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# ROOT CAUSE ANALYSIS REPORT
# EVENT ID# 15-004
# 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 on November 14, 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 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 15-004. 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 15-003.

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 not having guidelines for a reviewer to identify a sample as "unsuitable for testing."In this regard, Forensic Toxicology lacks defined criteria to guide reviewers when determining whether to reject a sample due to quality so poor that it interferes with laboratory analysis. The Root Cause Analysis Committee recommends that Forensic Toxicology revise its review procedure and establish these criteria and guidelines for reviewers.

## 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 enzyme immunoassay (EI) and gas chromatography/mass spectrometry (GC/MS). EI is a presumptive test used to evaluate blood or urine in determining the possible presence of controlled substances. EI uses antibodies and color change to indicate the possibility that a substance is present. If the EI result is positive, a confirmatory test by GC/MS is requested. GC/MS is a confirmatory test that is used to conclusively identify a controlled substance or any other drug of interest. GC/MS separates, identifies and measures many 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 will have identities assigned to endogenous compounds including non-drug peaks. During processing, it is necessary to delete peak labels representing endogenous compounds and incorrect identifications. Deletion of the peak label means that the compound is non-drug or not identified, and therefore, not reported in the result. The sample analysis, processing and first review of this data is completed by a trained criminalist or supervisor . The final, processed data undergoes a second review, which is completed by a supervisor before a Forensic Toxicology report is issued.

**Event Description**

On September 11, 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. The medical examiner noted on the Forensic Toxicology Request Form that drugs were found at the scene and that “Crystal Meth” is suspected. Crystal Meth is a street name for methamphetamine (an amphetamine class drug). The laboratory received the samples and scheduled testing.

On September 15, 2014, the laboratory tested decomposition fluid from the right pleural cavity by EI (the pleural cavity is a narrow space between the membranes of the lung and inner chest wall). The EI result was positive for amphetamines as a class of drugs and the GC/MS test was scheduled. The GC/MS result was negative. On November 14, 2014, Forensic Toxicology issued a report with negative results for decomposition fluid from the right pleural cavity.

On November 26, 2014, the medical examiner requested that the case be re-opened and that the sample be retested. In addition to the decomposition fluid from the right pleural cavity, the medical examiner requested that brain tissue be tested. The second round of testing confirmed all samples positive for methamphetamine and a second report was issued on February 13, 2015 reflecting this information.

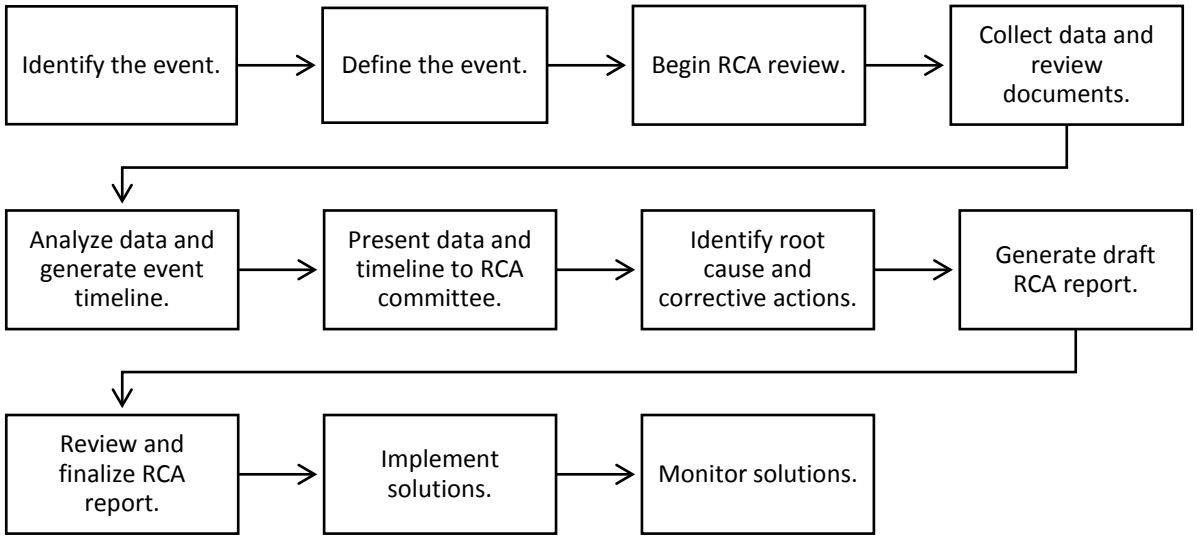
Forensic Toxicology repeated the testing of all samples that were processed simultaneously with the sample that was reported incorrectly. This re-testing was performed in March 2015 and involved 13 cases. No other discrepancies were discovered.

After reviewing the case, Forensic Toxicology modified their protocol. For cases in which the submitted samples appear decomposed, the samples will be simultaneously analyzed without dilution and with a 1:5 dilution. Dilution of the sample may improve the quality of the analysis and provide better results.

**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 EI and 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 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 procedure for troubleshooting difficult specimens is not standardized.*

The submitted sample was a decomposed sample. Decomposition can interfere with and complicate laboratory analysis of samples. Initially, the laboratory re-tested the sample for

amphetamines without modification. When presented with another set of results from the same sample, a senior criminalist asked that the sample be diluted before repeating the test. Dilution may often improve the quality of analysis for fatty or decomposed samples. The dilution technique is not always employed in the subject analysis in the laboratory.

Prior to the RCA, Forensic Toxicology modified its protocol for the subject analysis and now tests both diluted and undiluted samples from decomposed specimens. The RCA committee approves of this revision.

*Forensic Toxicology lacks defined criteria for calling a sample "unsuitable for testing."*
During discussion of the troubleshooting process, the RCA committee noted variations regarding when a reviewer called a sample "unsuitable for testing" and requested another aliquot or tissue sample for analysis. When the sample was initially tested, the criminalist deemed the chromatogram as "acceptable" and did not order further testing. When the data was reviewed by another criminalist, the chromatogram was deemed "unacceptable." This criminalist rejected the results, requested another aliquot and ordered additional tests. The criteria regarding what is considered an "acceptable" chromatogram and when to reject the chromatogram and request another sample is not defined in the laboratory.

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 there are decision points in the review process at which the inaccurate report could have been prevented from being released. These points represent decisions a reviewer has to make regarding the quality of the sample and data. The RCA committee found that the reviewer had little guidance regarding how to determine if the chromatogram was acceptable or not. The lack of guidelines for calling a chromatogram "unacceptable" and requesting another sample is the root cause of 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 review procedure. This revision must include the establishment of criteria or guidelines regarding when the laboratory will consider the chromatogram to be "unsuitable" and request another sample for testing. This will ensure that all reviewers have the same standards of acceptability when reviewing chromatograms. This will also ensure that poor quality samples that can affect laboratory analysis are rejected and a better sample is tested instead.

2. Forensic Toxicology must standardize the review procedure with all reviewers. This will eliminate the variation in practice due to the reviewer's having to determine if a chromatogram is unsuitable in the absence of defined criteria.

Once the 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 the reviewer may be forwarded to another criminalist.

| Root Cause | Corrective Action | Completion Date |
|---|---|---|
| Lack of criteria or guidelines for identifying "unsuitable" samples. | Establish criteria or guidelines for a reviewer to identify a chromatogram as "unacceptable" and to request another sample for testing. | 6/30/15 |
| Variation in practice regarding the identification of "unsuitable" samples. | Standardize identification of "unsuitable" chromatograms 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 |

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

**Appendix A**

## CHRONOLOGY OF EVENTS

| DATE | SOURCE OF INFORMATION | EVENT |
|---|---|---|
| **9/11/14** | Tox. Requisition | Basic screening requested for ME case M14-5422. ME notes on requisition that drugs were found at the scene and that crystal meth is suspected. |
| **9/11/14** | Tox. Lab report | Specimen received in laboratory. Lab# 3396/14. |
| **9/15/14** | Tox. Quantitation Report | Enzyme immunoassay test result is positive. Sample is then tested on gas chromatography/ mass spectrometry. GC/MS result is negative. |
| **11/14/14** | Tox. Lab report | Lab report issued. Results for decomposition fluid negative for methamphetamine. |
| **11/14/14** | CMS | Tox. Lab report uploaded to CMS. |
| **11/26/14** | Interview | Based on conversation with the medical examiner, case is re-opened. Medical examiner requests that the brain is included in repeat testing. |
| **11/26/14 – 1/2/15** | Memo to Tox. Case File | Three aliquots of the brain are tested because of complications due to decomposition. Methamphetamine is detected. |
| **11/26/14 – 1/22/15** | Memo to Tox. Case File | Four aliquots of the decomposition fluid are tested because of complications due to decomposition. The fluid is re-extracted and tested. Methamphetamine is detected. |
| **1/26/15** | Email | Lab responded to follow-up email requesting confirmation of initial negative results. The lab states that they are in the process of generating a report. |
| **2/13/15** | Tox. Lab report | Second report issued. Results for brain and decomposition fluid positive for methamphetamine. Test performed by enzyme immunoassay and gas chromatography/ mass spectrometry. |
| **2/17/15** | 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
Inconsistent troubleshooting practices in the lab.
Some difficult specimens undergo troubleshooting, some do
Staff developed their own protocol for troubleshooting
Lab lacks standardized procedure for troubleshooting specimens.
Materials
Inconsistent sample rejection practices
Some difficult samples are rejected while others
Staff developed their own criteria
Lab lacks criteria for "unacceptable"
Poor sample quality interferes with lab analysis.
Submitted samples were severely decomposed.
Decedent was found in a "moderate state of
Machines
No Machines-related causes were
Information
No Information-related causes were identified.
People
No People-related causes were identified.
Environment
Supervisors are unable to focus on
Supervisors are constantly interrupted
Co-workers/interns have complete
No protected time/space for
Supervisors are unable to focus on reviews.
Supervisors have too many responsibilities.
Only four supervisors to support GC/MS
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.

## Appendix C

| Event 15-004 - 5 Whys | Problem Statement: Inaccuracy of Toxicology report. | |
|---|---|---|
| **CATEGORY** | **WHY 1** | **WHY 2 - 5** |
| **Method** | Inconsistent troubleshooting practices in the lab. Why? | Some difficult specimens undergo troubleshooting, some do not. Why? |
| | | Staff developed their own protocol for troubleshooting specimens. Why? |
| | | Lab lacks standardized procedure for troubleshooting specimens. |
| | Inconsistent sample rejection practices in the lab. Why? | Some difficult samples are rejected while others are repeated. Why? |
| | | Staff developed their own criteria regarding sample rejection. Why? |
| | | Lab lacks defined criteria for "unacceptable" chromatogram and requesting another aliquot. |
| **Machines** | *No Machines-related causes were identified.* | |
| **Materials** | Poor sample quality interferes with lab analysis. Why? | Submitted samples were severely decomposed. Why? |
| | | Decedent was found in a "moderate state of putrefaction". |
| **Information** | *No Information-related causes were identified.* | |
| **Environment** | Supervisors are unable to focus on reviews. Why? | Supervisors are constantly interrupted. Why? |
| | | Co-workers/interns have complete access to supervisors. Why? |
| | | No protected time/space for supervisors to review. |
| | Supervisors are unable to focus on reviews. Why? | Supervisors have too many responsibilities. Why? |
| | | Only four supervisors to support GC/MS reviews. Why? |
| | | Additional criminalists have not been hired. |
| | Supervisors are unable to focus on reviews. Why? | Staff feel pressure to push out cases. Why? |
| | | Medical examiners call and ask for results. |
| **People** | *No People-related causes were identified.* | |