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ROOT CAUSE ANALYSIS REPORT
RCA# 2024-01
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Executive Summary

On July 31, 2024, 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 the contamination of eight Department of Forensic Biology cases during evidence examination. After careful review, the Quality Assurance 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 2, 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# 2024-01.

The RCA committee met and reviewed the contamination events, the evidence examination procedure, and the examination cleaning protocol. Based on the evidence presented, the committee made several recommendations for management to consider. These recommendations include adding detailed step-by-step instructions to the evidence examination cleaning protocol, developing resources for staff to review the evidence examination cleaning protocol after their initial training, and implementing a train-the-trainers program. Additionally, the committee suggested enhancing the supervision of evidence examination and incorporating a cross-contamination check as part of the laboratory's quality control program.

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, when evidence is submitted to the laboratory for testing, it is first examined by a criminalist. The initial examination includes a visual inspection of the evidence packaging and the type of seal used. Evidence items are removed from the packaging and then inspected and screened for the possible presence of biological fluid and collection of possible biological material. The criminalist documents the condition of the packaging and evidence and describes the stains that may be found in their notes.

Criminalists are trained to prevent the contamination of evidence during examination by using personal protective equipment (PPE), cleaning their tools, and decontaminating work surfaces.

The cleaning protocol specifically for tools consists of placing tools in a 10% bleach solution, followed by distilled water, and then 70% ethanol. Criminalists are also trained to change gloves or spray gloves with 10% bleach, clean the bench and tools, and replace the bench paper between cases. See Appendix A for a diagram of the general laboratory workflow.

Event Description

On June 26, 2024, a reporting analyst was reviewing case information when they noticed that the DNA profile of the bloodstain in a property crime case they were reviewing matched the DNA profile for another case they had recently worked on (property burglary). Both cases were examined by Criminalist #1 on June 11, 2024.

The reporting analyst reviewed all the cases examined by Criminalist #1 on June 11, 2024, and found a total of four cases in which the DNA profile matched the DNA profile from the case they had recently worked on; (property burglary, firearm case, robbery, and "other" case types". The reporting analyst notified the analysts of the involved cases and halted work on the reports until the contamination event was investigated.

On June 27, 2024, the reporting analyst informed the Forensic Biology Quality Assurance Manager of the issue.

On June 28, 2024, the Forensic Biology Quality Assurance Manager informed Criminalist #1 of the contaminations and reviewed Criminalist #1's examination process. Having no reason to believe this was anything other than an isolated instance of individual cleaning practices, the Quality Assurance Manager recommended that Criminalist #1 change gloves between cases, keep the examination scissors in ethanol, and dry the scissors with a sterile wipe when they are removed from the ethanol. A review of Criminalist #1's cases was also commenced.

On July 30, 2024, the Forensic Biology Quality Assurance Manager identified a second contamination event while reviewing Criminalist 1's cases. The Quality Assurance Manager found that on June 13, 2024, Criminalist #1 examined a sexual assault case and later contaminated a property crime case with DNA from the sexual assault case.

Forensic Biology managers informed Criminalist #1 of the second contamination event. The Nuclear DNA Technical Leader suspended Criminalist #1 from examination duties and required Criminalist #1 to undergo retraining.

On August 5, 2024, the Forensic Biology Quality Assurance Manager was notified of a third contamination event involving a different criminalist. The Quality Assurance Manager found that on July 1, 2024, Criminalist #2 examined a sexual assault case and later contaminated a property crime case with DNA from the sexual assault case.

Forensic Biology managers interviewed Criminalist #2 about their techniques. The Nuclear DNA Technical Leader suspended Criminalist #2 from examination duties and required Criminalist #2 to undergo retraining.

On August 8, 2024, the Forensic Biology Quality Assurance Manager was notified of a fourth contamination event involving another criminalist. The Quality Assurance Manager found that on June 17, 2024, Criminalist #3 examined a sexual assault case and later contaminated two property crime cases.

On August 9, 2024, out of an abundance of caution, the DNA Technical Leader temporarily paused operations for certain sections of the laboratory to further investigate the contamination events. The affected areas included evidence examination, uploading DNA profiles to CODIS, and report issuance.

On August 13, 2024, laboratory staff began reviewing sample data for all cases examined by individual examiners daily within the timeframe of May 1 to August 9th 2024 to determine if there were other cases affected by contamination.

On August 15, 2024, evidence examination resumed after all criminalists in the department completed an updated Basic Lab Cleaning and Decontamination Techniques training and passed a competency examination. The updated training included the following changes to the cleaning protocol:

- Examiners must change gloves between cases. Spraying gloves with bleach is no longer an option.
- Examiners must replace 10% bleach, water, and 70% ethanol solutions daily. Previously, criminalists were recommended to change 10% bleach daily but were permitted to keep the water and 70% ethanol solutions for up to a week.
- Examiners must place tools in bleach after use. The tools must remain in bleach while the examiner is preparing the sample. When the sample is ready, the examiner may resume the cleaning protocol as normal.
- Examiners must leave tools in ethanol after cleaning until needed. The tools should not be placed on a Kimwipe or bench paper.
- Examiners are limited to one pair of scissors to open packaging, one pair of scissors for sampling, and one pair of forceps. Previously, examiners were permitted to have multiple sets of tools for examination.
- Examiners must use disposable scalpels or razor blades to cut swabs and scrape. Scissors can be used to cut fabrics and other materials.

Staff also reorganized the evidence examination workspace. The evidence examination area now has designated stations for the examination of sexual assault kits, high template evidence (evidence where a large amount of DNA is present), low template evidence (evidence where only a small amount of DNA is present), mixed cases (cases with potentially high template evidence and low template evidence), and exemplars. Additionally, examiners were given guidelines and instructed to work at 1-2 stations per day and not examine more than two evidence types in a day. Supervisors reinforce the guidelines by assigning examiners to work on specific evidence types at the start of their shifts.

Forensic Biology staff completed a review of all evidence examinations conducted between May 1, 2024, and August 9, 2024. Out of 12,873 samples, 26 samples (belonging to 22 cases) were found to be affected by 16 contamination events (including the original 4 contamination events).

At the time of this writing, Forensic Biology staff have removed ten DNA profiles from the Combined DNA Index System (CODIS) and are working to amend eleven laboratory reports. None of the DNA profiles that have been removed from CODIS had resulted in a CODIS hit to a convicted offender.

Causes and Contributing Factors

The RCA committee reviewed the 16 contamination events and found that 9 criminalists were involved in the events. The laboratory has a total of 108 criminalists who perform evidence examinations. The 9 criminalists involved in the contamination events completed training between 2022-2024 and participated in laboratory proficiency tests with no issues. The committee also reviewed the laboratory's examination workload and found that the daily batch size is 55 cases. Forensic Biology managers reported that the batch size has been consistent since April 2023. Managers added that a criminalist typically examines 5-21 samples daily, depending on staffing and case complexity. Based on the information reviewed, the committee did not find evidence suggesting staff were overworked or pressured to skip steps due to increased workload.

The RCA committee was also informed that laboratory staff had found expired bleach in the examination area on August 8, 2024. The expired bleach included lots of Austins A-1 Bleach and Activate Bleach. The Austins A-1 bottle labels did not have expiration dates but instead listed the manufacturing dates as March 30, 2023, and September 29, 2023. The Activate Bleach bottle labels had expiration dates listed as November 21, 2023, and April 24, 2024. Staff tested the bleach to determine if there was reduced effectiveness in cleaning tools and work surfaces.

Laboratory staff first measured the chlorine concentration of the bleach with chlorine test strips. According to published literature, a 10% bleach solution is expected to have a chlorine concentration of approximately 5000 ppm. The laboratory found that a 10% solution of the Austin A-1 Bleach measured 2500 ppm and a 10% solution of the Activate Bleach measured 5000 ppm.

Laboratory staff then tested the expired bleach to determine its effectiveness in removing DNA. Staff measured effectiveness by cutting a blood stain card, cleaning the scissors by dipping them in conical tubes of the expired bleach followed by water and ethanol, cutting a new clean swab, and then testing that swab to see if DNA was present. Samples were extracted and quantified via current standard operating procedures for the Quantifiler Trio DNA Quantification Kit. In their tests, the laboratory did not detect DNA on the swabs after cleaning scissors with the expired bleach. Although the Austin A-1 Bleach was found to have a lower chlorine concentration, all bottles of bleach were found to effectively clean DNA from scissors.

The committee asked laboratory managers if the distilled water and 70% ethanol were also tested. Managers responded that those reagents were not tested because the water and ethanol are not used to remove DNA from tools. Distilled water is primarily used to remove the bleach from the tools, and ethanol is used to remove the water.

Although the laboratory tests indicated that the bottles of expired bleach were still effective in cleaning tools, the RCA committee could not rule out that bleach was a factor in the contaminations. The actual bleach used by laboratory staff to clean instruments and work surfaces between the May-August 2024 period had been consumed and could not be tested.

Additionally, the laboratory did not track the lot numbers and expiration dates of bleach bottles so further investigation could not be conducted.

The RCA committee was unable to determine with certainty the root cause for the contaminations because the actual bleach that was used to clean tools could not be tested and the timeframe of the retrospective study was limited. The discovery of additional contamination events necessitates expanding the retrospective study beyond May 2024 to determine the origin and extent of the contaminations. However, based on a review of procedures, evidence examination cleaning protocols, and interview data, the RCA committee identified the following causal factors for the 16 contamination events:

1. **Inconsistent cleaning technique among the criminalists performing evidence examinations.**

   Evidence: The committee reviewed Forensic Biology's "General Guidelines for Forensic Biology and DNA Casework" and "Evidence Examination" procedures and discussed training with managers. The committee also analyzed interview data collected by management between August 12, 2024, and August 23, 2024. The data was collected from interviews with 108 criminalists, focusing on the cleaning techniques used during evidence examination.

   The committee evaluated the cleaning techniques recommended as best practice against those used in actual practice, as documented in the interviews. The group found the following inconsistencies regarding how clean tools were handled and dried.

   Best Practice: Criminalists should leave their tools in ethanol after cleaning until they are needed.
   Actual Practice: According to the interview data, 29% of criminalists leave their tools in ethanol. 49% of criminalists reported placing their tools on a Kimwipe after cleaning. Some criminalists leave their tools in bleach solution, while others place them in a 50 mL conical tube along with a Kimwipe after cleaning.

   Best Practice: Criminalists should wipe tools dry after cleaning. They must inspect their tools and remove any visible debris during the drying process.
   Actual Practice: According to the interview data, 41% of criminalists dry their tools by wiping them. Additionally, 28% of criminalists wipe with a Kimwipe or wrap their tools with a Kimwipe to dry them, either doing one or both methods. 23% of criminalists allow their tools to air dry.

   Best Practice: Criminalists may use a separate piece of bench paper for tools, which should be changed after every cleaning.
   Actual Practice: A total of 26 responses were collected for this question. Among those, 42% of criminalists reported replacing the bench paper daily, 31% replaced it after a case, and 19% changed it as needed.

The committee noted that inconsistencies in cleaning techniques have the potential to increase the risk of cross-contamination during evidence examination. The inconsistent cleaning techniques among the criminalists were attributed to the following:

- The laboratory's procedures provide only general guidance on cleaning tools during evidence examination. A review of the "General Guidelines for Forensic Biology and DNA Casework" and "Evidence Examination" procedures found that the technical information regarding how to perform testing was very detailed, but information describing how cleaning should be done was vague. The procedures do not specify the minimum amount of time tools should stay in cleaning solutions or how tools should be dried to minimize the risk of contamination. The lack of a formal and detailed cleaning protocol contributed to the variation in cleaning techniques.

- The laboratory depended on its training program to provide how-to details for cleaning tools. However, based on the interview data, the information communicated to trainees varied from trainer to trainer. The committee evaluated the laboratory's training program and found it to be a robust program that included lectures, in-person demonstrations, opportunities to practice techniques with feedback, and a final assessment. However, the program does not have a training module or documentation that provides detailed instructions for cleaning tools during evidence examination. The training program relied on trainers to convey how-to information based on procedures and individual experiences. The lack of a formal, detailed cleaning protocol led to inconsistent information communicated to trainees, as trainers shared their own best practices.

- The laboratory did not adequately monitor the cleaning of tools during evidence examination. The committee reviewed the supervision of the evidence examination area and learned that there are two supervisors present to oversee evidence examinations. The supervisors oversee up to 18 criminalists and ensure that daily evidence exams are completed. Additionally, the supervisors are responsible for the following tasks:

    - Directly oversee new employees
    - Assign analysts to evidence to examine in priority order
    - Periodically evaluate the exam queue for that day and adjust staffing as needed
    - Troubleshoot evidence discrepancies
    - Contact customers to get more information if needed
    - Review all batches and send the batches to the laboratory
    - Create report shells for all negative serology cases
    - Review shell casings examination notes

    The committee noted that managing evidence examinations, overseeing new employees, troubleshooting discrepancies, creating report shells, and reviewing examination notes require a significant portion of a supervisor's time and attention. The time required to complete these tasks limits a supervisor's ability to effectively monitor the cleaning practices of criminalists and provide feedback when necessary.

2. **Criminalists did not separate high template evidence and low template evidence during evidence examination.**

   Evidence: The committee analyzed the 16 contamination events and found that in all cases, the criminalist first examined high template evidence, usually a sexual assault kit, and subsequently contaminated low template evidence with DNA from the previously examined high template evidence.

   The committee reviewed the evidence examination process in Forensic Biology and found that criminalists typically select evidence for examination from the laboratory's daily queue list. This selection is primarily based on workflow needs, with criminalists advised to prioritize more complex cases due to the longer time required to complete the examination.

   Because the laboratory lacks designated stations for different types of evidence, criminalists often examine various evidence types at the same workstation. The back-to-back examination of different evidence types, combined with inconsistent cleaning techniques, contributed to the cross-contamination of cases.

3. **The laboratory does not conduct cross-contamination checks for all samples.**

   Evidence: The committee reviewed the quality control processes of the Forensic Biology laboratory and found that several measures are in place to detect potential contamination. These measures include the use of positive and negative controls to identify contamination in reagents and comparing results against an elimination database to identify DNA contamination from individuals who have access to the laboratory or may have come into contact with evidence before processing. Additionally, analysts are required to review cases for possible cross-contamination before reporting CODIS matches. However, the committee noted that this review is conducted only on a small subset of the cases processed by the laboratory, and analysts do not perform a similar check for all samples examined.

   The committee also noted that the current ISO/IEC 17025:2017 accreditation standard does not mandate a check for cross-contamination between processed samples. However, the group recommends that one should be implemented as part of the laboratory's quality control program. 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 standardize the cleaning protocol to minimize variation and ensure all staff follow the same cleaning techniques. The cleaning protocol should include detailed how-to information that specifies when a criminalist should change their gloves and the minimum time tools should be immersed in cleaning solutions. Additionally, the protocol should describe how tools should be dried and where they should be placed after cleaning. The

committee also recommends that the cleaning protocol be evaluated, similar to the laboratory's bleach studies, to confirm its effectiveness.

2. Management should enhance the current training by developing a train-the-trainer program to ensure consistent and effective information delivery to staff. Trainers should be instructed to train staff on the verified cleaning protocol and not personal best practices. This train-the-trainer program should include a structured curriculum and periodic assessments to evaluate the effectiveness of the trainers. Additionally, the committee recommends utilizing a dedicated group of trainers to minimize variations in training delivery.

3. The committee recommends that managers develop resources for staff to review the cleaning protocol after initial training has been completed. Management should update current procedures by adding detailed information on how to perform cleaning and consider providing periodic refresher training to all staff on minimizing the risk of contamination. Managers should also consider creating training videos and making these videos available to staff on the intranet.

4. The committee recommends that managers improve supervision in the evidence examination area to ensure that procedures are properly followed and that evidence examiners receive adequate support. Managers should consider adding more supervisors in this area and reassigning or reducing some responsibilities to allow supervisors to be more available.

5. Management should separate the examination of high template evidence from low template evidence to reduce the risk of contamination.

   The committee was informed that on September 6, 2024, laboratory staff reorganized the evidence examination workspace. The evidence examination area now has designated stations for the examination of different types of evidence. Additionally, examiners were given guidelines and instructed to work at 1-2 stations per day and not examine more than two evidence types in a day. The committee found these actions to be appropriate.

6. The laboratory should implement a cross-contamination check of processed samples. The committee was informed that Forensic Biology managers have drafted a plan to review cases before they are distributed, to ensure that cross-contamination did not occur during evidence examination. Each week, managers will select two criminalists and review all the cases examined by those criminalists over a 3-day period.

   The committee recommends the following:
   - The proposed contamination check should randomly select criminalists for evaluation.
   - The proposed contamination check should be implemented for a limited duration, taking into account the effort and resources required, as well as the observed results.
   - If no contamination incidents are observed, Forensic Biology may reduce the frequency of random checks to once every 3 or 6 months.

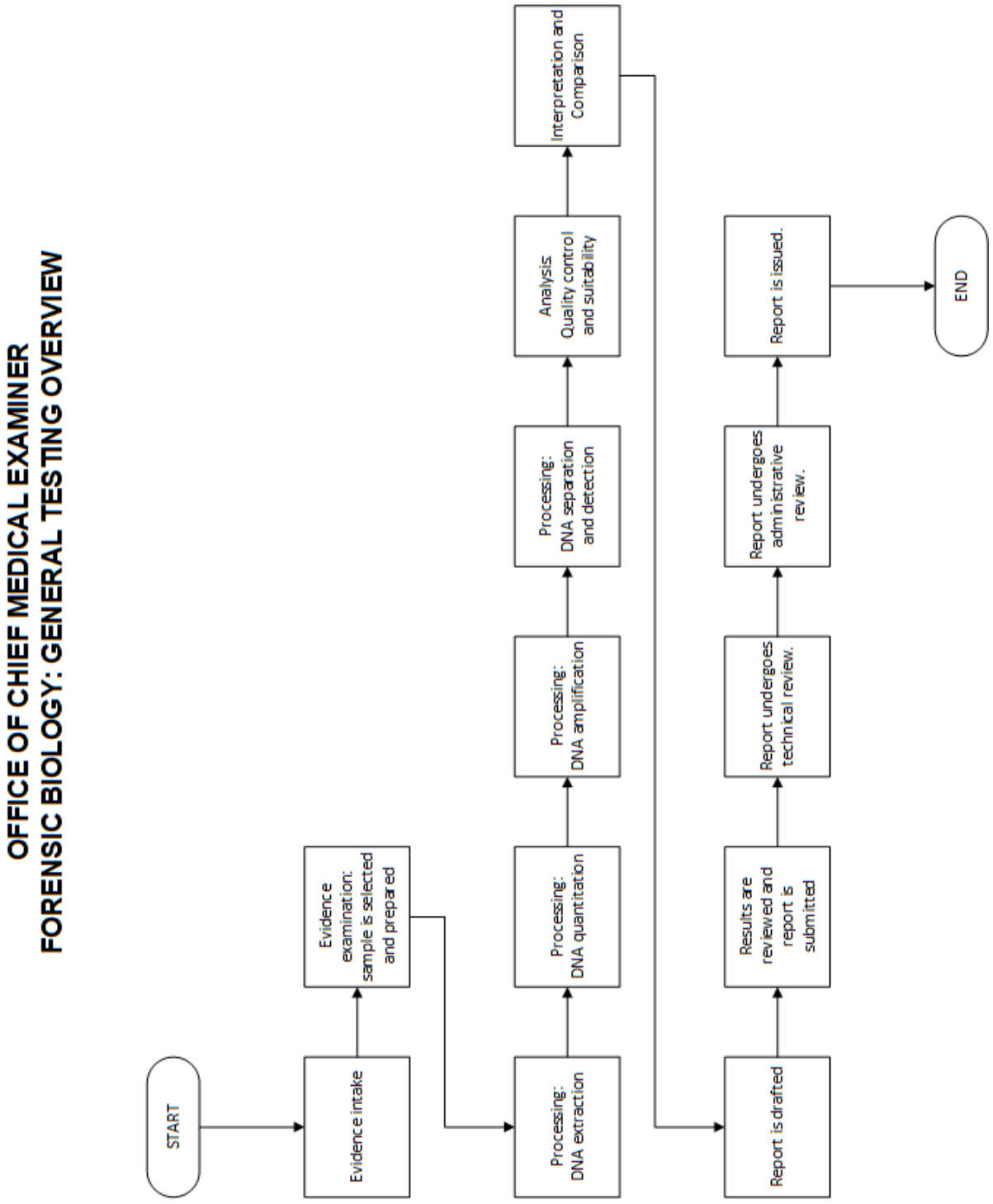
7. The committee recommends that managers extend the retrospective study because additional contamination events were identified between May 1, 2024, and August 9, 2024. The study should be extended by at least 2-3 months and further extended if additional contamination events are discovered. The committee also recommends that managers review all cases examined by criminalists involved in more than 2 contamination events.

8. The committee recommends that managers track the expiration date of the bleach used to prepare 10% bleach for cleaning.

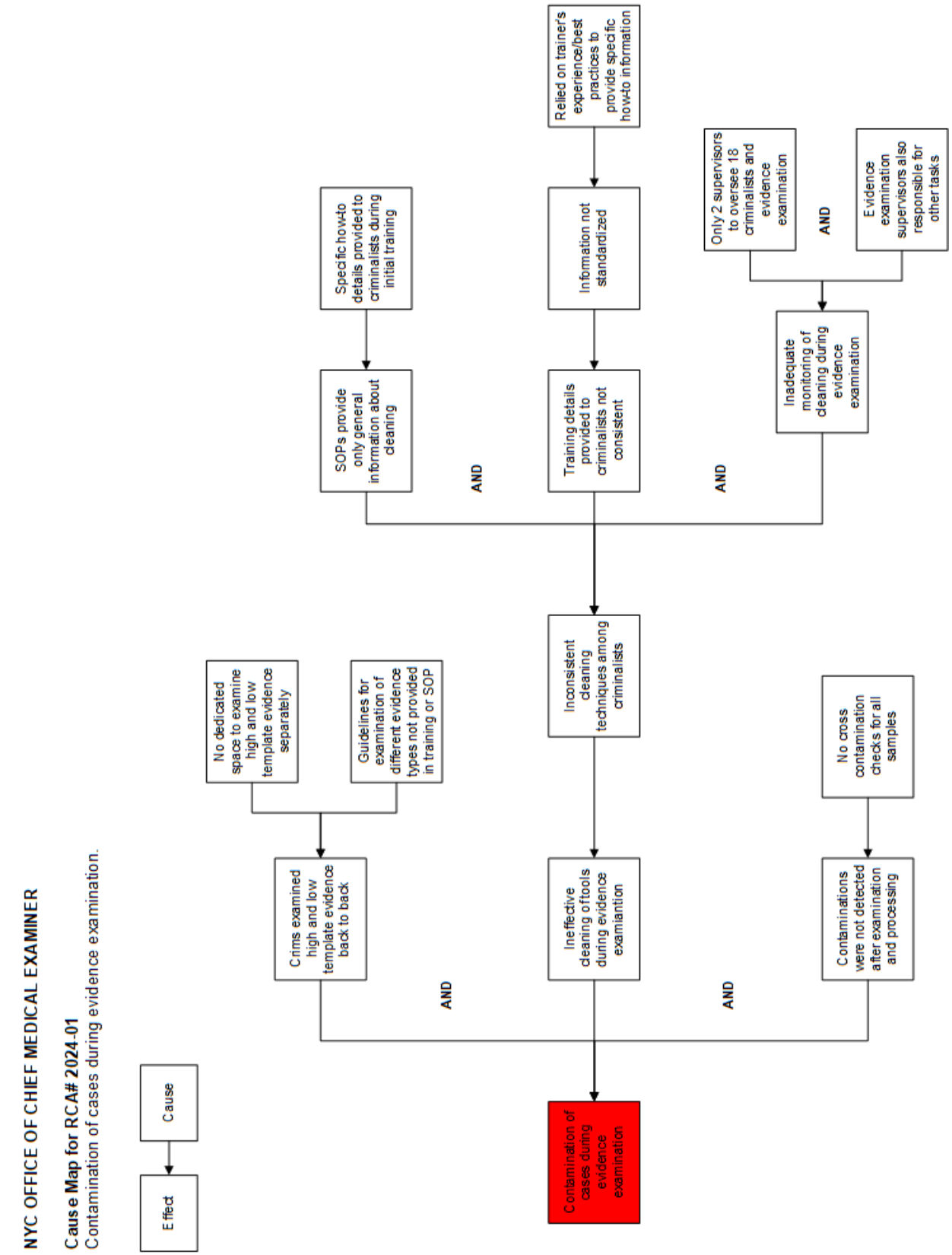
   The committee was informed that on August 19, 2024, Forensic Biology implemented the tracking of expiration dates and lot numbers for bleach bottles distributed to the laboratory. Management has also limited the number of in-use bottles.

   The committee also suggests that managers consider preparing bulk solutions for cleaning tools. The laboratory Quality Assurance team could prepare and test the solutions ensuring the consistency and quality of the cleaning solutions. Additionally, having bulk solutions saves time for evidence examiners. If implemented, the laboratory may also want to consider requiring criminalists to change all cleaning solutions after each case.

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# 2024-01
Contamination of cases during evidence examination.
Cause
Effect
Contamination of cases during evidence examination
Ineffective cleaning of tools during evidence examiantion
Contaminations were not detected after examination and processing
Crims examined high and low template evidence back to back
AND
AND
No dedicated space to examine high and low template evidence separately
Guidelines for examination of different evidence types not provided in training or SOP
Inconsistent cleaning techniques among criminalists
No cross contamination checks for all samples
SOPs provide only general information about cleaning
AND
Training details provided to criminalists not consistent
AND
Inadequate monitoring of cleaning during evidence examination
Specific how-to details provided to criminalists during initial training
Information not standardized
Relied on trainer's experience/best practices to provide specific how-to information
Only 2 supervisors to oversee 18 criminalists and evidence examination
AND
Evidence examination supervisors also responsible for other tasks