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ROOT CAUSE ANALYSIS REPORT
EVENT ID# 15-003
APRIL 13, 2015

Executive Summary

On February 13, 2015, the Office of the Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error from October 16, 2014 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 March 12, 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 15-003. A second Forensic Toxicology error was brought to the QA Director's attention on the same day. That error is the subject of the RCA Report for Event 15-004.

The Root Cause Analysis Committee met and reviewed the Forensic Toxicology Laboratory (Forensic Toxicology) examination process and identified several issues. The root cause was identified as the laboratory's not having a standard procedure regarding second review. In this regard, Forensic Toxicology lacks a standardized procedure that requires the review of processed data and the raw chromatograms. The Root Cause Analysis Committee recommends that Forensic Toxicology revise the second review process to require review of the processed data and printouts of the raw chromatograms in order to prevent recurrence.

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 help determine cause and manner of death.

A test routinely performed by Forensic Toxicology is the identification and quantification of toxins using gas chromatography/mass spectrometry (GC/MS). GC/MS separates, identifies and measures all components in a sample. The different components are visually represented as peaks on a chromatogram. This raw data must then undergo "processing." Processing refers to the analysis and review of the raw data. This includes reviewing the calibrators, controls and sample data against three compound libraries. The goal of processing is to prepare the data and identify the peaks on the chromatogram representing the compounds of interest. This is a necessary step since the raw data identifies endogenous compounds including non-drug peaks. During processing, it is necessary to delete peak labels representing endogenous compounds. Deletion of the peak label means that the compound is not identified, and therefore, not reported in the result. The processing and first review of this data is completed by a supervisor. The final,

processed data undergoes a second review, which is completed by another supervisor or manager before a Forensic Toxicology report is issued.

Event Description

On September 15, 2014, a medical examiner submitted samples to Forensic Toxicology for basic drug screening. Basic drug screening is the procedure designed to screen alkaline drugs in biological specimens using GC/MS. On the same day, the medical examiner also emailed the laboratory and informed them that the decedent was a known Angel Dust user. Angel Dust is the street name for Phencyclidine (PCP). The laboratory received the samples and scheduled testing.

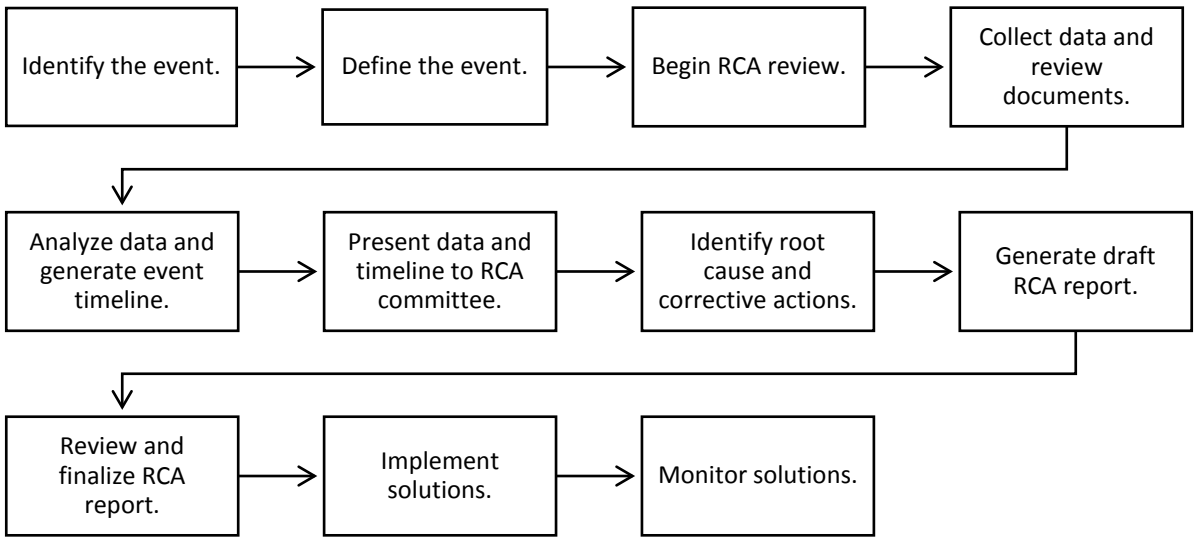
On October 4, 2014, the laboratory tested blood from the left pleural cavity by GC/MS (the pleural cavity is a narrow space between the membranes of the lung and inner chest wall). During processing, the peak labeled as PCP was deleted by the supervisor. On 10/16/2014, Forensic Toxicology issued a report with negative results for PCP for blood from the left pleural cavity.

On October 22, 2014, the medical examiner requested that the case be re-opened and that the sample be retested. In addition to blood from the left pleural cavity, Forensic Toxicology also tested blood from the heart and brain tissue. This time, all samples were positive for PCP, and a second report was issued on November 21, 2014 reflecting this information.

Forensic Toxicology repeated the testing of all samples that were processed simultaneously with the sample that was reported incorrectly. This re-testing was performed in March 2015 and involved 18 cases. No other discrepancies were discovered.

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 as 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 that serves in a medical or scientific research field. The members of this RCA committee include the following:

- The root cause analysis officer.
- Two laboratory employees who are knowledgeable in the subject area relating to the event.
- A member of the OCME executive management.
- Two managers from an OCME department that is not implicated by the event.
- A non-managerial employee from an OCME department that is not implicated by the event.
- An outside expert with experience in patient safety and risk management.

Findings and Root Cause

After reviewing the GC/MS testing process and the event timeline, the RCA committee further explored the workflow and used both the Fishbone diagram and the 5-Whys method to brainstorm 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.

The RCA committee identified the following as causal factors:

The second review is based on a paper copy of the already processed data.

When the supervisor is done processing the data, a paper copy of the final product is printed. The processing changes are summarized in this printed file but specific changes are not listed. This printed file is added to the case folder, which contains all of the paper records and documents associated with the case. The second review is based on a review of the case folder. The second review does not include review of the unmodified raw data.

The second review procedure is not standardized.

During discussion of the second review, it was stated that even though the paper copy of the processed data does not include specific processing changes, if a reviewer determines that further investigation is needed, he or she may retrieve the processed data and review and re-analyze it as necessary. Re-reviewing the processed data is not in the laboratory standard operating procedure, and determining if it is necessary is at the discretion of the reviewer. In this case, the second reviewer did not re-review the processed data. When asked, the laboratory employee participating in the RCA stated that she would have re-reviewed the processed data based on the information presented.

The software used to process raw data lacks features to prevent reporting errors.

The software does not notify the user or provide an alert before a peak label is deleted.

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 *distractions in the laboratory, staff feeling*

pressure to process cases, and *supervisors having too many responsibilities*. These factors impact the second reviewer's ability to focus on the technical review and to identify issues with the data.

Based on the above findings, the RCA committee determined that the process should have caught and identified the unintentional peak deletion at the second review, before the result was issued. The lack of a standardized procedure that requires the re-review of the processed data and the raw data is the root cause for this error. See Appendix B and C for Fishbone diagram and 5-Whys analysis.

Corrective Action Plan

The RCA committee recommends the following actions:

1. Forensic Toxicology must revise its second review procedure. This revision must include the review of the processed data and printouts of the raw chromatograms so that the second reviewer is able to determine whether peaks have been properly identified and integrated. This will ensure a second evaluation of unidentified peaks in the processed data vs.the previous review and give the second reviewer an opportunity to identify errors or unintentional deletions.

2. Forensic Toxicology must standardize the second review procedure. This will eliminate the variation in practice due to the reviewer's having the discretion to re-review the processed data or not. Once the second review 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 the implementation.

3. Forensic Toxicology must take steps to address the contributing factors by providing second reviewers with protected time or space to work on their cases with minimum interruptions. There are several possibilities to accomplish this. Dedicated space with a door can be made available for reviewers to work on cases undisturbed. Alternatively, a specific time of the day can be assigned to reviews. During this time, sample and instrument questions that normally go to the reviewer may be forwarded to another criminalist.

4. Lastly, the RCA committee recommends that Forensic Toxicology contact the software vendor and inquire about alerts and error prevention features. It is possible that the vendor may have introduced new functionality and features in a software update and not have communicated them to Forensic Toxicology. The vendor may also provide an alternative solution to address the question.

Root Cause	Corrective Action	Completion Date
Current procedure does not require re-review of processed data and raw data.	Revise second review procedure to include re-review of processed data and printouts of raw chromatograms.	6/30/15
Variation in practice regarding the re-review of processed data.	Standardize re-reviewl of processed data with all reviewers in the laboratory through training.	6/30/15
Interruptions in the laboratory distract reviewers.	Provide reviewers with protected time and space to minimize interruptions.	6/30/15
Lack of error prevention features in the processing software.	Contact the vendor and inquire about alerts and error prevention features.	6/30/15

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

Appendix A

CHRONOLOGY OF EVENTS

DATE	SOURCE OF INFORMATION	EVENT
9/15/14	Tox. requisition	Basic screening requested for ME case M14-5493.
9/15/14	Tox. Lab report	Specimen received in laboratory. Lab# 3451/14.
9/15/14	Email	Medical examiner emailed laboratory and confirmed that decedent is a known angel dust user. He requested comprehensive toxicology testing.
10/4/14	Tox. Quantitation Report	Lab tests blood from left pleural cavity. Test performed by gas chromatography and mass spectrometry. During processing, PCP is deleted by first reviewer.
10/6/14	Tox. Quantitation Report	Results are checked by second reviewer.
10/16/14	Tox. Lab report	Lab report issued. Results for blood (left pleural cavity) negative for PCP.
10/17/14	CMS	Tox. Lab report uploaded to CMS.
10/22/14	Interview	Based on conversation with medical examiner, the case is re-opened.
11/21/14	Tox. Lab report	Second report issued. Results for blood (heart), blood (left pleural cavity) and brain positive for PCP. Tests performed by gas chromatography and mass spectrometry.
1/28/15	Email	Lab responded to follow-up email requesting status of repeat testing. The lab states that PCP was detected on repeat testing and that the report is in final review.
2/3/15	CMS	Second Tox. Lab report 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 B


Problem Statement
Inaccuracy of Toxicology report.
Method
Deleted PCP label not discovered during review.
Processing data and raw data was not re-
Processing data and raw data is not
Review of processing data and raw data is not standard operating
Deleted PCP label not discovered during review.
Processing data is not reviewed by all reviewers
Lack of standardization of review
Reviewers developed own protocol for
Re-reviewing processing data
Materials
No Materials-related causes were identified
Machines
First reviewer not aware that peak label was
Software does not provide an alert or confirmation
Alert feature not available in software
Environment
Supervisors are unable to focus on reviews.
Supervisors are constantly interrupted.
-workers/interns have complete access
No protected time/space for
Supervisors are unable to focus on reviews.
Supervisors have too many responsibilities.
Only four supervisors to support GC/MS reviews.
Additional criminalists have not been hired.
Supervisors are unable to focus on reviews.
Staff feel pressure to push out cases.
Medical examiners call and ask for results.
Information
Processing data not readily available for review.
Software saves changes to data as another revision.
Software not designed to view changes made by a user as a list.
People
No People-related causes were identified.

Appendix C

Event 15-003 - 5 Whys	Problem Statement: Inaccuracy of Toxicology report.	
CATEGORY	WHY 1	WHY 2 - 5
Method	Deleted PCP label not discovered during second review. Why?	Processing data and raw data was not re-reviewed. Why?
		Processing data and raw data is not included in reviewed copy. Why?
		Review of processing data and raw data is not standard operating procedure.
	Deleted PCP label not discovered during second review. Why?	Processing data is not reviewed by all reviewers. Why?
		Lack of standardization of second review procedure. Why?
		Second reviewers developed their own criteria/protocol for review. Why?
		Re-reviewing processing data is not standard operating procedure.
Machines/Measurement	First reviewer not aware that peak label was deleted. Why?	Software does not provide an alert or confirmation of deletion. Why?
		Alert feature is not available in software.
Materials	*No Materials-related causes were identified.*	
Information	Processing changes not readily available for review. Why?	Software saves changes to data as another revision. Why?
		Software not designed to view changes made by a user as a list.
Environment	Supervisors are unable to focus on work and reviews. Why?	Supervisors are constantly interrupted. Why?
		Co-workers and interns have complete access to supervisors. Why?
		No protected time/space for supervisors to conduct second reviews.
	Supervisors are unable to focus on work and reviews. Why?	Supervisors have too many responsibilities. Why?
		There are only four supervisors to support GC/MS reviews. Why?
		Additional criminalists have not been hired.
	Supervisors are unable to focus on work and reviews. Why?	Staff feel pressure to push out cases. Why?
		Medical examiners call and ask for results.
People	*No People-related causes were identified.*	