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ROOT CAUSE ANALYSIS REPORT
RCA# 2018-01
May 31, 2018

Executive Summary

On March 22, 2018, the Office of Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error relating to the 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 April 30, 2018, 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# 2018-01.

The RCA Committee met and reviewed the laboratory's testing process and identified areas for improvement. The root causes for this event were the approval and reporting of trazodone and m-chlorophenylpiperazine (m-cpp) as "detected" when the analytical data did not support the finding and the failure to identify the error during final review. In addition to measures taken by the laboratory, the RCA committee recommends increasing staff awareness of working with difficult samples and verifying that all testing has been completed by reviewing instrument printouts before submitting the case file to clerical staff. The committee also recommends that the laboratory complete the retrospective study, review the findings, and expand the retrospective study if additional significant errors are discovered.

Background

The primary mission of the 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. The laboratory also performs analysis on cases submitted by the New York City Police Department (NYPD), District Attorney Offices, or other law enforcement agencies to determine the absence or presence of alcohol and other drugs. Examples of cases involving non-OCME samples are driving under the influence of alcohol and other drugs (DWI) and drug facilitated sexual assaults (DFSA).

Non-OCME samples are submitted to the Evidence Unit and then delivered to Forensic Toxicology for testing. The samples are received and accessioned by laboratory staff. The laboratory director or assistant director will then schedule the initial tests for the case. Analysts prepare the samples to be tested and perform the initial tests. For Gas Chromatography/Mass Spectrometry (GCMS) screening, an analyst will review the data and identify peaks on the chromatogram representing compounds of interest. The analyst will then submit the results to a supervisor for second review. If the supervisor approves the results, the supervisor will report the

results on the test record form. After the last result is reported, clerical staff type a draft laboratory report and lab directors review the complete case file and results and decide if additional testing is required. If there are no issues with the report, and no further tests are required, it is signed out and uploaded to the Case Management System.

See Appendix A for a diagram of the DWI workflow and Appendix B for a diagram of the GCMS screening workflow.

Event Description

On February 21, 2018, Forensic Toxicology received two blood specimens for a DWI incident.

On March 15, 2018, the laboratory issued a report which stated trazodone and its metabolite, m-cpp, were detected by GCMS testing.

On March 16, 2018, a Forensic Toxicology Laboratory manager reviewed the data of a different extract from the same case and found that trazodone and m-cpp were **not detected** in the blood specimen.

On March 22, 2018, the manager discovered that the lab report had been issued and informed the laboratory director of the error. The laboratory notified the Assistant District Attorney of the error and issued an amended report which stated that trazodone and m-cpp were not detected.

See Appendix C for a detailed chronology of events.

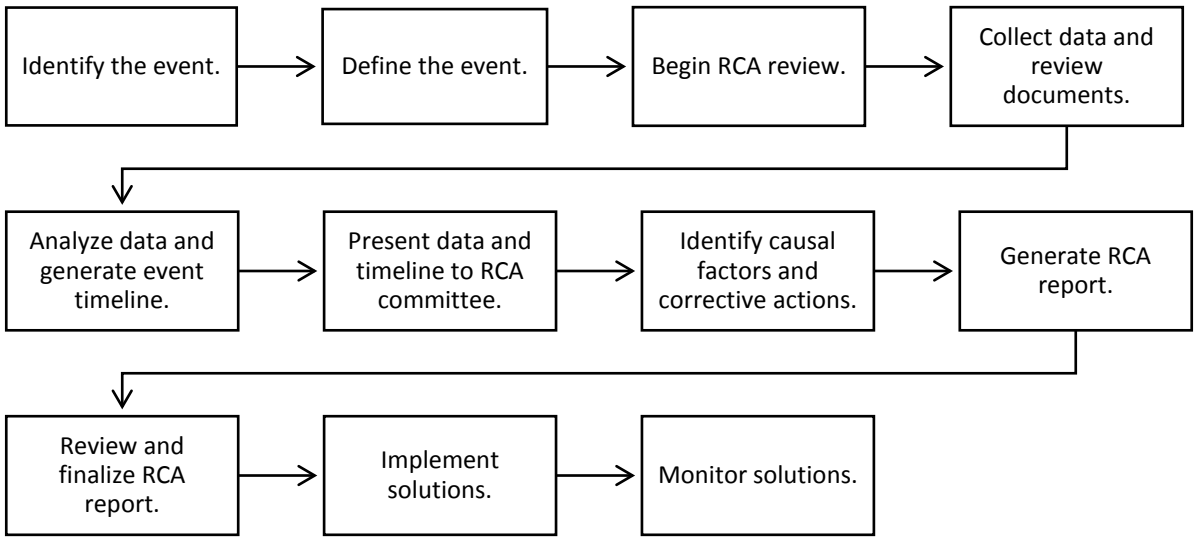
Composition of RCA Committee

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 District Attorney's Office of the error and amended the laboratory report.

- The assistant director who signed out the report was not assigned DWI and DFSA cases to sign out until the RCA was completed.

- A retrospective study was initiated to determine if the assistant director made similar errors. The review includes all DWI, DFSA, and homicide cases signed out by the assistant director between January 2018 and March 2018. The review also includes a review of 250 randomly selected postmortem cases signed out by the assistant director between January 2018 and March 2018. The retrospective review is still in progress.

The RCA committee found the actions taken by the laboratory to be appropriate. The committee recommends that laboratory complete the retrospective study. For any new error discovered, the laboratory must correct the error and notify the customers. If additional significant errors are discovered, the laboratory must expand the timeframe of cases reviews.

Causes and Contributing Factors

The RCA committee further examined the workflow and employed cause and effect analysis to identify causes and contributing factors for reporting trazodone and m-cpp as detected. Using this methodology, the RCA committee identified the following causal factors:

1. *A laboratory supervisor approved and reported trazodone and m-cpp as detected on the test record form. The reported results were not supported by the analytical data.*

Evidence:
The RCA committee reviewed the laboratory's workflow for DWI samples and GCMS screening. In addition, the Root Cause Analysis officer reviewed the standard operating procedures describing the workflow.

During the review of the DWI and GCMS screening workflows, the RCA committee learned that the laboratory has a multi-level review system. The first review is performed by the analyst who reviews the analytical data and identifies the peaks representing compounds of interest on the chromatogram. This analyst will stamp the instrument printout with a "Checked" stamp and then write their initials and date. The paperwork is then submitted to a supervisor for a second analytical review. If the supervisor agrees with the analyst's findings, (s)he then stamps the printout with an "Approved" stamp and writes their initials and date. The supervisor will then write the results on a separate test record form. After testing is completed, clerical staff will draft the report using the test record form. The draft report and the case file are submitted to the director or assistant director for final review and sign out.

The committee reviewed the test record form and the instrument printouts for this case. They found that the GCMS screening data was reviewed twice. It was first reviewed on March 1, 2018 and then again on March 15, 2018. The analyst who reviewed the data on March 1 noted that the following compounds were detected: cotinine, DPH, doxylamine, dextromethorphan, mirtazapine, sertraline, and norsertraline. These results were approved by a supervisor and entered on the test record form. On March 15, a second analyst wrote the following note: "Re-reviewed for trazodone; Poor chromatography, see LSC (library search compound) attached at end. Trazodone, m-cpp detected." Trazodone and m-cpp were approved and entered on the test record form.

Laboratory managers reviewed the screening data and chromatograms and stated that trazodone and m-cpp should not have been reported as "detected". The analytical data did not support the finding. The managers also stated that the chromatogram was "poor' and that there was insufficient data to report trazodone and m-cpp based on the GCMS screening data.

During an interview with the supervisor who approved the March 15 results, the supervisor was asked why she approved the analyst's findings and reported trazodone and m-cpp as detected. The supervisor could not recall why she approved the findings and stated she was possibly rushing. Managers added that she was possibly distracted by a stressful family health situation. Managers also stated that although the supervisor has 15 years experience working with GCMS data, she is a new supervisor with approximately one year experience approving results. The RCA committee discussed the supervisor's past performance and the workload volume. No issues with the supervisor's past performance were found and the workload volume was considered typical for the day.
The committee found that the poor chromatogram and stressful family situation contributed to the supervisor reporting trazodone and m-cpp as detected. Additionally,

she is a new supervisor with limited experience approving results for difficult chromatograms. The committee also noted that the lab did not have a formal mechanism to resolve different technical opinions before final review by the director or assistant director.

2. *The case was submitted to clerical staff to draft the report before testing was completed.*

Evidence:
As tests are scheduled and completed, a supervisor records the results on the test record form. The supervisor will then mark the test as completed and write any new test requests on the outside front cover of the case file folder. If all tests have been completed, the supervisor who writes the last result on the test record form submits the case to the clerical staff so that the report is drafted.

In this event, the committee learned that the supervisor, who entered the final results on the test record form, noted data which suggested the presence of a small amount of trazodone. She asked the assistant director if tests should be scheduled to quantitate trazodone and he replied that it was not necessary. The supervisor noted this conversation on the instrument printout on March 15.

During an interview with the supervisor, she stated that the assistant director felt the additional testing was not necessary due to the nature of the case. The case was a DWI case and the primary interest is determining whether or not there is alcohol or drugs present in the sample. Testing performed in order to quantitate a very small amount of an antidepressant would be of little value to customers and delay the report.

Because the assistant director did not request the quantitation of trazodone, and the supervisor was not aware of any pending tests, it is likely she submitted the case to clerical staff to type a draft laboratory report. However, a review of the instrument printout for confirmatory testing found that an additional test was requested. The analyst who reviewed the quantitation results had written “BMS 3/14” on the top right corner of the instrument printout. This indicates that blood mass spectrometry analysis was requested on March 14. The analyst also documented the request on the GC/MS Request Form. The GC/MS Request Form is a paper form used by staff to add cases to the next GCMS run and it is not included as part of the case file. The supervisor who approved the quantitation results did not see the handwritten note on the printout and was not aware of the analyst’s test request when she approved the results on March 15.

While reviewing the case file paperwork, the committee found that analyst notes, new test requests, and test results were documented as handwritten notes on forms, printouts, or the outside front cover of the case file folder. Because the information is not standardized or consolidated in one location, a supervisor must review every page of the case file manually to make sure (s)he does not miss a requested test or note. The committee noted that some of these pages may have notes entered on a different days making it difficult to follow the test history of the case.

The committee also noted that the current process requires an analyst to write their findings on the instrument printout and the supervisor to rewrite the same information on the test record form. This introduces the possibility of error while rewriting the same information and the possibility of the supervisor missing an analyst note or test request during review.

Human error and the lack of a structured form to capture test request information, contributed to the report being signed out before testing was completed. The committee also noted that the assistant director did not review the screening results and analyst notes when the supervisor asked him if trazodone should be quantitated. Managers stated a review of the data should have been conducted in order to determine if additional testing was necessary. Because the review was not conducted, the assistant director was not aware of the results of the second analyst review and the request for additional testing.

3. The assistant director did not review the GCMS screening results and analyst notes during final review.

Evidence:
Clerical staff draft the laboratory report based on the test record form. The case file and draft report are then submitted to the laboratory director or assistant director for final review. According to the laboratory procedure titled "Data Review and Reporting", the final review includes a review of the "chain of custody documentation, case history, and further review of analytical data". The procedure also states that the draft report "is checked against the analytical and case information by the Director or Assistant Director". After the review, the report is signed out and passed back to clerical staff. Clerical staff perform a final check for clerical errors and upload the report to the case management system.

During the review of this event, the assistant director resigned his OCME employment effective April 6, 2018. Consequently, the assistant director was not interviewed for this root cause analysis.

The committee reviewed the case paperwork in order to determine if there was sufficient information in the case file for the assistant director to have identified the error during final review on March 15. The following information was found and should have prompted the assistant director to conduct further review:

- The Toxicology Test Record form had the approved results for two reviews of the GCMS screening data.
- The instrument printout of the GCMS screening results included two sets of analyst notes. The second analyst note stated "re-reviewed for trazodone" and "poor chromatography".
- The printouts of the gas chromatography and mass spectrometry screening data which suggested the presence of a small amount of trazodone.
- The printout of the confirmatory testing with the analyst's request for additional testing.

Based on the above information, the committee concluded that there was sufficient information present in the case file for the assistant director to have caught the error during final review. The two sets of analyst notes and the analytical data suggesting the presence of trazodone should have prompted the assistant director to further investigate the data or request additional testing. The analyst's test request noted on the confirmatory testing printout should have prompted the assistant director to inquire about the results of that test (since the results were not in the case file on March 15). Without additional information from the assistant director himself, the committee was unable to determine why the final review did not identify the error.

The committee reminded the laboratory that the review of the assistant director's cases must be completed in order to determine if similar errors had occurred.

See Appendix D for the cause and effect analysis.

Corrective Action Plan

Before the RCA committee met, Forensic Toxicology informed the committee of the following:

- Forensic Toxicology managers reviewed the event with staff. Managers reminded supervisors that if they are approving results for samples with poor chromatography, they should submit as much analytical data as possible to support the reported results. This measure should improve the quality of reporting because supervisors will need to make a stronger case for the results they approve.

- Forensic Toxicology managers are developing an updated version of the test record form. The updated paper form will improve the documentation of test results, capture test requests, and function as a communication log for the case file. The form will eliminate the need to write the tests performed on the front cover of the case file folder and allow managers to view the case history on a single document.

The RCA committee reviewed the above actions and found them to be appropriate. In addition to these measures, the RCA committee recommends the following actions to address the identified causal factors:

1. Forensic Toxicology must provide feedback to involved staff and review analyzing poor chromatograms and approving results with analysts and supervisors. This will help to increase the laboratory's awareness of difficult samples and promote best practices when analyzing poor chromatograms.

2. Until the new test record form is implemented, Forensic Toxicology should require supervisors to verify that all tests have been completed by reviewing the instrument printouts, not the front of the case file folder, before submitting the case to clerical. This will require supervisors to verify that testing has been completed and the analytical results for all tests are included in the case file.

3. Forensic Toxicology must complete the retrospective study. For any new error discovered, the laboratory must correct the error and notify the customers. If additional significant errors are discovered, the laboratory must expand the timeframe of cases reviewed.

Lastly, The RCA committee strongly recommends that the agency purchase and implement a laboratory information management system (LIMS) for Forensic Toxicology. A LIMS will support staff and laboratory workflows by enhancing the laboratory's information management capability.

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

The RCA committee offers the following suggestions for consideration:

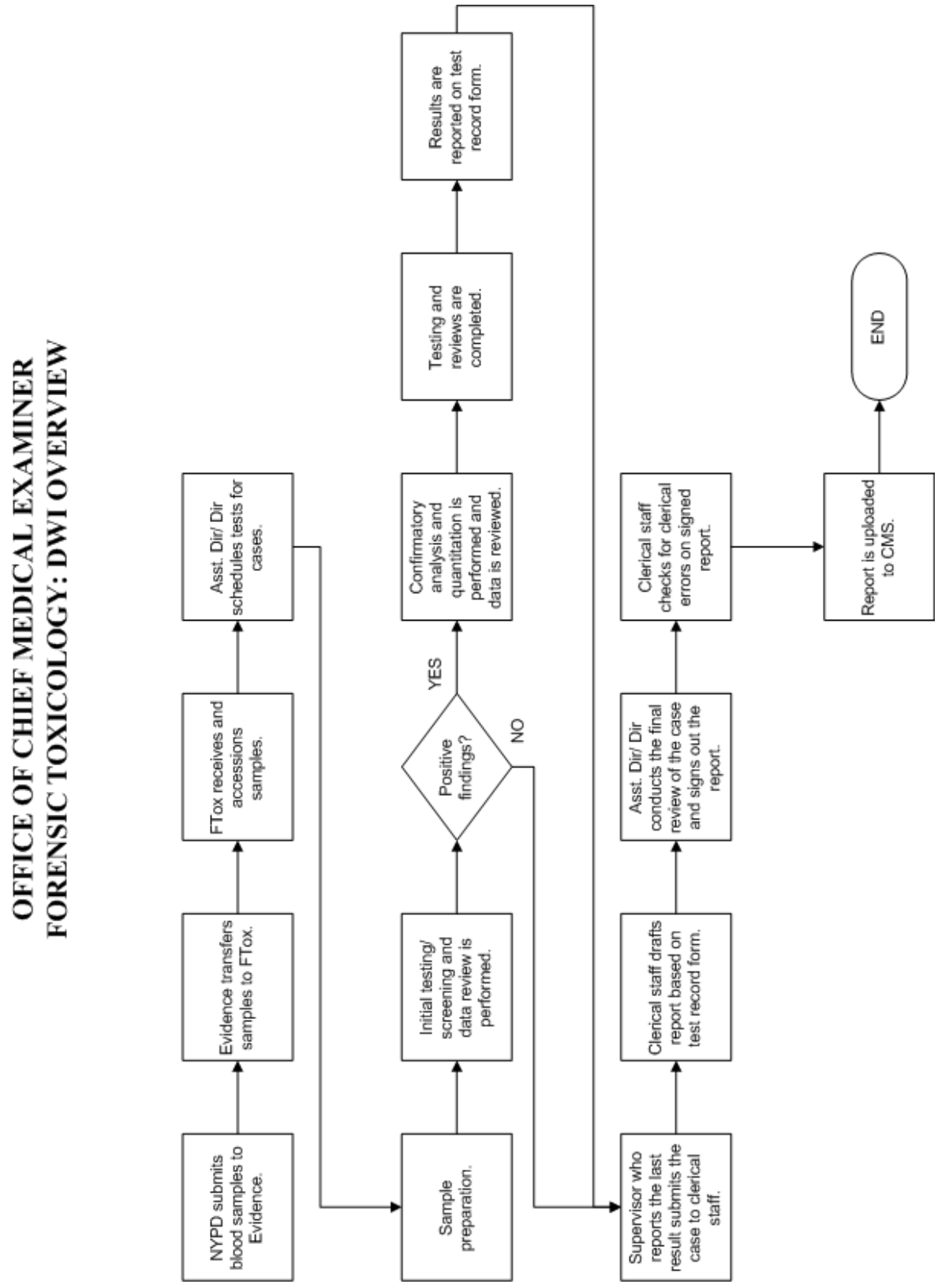
- Management should consider adding more information/guidance to their procedures for approving results with poor chromatography.
- Management should consider implementing a checklist for final review. A checklist will help ensure that a complete case review is conducted before sign out.
- Management should consider developing a formal mechanism to resolve different technical opinions before final review. This mechanism would act as a quality control step by resolving conflicting analyst opinions before final review.
- Management should consider permitting analysts, instead of supervisors, to enter results on the test record form. This would simplify the process and minimize transcription errors.
- Management should consider assigning an analyst to a case. This would enhance management of a case by promoting case ownership.

Summary of Corrective Actions

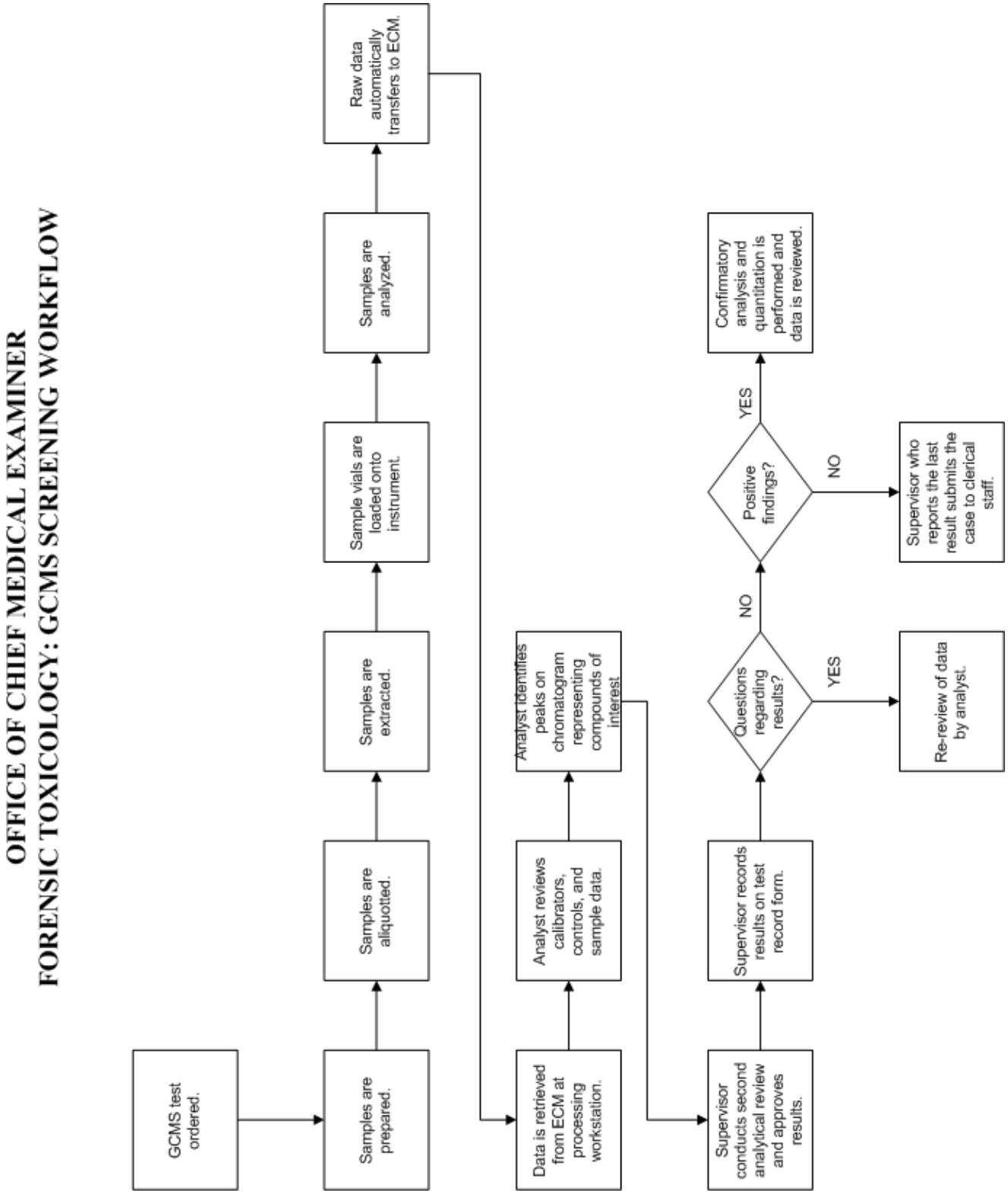
Causal Factor	Corrective Action	Recommended Completion Date
A laboratory supervisor approved and reported trazodone and m-cpp as detected on the test record form.	1. Forensic Toxicology must provide feedback to involved staff and review analyzing poor chromatograms and approving results with analysts and supervisors. 2. Managers reminded supervisors that if they are approving results for samples with poor chromatography, they should submit as much analytical data as possible to support the reported results.	9/1/18 Completed
The case was submitted to clerical to draft the report before testing was completed.	1. Forensic Toxicology must develop an updated version of the test record form. 2. Until the new test record form is implemented, Forensic Toxicology should require supervisors to verify all tests have been completed by reviewing the instrument printouts, not the front of the case file folder, before submitting the case to clerical.	9/1/18 9/1/18
The assistant director did not review the GCMS screening results and analyst notes during final review.	Forensic Toxicology must complete the retrospective study.	9/1/18

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

Appendix A


OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC TOXICOLOGY: DWI OVERVIEW
NYPD submits blood samples to Evidence.
Evidence transfers samples to FTox.
FTox receives and accessions samples.
Asst. Dir/ Dir schedules tests for cases.
Sample preparation.
Initial testing/ screening and data review is performed.
Positive findings?
YES
NO
Confirmatory analysis and quantitation is performed and data is reviewed.
Testing and reviews are completed.
Results are reported on test record form.
Supervisor who reports the last result submits the case to clerical staff.
Clerical staff drafts report based on test record form.
Asst. Dir/ Dir conducts the final review of the case and signs out the report.
Clerical staff checks for clerical errors on signed report.
Report is uploaded to CMS.
END

Appendix B

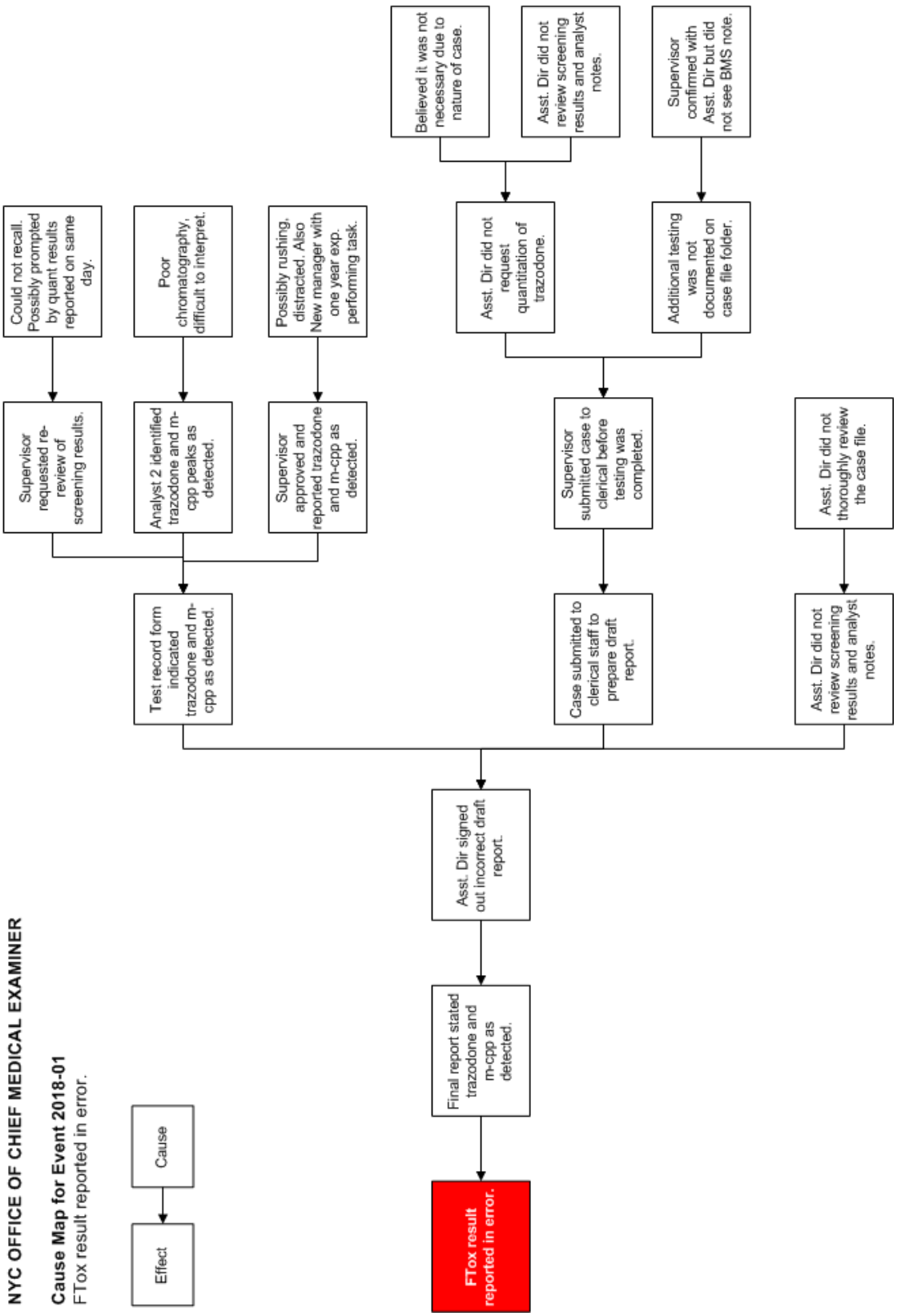

OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC TOXICOLOGY: GCMS SCREENING WORKFLOW
GCMS test ordered.
Samples are prepared.
Samples are aliquotted.
Samples are extracted.
Sample vials are loaded onto instrument.
Samples are analyzed.
Raw data automatically transfers to ECM.
Data is retrieved from ECM at processing workstation.
Analyst reviews calibrators, controls, and sample data.
Analyst identifies peaks on chromatogram representing compounds of interest
Supervisor conducts second analytical review and approves results.
Supervisor records results on test record form.
Questions regarding results?
YES
Re-review of data by analyst.
NO
Positive findings?
NO
Supervisor who reports the last result submits the case to clerical staff.
YES
Confirmatory analysis and quantitation is performed and data is reviewed.

Appendix C

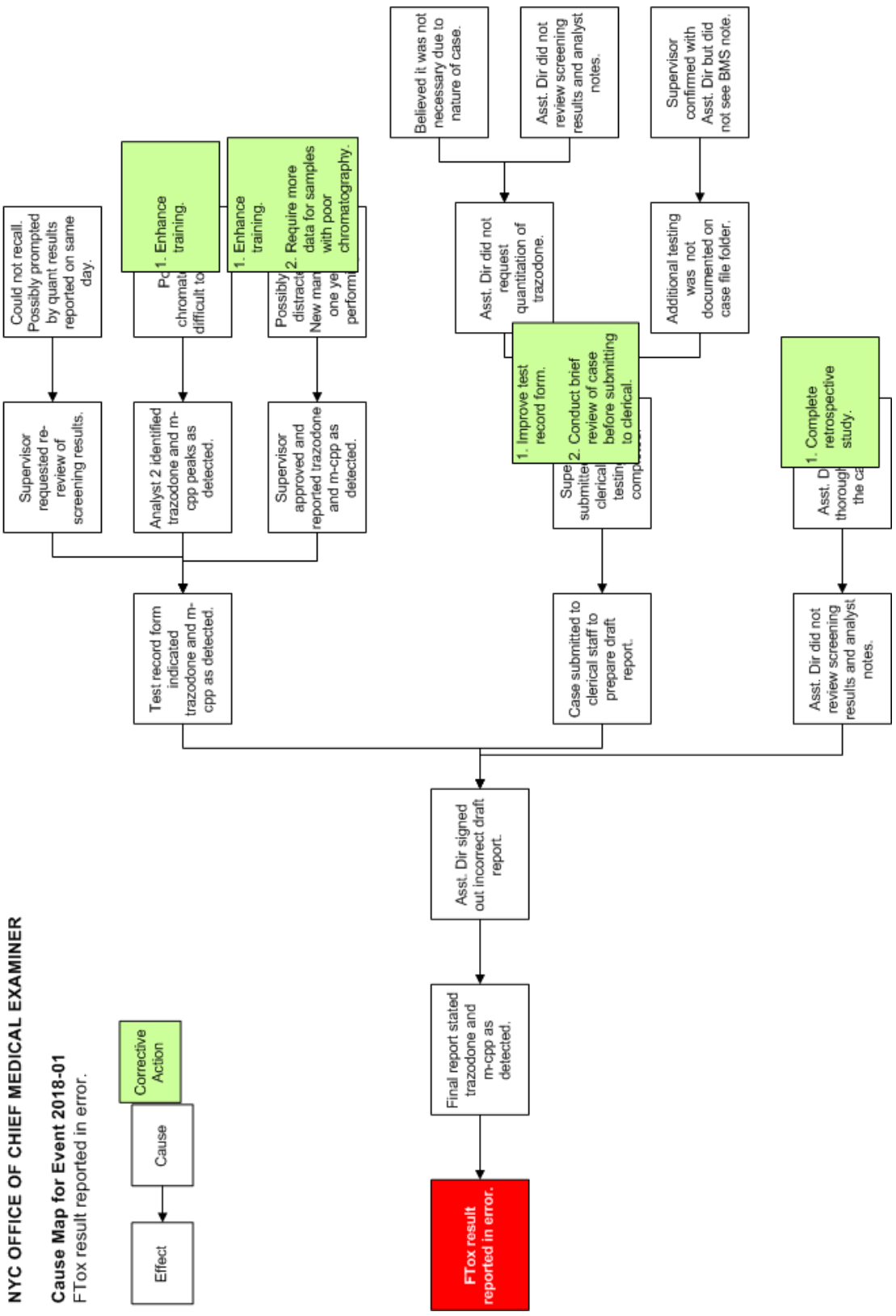
CHRONOLOGY OF EVENTS

DATE	SOURCE OF INFORMATION	EVENT
2/21/18	FTox Lab Report	FTox received blood specimens for DWI incident.
2/23/18 – 2/27/18	Toxicology Test Record/ Instrument Report	Blood analyzed by HSGC and results documented on test record. Blood analyzed by GCMS.
3/1/08	Instrument Report/ Toxicology Test Record	GCMS batch results processed by analyst 1 and approved by assistant director. Assistant director documented results on test record.
3/6/18	Toxicology Test Record	Blood sample analyzed by ELISA and results documented on test record.
3/13/18	Toxicology Test Record	Blood sample analyzed by HPLC and results documented on test record.
3/15/18	Toxicology Test Record/ FTox Report	Re-review by analyst 2. Trazodone and m-chlorophenylpiperazine added as "detected" and noted on test record. FTox issued a laboratory report which stated trazodone and m-chlorophenylpiperazine were detected by GC/MS.
3/16/18	Email/ Instrument Report	Lab manager reviewed data on a different extract from the same case and trazodone and m-chlorophenylpiperazine were not detected. Results were approved by assistant director.
3/22/18	Case File/ FTox Report	Laboratory manager discovered that the lab report reported trazodone and m-chlorophenylpiperazine as detected but the analytical data did not support the finding (did not meet acceptance criteria). FTox notified the ADA and issued an amended report which stated trazodone and m-chlorophenylpiperazine were not detected by GC/MS.

Appendix D


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for Event 2018-01
FTox result reported in error.
Cause
Effect
FTox result reported in error.
Final report stated trazodone and m-cpp as detected.
Asst. Dir signed out incorrect draft report.
Test record form indicated trazodone and m-cpp as detected.
Case submitted to clerical staff to prepare draft report.
Asst. Dir did not review screening results and analyst notes.
Supervisor requested re-review of screening results.
Analyst 2 identified trazodone and m-cpp peaks as detected.
Supervisor approved and reported trazodone and m-cpp as detected.
Supervisor submitted case to clerical before testing was completed.
Asst. Dir did not thoroughly review the case file.
Asst. Dir did not request quantitation of trazodone.
Additional testing was not documented on case file folder.
Could not recall. Possibly prompted by quant results reported on same day.
Poor chromatography, difficult to interpret.
Possibly rushing, distracted. Also New manager with one year exp. performing task.
Believed it was not necessary due to nature of case.
Asst. Dir did not review screening results and analyst notes.
Supervisor confirmed with Asst. Dir but did not see BMS note.

Appendix E


NYC OFFICE OF CHIEF MEDICAL EXAMINER
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Corrective Action
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Analyst 2 identified trazodone and m-cpp peaks as detected.
Supervisor approved and reported trazodone and m-cpp as detected.
Could not recall. Possibly prompted by quant results reported on same day.
1. Enhance training.
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2. Require more data for samples with poor chromatography.
Asst. Dir did not request quantitation of trazodone.
1. Improve test record form.
2. Conduct brief review of case before submitting to clerical.
Believed it was not necessary due to nature of case.
Asst. Dir did not review screening results and analyst notes.
Additional testing was not documented on case file folder.
Supervisor confirmed with Asst. Dir but did not see BMS note.
1. Complete retrospective study.