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ROOT CAUSE ANALYSIS REPORT
EVENT ID# 15-011
OCTOBER 15, 2015

Executive Summary

On July 31, 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 September 16, 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 15-011.

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 laboratory not having a stop point in its process to review procedure with staff after a deviation has been approved 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 implement a time out procedure for approved deviations, 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

In April 2014, the Forensic Biology received a voucher containing three gun swabs. After examination, one swab was found to be "not suitable for comparison" and the remaining two swabs contained "an insufficient amount of DNA for further testing". In September 2014, the

Assistant District Attorney contacted Forensic Biology and asked if additional testing was possible.

In October 2014, the Forensic Biology Laboratory approved a planned deviation to amplify one of the two samples that was below the required minimum of 20pg/µl. The results showed the sample to be a non-deducible mixture that was deemed suitable for comparison, but would require a statistical evaluation in order to report a positive association of an exemplar to the mixture.

In December 2014, a suspect exemplar came to the lab for comparison to the above sample. A positive association was made and the laboratory used the Forensic Statistical Tool to calculate a likelihood ratio that was then reported out on January 30, 2015.

On June 15, 2015, the defense attorney working on the case which involved the suspect exemplar contacted the Forensic Biology Lab and asked about the FST validation and how the sample was used in FST. The Forensic Biology Laboratory reviewed the case and discovered that the Forensic Statistical Tool should not have been used. The comparison should not have been made because FST was not validated and approved to run samples that were amplified with 28 cycles and with DNA amounts below 100pg. In this case, the sample was 97.7pg.

The Forensic Biology Laboratory began to explore whether further testing could be done using the low copy number DNA Testing method in order to allow a comparison using FST. In late-July, it was determined that no further testing was possible due to insufficient testing material. An amended report was then issued to indicate that the comparison of the DNA profiles was inconclusive. See Appendix B for a detailed chronology of events.

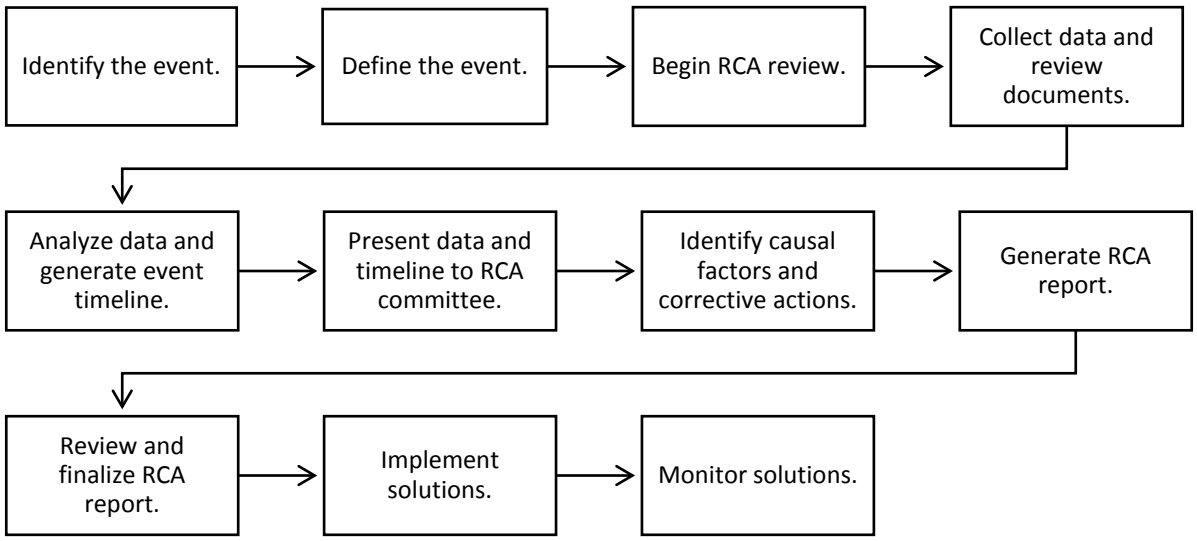
Composition of RCA Committee

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 hospital operations and risk management.

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 it was determined that no further testing was possible, the laboratory issued an amended report and notified the assistant district attorney and defense attorney. Forensic Biology then proceeded to review all deviations approved by the Technical Leader over a 24 month period in order to determine if other cases were impacted by a similar error. Thirty-two cases were reviewed and no other errors were identified. 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. Lack of a stop point to review procedure after the deviation had been approved.

Evidence: After the deviation had been discussed and approved, the low template sample was amplified using high copy number methods and continued following the laboratory's high copy number workflow. The analyst and the reviewer did not realize that because of the deviation, the low template sample should not have been processed as a routine high template sample. After the deviation was approved, the team did not meet to review and discuss the impact of the deviation to standard procedure.

2. 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.

3. The FST standard operating procedure does not state that low template samples amplified with high copy number methods cannot be used with FST.
Evidence: The non-conformity report for this event stated that the FST procedure included "the template DNA amounts that are in the normal range for this testing but does not state that samples below this value cannot be run". A review of the FST procedure confirmed that the procedure does list acceptable DNA amounts for FST analysis. However, the procedure does not clearly state that it is the laboratory's policy that the low template samples amplified with high copy number methods cannot be used with FST. This guidance was only provided through initial training and verbal direction. The lack of a clear policy statement contributed to the analyst and reviewer failing to realize that the low template sample was not suitable for this type of FST analysis.

4. This deviation was a rare occurrence for the laboratory.
Evidence: Another contributing factor was that this was a very rare deviation for Forensic Biology. In their review of previous deviations, the laboratory identified 32 approved deviations in the last twenty-four months. Of those 32 approved deviations, only two other cases were similar to this one and both of those cases involved single source samples that did not require FST analysis. Because of the rarity of this particular event, laboratory staff had little prior experience to foresee the impact the deviation would have on FST analysis.

The RCA committee also reviewed the decision to deviate from procedure and amplify the low template sample using high copy number methods. The RCA committee found no issue with the decision to approve the deviation. In this case, the laboratory considered the science, weighed the risks and selected the best methodology for the last probative item in the case.

Based on the above findings, the RCA committee determined that the error could have been prevented before the sample was entered into the FST program. The root causes for this error were the lack of a stop point in the process to review the approved deviation with the team and the lack of prompts or feedback in the FST home screen. The rarity of this particular deviation and a lack of clarity regarding sample requirements in the FST procedure 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 must implement a stop point in its workflow to review the deviation and the impact on procedure with staff. Similar to a "timeout" in healthcare, this brief meeting will give staff an opportunity to stop activities, focus on communication and verify the deviation and its impact to procedure before moving forward with testing. This meeting should include team leaders, assistant team leaders, analysts and supervisors.

Forensic Biology should also consider enhancing documentation of the deviation. The deviation should be documented immediately after the deviation is approved. This documentation should define the deviation, the reason for the deviation and outline the consequences of the deviation on laboratory processes.

2. 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.

3. Forensic Biology must revise their procedure and include a statement that clarifies the laboratory's policy that low template samples amplified with high copy number methods cannot be used with FST. 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.

4. Forensic Biology must increase awareness of FST sample requirements and design limitations. This can be accomplished by reviewing key principles during laboratory meetings, in-services, initial training or emails. Communicating FST sample requirements to all laboratory staff will help increase staff awareness of the issue and prevent similar errors in the future.

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

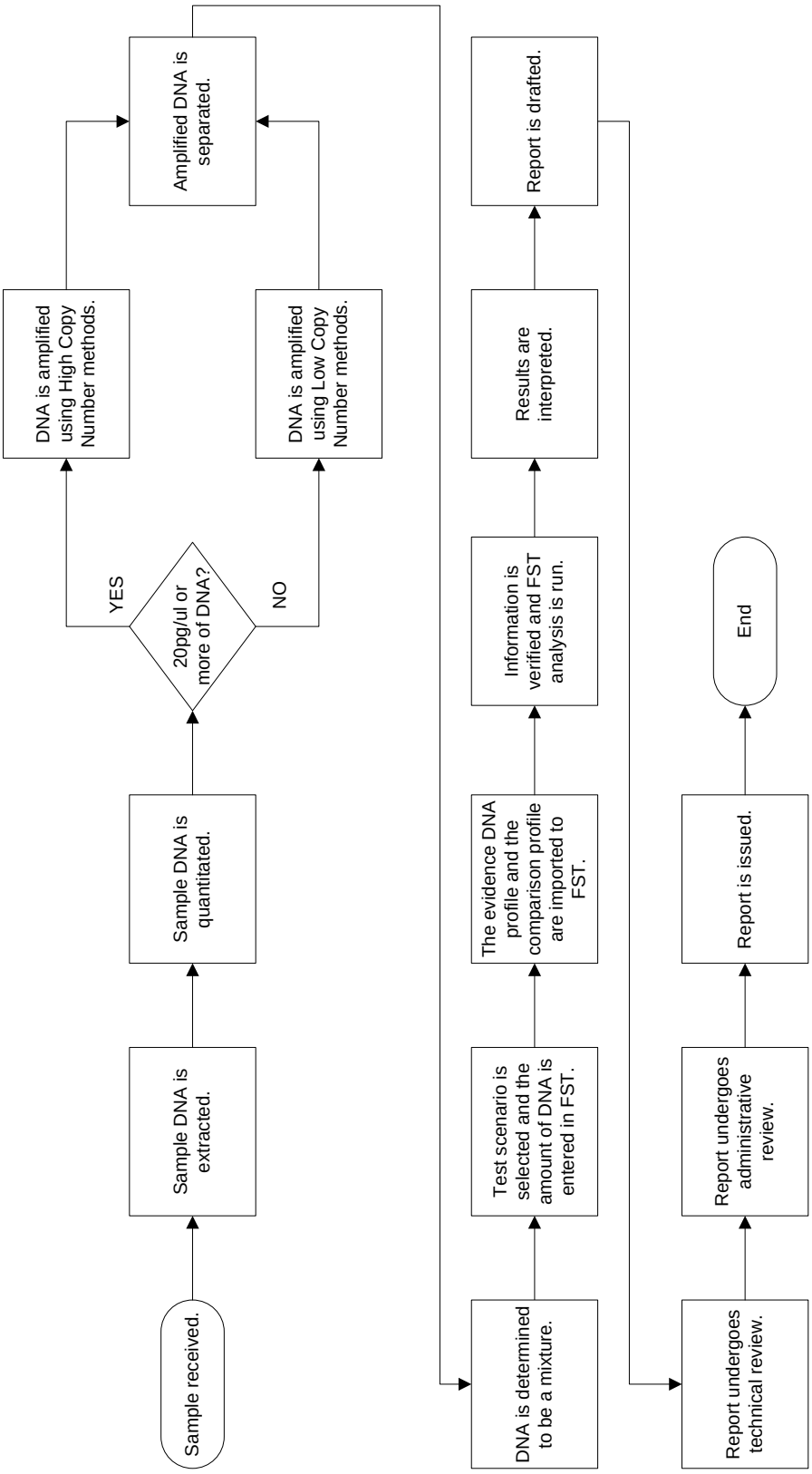
Summary of Corrective Actions

Causal Factor	Corrective Action	Recommended Completion Date
Lack of a stop point to review procedure after the deviation had been approved.	Forensic Biology must implement a stop point in its workflow to review the deviation and the impact on procedure with staff.	12/31/15
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.	12/31/15
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 statement that clarifies the laboratory's policy that low template samples amplified with high copy number methods cannot be used with FST.	12/31/15
This deviation was a rare occurrence for the laboratory.	Forensic Biology must increase awareness of FST sample requirements and design limitations.	12/31/15

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

Appendix A

OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC BIOLOGY: FORENSIC STATISTICAL TOOL PROCEDURE

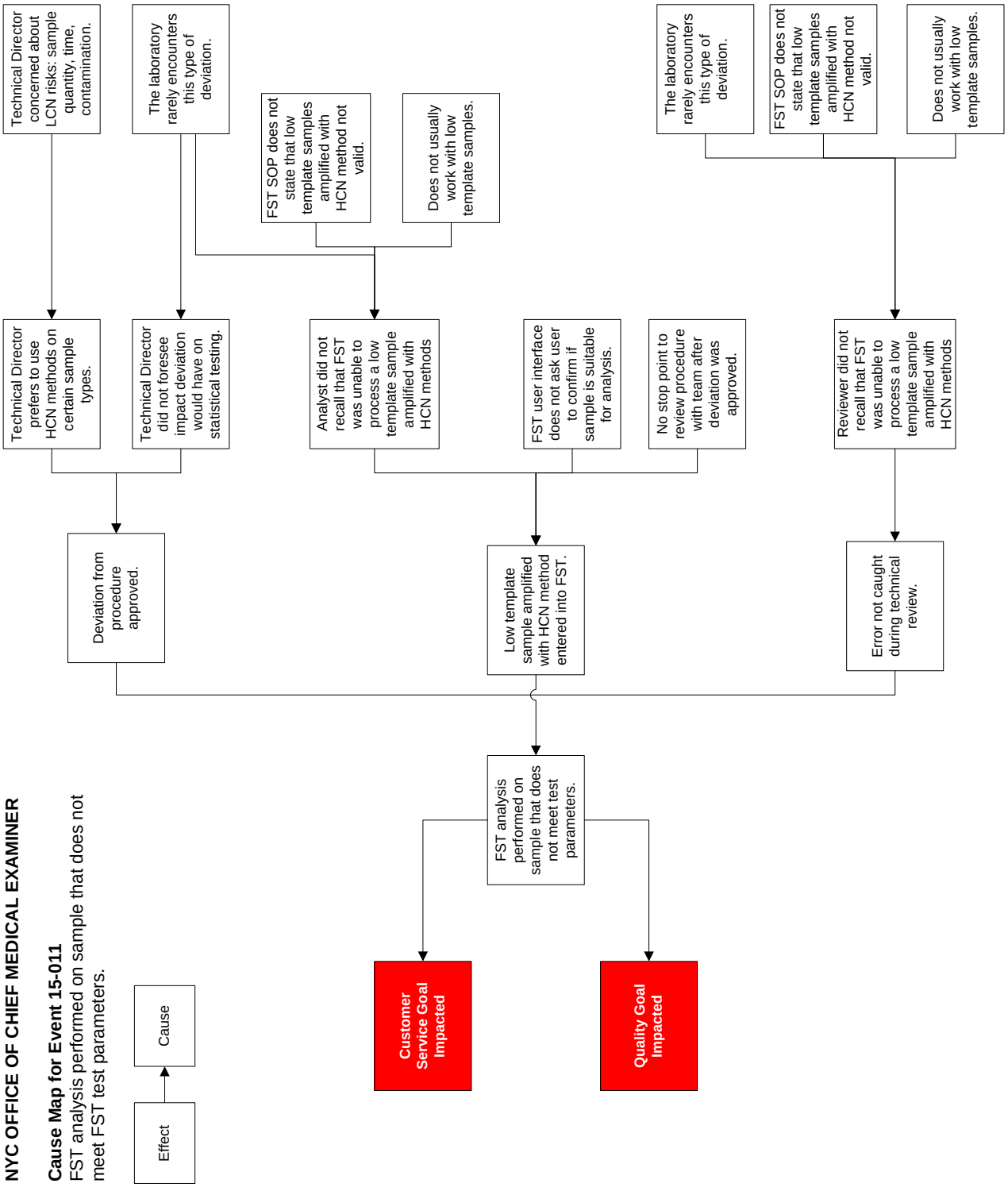


Appendix B

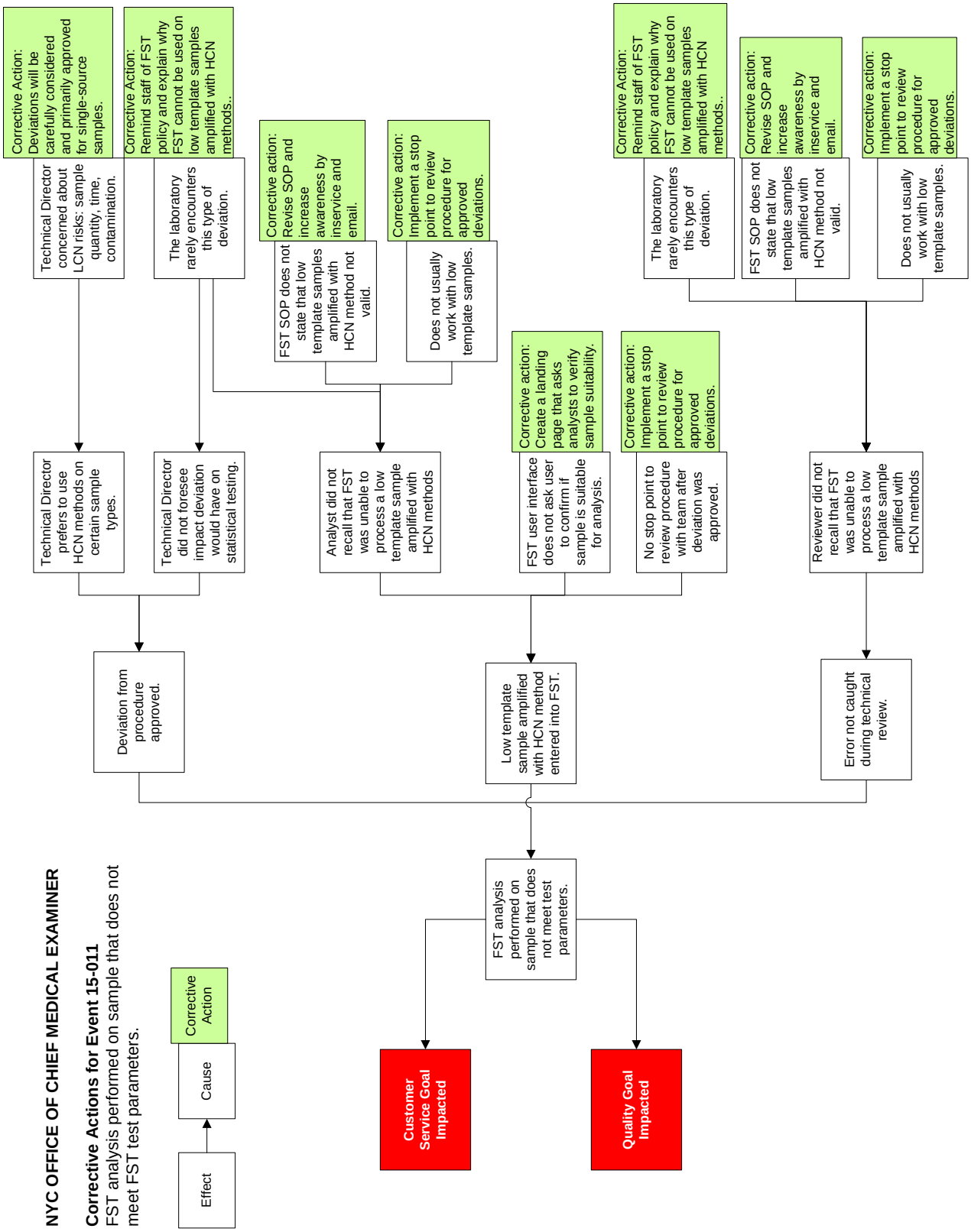
CHRONOLOGY OF EVENTS

DATE	EVENT
4/28/14	Voucher containing three gun swabs is received by Forensic Biology (FBio)
8/7/14	The swabs are examined by FBio.
9/9/14	FBio released a report indicating that one swab was found to be "not suitable for comparison" and two swabs contained "an insufficient amount of DNA for further testing".
9/11/14	Assistant District Attorney contacted the laboratory requesting additional testing.
10/28/14	Technical Leader approved testing the sample from the "slide grip grooves" using High Copy Number amplification. This sample was selected because it contained 19.54pg/ul of DNA and the minimum amount needed for High Copy Number testing is 20pg/ul.
12/4/14	FBio released a report stating that a mixture of DNA was obtained from the "slide grip grooves" and it is suitable for comparison.
12/24/14	Known sample from suspect is received by FBio.
1/12/15	Known sample from suspect is examined and compared to the mixture of DNA seen on the swab from the "slide grip grooves" using the Forensic Statistical Tool (FST) software.
1/30/15	FBio released a report stating a positive association of the suspect to the mixture of DNA seen on the swab from the "slide grip grooves". The report listed the results of the FST analysis.
6/15/15	Defense Attorney contacted the laboratory and requested a discussion of results. At this time, the analyst realized that the sample should not have been run in FST due to limits of FST validation parameters. (FST was not validated to run high copy number analysis on a sample with a quantitation value of less than 20pg/ul total)
6/15/15-7/15/15	FBio Management determined that the reported FST results are not valid and that additional testing, using low copy number methods, is not possible.
7/21/15	FBio released an amended report stating that the comparison of the suspect's DNA profile to the mixture of DNA seen on the swab from the "slide grip grooves" is "Inconclusive".

Appendix C


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for Event 15-011
FST analysis performed on sample that does not meet FST test parameters.
Effect
Cause
Technical Director concerned about LCN risks: sample quantity, time, contamination.
The laboratory rarely encounters this type of deviation.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
The laboratory rarely encounters this type of deviation.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
Technical Director prefers to use HCN methods on certain sample types.
Technical Director did not foresee impact deviation would have on statistical testing.
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.
No stop point to review procedure with team after deviation was approved.
Reviewer did not recall that FST was unable to process a low template sample amplified with HCN methods
Deviation from procedure approved.
Low template sample amplified with 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
Corrective Actions for Event 15-011
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
Deviation from procedure approved.
Low template sample amplified with HCN method entered into FST.
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Analyst did not recall that FST was unable to process a low template sample amplified with HCN methods
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No stop point to review procedure with team after deviation was approved.
Reviewer did not recall that FST was unable to process a low template sample amplified with HCN methods
Technical Director concerned about LCN risks: sample quantity, time, contamination.
The laboratory rarely encounters this type of deviation.
FST SOP does not state that low template samples amplified with HCN method not valid.
Does not usually work with low template samples.
The laboratory rarely encounters this type of deviation.
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: Deviations will be carefully considered and primarily approved for single-source samples.
Corrective Action: Remind staff of FST policy and explain why FST cannot be used on low template samples amplified with HCN methods..
Corrective action: Revise SOP and increase awareness by inservice and email.
Corrective action: Implement a stop point to review procedure for approved deviations.
Corrective Action: Remind staff of FST policy and explain why FST cannot be used on low template samples amplified with HCN methods..
Corrective action: Revise SOP and increase awareness by inservice and email.
Corrective action: Implement a stop point to review procedure for approved deviations.
Corrective action: Create a landing page that asks analysts to verify sample suitability.
Corrective action: Implement a stop point to review procedure for approved deviations.