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ROOT CAUSE ANALYSIS REPORT
EVENT ID# 15-008
AUGUST 24, 2015

Executive Summary

On May 19, 2015, Office of the Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error from March 3, 2015 which resulted in an incorrectly reported result from OCME's Forensic Toxicology laboratory. 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 June 23, 2015, OCME assembled a Root Cause Analysis Committee to identify the causal factors and corrective actions to be taken for this event, which was identified as Event 15-008.

The Root Cause Analysis Committee met and reviewed the Forensic Toxicology Laboratory (Forensic Toxicology) test process and identified several issues. The root causes were identified as the laboratory's not having standard procedure for (1) documenting sample quality issues and ultraviolet (UV) spectra which do not match the UV spectrum of calibrators and (2) the final review of cases. The Root Cause Analysis Committee recommends that Forensic Toxicology revise their final review procedure to include documentation that must be reviewed prior to sign out and implement a procedure that requires reviewers to document both sample quality issues and UV spectra that do not match.

Background

The primary mission of Forensic Toxicology is post mortem analysis which determines 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 assist in determining the cause and manner of death.

High Performance Liquid Chromatography (HPLC) is a test routinely performed by Forensic Toxicology that is used to identify, confirm and quantify drugs indicated by enzyme immunoassay (EI). EI is a presumptive test used to evaluate blood or urine to determine the possible presence of controlled substances (among others). EI uses antibodies and color change to indicate the possibility that a substance is present. If the EI result is positive, a confirmatory test, such as HPLC, is scheduled.

The data collected by HPLC is visually represented as peaks on a chromatogram. For quantitative results the data must be "processed". Processing includes establishing the calibration curve, performing computer evaluation of standard samples, quality control samples and unknown samples against the calibration curve, and reviewing all data for acceptability on screen before hard copies are printed.

The sample analysis, processing and first review of this data is completed by a trained criminalist or supervisor. The hard copies of the processed quality control data undergo a second review, which is completed by another experienced criminalist or supervisor. After this review, hard copies of all data are printed and individual results reported on the appropriate case summary sheet. When all testing is completed on a case, the Director or an Assistant Director reviews all data before a Forensic Toxicology report is issued. See Appendix A for a diagram of the laboratory workflow.

Event Description

On December 10, 2014, a medical examiner submitted samples to Forensic Toxicology for comprehensive drug screening. Comprehensive drug screening involves testing for the presence of multiple drugs in blood and other submitted specimens. The laboratory received the specimens and scheduled the appropriate tests.

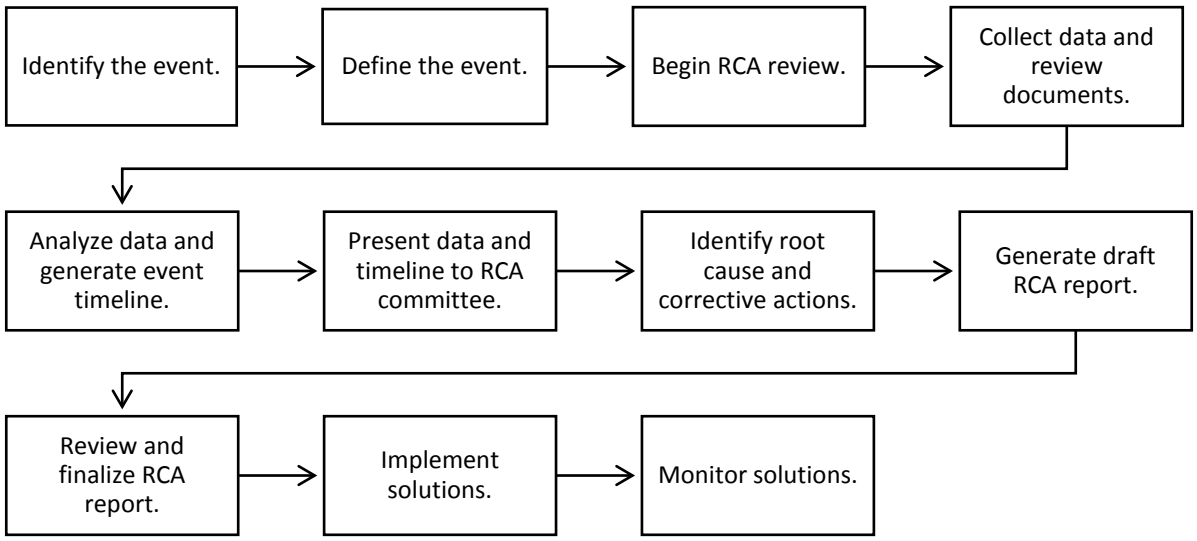
On December 19, 2014, a criminalist performed the extraction for the barbiturates batch. That individual was unable to run the liquid chromatography sequence since he was scheduled for vacation. A second criminalist was assigned to run the liquid chromatography sequence, process and review the data. However, the second criminalist was unable to complete the review because he was transferred to another section of the laboratory.

On December 30, 2014, the Assistant Director reviewed the results, controls and quality control data. On March 2, 2015, the laboratory reported a positive result for pentobarbital, 8.0 mg/L by liquid chromatography in femoral blood.

On March 9, 2015, the medical examiner requested analysis of gastric contents. The medical examiner requested this analysis because the positive pentobarbital result was a significant factor in determining the cause and manner of death. While analyzing the gastric contents, the Forensic Toxicology Laboratory did not detect any pentobarbital. The femoral blood was retested and pentobarbital was not detected. At this point, the Forensic Toxicology Laboratory discovered that during the initial analysis of femoral blood, a decomposition peak was mistakenly identified as pentobarbital. On May 19, 2015, the Forensic Toxicology Laboratory issued an amended report. See Appendix B for a detailed chronology of events.

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:



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 subject 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 experience in hospital laboratory operations and patient safety.

Findings and Root Cause

After reviewing the testing process and the event timeline, the RCA committee reviewed the corrective action taken by Forensic Toxicology. Although the medical examiner was immediately informed of the error and an amended report was issued, the laboratory did not take steps to determine if other cases were affected. The RCA committee recommends that Forensic Toxicology review the cases that were processed and analyzed by the criminalist who identified the decomposition peak as pentobarbital. This review should be documented as part of the laboratory's corrective action for this error.

The RCA committee further explored the workflow and used both the Fishbone diagram and the 5-Whys method to explore possible causes for the release of the inaccurate report. The following categories of Fishbone diagram were used to evaluate the system and to group the possible causes: Environment, Information, Methods, People, Materials and Machines.

Using this methodology, the RCA committee identified the following causal factors:

1. *Forensic Toxicology does not have a written requirement to document findings or concerns during processing and analysis.*
The RCA committee learned that the criminalist who initially reviewed the HPLC data noted that the peak in question may have been a decomposition product but did not document this or schedule additional testing. A review of memos related to the error and the laboratory's Corrective Action Form indicated that the analyst had observed that the sample UV spectrum did not match the calibrator UV spectrum. Because this finding was not documented, the Assistant Director was not made aware of any issues regarding that peak during final review. The RCA committee reviewed the laboratory's procedure for this process and found that the procedure does not require analysts to document their findings during processing and analysis.

Further investigation showed that some analysts in other sections of the laboratory documented notes and findings directly on the chromatogram so that it is clearly visible for the reviewer. This documentation included an overlay of the sample UV spectra and calibrator UV spectra along with a brief note.

Although documenting sample issues is reviewed during training and orientation, the lack of a written requirement has contributed to the lack of standardization in practice.

2. *The review procedure lacks standardization regarding which documents need to be reviewed and who is responsible for that review.*
The review process represents the laboratory's final quality check before the report is signed and issued. The RCA committee examined the procedure for the review process and found that the protocol lacked details regarding what documents must be reviewed and who is responsible for that review.

The laboratory relies heavily on the skill and experience of the reviewers to conduct a complete and accurate final check of all documents. The RCA committee recognizes the value of this experience and the necessity to exercise discretion in the laboratory. However, it also recognizes that, in complex testing such as forensic toxicology, greater standardization of the review procedure could have prevented this error.

In addition to these process issues, the RCA committee also identified several contributing factors. Contributing factors influence the likelihood of the error to occur but are not root causes in themselves. These contributing factors include *supervisors having too many responsibilities*, *lack of a protocol for the handoff of cases in the middle of review*, and a *lack of awareness regarding the impact decomposition has on toxicology analysis*. These factors contribute to potential loss of critical information and impact the reviewer's ability to identify issues during review.

Based on the above findings, the RCA committee determined that the lack of a written requirement to document issues or concerns identified during data processing and analysis and the lack of standardization of the review procedure are the root causes for this error. See Appendices C and D for Fishbone diagram and 5-Whys analysis.

Corrective Action Plan
The RCA committee recommends the following actions:

1. Forensic Toxicology must perform a retrospective analysis of the reviewer's work and determine if other cases had similar errors. The committee recommends reviewing cases that will provide a minimum confidence level of 95% for the last 3-6 months of work.

2. Forensic Toxicology must revise the data review and analysis procedure. This revision must include a requirement to document any identified issues or concerns identified during data review and analysis. Once the procedure has been revised, all staff must be informed and trained regarding the change in procedure. A copy of the SOP must be readily available to all laboratory staff and laboratory leadership must monitor its implementation.

3. Forensic Toxicology must standardize the data review and analysis procedure. The RCA committee recommends that the practice of overlaying sample UV spectra and calibrator UV spectra for all positively identified drugs be standardized.

4. Forensic Toxicology must revise the final review procedure. The revised procedure must include details regarding what documents must be reviewed and who is responsible for that review. Once the procedure has been revised, all staff must be informed and trained regarding the change in procedure. A copy of the SOP must be readily available to all laboratory staff and laboratory leadership must monitor its implementation.

5. Forensic Toxicology must standardize the final review procedure. The RCA committee recommends that the laboratory pilot the use of a form or checklist for reviewers. This form will help to standardize quality control and reviewer notes and ensure consistency and completeness.

6. Forensic Toxicology must take steps to address the contributing factors by reviewing workload and assessing staffing needs. The laboratory should also review its structure and organization so that case reviews and supervisory responsibilities are equally distributed among reviewers. Addressing these issues will help the laboratory ensure that reviewers have sufficient uninterrupted time to focus on reviews.

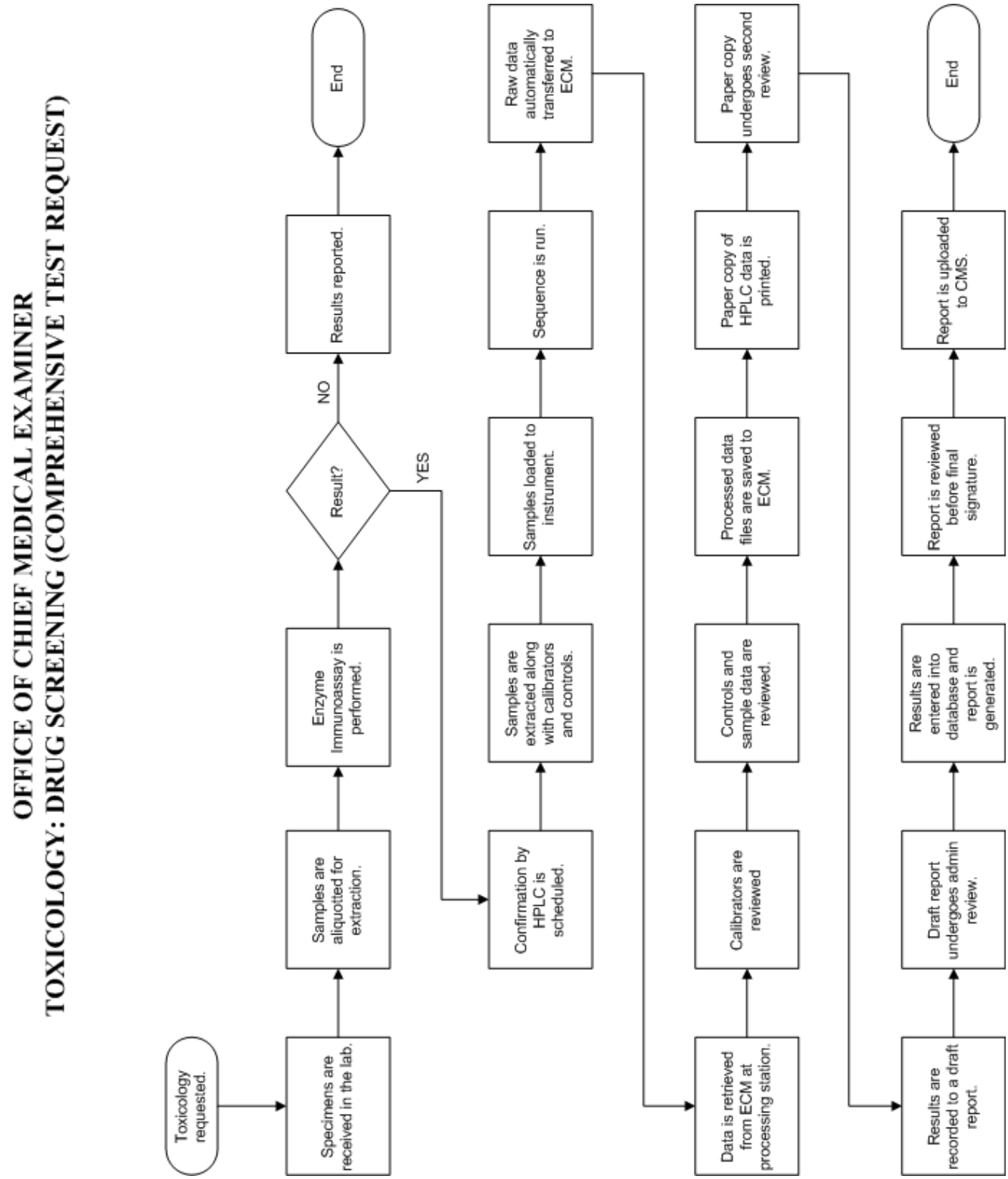
7. Forensic Toxicology should explore the use of a handoff protocol whenever a criminalist is unable to complete a review for a case. Handoffs are known to be vulnerable points in any process and often lead to a loss of information. Implementing a handoff protocol would help to ensure that any issues or concerns regarding a case are communicated and not lost.

8. Forensic Toxicology should also consider providing feedback to medical examiners or holding regular customer meetings with them. The lab should also communicate how critical it is for medical examiners to document any signs of decomposition on the Forensic Toxicology Request Form and how that information can help the lab conduct the best possible analysis.

Causal Factor	Corrective Action	Recommended Completion Date
The laboratory did not take steps to determine if other cases were affected.	Forensic Toxicology must perform a retrospective analysis of the reviewer's work and determine if other cases had similar errors.	11/30/15
Current procedure does not have a written requirement to document findings or concerns during processing and analysis.	Revise the procedure to include a requirement to document any identified issues or concerns identified during data review and analysis.	11/30/15
Variation in practice regarding documenting findings or concerns during processing and analysis.	Standardize the practice of overlaying sample UV spectra and calibrator UV spectra for all positively identified drugs.	11/30/15
Current final review procedure does not clearly indicate who is performing the review and what documents must be reviewed.	Revise the review procedure to include details regarding who is performing reviews and a list of documents that must be reviewed before the report is issued.	11/30/15
Variation in practice regarding the final review of cases.	Standardize review process by piloting the use of a form or a checklist for reviewers.	11/30/15
Supervisors have too many responsibilities/ Insufficient time to review cases.	The laboratory should review its structure and organization so that case reviews and supervisory responsibilities are equally distributed among reviewers.	11/30/15
Criminalist was unable to complete the review and did not communicate their concerns regarding a decomposition peak.	Forensic Toxicology should explore the use of a handoff protocol whenever a criminalist is unable to complete a review for a case.	11/30/15
Lack of awareness regarding how decomposition impacts technical analysis.	Forensic Toxicology should consider holding a customer meeting with medical examiners to inform them how decomposition impacts analysis.	11/30/15

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

Appendix A


OFFICE OF CHIEF MEDICAL EXAMINER
TOXICOLOGY: DRUG SCREENING (COMPREHENSIVE TEST REQUEST)
Toxicology requested.
Specimens are received in the lab.
Samples are aliquotted for extraction.
Enzyme Immunoassay is performed.
Result?
NO
YES
Results reported.
End
Confirmation by HPLC is scheduled.
Samples are extracted along with calibrators and controls.
Samples loaded to instrument.
Sequence is run.
Raw data automatically transferred to ECM.
Data is retrieved from ECM at processing station.
Calibrators are reviewed
Controls and sample data are reviewed.
Processed data files are saved to ECM.
Paper copy of HPLC data is printed.
Paper copy undergoes second review.
Results are recorded to a draft report.
Draft report undergoes admin review.
Results are entered into database and report is generated.
Report is reviewed before final signature.
Report is uploaded to CMS.
End

Appendix B

CHRONOLOGY OF EVENTS

DATE	SOURCE OF INFORMATION	EVENT
12/10/14	Tox. requisition	Comprehensive screening requested for ME case.
12/11/14	Tox. Lab report	Specimen received in laboratory.
12/19/14	Tox. laboratory results	Criminalist III performs extraction for barbiturates batch. Emails Criminalist IV to run liquid chromatography sequence since he is unable to complete due to scheduled vacation.
12/24/15	Tox. laboratory results	Criminalist IV runs liquid chromatography sequence.
12/26/15	Tox. laboratory results	Criminalist IV processes and reviews the data. He does not complete the review because he is transferred to another section.
12/30/15	Tox. laboratory results	Results, controls, QC data are reviewed by the Assistant Director.
3/2/15	Tox. Lab report	Lab report issued. Results for pentobarbital positive, 8.0 mg/L by liquid chromatography in blood (femoral).
3/3/15	CMS	Tox. Lab report is uploaded to CMS.
3/9/15	Email	Medical examiner requests analysis of gastric content. Case is re-opened.
3/12/15 – 3/27/15	Internal memos	The laboratory tests the gastric content and pentobarbital is not detected. Femoral blood is retested and pentobarbital is not detected. The laboratory discovers that a decomposition peak was mistakenly identified as pentobarbital. Management and the medical examiner are alerted.
5/19/15	Tox. Lab report	Amended and Supplementary reports are issued. Results for blood (femoral), urine, vitreous humor, gastric content negative for Pentobarbital.
5/20/15	CMS	Amended and Supplementary Tox. Lab reports are uploaded to CMS.

CMS refers to the OCME's Case Management System. It is web-based information management system that supports agency work units including medical examiners, morgues, investigations and identification.

Appendix C


Problem Statement
Decomposition peak misidentified as pentobarbital.
Methods
Misidentified peak was not discovered during
Final review does not include retrieval/review
Final review relies on skill and
Review SOP lacks details
Misidentified peak was not discovered
Reviewer was not aware of analyst concerns
Analyst did not document concerns
Documenting decomp issues not
Documenting decomp issue
Machines
No Machines-related causes were
Environment
No Environment-related causes were identified.
People
Supervisors are unable to focus on reviews.
Supervisors have too many responsibilities.
Insufficient number of supervisors/reviewers
Additional staff have not been hired.
Materials
Decomposed sample complicates
Sample quality is diminished and
Decompositon products can produce
Information
Decomposed sample was not identified.
Decomposition was not documented when
Lack of awareness of decomposition impact to
Little to no feedback to medical examiners or
Loss of information due to multiple
Failure to document or communicate
Lack of protocol for handoff of

Appendix D

Event 15-008 - 5 Whys	Problem Statement: Decomposition peak misidentified as pentobarbital.	
CATEGORY	WHY 1	WHY 2 - 5
Method	Misidentified peak was not discovered during review. Why?	Final review does not include retrieval/review of original data. Why?
		Final review relies on skill and experience of reviewer. Why?
		Review SOP lacks details regarding how to perform final review.
	Misidentified peak was not discovered during review. Why?	Reviewer was not aware of analyst concerns regarding peak. Why?
		Analyst did not document concerns regarding peak. Why?
		Documenting decomp issues not standard practice in lab. Why?
		Documenting decomp issue not required in SOP.
People	Supervisors are unable to focus on reviews. Why?	Supervisors have too many responsibilities. Why?
		Insufficient number of supervisors/reviewers in lab. Why?
		Additional staff have not been hired.
Materials	Decomposed sample complicates analysis. Why?	Sample quality is diminished and interference with technical analysis. Why?
		Decompositon products can produce false positive results.
Information	Decomposed sample was not identified. Why?	Decomposition was not documented when sampled or analyzed. Why?
		Lack of awareness of decomposition impact to analysis. Why?
		Little to no feedback to medical examiners or lab staff.
	Loss of information due to multiple handoffs. Why?	Failure to document or communicate concerns regarding peak. Why?
		Lack of protocol for handoff of cases in the middle of review.
Machines	No Machines-related causes were identified.	
Environment	No Environment-related causes were identified.	