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ROOT CAUSE ANALYSIS REPORT
RCA# 2023-01
March 4, 2024

Executive Summary

On December 1, 2023, the Office of Chief Medical Examiner (OCME) Quality Assurance Director was informed of an event that occurred in the Department of Forensic Biology. The event involved violations of standard operating procedures and accreditation standards. 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 January 25, 2024, OCME assembled a Root Cause Analysis (RCA) Committee to identify the causal factors and recommend corrective actions for this event, which was identified as RCA# 2023-01.

The RCA Committee met and reviewed the technical review workflow and event details. The committee analyzed the causes of the violations and made several recommendations for agency leadership to consider based on the evidence presented. The RCA committee recommended that the laboratory work with their Laboratory Information Management System (LIMS) vendor to develop a fix to prevent a technical reviewer from selecting a case in which they authored case examination records or drafted the report. The committee also recommended that management monitor the technical review step and enhance the laboratory's existing ethics program. Additionally, it was recommended that the laboratory ethics program be supported by an agency-wide ethics policy, a dedicated agency ethics officer, and a mechanism for reporting ethics violations confidentially with no retaliation.

Background

The Department of Forensic Biology is a laboratory operating within the Office of Chief Medical Examiner and has the mission of performing DNA testing on physical evidence from criminal cases within the City of New York. Staffed by more than 181 criminalists, supervisors and managers, the Department of Forensic Biology performs serology and DNA testing on nearly every category of crime including homicide, sexual assault, felony assault, robbery, burglary, hate crimes, and weapons possession.

Generally, a report analyst functions as the case manager and oversees the evidence examination and testing process. The report analyst is responsible for evaluating the examination notes and analytical data, interpreting the results, and authoring the final report. The report analyst submits the report to a second analyst for technical review. Technical review is a review of the examination notes, data, and other documents in the case file to ensure that the case report accurately reflects the results of testing, and all interpretations are based on objective scientific observations. See Appendix A for a diagram of the general laboratory workflow.

The Department of Forensic Biology is accredited by ANSI National Accreditation Board (ANAB) and must comply with all accreditation requirements in ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories and ANAB's Accreditation Requirements for Forensic Testing and Calibration accreditation requirements. Additionally, Forensic Biology must comply with all standards in the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. These requirements include standards that do not permit a technical reviewer to review a case in which they authored the examination records, including drafting the report. These standards ensure that evidence is handled in an ethical manner and that criminalists avoid potential conflict of interest that may bias examination or interpretation of data.

Event Description

On November 20, 2023, during a quality review of cases prompted by a non-casework related event (suspected cheating by three criminalists on an internal promotional exam), Forensic Biology staff identified quality assurance issues involving laboratory processes. Staff found several cases in which a criminalist (Criminalist #1) authored the case report and other records within the casefile, different criminalists (Criminalist #2 or Criminalist #3) electronically signed the case report as the author, and the criminalist who had authored the case report (Criminalist #1) also performed the technical review of their own work. The laboratory found this information through an audit of the OCME Laboratory Information Management System (LIMS), where all case examinations, reports and reviews are documented.

On November 27, 2023, the laboratory conducted the following quality assurance reviews to assess the issue:

- Assigned Forensic Biology analysts evaluated the LIMS case audit trails of cases in which Criminalists #2 or #3 electronically signed the reports and Criminalist #1 performed the technical review to assess whether Criminalist #1 authored the case report.

- Assigned Forensic Biology staff began to review all cases in which other direct reports/mentored colleagues of Criminalist #1 electronically signed the reports, and Criminalist #1 performed the technical review.

- Assigned Forensic Biology staff also began to review 10% of cases electronically signed by all other analysts, and Criminalist #1 performed the technical review.

On December 1, 2023, Forensic Biology staff completed the audit trail screenings of over one thousand cases. Staff found thirty-one cases in which Criminalist #1 authored the case report, either Criminalist #2 or Criminalist #3 electronically signed the report, and Criminalist #1 performed the technical review. These cases were assigned to a new analyst and technical reviewer and new reports were issued. There were no substantive changes between the previously issued reports and the newly issued reports.

Assigned Forensic Biology staff also evaluated all cases logged into the Laboratory Information Management System in which Criminalist #1, Criminalist #2, or Criminalist #3 provided trial or grand jury testimony. All cases were found to have reports that were either written and/or technically reviewed by individuals other than the three criminalists and were not cases identified as part of the quality assurance issue.

The three criminalists were summarily removed from all casework activities. Forensic Biology management notified customers and its accreditation bodies of the event and provided an update regarding their investigation.

Forensic Biology managers informed the committee that staff are working with the agency's IT department to develop a query that will allow managers to audit all technical reviewers in the LIMS database. The committee strongly recommended that the laboratory complete the development of the LIMS query and review the results to determine with certainty that this event was limited to the three criminalists and thirty-one cases that were identified on December 1, 2023.

Causes and Contributing Factors

The RCA committee noted that the three criminalists involved in this event were not available for questioning. The event is under New York City Department of Investigation review and OCME staff were advised not to question the criminalists.

The RCA committee assessed the laboratory's work environment for evidence that may suggest staff are overworked or pressured to meet unrealistic productivity goals. The committee reviewed various indicators for signs of decreased productivity, an increased attrition rate due to burnout, an increase in total nonconformities, and complaints made to the union.

The RCA committee reviewed management practices and laboratory productivity goals and found that report writers and technical reviewers are expected to complete 1.5 to 2 reports or technical reviews of reports per day. According to managers, most Criminalists meet this productivity goal without issue and there are no recent trends that suggest a decrease in productivity. Managers stated that staff are not placed on probation or terminated if they do not meet productivity goals. Managers may give staff a performance improvement plan to help improve their productivity or note it as an improvement goal in their annual evaluation.

The RCA committee reviewed laboratory turnover data for evidence that may suggest staff left the laboratory due to burnout or stress. The committee found that Forensic Biology has an average 10% voluntary attrition rate. The committee noted that the 10% attrition rate has been consistent for the last 25 years. By comparison, the New York State government employee attrition rate was 12.4% in 2021. According to averages in various industries, an attrition rate of 20% or higher is considered high and may signal issues with staff retention. The most common reasons Forensic Biology staff provided for leaving the agency include better pay, shorter commute/remote work, and a spouse finding a job elsewhere.

The committee also reviewed nonconformity data for trends that suggested staff were meeting productivity goals but submitting work with an increasing number of errors. After reviewing the total number of nonconformities for 2020, 2021, and 2022, the committee found that the total number of Type II nonconformities (excluding contamination events) decreased in recent years. Contamination events were excluded from the annual totals for this analysis because the contamination events during this period were due to new instrument sensitivity and were not caused by analyst actions. Based on the data provided, the committee did not find evidence that suggested staff were submitting poor quality work due to overwork.

The Quality Assurance Director also spoke with managers regarding complaints from staff. Managers stated that they were not aware of any formal complaints that had been filed to the union about overwork or pressure to meet productivity goals.

Based on the information presented, the committee did not find evidence suggesting that staff are overworked or pressured to draft reports.

The RCA committee reviewed the technical review process and employed cause and effect analysis to identify the causes for the Criminalists to violate procedure for writing and technically reviewing reports. Using this methodology, the RCA committee identified the following causal factors:

1. The technical review workflow permits criminalists to assign cases to themselves.

Evidence:
The committee reviewed Forensic Biology's "Technical Review" procedure and observed the workflow. The technical reviewer began by either working on a case that had been assigned to them or assigning themself a case from the LIMS Case Report List. According to staff, few cases are assigned to a technical reviewer, and it is more common for a technical reviewer to select a case and assign one to themselves. The laboratory's procedure includes guidelines to assist reviewers in choosing cases for technical review.

After selecting a case, the technical reviewer will review administrative paperwork and testing records and confirm that laboratory procedures were followed. The reviewer will then verify that all results and interpretations are accurate and supported by the data. After the report is verified to be complete and found to accurately reflect the supporting data, the technical reviewer will approve the report. The technical reviewer's approval is recorded in LIMS via an electronic signature which is authenticated by a unique username and password combination.

The audit trail screenings of the thirty-one cases staff had identified as having violated accreditation standards showed that Criminalist #1 authored examination records or drafted the case report but did not complete the electronic signature step as the reporting analyst. Criminalist #2 or Criminalist #3 logged in to LIMS and completed the electronic signature step as the case reporting analyst. Criminalist #1 then returned to the case and completed the electronic signature step as the technical reviewer.

After reviewing the above information, the committee noted that technical reviewers assign themselves to most of their cases. Managers stated that reviewers are permitted to select their cases because cases are chosen in a first in first out process to keep the flow of casework moving. Assigning cases to reviewers is a time-consuming task and would require dedicated staff to assess the appropriateness of a case to a reviewer. Additionally, the LIMS application does not prevent a technical reviewer from selecting a case in which the reviewer authored examination records or drafted the report. The process relies on staff following protocol and selecting cases that are appropriate for them to review.

While observing the technical review workflow, it was also noted that the LIMS Case Record screen only displays the name of the report analyst who completed the electronic signature step. However, a case may have several criminalists who interact with the case and author records. The limited visibility on the Case Record screen of all criminalists who interacted with the case is likely a contributing factor that made it easier for the violations to go unnoticed by staff.

2. The laboratory does not have an inspection step in place to verify that technical reviewers are not reviewing their own work.

Evidence:
The Quality Assurance Director reviewed Forensic Biology's "Technical Review" procedure, the "Audits and Assessments" procedure, and Case Management Checklists. The Director found that the laboratory does not have an audit or inspection step that verifies a technical reviewer did not review a case in which they authored examination records or drafted the report.

The Director discussed monitoring of the technical review process with laboratory managers and they stated that although the laboratory has implemented multiple audits and case file reviews, managers did not anticipate a need to check this specific step in the technical review process. Managers generally rely on criminalists to follow the technical review protocol, as well as accreditation requirements, and select the appropriate cases based on the guidelines provided.

3. The laboratory's ethics program is adequate but would benefit from additional support.

Evidence:
The committee reviewed the Forensic Biology ethics program and learned that the program has three components. These components are based on the ANSI National Accreditation Board (ANAB) Guiding Principles of Professional Responsibility for Forensic Science Providers and Forensic Personnel document. This document provides a general framework for ethical and professional responsibilities for forensic scientists. It describes nineteen responsibilities in the areas of professionalism, competency and proficiency, and communication.

The first component of the ethics program is the "Ethics in Forensic Science" training lecture. The lecture is part of the laboratory's new employee onboarding. It provides staff with a general introduction to ethics, examples of forensic science misconduct, and a review of the ANAB Guiding Principles.

The second component of the ethics program is the ANAB Guiding Principles Annual Review. The review consists of a Microsoft PowerPoint presentation that lists the nineteen guiding principles and a five-question quiz.

The third component of the ethics program is the "Quarterly Lab-wide Ethics" lecture. The goal of the lecture is to raise general awareness of ethical issues in the forensic laboratory. The quarterly presentation focuses on current and past high-profile cases of scientific misconduct at forensics labs.

The committee found Forensic Biology's ethics program to be adequate and similar to other ISO-accredited laboratories at the agency.

The committee noted that Forensic Biology does not have a formal written policy that states the laboratory's ethics policy and the consequences of violations. It was also noted that the training does not provide a clearly identified mechanism for staff to report ethical issues confidentially and without fear of retaliation. The ethics training instructs staff to report ethical issues directly to laboratory managers or the Human Resources Department. The training material informs staff that they can contact the New York City Department of Investigation or the New York State Office of the Inspector General but there is no mention that reporting is confidential or protected from retaliation.

The laboratory's ethics training is based on the ANAB Guiding Principles document which is a general ethics framework that can be used by any forensic science provider. As a result, the laboratory's training is broad and general, and includes few examples of violations or ethical scenarios specific to the Forensic Biology laboratory. The committee also noted that training predominantly relies on passive learning. Training consists of lectures and does not include opportunities to apply new information, discuss practical applications of ethical principles in the laboratory, or learn through experience.

Ethics training is an additional responsibility for laboratory managers who are already responsible for overseeing casework and supervising staff. The laboratory does not have a designated person responsible for the oversight of the ethics program or a designated individual who can serve as a point person for ethical issues. See Appendix B for the cause and effect analysis diagram.

Recommendations

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

1. Laboratory managers should explore the development of a LIMS-based fix that prevents a technical reviewer from selecting a case in which they authored examination records or drafted the case report. The committee believes this to be the strongest and simplest countermeasure to address the root cause and prevent future violations. Preventing a technical reviewer from selecting inappropriate cases prevents violations at the beginning of the workflow. Additionally, a software-based solution is efficient because it avoids the time-consuming task of manually assigning cases to technical reviewers.

   The committee also suggested that managers consider adding an acceptable use disclaimer on the LIMS login screen. The disclaimer should state that user actions are recorded by the system and what the consequences of violating the policy will be.

2. Management should implement an audit of the technical review process. When laboratory managers became aware of the issue, they initiated development of a LIMS query that will allow them to audit all technical reviewers and determine if there are additional similar violations. The committee recommends that moving forward, managers use this query to periodically audit all technical reviewers. This review should be implemented as part of the laboratory's audit procedure.

3. Agency leadership should consider supporting laboratory ethics programs with an agency-wide ethics policy and an ethics officer. The committee noted that an ethical environment is critical not just to the work of the Forensic Biology laboratory, but all forensic scientists, medical examiners, and operational staff at the OCME. Laboratory ethics programs would be better supported by initiatives at the agency level instead of each laboratory developing its own policies and procedures. The policy should state the agency's ethics policy, examples of ethics violations, an employee's obligation to promptly report misconduct, and the consequences of ethics violations.

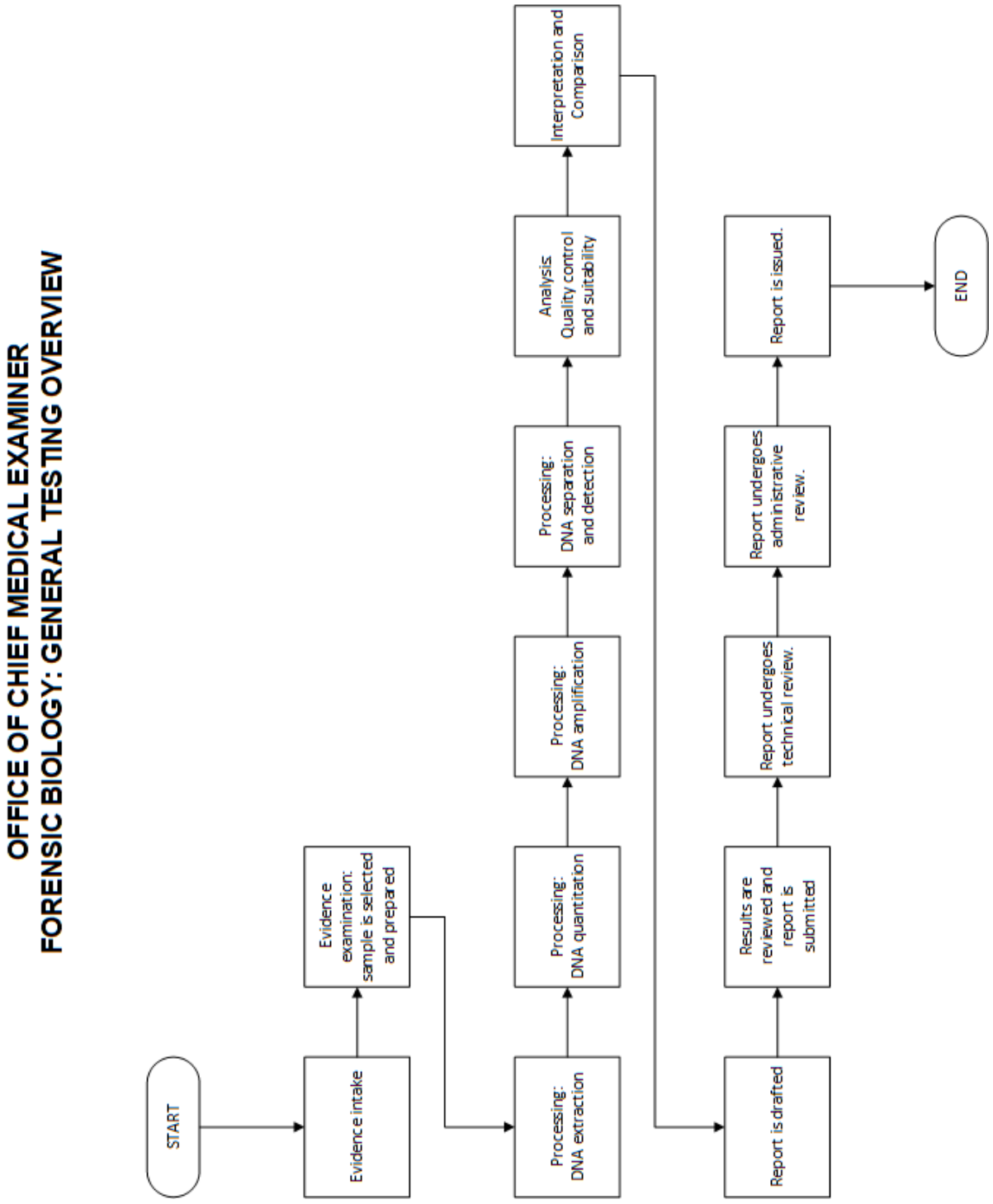
   Additionally, agency leadership should consider supporting laboratory ethics programs with an agency ethics officer. A dedicated ethics officer can support agency managers by serving as the agency's point person for ethics and improprieties, allegations of misconduct, and complaints. The ethics officer should also conduct surveys to assess ethics risks, investigate misconduct, deliver ethics training to staff, create ongoing awareness-raising programs, and be a resource to managers and employees regarding ethical issues.

4. The committee recommends the agency consider supporting laboratory ethics programs by implementing a reporting mechanism that allows all staff to report misconduct and ethical issues. A critical component of this reporting mechanism is that staff feel comfortable raising difficult issues in a safe environment. Staff should be informed that they can report issues confidentially and without fear of retaliation.

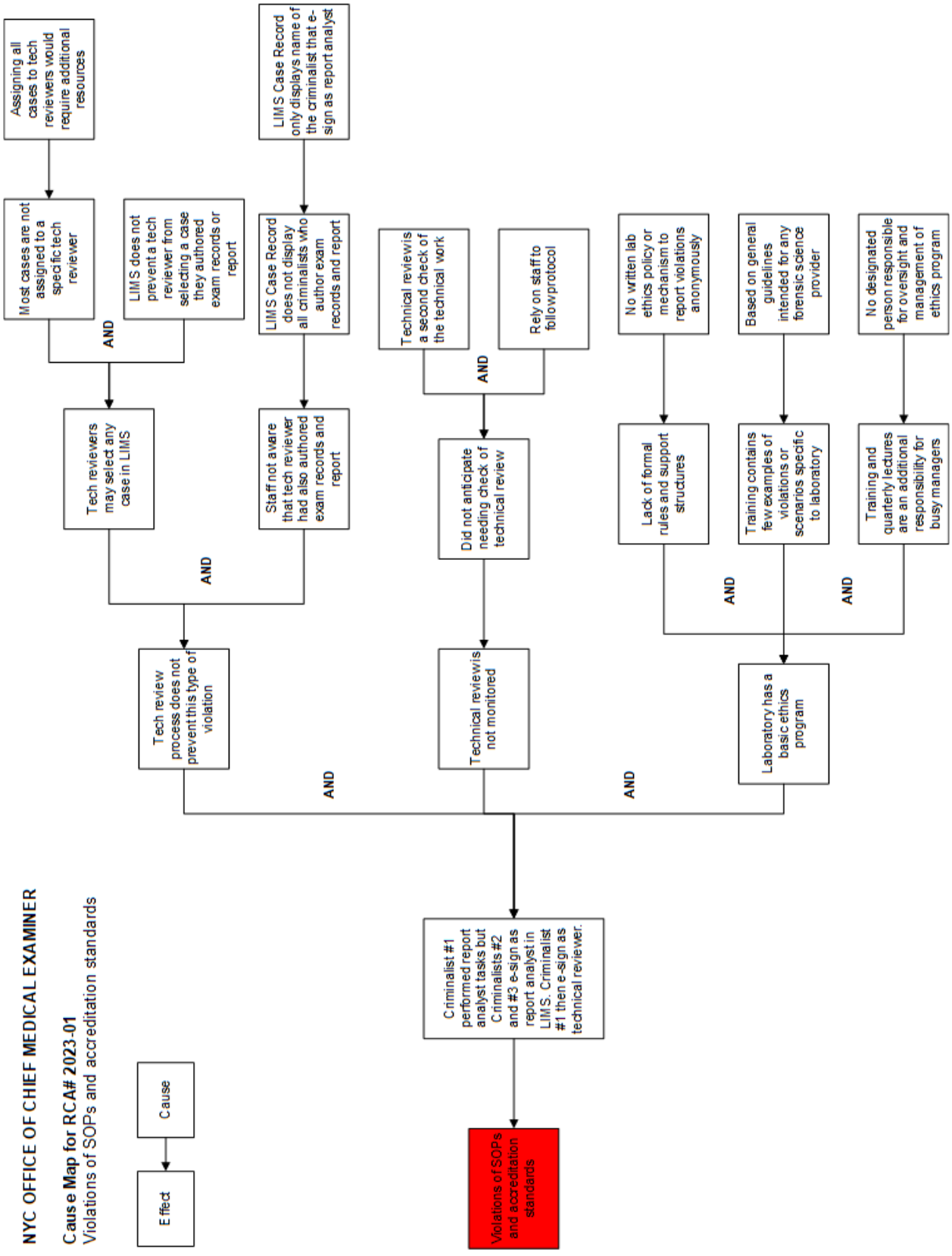
   All reports should be promptly reviewed and investigated by a designated individual or group. A final report summarizing the results of the investigation should be submitted to agency leadership for review.

5. The committee recommends that laboratory managers enhance the ethics training program by conducting training in smaller groups and utilizing a scenario-based learning approach. Research in education has shown that training in smaller groups and utilizing scenario-based learning increases engagement and critical thinking. This approach also promotes understanding and improves retention of the material. More importantly, it provides staff with an opportunity to apply what was learned by simulating real-world situations they may encounter specific to Forensic Biology and answering questions regarding the practical application of ANAB's Guiding Principles.

Appendix A


OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC BIOLOGY: GENERAL TESTING OVERVIEW
START
Evidence intake
Evidence examination: sample is selected and prepared
Processing: DNA extraction
Processing: DNA quantitation
Processing: DNA amplification
Processing: DNA separation and detection
Analysis Quality control and suitability
Interpretation and Comparison
Report is drafted
Results are reviewed and report is submitted
Report undergoes technical review.
Report undergoes administrative review.
Report is issued.
END

Appendix B


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for RCA# 2023-01
Violations of SOPs and accreditation standards
Effect
Cause
Violations of SOPs and accreditation standards
Criminalist #1 performed report analyst tasks but Criminalists #2 and #3 e-sign as report analyst in LIMS. Criminalist #1 then e-sign as technical reviewer.
AND
Tech review process does not prevent this type of violation
Technical review is not monitored
Laboratory has a basic ethics program
AND
Tech reviewers may select any case in LIMS
Staff not aware that tech reviewer had also authored exam records and report
Did not anticipate needing check of technical review
Lack of formal rules and support structures
Training contains few examples of violations or scenarios specific to laboratory
Training and quarterly lectures are an additional responsibility for busy managers
AND
Most cases are not assigned to a specific tech reviewer
LIMS does not prevent a tech reviewer from selecting a case they authored exam records or report
LIMS Case Record does not display all criminalists who author exam records and report
Technical review is a second check of the technical work
Rely on staff to follow protocol
No written lab ethics policy or mechanism to report violations anonymously
Based on general guidelines intended for any forensic science provider
No designated person responsible for oversight and management of ethics program
Assigning all cases to tech reviewers would require additional resources
LIMS Case Record only displays name of the criminalist that e-sign as report analyst