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ROOT CAUSE ANALYSIS REPORT
RCA# 2022-01
November 18, 2022

Executive Summary

On August 26, 2022, the Office of Chief Medical Examiner (OCME) Quality Assurance Director was informed of an event which occurred in the Manhattan autopsy room. This event resulted in incorrect Forensic Toxicology and autopsy reports. 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 October 14, 2022, 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# 2022-01.

The RCA Committee met and reviewed the examination workflow and event details. The committee analyzed the causes for the identified labeling error and made two recommendations for agency leadership to consider based on the evidence presented. The RCA committee recommends that medical examiners implement a time-out procedure before beginning their examination similar to surgical time-outs in healthcare. The purpose of the time-out is for medical examiners to confirm the correct decedent is being examined and to verify that body tags, specimen container labels, and case paperwork match. The committee also recommends that the agency track specimen identification errors through the online Incident Report Form and share data with deputy chief medical examiners to increase awareness of these errors and monitor performance in this area.

Background

The OCME has the responsibility to investigate certain deaths, including those occurring from criminal violence, by accident, by suicide, suddenly when in apparent health, or in any unusual or suspicious manner. The agency also investigates any death that may present a threat to public health.

Generally, medical examiners review cases during the morning triage meeting and then assign cases to individual medical examiners. The Identification Unit then prints requisition forms and specimen container labels for all assigned cases. The medical examiner retrieves the forms and labels for their assigned cases and proceeds to conduct their examinations. After the examination is completed, the medical examiner submits specimens for laboratory testing and returns the completed paperwork to the Identification Unit.

See Appendix A for a diagram of the general autopsy examination workflow.

Event Description

On July 20, 2022, Case 1 was checked into to the Manhattan morgue. This was a medical examiner case involving an adult male with a brain tumor who was found dead at home.

On July 21, 2022, Case 2 was checked into to the Manhattan morgue. This was a medical examiner case involving an adult female with a history of substance misuse who was found dead in her room at an adult care facility at 4:56.

At 9:45, the medical examiner performed the autopsy examination on Case 2. Blood, tissue, urine, and vitreous specimens were collected and submitted to OCME laboratories for further analysis. The specimens were incorrectly labeled as Case 1 and the Forensic Toxicology Laboratory specimens were submitted along with the requisition form for Case 1.

At 11:25am, the same medical examiner performed an external examination on Case 1. Blood, urine, and vitreous specimens were collected and submitted to the Forensic Toxicology Laboratory for analysis. The specimens were incorrectly labeled as Case 2 and submitted along with the requisition form for Case 2.

On August 8, 2022, the Forensic Toxicology Laboratory issued the report for Case 2. Alcohol and drugs were not detected in the submitted blood sample.

On August 10, 2022, the medical examiner issued the autopsy report and certified the death certificate for Case 2. The medical examiner also informed the decedent's family that the manner of death was determined to be "natural" due to cardiovascular disease.

On August 25, 2022, the Forensic Toxicology Laboratory issued the report for Case 1. Fentanyl analogs and metabolites were detected in the blood sample. The medical examiner noted that the results were not consistent with the case information and realized that she had mislabeled the submitted specimens for Case 1 and Case 2. The medical examiner notified the laboratories of the error.

On September 15, 2022, the Forensic Toxicology Laboratory issued an amended report for Case 1. The laboratory issued an amended report for Case 2 the following day.

On October 4, 2022, a senior medical examiner amended the death certificate for Case 2 and notified the decedent's sister of the error.

On October 7, 2022, the senior medical examiner amended the autopsy report for Case 2.

See Appendix B for the chronology of events.

Causes and Contributing Factors
The RCA committee reviewed the examination workflow and event details and employed cause and effect analysis to identify the causes for the incorrect reports. Using this methodology, the RCA committee identified the following causal factors:

1. The medical examiner applied the incorrect labels on the specimen containers.

Evidence:
In addition to reviewing the examination workflow and event details, the RCA committee reviewed photos of the autopsy work area and the submitted laboratory specimen containers for Case 1 and Case 2. The committee also reviewed the requisition forms, case labels, Forensic Toxicology Laboratory reports, and autopsy reports for the involved cases.

The committee noted that there are potential risks for specimen identification errors with the current workflow. After the morning triage meeting, cases are assigned to individual medical examiners. The Identification Unit prints the needed requisition forms and a sheet of specimen container labels for each case assigned to medical examiners. The medical examiners pick up the forms and labels from the Identification Unit office and begin their examinations. The process is convenient and efficient. However, pre-printing forms and labels for multiple cases before specimen collection increases the risk of identification errors. If the medical examiner is not attentive, they can potentially use the wrong set of labels to label their specimens. Additionally, medical examiners do not discard unused case labels after the examination. These unused labels may later be used to incorrectly label specimen containers.

After speaking with staff, the committee identified a discrepancy between medical examiner expectations and the Identification Unit's perception of the label printing process. The Quality Assurance Director asked the medical examiner who submitted the specimens if she had verified the case labels before beginning her examination. The medical examiner replied that the Identification Unit staff had already collated the labels with the correct paperwork so it was not necessary to verify them. The medical examiner added that the Identification Unit staff have always performed this function and generally perform it well. This view of the label printing process did not match the Identification Unit's view. Identification Unit managers view the process as a task completed by the Identification Unit staff to facilitate the morning work and help the medical examiners begin their examinations. Identification Unit managers added that when the unit was assigned the task, it was not communicated to them that staff must match the forms and case labels before distribution, though paperwork is typically distributed in a collated packet for efficiency.

Pre-printed labels for multiple cases and a disconnect between medical examiners and management regarding the verification of paperwork contributed to the mislabeling error. Pre-printed labels increase the risk of an identification error in the autopsy room because it gives medical examiners multiple sets of labels to manage during their examinations. The risk of an identification error is further increased by the lack of clarity regarding who is responsible for verifying paperwork and labels printed by the Identification Unit.

Although senior medical examiners acknowledge that it is the medical examiner's responsibility to verify labels, the expectation is that the Identification Unit staff should verify and match case labels to the paperwork before distribution.

2. The specimen container labels were not verified before the specimens were submitted to the laboratories for testing.

Evidence:
Medical examiners have an opportunity to verify the labels on the specimen containers before the containers are submitted to the laboratories for testing. The Quality Assurance Director asked the medical examiner if she verified the labels applied to the containers. The medical examiner replied that she did not check the labels because she trusted the paperwork and labels given to her by the Identification Unit. She added that it was the Identification Unit's normal practice to verify paperwork and labels before distributing them to the medical examiners.

The Quality Assurance Director reviewed the medical examiner "Autopsy and Examination" protocol and did not find any guidelines regarding specimen collection or the labeling of specimen containers. The committee also noted that the medical examiner protocol does not include a witness step during labeling or an independent double-check of labeled specimen containers by a second individual.

3. Laboratory staff cannot detect identification errors that occur in the autopsy room.

Evidence:
The committee reviewed the examination workflow to determine if any quality control checks could have detected the mislabeling after the specimens were submitted to the laboratories. Committee members determined that due to the nature of the mislabeling, the error was not detectable to staff after the specimens left the autopsy room. Incorrectly labeled specimens that are submitted to the laboratories with requisitions forms that match the incorrect case number are not recognized as an error by laboratory staff. The case number and patient information on the incorrectly labeled specimen containers and the requisition forms matched so there was no discrepancy from the laboratory perspective. As a result, the information on the specimen labels and requisitions forms appeared "correct" to staff accessioning the specimens into the laboratory information management system.

See Appendix C for the cause and effect analysis diagram.

Recommendations

The lack of clarity regarding who is responsible for verifying paperwork must be addressed for the agency to minimize the risk of identification errors. Medical examiners must be reminded that ultimately, they are responsible for verifying the information on case labels used to label submitted specimens. Additionally, agency staff should be periodically reminded that decedent

identification is a shared responsibility that requires staff in all units to verify decedent information while performing their duties.

The RCA committee recommends the following actions to address the identified causal factors:

1. Medical examiners should implement a time-out procedure similar to surgical time-outs in healthcare. In a hospital setting, a surgical time-out is a pause taken by the team before the first surgical incision. The purpose of the time-out is for the team to confirm the correct patient, procedure, and site. The committee recommends that medical examiners and mortuary technicians conduct a time-out before the start of the examination to confirm that the correct decedent is being examined and verify body tags, specimen container labels, and case paperwork. To maximize effectiveness, the medical examiner and mortuary technician should stop what they are doing and actively participate in the time-out by verbally confirming the case number and decedent's name on the body tags, labels, and paperwork. Based on several committee members' experience, the time-out procedure should take less than a minute to perform. The committee also recommends that the time-out be documented by having the medical examiner sign an attestation statement on the case worksheet.

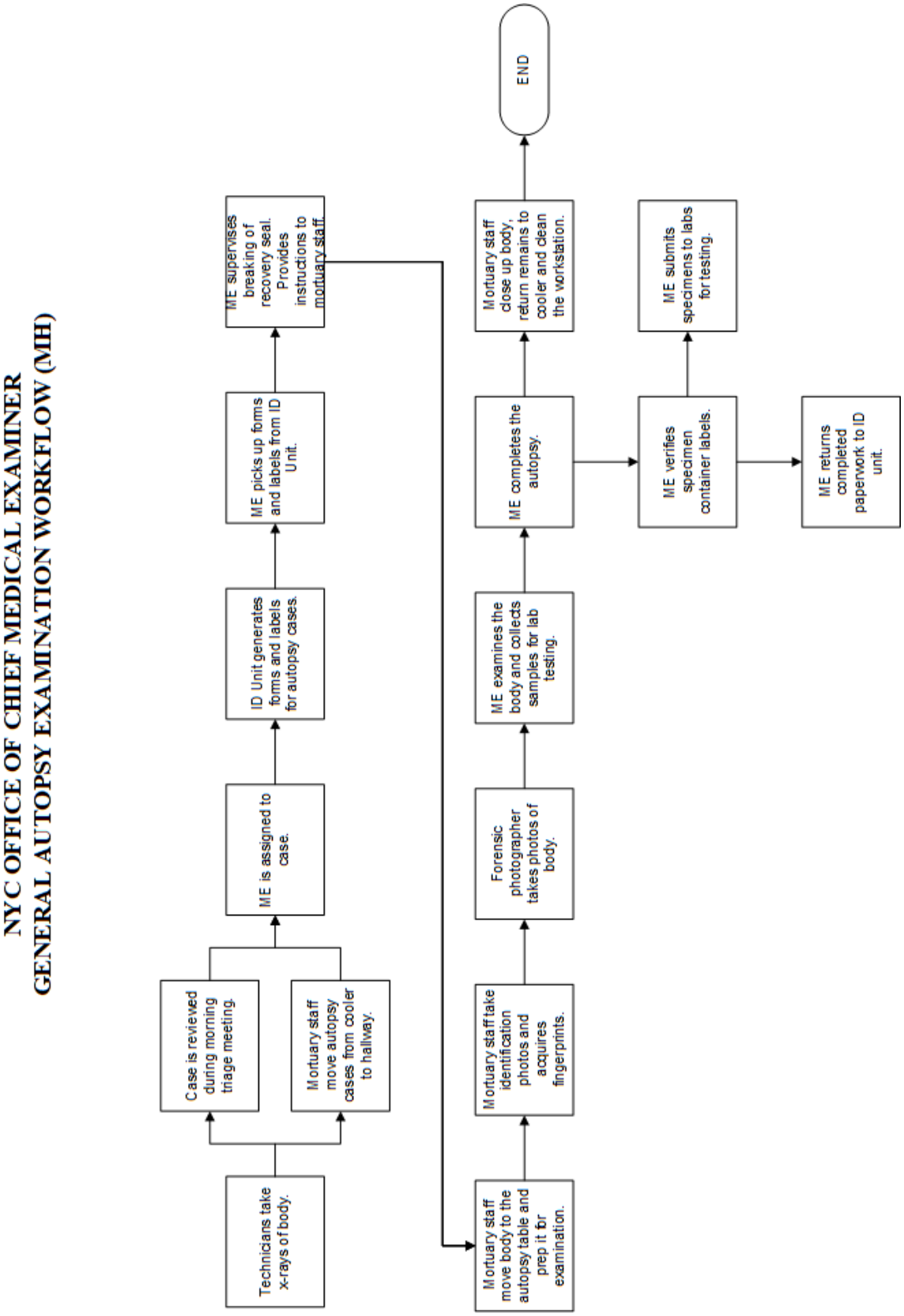
The low detectability of specimen identification errors emphasizes how critical the labeling of specimens in the autopsy room is for accurate testing. Special care and attention must be given when labeling specimens because a misidentification will follow a case through the entire testing process and ultimately impact the medical examiner's cause of death and manner of death determinations. A time-out procedure embedded into the medical examiner workflow will help to prevent these errors.

2. Medical examiners should report specimen identification errors through the agency's online Incident Report Form. The agency already uses the Incident Report Form to report potential adverse events such as wristband errors and postmortem injuries. The incident reports are forwarded to the agency's Executive Team, the Executive Director of Administration and Stakeholder Affairs, and the Director of Quality Assurance for awareness. The committee recommends that the agency add specimen identification errors to the list of potential adverse events captured by the reporting system to increase awareness and enhance agency-wide monitoring of identification errors.

The committee also recommends that all OCME laboratories track specimen identification errors and share the data with the deputy chief medical examiners. Currently, laboratory staff resolve identification errors by contacting the medical examiner who submitted the specimens. Sharing specimen identification error data with the deputy chief medical examiners makes senior medical examiners aware of the issue and allows them to monitor performance in this area. Reporting identification errors and providing quality data to medical examiners are also practices aligned with the requirements of the Patient Safety and Health Care Quality Focus Areas of the Accreditation Council for Graduate Medical Education (ACGME) Clinical Learning Environment Review (CLER) program.

Lastly, when resources become more available, it is suggested that the agency consider implementing an on-demand printing solution for labels. This would reduce the risk of human error in the labeling process by only printing the necessary labels when they are needed.

Appendix A

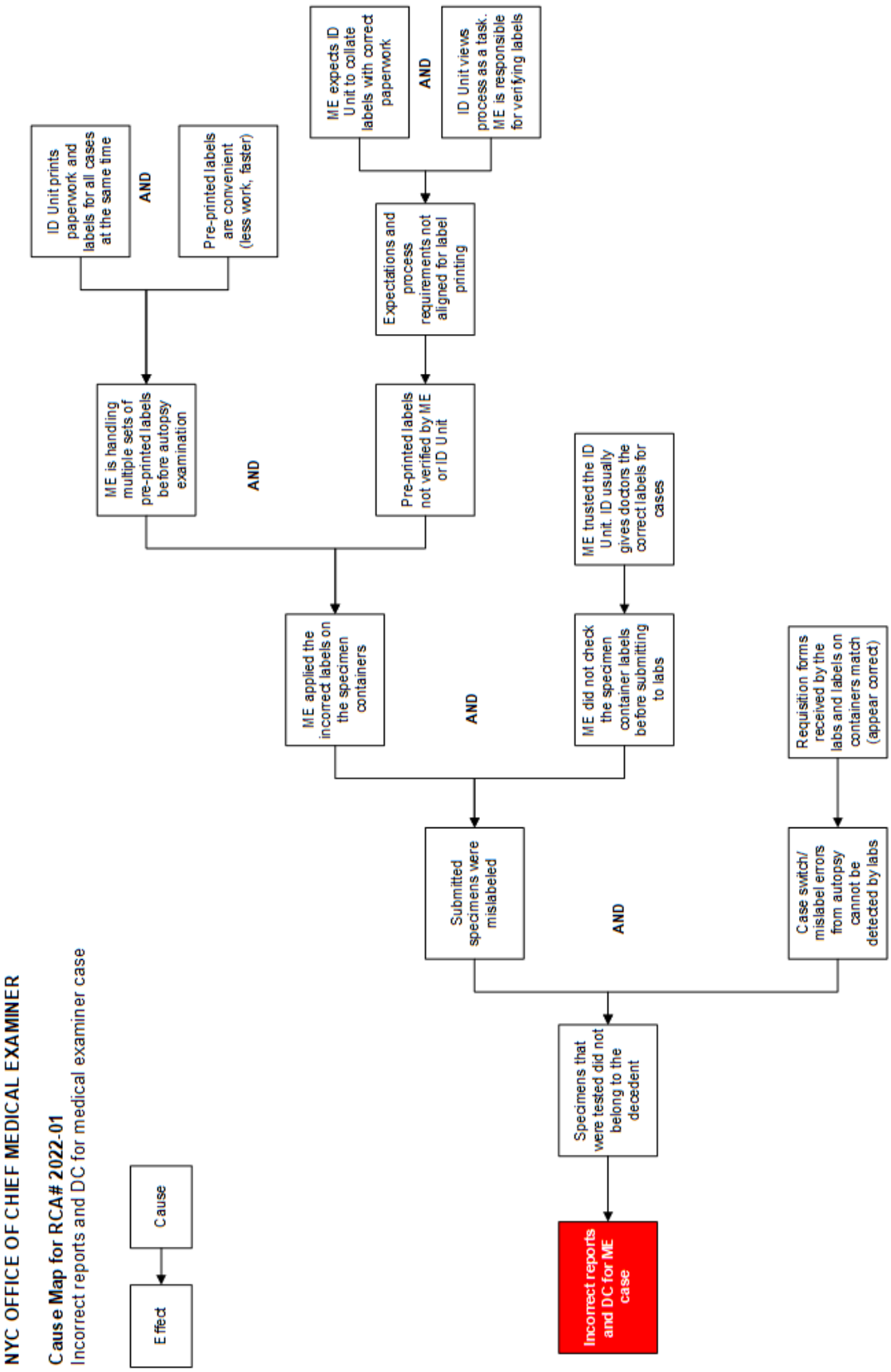

NYC OFFICE OF CHIEF MEDICAL EXAMINER
GENERAL AUTOPSY EXAMINATION WORKFLOW (MH)
Technicians take x-rays of body.
Case is reviewed during morning triage meeting.
Mortuary staff move autopsy cases from cooler to hallway.
ME is assigned to case.
ID Unit generates forms and labels for autopsy cases.
ME picks up forms and labels from ID Unit.
ME supervises breaking of recovery seal. Provides instructions to mortuary staff.
Mortuary staff move body to the autopsy table and prep it for examination.
Mortuary staff take identification photos and acquires fingerprints.
Forensic photographer takes photos of body.
ME examines the body and collects samples for lab testing.
ME completes the autopsy.
Mortuary staff close up body, return remains to cooler and clean the workstation.
END
ME verifies specimen container labels.
ME submits specimens to labs for testing.
ME returns completed paperwork to ID unit.

Appendix B

CHRONOLOGY OF EVENTS

DATE	EVENT
7/20/2022	At 21:18, Case 1 was checked into to the Manhattan morgue. This was a medical examiner case involving an adult male with a brain tumor who was found dead at home.
7/21/2022	At 4:56, Case 2 was checked into to the Manhattan morgue. This was a medical examiner case involving an adult female with a history of substance misuse who was found dead in her room at an adult care facility. At 9:45, the medical examiner performed the autopsy examination on Case 2. Blood, tissue, urine, and vitreous specimens were collected and submitted to OCME laboratories for further analysis. The specimens were incorrectly labeled as Case 1 and the Forensic Toxicology specimens were submitted with the requisition form for Case 1. At 11:25am, the same medical examiner performed an external examination on Case 1. Blood, urine, and vitreous specimens were collected and submitted to Forensic Toxicology for analysis. The specimens were incorrectly labeled as Case 2 and submitted with the requisition form for Case 2.
8/8/2022	Forensic Toxicology issued the report for Case 2. Alcohol and drugs were not detected in the blood sample.
8/10/2022	The medical examiner issued the autopsy report and certified the death certificate for Case 2. The medical examiner also informed the family that the manner of death was determined to be “Natural” due to hypertensive and atherosclerotic cardiovascular disease.
8/25/2022	Forensic Toxicology issued the report for Case 1. Fentanyl analogs and metabolites were detected in the blood sample. The medical examiner noted that the results were not consistent with the case information and realized that she had mislabeled the submitted specimens for Case 1 and Case 2. The medical examiner notified the laboratories of the error.
9/15/2022	Forensic Toxicology issued an amended report for Case 1.
9/16/2022	Forensic Toxicology issued an amended report for Case 2.
10/4/2022	A senior medical examiner amended the death certificate for Case 2 and notified the decedent’s sister of the error.
10/7/2022	The senior medical examiner amended the autopsy report for Case 2.

Appendix C


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for RCA# 2022-01
Incorrect reports and DC for medical examiner case
Cause
Effect
Incorrect reports and DC for ME case
Specimens that were tested did not belong to the decedent
AND
Submitted specimens were mislabeled
Case switch/ mislabel errors from autopsy cannot be detected by labs
Requisition forms received by the labs and labels on containers match (appear correct)
AND
ME applied the incorrect labels on the specimen containers
ME did not check the specimen container labels before submitting to labs
ME trusted the ID Unit. ID usually gives doctors the correct labels for cases
AND
ME is handling multiple sets of pre-printed labels before autopsy examination
Pre-printed labels not verified by ME or ID Unit
Expectations and process requirements not aligned for label printing
ID Unit prints paperwork and labels for all cases at the same time
Pre-printed labels are convenient (less work, faster)
AND
ME expects ID Unit to collate labels with correct paperwork
ID Unit views process as a task. ME is responsible for verifying labels
AND