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ROOT CAUSE ANALYSIS REPORT
EVENT ID# 15-007
JUNE 25, 2015

Executive Summary

On April 7, 2015, the Office of the Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error from January 30, 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 May 5, 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 15-007.

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 protocols for (1) required verification that all confirmatory tests were scheduled, and (2) the final review of cases. The Root Cause Analysis Committee recommends that Forensic Toxicology implement the use of checklists during scheduling and final review 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 assist in determining the cause and manner of death.

A test routinely performed by Forensic Toxicology is the identification, confirmation and quantification of drugs indicated by enzyme immunoassay (EI) using liquid chromatography/mass spectrometry (LC/MS). 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 is scheduled using the most appropriate method. LC/MS, one of a number of confirmatory tests, is currently used to separate, identify and quantitate a panel of opiates, opioids, cocaine and two cocaine metabolites together in one assay.

The data collected by the LC/MS is visually represented as peaks on a chromatogram. For quantitative results the date must be "processed". Processing includes establishing the calibration curve, performing computer evaluation of quality control 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, hardcopies 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 Assistant Directors review all data before a Forensic Toxicology report is issued. See Appendix A for a diagram of the laboratory workflow.

Event Description

On December 29, 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 "substance abuse" and "methadone" on the Forensic Toxicology Request Form. The laboratory received the samples and scheduled testing.

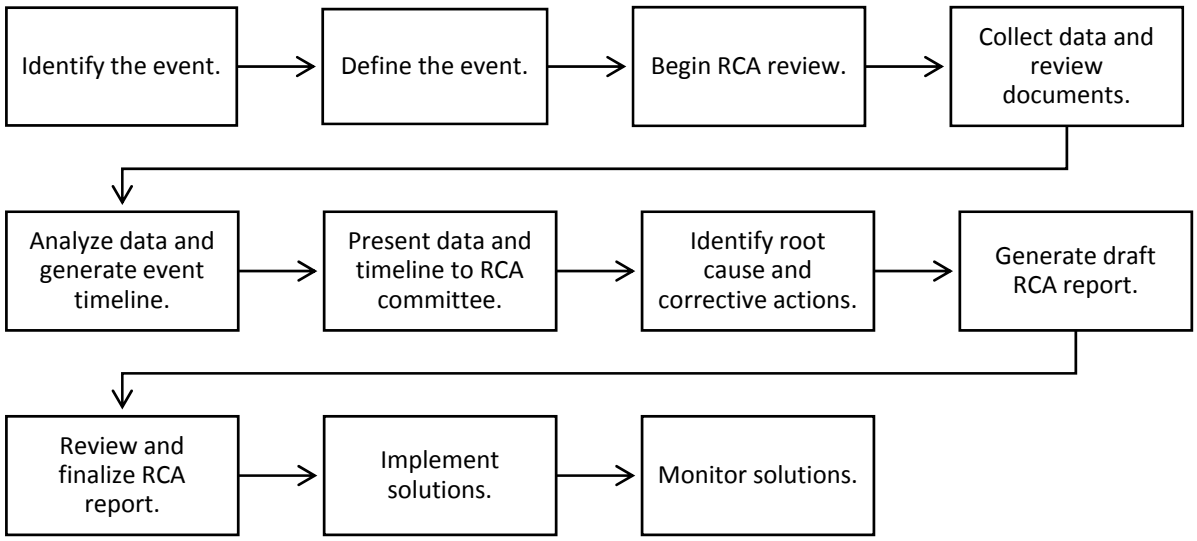
On December 31, 2014, the laboratory tested femoral blood and urine by EI and GC/MS. The EI result was positive for cocaine metabolite, benzodiazepines, and methadone and negative for morphine. The laboratory scheduled confirmatory tests by GC/MS for benzodiazepines and methadone but did not schedule a confirmatory test for cocaine. On January 30, 2015, Forensic Toxicology issued a report with positive results for benzodiazepines and methadone only.

On March 24, 2015, the medical examiner requested that the case be re-opened and that the sample be retested. The medical examiner questioned the result since drug paraphernalia was found at the scene, strongly suggesting the possibility of illicit or other additional substances. In addition to the femoral blood and urine, Forensic Toxicology also tested vitreous humour. This time, in addition to benzodiazepines and methadone, all samples were found to be positive for morphine and cocaine. A second report was issued on April 2, 2015 reflecting the new information. See Appendix B for a complete event chronology.

Forensic Toxicology reviewed and verified that the appropriate confirmatory tests were scheduled for all cases analyzed by involved personnel on December 31, 2014. This review was conducted between May 6, 2015 and May 14, 2015 and involved 36 cases. No other scheduling errors 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 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 both toxicology and patient safety.

Findings and Root Cause

After reviewing the 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 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.

In this event, cocaine and morphine were found to be positive after the medical examiner requested that the case be re-opened. The RCA committee reviewed each new result separately.

Regarding morphine, the RCA committee determined that no error had occurred and that the criminalist followed established protocol. Morphine was not reported in the initial laboratory report because the sample result was below the established EI reporting threshold concentration for morphine. The reporting threshold concentration is the cut-off value above which a sample is considered as "positive". A cut-off value is set by the sensitivity limits of the commercial methodology and the confirmatory instrumentation. A sample result that is not above the cut-off value does not necessarily mean that the substance is not present, only that it did not meet

reporting threshold criteria. Because the sample did not meet the cut-off value, it was not scheduled for confirmatory testing for morphine.

Regarding cocaine, the RCA committee determined that the error occurred due to an error in the scheduling process. The committee identified the following causal factors:

1. The scheduling process does not verify that all confirmatory tests have been scheduled.
After the EI results are reviewed, the samples with positive results are scheduled to be confirmed. The criminalist manually schedules the confirmatory tests on the case file and in the DataEase database application. Verifying that confirmatory tests have all been scheduled is not standard procedure in the laboratory.

2. The final review procedure does not verify that all confirmatory tests have been scheduled.
The final review represents the laboratory's final quality check before the report is signed and issued. This final check involves a review of the complete case file, including all paper records and documents associated with the case and, of equivalent importance, evaluation of the data for consistency with the history provided. The RCA committee confirmed that the EI test results and the medical examiner note regarding "substance abuse" were available during review. Review of these documents should have led to the discovery of the missed test. The committee also learned that the laboratory's review procedure does not include verifying that all appropriate tests were scheduled. The laboratory relies on the skill and experience of the reviewer to conduct a complete and accurate final check of all documents.

3. The laboratory software is antiquated and is not integrated with the laboratory equipment.
The system is unable to provide the laboratory any error checking or test scheduling assistance.

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 *insufficient time to complete reviews*, *staff feeling pressure to process cases*, and *supervisors having too many responsibilities*. These factors impact the 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 the missing confirmatory test before the report was issued, during either scheduling or final review. The lack of a standardized procedure that requires verifying scheduled tests and reviewing the list of tests scheduled 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 revise its scheduling procedure. This revision must include verification that all needed confirmatory tests have been scheduled in DataEase. Once the scheduling 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.

2. Forensic Toxicology must standardize the scheduling procedure. The RCA Committee recommends that the laboratory pilot the use of a checklist that includes the critical steps in the scheduling procedure. The checklist will help to ensure consistency and completeness by serving as a memory aid for the criminalist scheduling tests.

3. Forensic Toxicology must revise the final review procedure. The revised procedure must include verification that all confirmatory tests were scheduled. This procedure must also identify who is responsible for reviewing documents and identify the critical documents that must be reviewed before a report is issued. 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 its implementation.

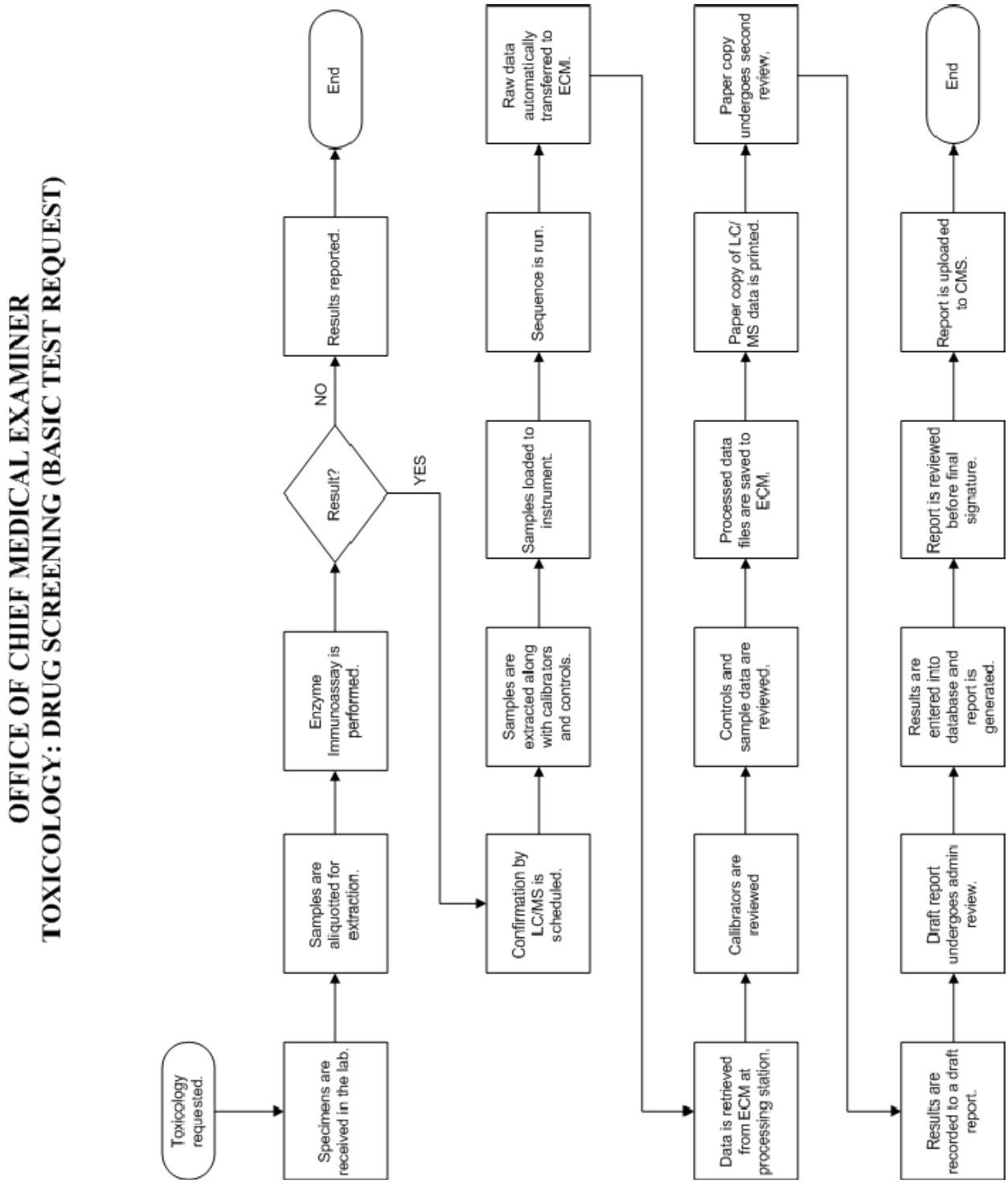
4. Forensic Toxicology must standardize the final review procedure. The RCA committee recommends that the laboratory pilot the use of a checklist for reviewers. The checklist will help to ensure consistency and completeness by serving as a memory aid for the reviewers.

5. 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.

Causal Factor	Corrective Action	Recommended Completion Date
Current test scheduling procedure does not require verification that all confirmatory tests have been scheduled.	Revise the scheduling procedure to include verification that all needed confirmatory tests were scheduled.	9/30/15
Variation in practice regarding scheduling of tests.	Standardize verification of scheduled tests by piloting the use of a checklist.	9/30/15
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 verification that all needed confirmatory tests were scheduled, details regarding who is performing reviews and a list of documents that must be reviewed before the report is issued.	9/30/15
Variation in practice regarding the final review of cases.	Standardize review process by piloting the use of a checklist.	9/30/15
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.	9/30/15

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

Appendix A


OFFICE OF CHIEF MEDICAL EXAMINER
TOXICOLOGY: DRUG SCREENING (BASIC 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 LC/MS 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 LC/ MS 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

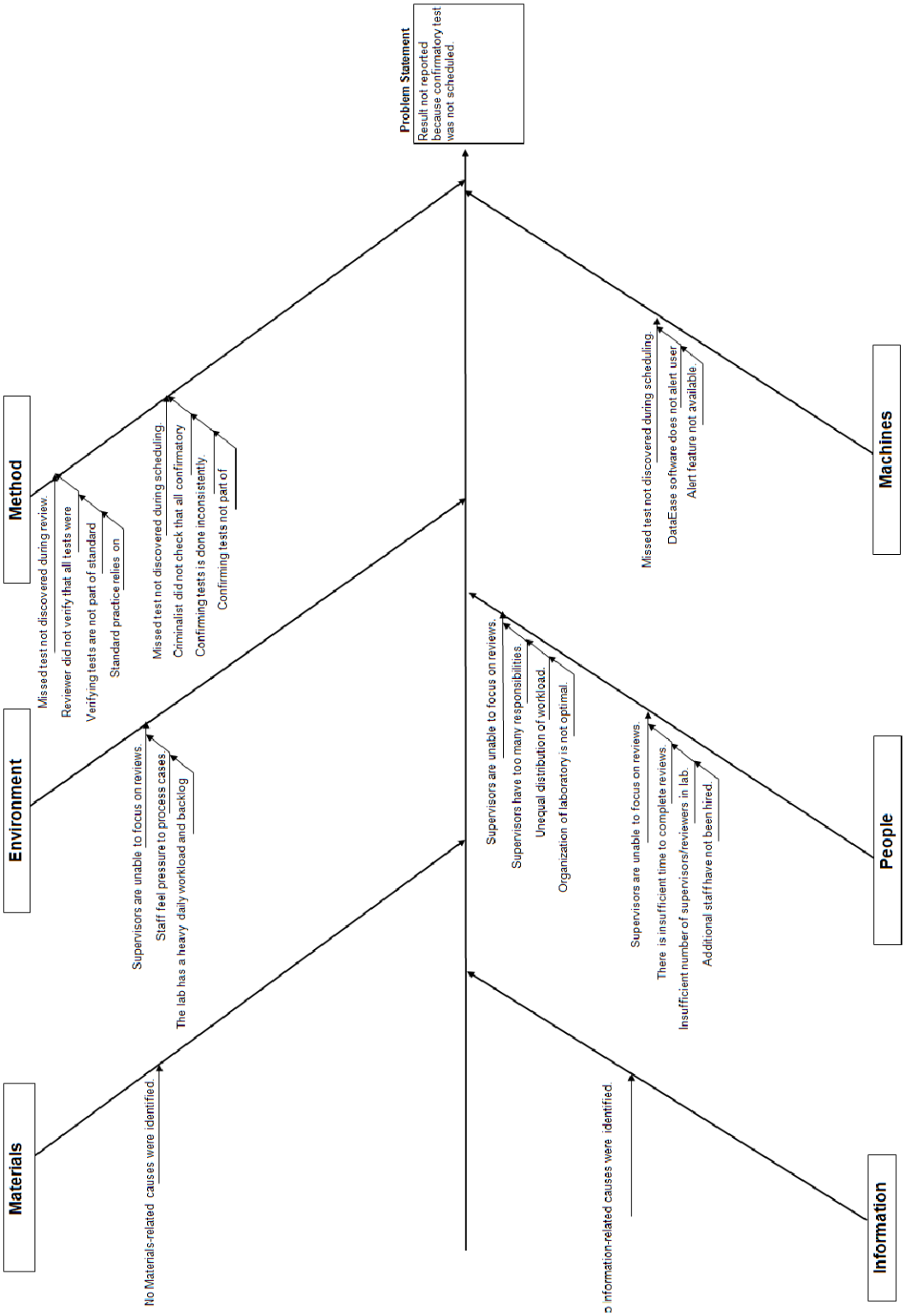
Appendix B

CHRONOLOGY OF EVENTS

DATE	SOURCE OF INFORMATION	EVENT
12/29/14	Tox. requisition	Basic screening requested for ME case B14-5695.
12/29/14	Tox. Lab report	Specimen received in laboratory. Lab# 4839/14.
12/31/14	Tox. Immunoassay results	Lab tests femoral blood by immunoassay. Cocaine metabolite = positive. Confirmatory test for cocaine metabolite is not scheduled. Opiates = negative. Result was below the laboratory's concentration threshold.
1/30/15	Tox. Lab report	Technical review conducted.
1/30/15	Tox. Lab report	Lab report issued. Results for blood (femoral) and urine positive for methadone. Review process does not catch unscheduled confirmatory test for cocaine metabolite.
2/3/15	CMS	Tox. Lab report uploaded to CMS.
3/24/15	Email	Medical examiner requested confirmation regarding cocaine and morphine because decedent was found with drug paraphernalia. Case was re-opened.
3/26/15 – 3/31/15	Tox. Quantitation Report	Lab tested blood (femoral), urine and vitreous humour by liquid chromatography and mass spectrometry.
4/2/15	Tox. Lab report	Lab report issued. Results for blood (femoral), urine and vitreous humor positive for cocaine and morphine.
4/3/15	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 C


Problem Statement
Result not reported because confirmatory test was not scheduled.
Method
Missed test not discovered during review.
Reviewer did not verify that all tests were
Verifying tests are not part of standard
Standard practice relies on
Missed test not discovered during scheduling.
Criminalist did not check that all confirmatory
Confirming tests is done inconsistently.
Confirming tests not part of
Environment
Supervisors are unable to focus on reviews.
Staff feel pressure to process cases.
The lab has a heavy daily workload and backlog.
Materials
No Materials-related causes were identified.
Machines
Missed test not discovered during scheduling.
DataEase software does not alert user
Alert feature not available.
People
Supervisors are unable to focus on reviews.
Supervisors have too many responsibilities.
Unequal distribution of workload.
Organization of laboratory is not optimal.
Supervisors are unable to focus on reviews.
There is insufficient time to complete reviews.
Insufficient number of supervisors/reviewers in lab.
Additional staff have not been hired.
Information
o nformation-related causes were identified.

Appendix D

Event 15-007 - 5 Whys	Problem Statement: Result not reported because confirmatory test was not scheduled.	
CATEGORY	WHY 1	WHY 2 - 5
Method	Missed test was not discovered during review. Why?	Reviewer did not verify that all tests were scheduled. Why? Verifying tests are not part of standard procedure. Why? Standard practice relies on reviewer skill and experience only.
	Missed test was not discovered during scheduling. Why?	Criminalist did not check that all confirmatory tests were scheduled. Why? Confirming tests is done inconsistently. Why? Confirming tests not part of standard procedure.
Machines	Missed test not discovered during scheduling. Why?	DataEase software does not alert user that was test not scheduled. Why? Alert feature not available.
Environment	Supervisors are unable to focus on reviews. Why?	Staff feel pressure to process cases. Why? The lab has a heavy daily workload and backlog to review.
People	Supervisors are unable to focus on reviews. Why?	Supervisors have too many responsibilities. Why? Unequal distribution of workload. Why? Organization of laboratory is not optimal.
	Supervisors are unable to focus on reviews. Why?	There is insufficient time to complete reviews. Why? Insufficient number of supervisors/reviewers in lab. Why? Additional staff have not been hired.
Materials	No Materials-related causes were identified.	
Information	No Information-related causes were identified.	