

The Quality Manager and Laboratory Director will monitor the implementation and effectiveness of improvements.

**Appendix A**

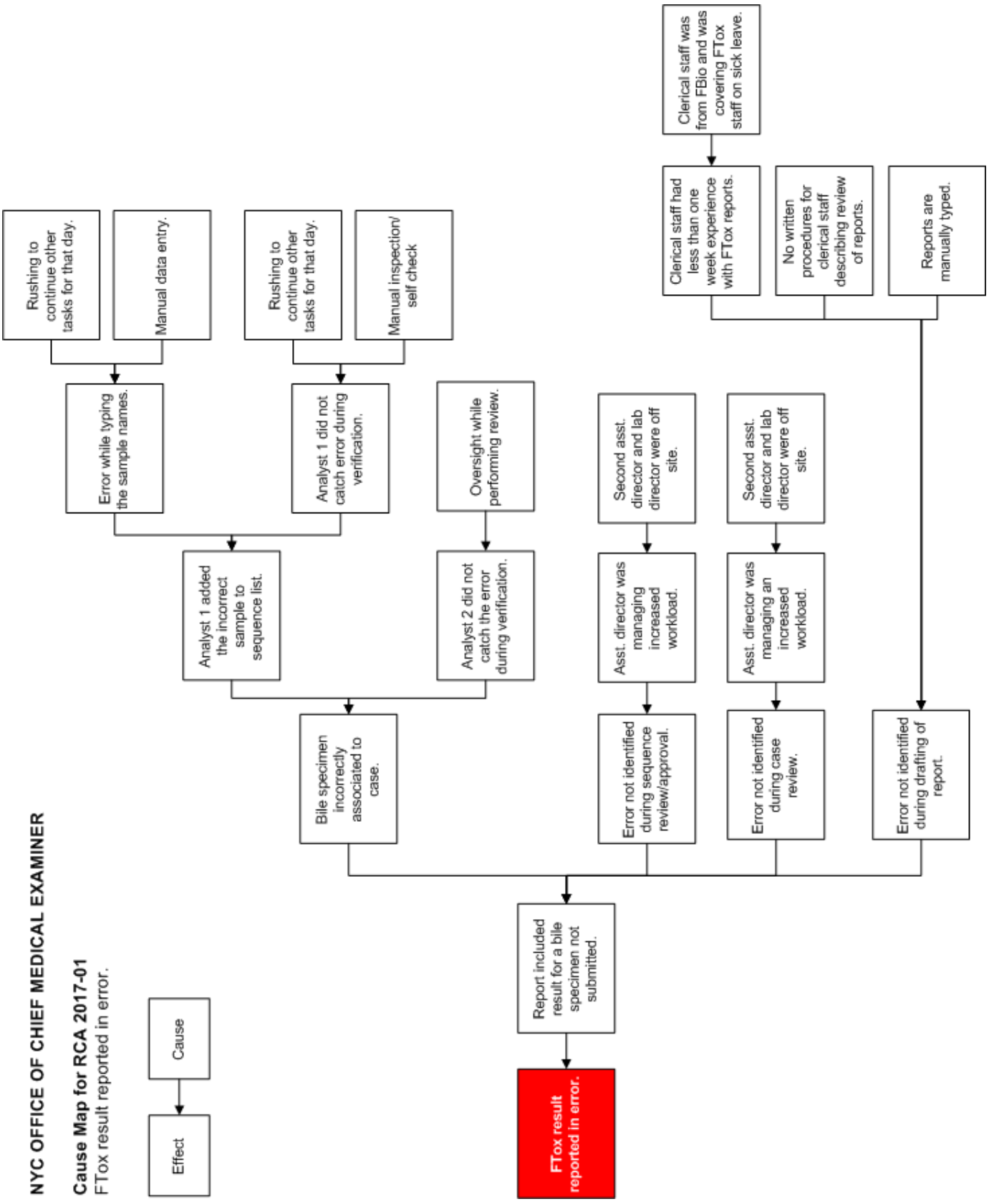

OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC TOXICOLOGY: POST MORTEM CASE WORKFLOW
ME submits samples to FTox.
FTox receives and accessions samples.
Sample preparation.
Analyst 1 types sequence list (sample list) and verifies info.
Analyst 1 loads vials onto instrument.
Analyst 2 verifies sequence list and vial position.
Samples are tested.
Analyst 1 unloads samples and verifies sequence list and vial position.
Analyst 1 processes results utilizing software.
Analyst 1 passes results to directors for review/approval and report to case file.
Asst Director reviews sequence list for accuracy.
Asst Director approves sequence list and reports findings.
Clerical staff drafts report.
Lab or Asst Directors review case.
Case is signed out.
Clerical staff reviews signed report.
Report is uploaded to CMS.
END

**Appendix B**

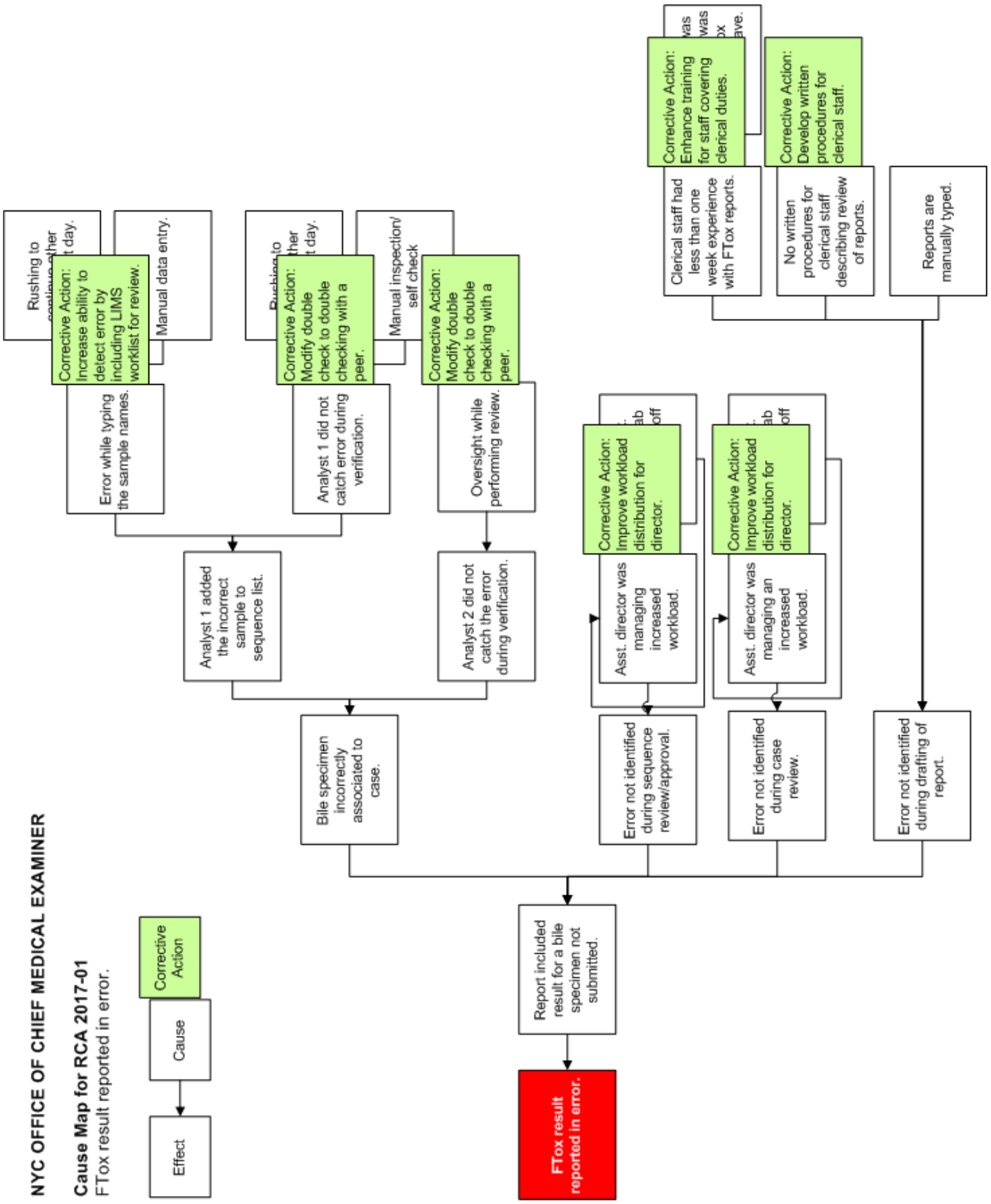
## CHRONOLOGY OF EVENTS

| DATE | EVENT |
|---|---|
| **1/5/17** | Medical Examiner case is transported to mortuary. |
| **1/6/17** | Medical Examiner performed autopsy and submitted decomp. fluid, liver and vitreous humour to FTox for comprehensive testing. |
| **1/9/17** | FTox received specimens for testing. |
| **1/17/17** | FTox samples tested. A bile sample from another case was incorrectly associated with this case while the analyst typed the sequence list. |
| **1/19/17** | Asst. Director reviewed and approved the sequence list. |
| **1/20/17 – 2/8/17** | Lab completed testing of case samples. |
| **2/13/17** | Clerical staff drafted the report and the assistant director reviewed the case.<br><br>FTox issued the laboratory report which included results for decomp. fluid, bile and vitreous humour.<br><br>The medical examiner emailed the laboratory and inquired about the significance of the bile result. |
| **2/14/17** | FTox staff reviewed the case and discovered that a bile specimen was not received and should not have been reported. The medical examiner was notified of the error. |
| **2/15/17** | FTox issued an amended report. |

## Appendix C


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for RCA 2017-01
FTox result reported in error.
Effect
Cause
FTox result reported in error.
Report included result for a bile specimen not submitted.
Bile specimen incorrectly associated to case.
Error not identified during sequence review/approval.
Error not identified during case review.
Error not identified during drafting of report.
Analyst 1 added the incorrect sample to sequence list.
Analyst 2 did not catch the error during verification.
Asst. director was managing increased workload.
Asst. director was managing an increased workload.
Error while typing the sample names.
Analyst 1 did not catch error during verification.
Oversight while performing review.
Second asst. director and lab director were off site.
Second asst. director and lab director were off site.
Rushing to continue other tasks for that day.
Manual data entry.
Rushing to continue other tasks for that day.
Manual inspection/ self check
Clerical staff had less than one week experience with FTox reports.
No written procedures for clerical staff describing review of reports.
Reports are manually typed.
Clerical staff was from FBio and was covering FTox staff on sick leave.

## Appendix D


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for RCA 2017-01
FTox result reported in error.
Corrective Action
Cause
Effect
FTox result reported in error.
Report included result for a bile specimen not submitted.
Bile specimen incorrectly associated to case.
Analyst 1 added the incorrect sample to sequence list.
Error while typing the sample names.
Rushing to
Manual data entry.
Corrective Action: Increase ability to detect error by including LIMS worklist for review.
Analyst 2 did not catch the error during verification.
Oversight while performing review.
Manual inspection/ self check
Corrective Action: Modify double check to double checking with a peer.
Analyst 1 did not catch error during verification.
Rushing to
Corrective Action: Modify double check to double checking with a peer.
Error not identified during sequence review/approval.
Asst. director was managing increased workload.
Corrective Action: Improve workload distribution for director.
Error not identified during case review.
Asst. director was managing an increased workload.
Corrective Action: Improve workload distribution for director.
Error not identified during drafting of report.
Reports are manually typed.
No written procedures for clerical staff describing review of reports.
Corrective Action: Develop written procedures for clerical staff.
Clerical staff had less than one week experience with FTox reports.
Corrective Action: Enhance training for staff covering clerical duties.