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ROOT CAUSE ANALYSIS REPORT
EVENT ID# 15-013
DECEMBER 21, 2015

Executive Summary

On September 25, 2015, the Office of the Chief Medical Examiner (OCME) Quality Assurance Director was informed of an error which resulted in an incorrectly reported result from OCME's Department of Forensic Biology (Forensic Biology). 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 November 23, 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 15-013.

The Root Cause Analysis Committee met and reviewed Forensic Biology's test process and identified several issues. The root causes were identified as (1) the LIMS amplification sheet not providing feedback to the analyst and (2) the Forensic Statistical Tool (FST) user interface lacking a confirmation step before the samples are analyzed. The Root Cause Analysis Committee recommends that Forensic Biology modify the LIMS amplification sheet so that an alert is triggered when sample requirements do not meet amplification protocol criteria, update the FST user interface to include a confirmation step for the analyst and increase staff awareness regarding FST design and limitations.

Background

Forensic Biology is a laboratory operating within the Office of the 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 160 criminalists, supervisors and managers, 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.

The Forensic Statistical Tool is an OCME developed and validated software used for the statistical analysis of DNA mixtures from evidence and reference DNA profiles. Mixtures are DNA samples where more than one individual contributed biological material to the DNA sample. FST calculates the probability of whether a certain DNA profile is more likely or less likely present in the mixture. See Appendix A for a diagram of the laboratory workflow.

Event Description

On February 3, 2014, the Department of Forensic Biology received a sexual assault kit for testing. Between February 24, 2014 and May 7, 2014, Forensic Biology received additional items for testing including a T-shirt and pants.

Between May 28, 2014 and May 29, 2014, a sample from the pants was extracted, concentrated and amplified using high copy number method (ID28).

On August 4, 2014, a suspect exemplar came to the lab for comparison to the above sample. The laboratory had identified that a DNA mixture was obtained for the sample labeled "pants stain 2 recut, sperm cell fraction". The suspect was determined to be excluded from the mixture. However, the alleged victim and her consensual partner could not be excluded from this mixture of DNA. Therefore, the laboratory used the Forensic Statistical Tool (FST) to calculate a likelihood ratio that was then reported out on September 18, 2014.

On September 1, 2015, an attorney for the Bronx Legal Aid Society contacted Forensic Biology and asked if low copy number methods were used for DNA analysis of the pants stain 2 recut, sperm cell fraction.

Between September 1, 2015 and September 4, 2015, the Forensic Biology Laboratory reviewed the case and determined the Forensic Statistical Tool should not have been used to perform quantitative analysis on the pants stain 2 recut, sperm cell fraction sample. The Forensic Statistical Tool should not have been used because the Forensic Statistical Tool was not validated and approved for use on samples that were amplified with 28 cycles but with DNA amounts below 100 picograms (pg). In this case, the sample was estimated to be 72pg.

On September 25, 2015, the laboratory issued an amended report that stated the sample was inconclusive and was not eligible for use in the Forensic Statistical Tool. See Appendix B for a detailed chronology of events.

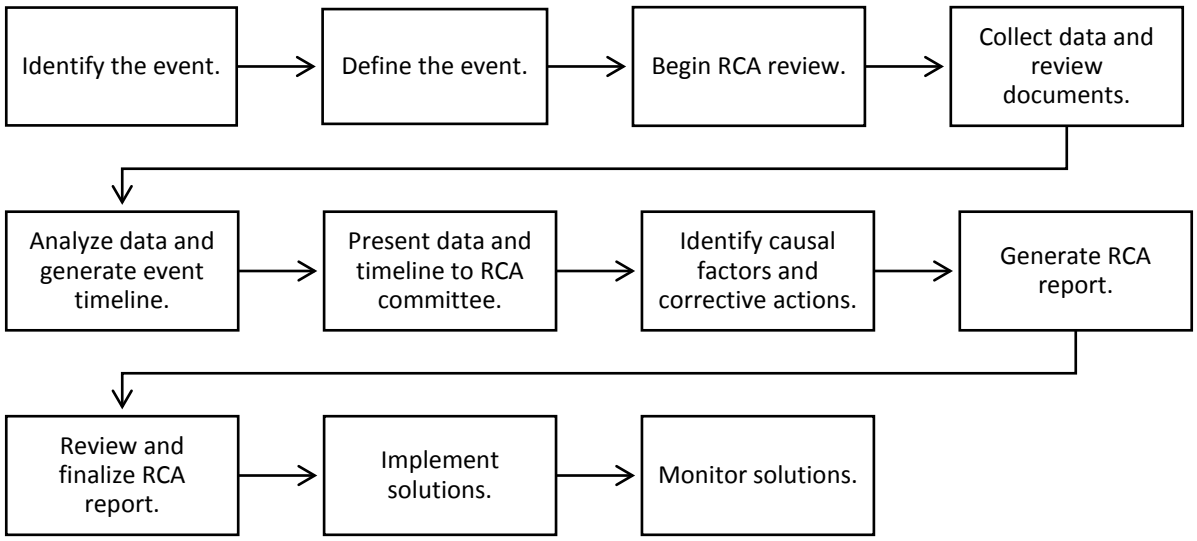
Composition of RCA Committee

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.
- Two laboratory employees who are knowledgeable in the 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 scientific research laboratories.

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:



Causes and Contributing Factors

Following review of the testing process and the event timeline, the RCA committee reviewed the remedial actions taken by Forensic Biology. After the laboratory determined that an error was made and that FST should not have been used, the laboratory issued an amended report and notified the assistant district attorney and defense attorney. Forensic Biology then performed a retrospective review in order to determine if other cases were impacted by a similar error. Cases from May 2014 through October 2014 which involved the same analyst and reviewer were reviewed by the Forensic Biology QA Manager for potential quantitation or amplification value errors. Eight cases were found to match the specified search criteria and no additional errors were found during the review. The RCA committee found the actions taken by Forensic Biology to be appropriate.

The RCA committee further examined the workflow and employed cause and effect analysis to identify possible causes for the use of FST on the low template sample. Using this methodology, the RCA committee identified the following causal factors:

1. The LIMS amplification sheet does not provide the analyst feedback when a low template sample is submitted for testing via high copy number methodology.

Evidence: The RCA committee learned that when an analyst prepares samples for amplification, an amplification sheet in the Laboratory Information Management System (LIMS) must be generated. The analyst must enter the DNA concentration and select the amplification protocol. If the sample has DNA concentrations greater than 20pg/µl, then it is amplified with the ID28 protocol (high copy number method). Samples with DNA concentrations less than 20pg/µl are amplified with ID31 protocol (low copy number method). The Root Cause Analysis officer reviewed the laboratory SOPs and found the criteria for amplification protocols to be clearly stated and well documented.

An audit of LIMS records shows that the analyst entered a sample with DNA concentration of 14.4 pg/µl for ID28 amplification. The LIMS amplification sheet does not provide any feedback

or alert when a sample with DNA concentration less than 20pg/µl is set up to be amplified with the ID28 protocol.

2. The Forensic Biology laboratory was undergoing a significant change in case workflow.
Evidence: The RCA committee learned that in early 2014, the time this case was processed in the laboratory, the Forensic Biology laboratory was undergoing a significant change in terms of how it managed incoming cases. The entire laboratory was moving from a batch processing model involving specialized teams to a more continuous flow processing model. During this transition, a small number of analysts were processing all of the cases remaining in the old processing system. During review of the event timeline, the RCA committee learned that the analyst failed to note that the DNA amount was insufficient for amplification by ID28 and did not send the sample for re-quantitation after concentration. Interviews with the analyst and reviewer confirmed that the change in processing was a source of distraction and a contributing factor to this error. In addition, the few analysts processing these cases may have been overburdened as these cases were being completed.

The RCA committee also discussed the training and performance records of the analyst and reviewer involved in this event. The Forensic Biology QA Manager reported that no issues were identified during her review.

3. The Forensic Statistical Tool user interface does not require analysts to confirm if the DNA sample is suitable for FST analysis.
Evidence: The RCA committee also discussed the FST user interface and how it contributed to the error. The committee learned that when the FST software is accessed, the FST home screen allows the analyst to immediately begin selecting the test scenario and importing the DNA comparison profile. The software does not prompt the user to verify the suitability of the sample before running the analysis nor does it provide any feedback to the user based on the information entered. The software home screen also does not provide any reminders regarding FST sample requirements or FST limitations.

4. The FST standard operating procedure does not state that errors may occur if samples do not meet FST sample criteria.
Evidence: A review of the FST procedure confirmed that the procedure lists acceptable DNA amounts for FST analysis. However, the procedure does not emphasize that these are the only acceptable criteria and samples that do not meet these criteria may lead to potential error. This guidance was only provided through initial training and verbal direction. The lack of a note that emphasized the potential for error if FST sample criteria was not met contributed to the analyst and reviewer failing to realize that the low template sample was not suitable for this type of FST analysis.

Based on the above findings, the RCA committee determined that the error could have been prevented before the sample was amplified and before the sample was entered into the FST program. The root causes for this error were the lack of feedback or alert in the LIMS amplification sheet and the lack of prompts or feedback in the FST home screen. The distraction caused by the change in the laboratory workflow and the lack of a note that emphasized the potential for error if FST sample criteria was not met contributed to the error not being identified before the report was released. See Appendix C for the cause and effect analysis.

Corrective Action Plan
The RCA committee recommends the following actions:

1. Forensic Biology should modify the LIMS amplification sheet. The modification should include feedback or an alert when an analyst enters a sample that does not meet the DNA concentration criteria for the selected amplification protocol. Feedback should include a step that asks the analyst to verify that the entered information is correct before proceeding with amplification.

2. Forensic Biology has successfully implemented the new workflow and staff are accustomed to the new routine. For future large-scale changes to the laboratory workflow, it is recommended that Forensic Biology consider using cognitive aids, such as checklists, and workload monitoring as part of the change management plan. Cognitive aids will remind staff of actions that must be taken and enhance adherence during significant changes in workflow. Active workload monitoring will ensure that that the laboratory is made aware of any analysts that are stressed or overburdened during transition periods.

3. Forensic Biology should develop an alternate landing page for the FST software. This alternate landing page will be presented to the analyst before the analyst is allowed to enter data and import DNA profiles. The alternate landing page should provide information that reminds the analyst of FST sample requirements. The alternate landing page should also prompt staff to verify key pieces of information regarding the sample before permitting access to the FST home screen. The alternate page should also include a reminder that states if an analyst has any questions they should consult with their supervisor before proceeding with testing.

4. Forensic Biology must revise their procedure and include a note that emphasizes the potential for error if FST sample criteria is not met. Once the procedure has been revised, all staff must be informed and trained regarding the change in procedure. A copy of the procedure must be readily available to all laboratory staff and laboratory leadership must monitor its implementation.

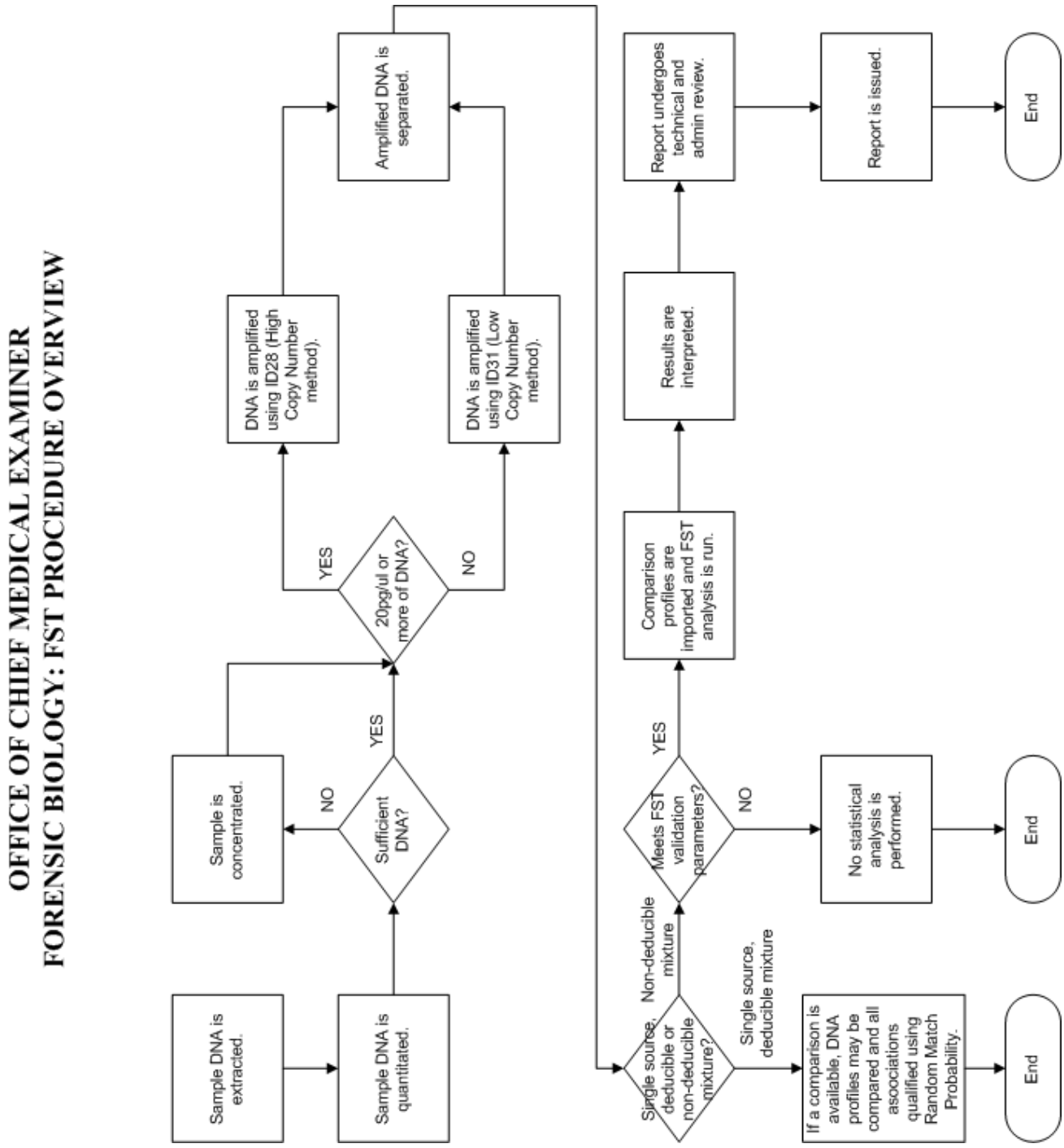
See Appendix D for a cause map with identified corrective actions.

Summary of Corrective Actions

Causal Factor	Corrective Action	Recommended Completion Date
The LIMS amplification sheet does not provide the analyst feedback when a low template sample is submitted for high copy number method.	Forensic Biology should modify the LIMS amplification sheet to provide an alert when an analyst enters a sample that does not meet the DNA concentration criteria for the selected amplification protocol.	3/31/16
The Forensic Biology laboratory was undergoing a significant change in case workflow.	Forensic Biology should consider using cognitive aids, such as checklists, and workload monitoring as part of the change management plan when significant changes to laboratory workflow are introduced.	3/31/16
The FST user interface does not require analysts to confirm if the DNA sample is suitable for FST analysis.	Forensic Biology must develop an alternate FST landing page.	3/31/16
The FST standard operating procedure does not state that low template samples amplified with high copy number methods cannot be used with FST.	Forensic Biology must revise their procedure and include a note that emphasizes the potential for error if FST sample criteria is not met All staff must be informed and trained on the new policy. Increase awareness and educate staff through lab meetings, inservice and email.	3/31/16

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

Appendix A

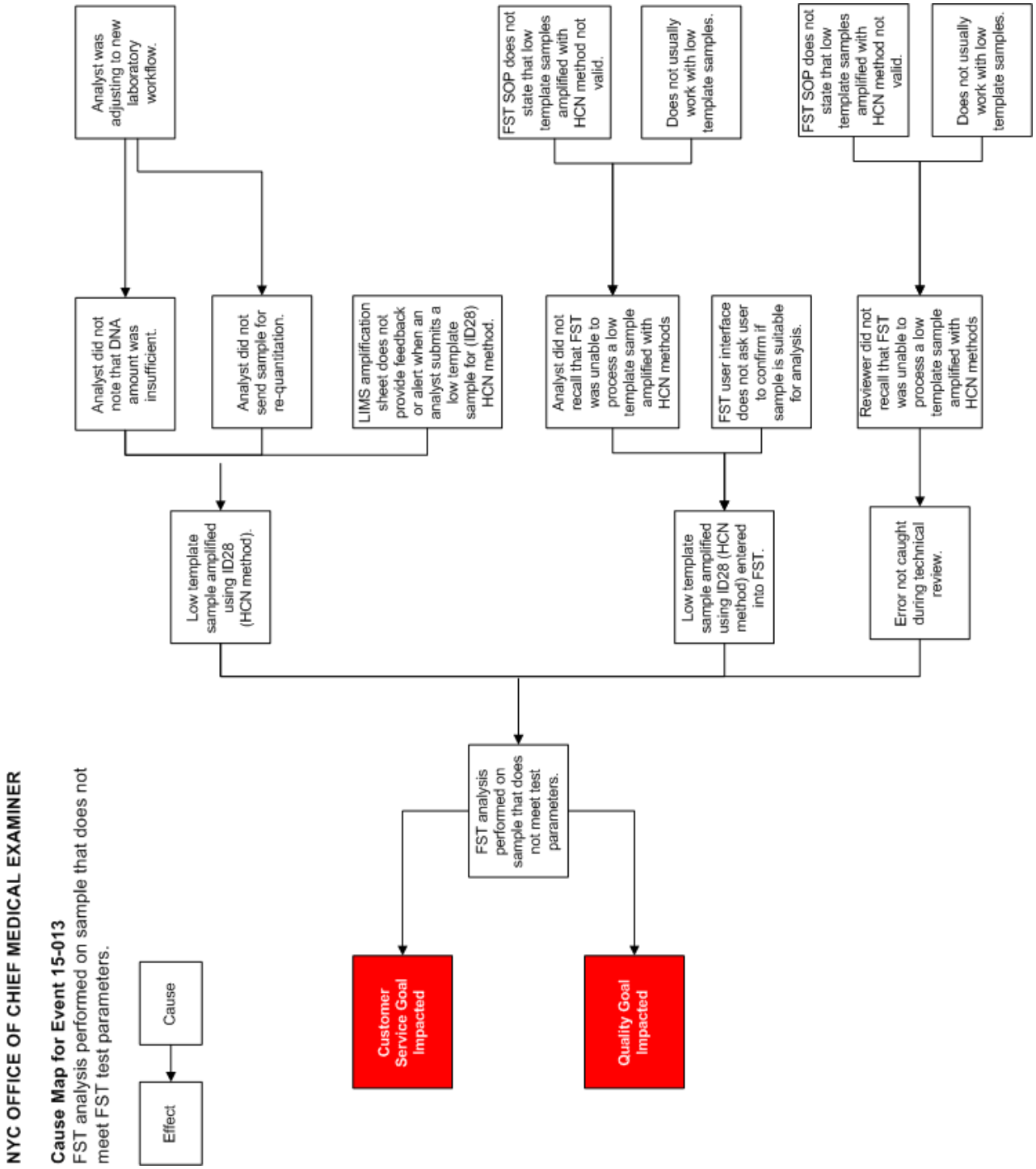

OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC BIOLOGY: FST PROCEDURE OVERVIEW
Sample DNA is extracted.
Sample DNA is quantitated.
Sufficient DNA?
NO
Sample is concentrated.
YES
20pg/ul or more of DNA?
YES
DNA is amplified using ID28 (High Copy Number method).
NO
DNA is amplified using ID31 (Low Copy Number method).
Amplified DNA is separated.
Single source, deducible or non-deducible mixture?
Non-deducible mixture
Single source, deducible mixture
Meets FST validation parameters?
YES
NO
Comparison profiles are imported and FST analysis is run.
Results are interpreted.
Report undergoes technical and admin review.
Report is issued.
End
No statistical analysis is performed.
End
If a comparison is available, DNA profiles may be compared and all asociations qualified using Random Match Probability.
End

Appendix B

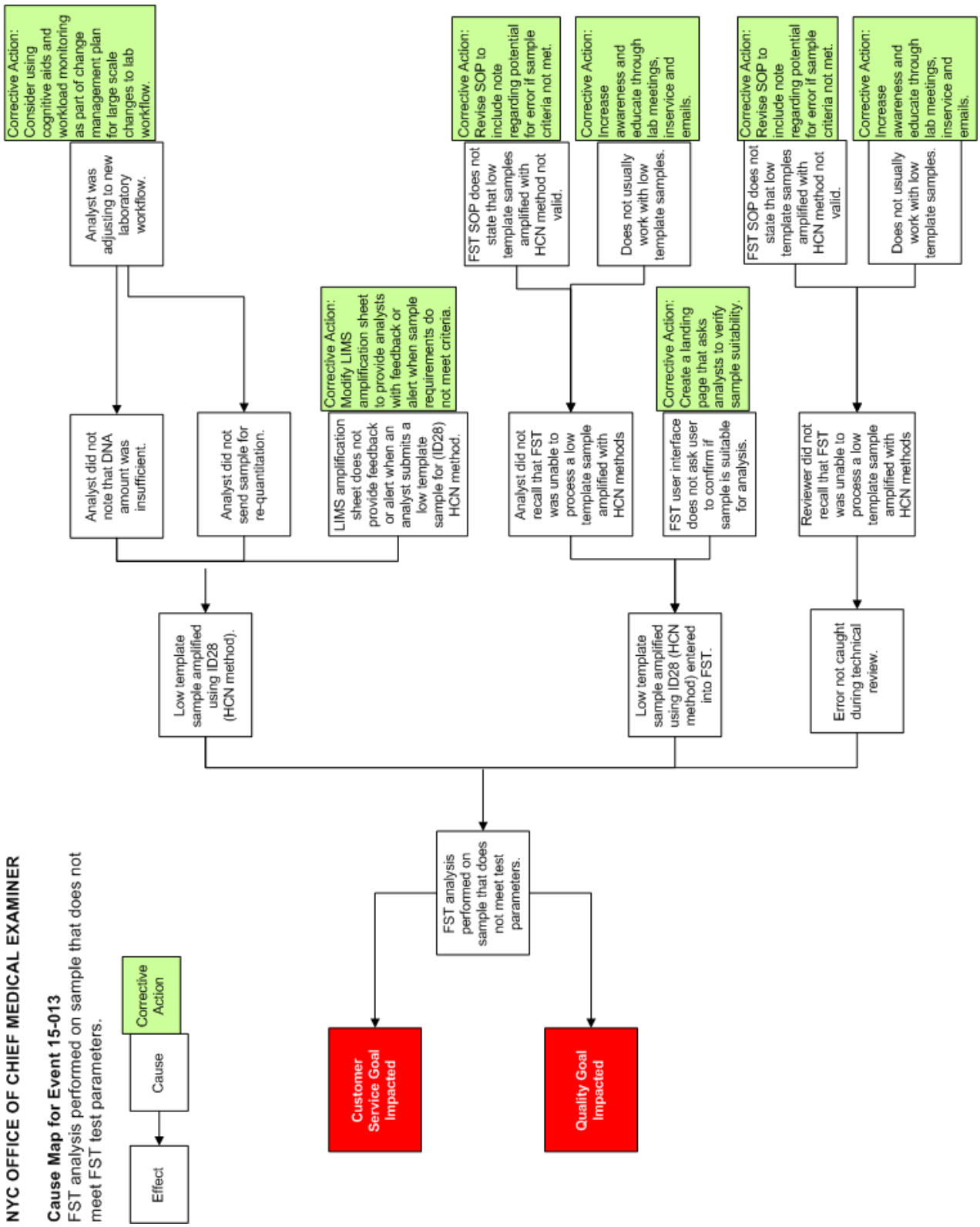
CHRONOLOGY OF EVENTS

DATE	EVENT
2/3/14	Sexual assault kit for testing is received by Forensic Biology (FBio).
2/24/14 – 5/7/14	Additional items for testing (including t-shirt and pants) are received for testing by FBio.
5/28/15- 5/29/14	The analyst extracts and submits the "pants stain 2 recut, sf" sample for quantitation. The results are reviewed and interpreted as "Sample exhibits low background fluorescence. Microcon".
5/29/14	The sample was concentrated by Microcon. The initial concentration is entered as 2pg/ul and the final concentration is calculated to be 14.40pg/ul.
5/29/14	The sample was amplified using the ID28 protocol. The amplification test batch was reviewed by a second analyst. The amount submitted was below the required minimum of 20pg/ul for the ID28 protocol (high copy number amplification).
8/4/14	DNA sample from the suspect is received for comparison by the laboratory.
9/18/14	FBio released a report indicating that the "pants stain 2 recut, sf" sample was found to be a mixture of DNA from at least two people. The laboratory used the Forensic Statistical Tool (FST) to calculate a likelihood ratio for the inclusion of victim and consensual partner in mixture. The FST results were included in the report.
9/1/15	Attorney from the Bronx Legal Aid Society contacted FBio and asked if low copy number methods were used for DNA analysis of the "pants stain 2 recut, sf" sample.
9/1/15- 9/4/15	FBio management reviewed the case and determined that the sample should not have been run in FST due to limits of FST validation parameters. FST was not validated to run a low template sample amplified with 28 cycles and with DNA amounts less than 20pg/ul total. The error was not recognized by the analyst or technical reviwer.
9/25/15	FBio released an amended report stating that the comparison of the DNA profiles to the "pants stain 2 recut, sf" sample is inconclusive and the sample was not eligible for use in the Forensic Statistical Tool.

Appendix C


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for Event 15-013
FST analysis performed on sample that does not meet FST test parameters.
Cause
Effect
Analyst was adjusting to new laboratory workflow.
Analyst did not note that DNA amount was insufficient.
Analyst did not send sample for re-quantitation.
LIMS amplification sheet does not provide feedback or alert when an analyst submits a low template sample for (ID28) HCN method.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
Analyst did not recall that FST was unable to process a low template sample amplified with HCN methods
FST user interface does not ask user to confirm if sample is suitable for analysis.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
Reviewer did not recall that FST was unable to process a low template sample amplified with HCN methods
Low template sample amplified using ID28 (HCN method).
Low template sample amplified using ID28 (HCN method) entered into FST.
Error not caught during technical review.
FST analysis performed on sample that does not meet test parameters.
Customer Service Goal Impacted
Quality Goal Impacted

Appendix D


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for Event 15-013
FST analysis performed on sample that does not meet FST test parameters.
Corrective Action
Cause
Effect
FST analysis performed on sample that does not meet test parameters.
Customer Service Goal Impacted
Quality Goal Impacted
Low template sample amplified using ID28 (HCN method).
Low template sample amplified using ID28 (HCN method) entered into FST.
Error not caught during technical review.
Analyst did not note that DNA amount was insufficient.
Analyst did not send sample for re-quantitation.
LIMS amplification sheet does not provide feedback or alert when an analyst submits a low template sample for (ID28) HCN method.
Analyst did not recall that FST was unable to process a low template sample amplified with HCN methods
FST user interface does not ask user to confirm if sample is suitable for analysis.
Reviewer did not recall that FST was unable to process a low template sample amplified with HCN methods
Analyst was adjusting to new laboratory workflow.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
Corrective Action: Consider using cognitive aids and workload monitoring as part of change management plan for large scale changes to lab workflow.
Corrective Action: Modify LIMS amplification sheet to provide analysts with feedback or alert when sample requirements do not meet criteria.
Corrective Action: Revise SOP to include note regarding potential for error if sample criteria not met.
Corrective Action: Increase awareness and educate through lab meetings, inservice and emails.
Corrective Action: Create a landing page that asks analysts to verify sample suitability.
Corrective Action: Revise SOP to include note regarding potential for error if sample criteria not met.
Corrective Action: Increase awareness and educate through lab meetings, inservice and emails.