**ID** 79452
**Current Step is** Quality Manager Review
**Initiated by** Workflow Initiator
**Launched by Workflow** Quality Incident Review (ID: 78225) on 12/14/2023 2:44:21 PM
**Submit to Quality Manager by** [redacted] on 2/12/2024 10:46:54 AM
**Needs to be processed by** [redacted]

## Quality Manager Review

**Date of Incident**
Date of Incident
9/19/2023 12:00:00 AM

**Employee's Name**
[redacted]

**Lab Name**
Denver

**Section**
Biology

**Initial Description**
Initial Description
[redacted] was contacted on 9/19/23 by [redacted] regarding an issue an intern observed during a data mining project on vestibular swabs. The intern was required to enter DNA quantitation data for vestibular swab samples to evaluate the usefulness of running these samples and the success of the DNA profiles obtained. The following quant target information was being researched: SA (small autosomal), Y (male target), M:F (male:female ratio). She noticed sample D18-1206, Item 1.8.1 had a Y (male target) Ct value (Cycle threshold), but no male quant value. According to the instructions used by the intern, this was not a set of values that could have been generated by the instrument, and was not consistent with all other samples. The intern inquired [redacted] on what to do and [redacted] contacted [redacted]. [redacted] instructed the intern to highlight the sample for further investigation. [redacted] was assigned to look into the case and who ran the sample. She indicated that the case was worked on by forensic scientist (FS) Missy Woods.

The Applied Biosystems 7500 real-time PCR instrument is utilized to quantify or "quant" DNA samples within DNA batches. A sample cannot be detected by the quant analysis software as passing the cycle threshold (CT) unless there is DNA detected in the sample. If DNA is detected, a quant value is generated. The quantitation data is exported off the instrument into an Excel spreadsheet with quant results and a PDF with target slopes. The DNA TL team researched additional cases from 2018 to see if there were any other instances of missing quant values in the quant Excel spreadsheet(s) for FS Woods. The team also checked their own batch notes for missing values, and it was verified that there were none. It was investigated and determined that quant target values could not be manipulated on the instrument prior to export.

[redacted] notified [redacted] on 9/25/23 (Monday) regarding this quant data discrepancy and he asked the TL team to look into other years in order to see if there were any additional instances in which the DNA quant data was missing and/or possibly altered. [redacted] notified [redacted] and [redacted] regarding this on 9/26/23. [redacted] was notified on 9/26/23 by [redacted]

The TL team began researching DNA batch notes from 2008 to 2023 for FS Woods and identified numerous instances where reagent blanks and evidentiary samples had missing, altered, or manipulated quant data.

[redacted] and [redacted] met with FS Woods on 9/28/23 to discuss the identified issues. Woods did not explain how the issues could have occurred. [redacted] retained Woods' computer and informed her she would be off duty until further notice. On 10/3/23 Woods was placed on administrative leave and an internal affairs investigation was initiated.

The CBI-FS Biological Sciences technical leader team and the quality unit continued to initially investigate the issue throughout the month of October and into November. For details of the initial investigation see TL/Management evaluation section below. Please see the attached "copy of summary of affected samples/batches" document summary tab for initial alterations found list.

ANAB was contacted via email on 10/30/23 in order to schedule a videoconference to notify ANAB of the issue in accordance with ISO 17025:2017 (Section 5.4.2) and CBI-FS QP11 (Section III.C.3). This initial videoconference with ANAB occurred on 11/2/23. [redacted], [redacted], and [redacted] participated in this meeting from the CBI-FS. On 11/2/23 a letter summarizing the conversation on 11/2/23 was emailed to ANAB (see attached notification to ANAB).

**CAR - Immediate Action Taken**

The DNA Technical Working group met on 11/9/23 to discuss immediate corrective actions that could be made to the DNA policies and procedures. Based on that discussion the following immediate corrective actions were implemented:

Previous policy/practice: The biological sciences unit in all four CBI-FS laboratories maintained different instrument data retention practices according to instrument data storage limitations unique to that laboratory.
Identified Risk: Instances of FS Woods' altered data became difficult to understand without the accompanying .eds raw data quant files.
Corrective Action: The immediate retention of .eds raw data quant files and the backup of all .eds data files to external hard drives to be maintained indefinitely.
Completion Date/responsible party: added to DOM DNA 05 on 12/18/23 by [redacted]

Previous policy/practice: Primer peak data was not retained or reviewed routinely.
Identified Risk: Without the confirmed presence of the primer peak, it is unclear that control/sample tampering did not occur.
Corrective Action: A new policy was implemented that mandated the printing and retention of all electropherograms for all reagent blanks and controls in order to demonstrate the presence of a primer peak. These electropherograms are to be incorporated into the DNA batch notes for technical review.
Completion Date/responsible party: added to DOM DNA 10-11 on 11/10/23 by [redacted]

Previous policy/practice: Quantitation results by well were not previously included as a PDF since the results were included in the case file in an Excel format.
Identified Risk: The Excel file is more easily editable than a PDF document
Corrective Action: A new policy was implemented that requires the "results by well" quantitation data to be incorporated into the quant PDF. The PDF is printed as a report from the instrument and embedded into the workbook.
Completion Date/responsible party: added to DOM DNA 10-16 on 11/10/23 by [redacted]

Previous policy/practice: Batch reviewer notes were typed into an excel based DNA batch workbook and uploaded by the reporting analysts after the review was completed.
Identified Risk: Changes to the DNA workbook could be made by the reporting analyst after the batch technical review was completed.
Corrective Action: A new policy was implemented that requires the DNA batch notes for each case within the DNA batch to be uploaded into FA by the batch note technical reviewer instead of the reporting analyst. The DNA batch note technical review process will be documented as a review in Forensic Advantage so that all comments can be tracked and documented. Any changes to the DNA batch note version after upload to Forensic Advantage by the technical reviewer would require explanation and reasoning documented by the analyst.
Completion Date/responsible party: added to DOM DNA 12-03 on 12/20/23 by [redacted]

Identified Risk: 89 no match determinations of CBI Arvada to CBI Arvada potential CODIS hits were only reviewed by Woods. This review did find that two profiles from a staff member had hit to one another, but Woods dispositioned it as a no match. Since the root cause of issues discovered in Woods' work are integrity related, this unverified no match disposition posed potential risk.
Corrective Action: Notification of the state CODIS administrator, Denver LDIS administrator, NDIS regarding the removal of analyst Missy Woods as a CODIS user and proper documentation of the incident in a QIR.
Completion date/responsible party: by [redacted]

Expected outcome: Analysts will now have a 2nd analyst's opinion of the no match disposition to reduce the probability of human error.

**TL Management Evaluation**
Management Evaluation
Further Investigation of Woods' Cases 9/25/23 to 11/6/23

Initial review consisted of the TL team reviewing multiple batches from each year from 2008 - 2023 and looking at multiple cases in each batch. This review expanded to review each batch worked by FS Woods from 2008 - 2023 and multiple cases within each of those batches. A member of the Quality Unit was added to this review process.

This batch and case review identified the following issues:
Reagent blanks with a CT value but missing a quant value
Reagent blanks with a quant value but missing a CT value
Evidence samples with a CT value but missing a quant value
Evidence samples with a quant value but missing a CT value
Entire male target row is missing for evidence sample

On 10/20/23 the review team began checking the 7500 real-time PCR .eds data files from the two 7500 real-time PCR instruments, D1 and D3, within the Arvada laboratory in order to verify if Woods' quant results present in the DNA batch notes corresponded to those seen in the data files on the instrument. Data from the instrument was compared to the respective case information within FA in order to see if there were any discrepancies. Raw quant data from the D1 and D3 7500 real-time PCR instruments was only available back to approximately August of 2019, as the previous DNA TL had directed the power users to delete the raw data. This previous practice of deleting the raw data has been stopped and a raw data backup procedure is now in place in DNA DOM 10-12 so that all data is retained (see Immediate Corrections Actions section below for more details).

This data review identified the following issues:
Re-quant of all samples in the analyst's DNA batch with no documentation explaining the reason why in instances in which quant values were present in reagent blanks on the first quant and absent in the second quant. There was a re-quant performed on all samples in the DNA batch with no documentation explaining the reason why.
Missing male quant values
Reagent blank quant data value manipulation
Missing quant values for reagent blanks
Quant values not matching those seen in the .eds data files

**Quality Manager Review**
Quality Manager Review
A meeting with the CBI-FS Director group occurred on 11/7/23 in order to discuss the different facets of the quality investigation that needed to occur. For a detailed list of these projects see the Quality Manager Review section below.

A meeting with the CBI-FS staff was held on 11/8/23 in order to provide some details regarding the investigation. This was done to enlist the entire staff to assist with various aspects of the quality investigation to determine the scope and extent of the issue more efficiently.

Also on 11/8/23, a quality unit meeting was held in order to discuss the different facets of the quality investigation in more detail. Project managers for the different facets of the project were also identified.

On 11/9/23 a meeting was held with the CBI-FS BIO staff in order to discuss the issue in more detail and to brainstorm immediate corrective actions to implement in the Biological Sciences discipline. Several immediate corrective actions were implemented on 11/13/23 as a result of this discussion (see Immediate Corrective Action Taken section below for details).

On 11/14/23 [redacted], [redacted], and [redacted] again met with ANAB representatives via conference call.

Discussion topics included updates on the quality investigation, the robust data mining effort that was started, and the possible creation of an external panel composed of DNA personnel from other labs to assist in an advisory role. ANAB requested that we continue to update ANAB of this issue on a monthly basis, or immediately after any significant developments. A written letter was emailed to ANAB on 11/15/23 as a follow-up to this conversation. This letter detailed the different facets/projects of the quality investigation and the expected outcomes from these projects (see attached letter).

On 11/17/23 an initial meeting was held with the members of the external advisory panel. CBI-FS representation for this meeting included [redacted], [redacted], [redacted], and [redacted]. The panel members included representation from the Idaho State Police, the Utah Department of Public Safety, the Georgia Bureau of Investigation, and the Texas Department of Public Safety. Topics discussed included information regarding the issue, purpose and desired outcomes of the committee, initial recommendations regarding the investigation, and confidentiality.

On 11/16/23 and 11/17/23 several members of the CBI-FS were walled off for ethical reasons due to being identified as potential witnesses for the internal affairs and criminal investigations.

On 2/9/24 the ethical screen was lifted for [redacted]

On 3/7/24 the ethical screen was lifted for [redacted]. Therefore, management of this CAR was slowly transitioned back to [redacted]

The non-conformances identified in the Initial Description and TL Review are major policy violations and fail to meet CBI's ethics and integrity standards. The specific violations to policy/procedure include:

Quality Manual:
1.2. All CBI-FS personnel are expected to understand and adhere to the established policies and procedures in all applicable Forensic Services, CBI, and state of Colorado manuals.

QP01:
A.1. The CBI-FS is dedicated to consistent, ethical professional practice.
A2. The CBI-FS will provide a work product that is accurate, unbiased and scientifically objective in order to ensure the quality of the analytical work conducted.

QP10:
I.Purpose. All of the information we provide will be clear, concise, accurate, and confidential.

QP14:
III.B.2 Technical records to support a report (including results, opinions, and interpretations) shall be such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.
III.C.1 1. Any changes made to completed case-related documentation shall be tracked in the LIMS. Both original and amended data files shall be retained.
III.D. All case/database-related and quality records are secured and stored electronically. All records are permanent in nature.

QP28:
III. The CBI-FS will report the results of each test or series of tests accurately, clearly, unambiguously, objectively and in accordance with this procedure.

ANAB Guiding Principles and Mission:
14. Present accurate and complete data in reports, testimony, publications and oral presentations.
15. Make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field. Reports are prepared in which facts, opinions and interpretations are clearly distinguishable, and which clearly describe limitations on the methods, interpretations and opinions presented.
16. Do not alter reports or other records, or withhold information from reports for strategic or tactical litigation advantage

ISO 17025:2017

7.5.2: The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

AR3125:
7.5.1.3: The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.
7.5.1.4: Records shall be created or maintained in a permanent manner.

CBI Code of Conduct
2.2: Authority and Public Trust: Employees shall utilize their authority and power lawfully and appropriately.
2.2.1: Employees shall conduct themselves in a manner to preserve public trust. Employees shall not conduct themselves in a manner that is an abuse or a misuse of the authority conferred upon them.
2.3: Conduct: Employees shall use reasonable judgment and refrain from conduct which reflects unfavorably on the CBI. This includes conduct that: 2.3.1 Brings the CBI into disrepute; or 2.3.2 Reflects discredit upon the individual as an employee of the CBI; or 2.3.3 Impairs the operation, effectiveness, or efficiency of the CBI or its employees.
2.5: Lawful Conduct: Employees shall obey the United States and Colorado Constitutions, the laws of the United States, and of any state or local jurisdiction. A conviction for a law violation is prima facie evidence of a violation of this rule.
2.7.1 Employees shall not access, review, or remove any record in any form for other than authorized departmental purposes.
2.8 Truthfulness: Employees shall be truthful and complete in all matters associated with CBI responsibilities.

The following Corrective Action Report (CAR) will include investigation of quality issues, corrective actions, and further monitoring. The CAR is the CBI Forensic Services Quality System response to this issue and is separate but complementary to the CBI Internal Affairs Investigation.

Throughout the investigation ANAB was updated monthly on the progress of the investigation and all significant developments were reported immediately. Subsequent meetings occurred via video conference on: 12/12/23, 1/23/24, 2/1/24, 2/20/24, 3/19/24, and 4/23/24. A memo was issued after each scheduled meeting to summarize what was discussed (see attached).

The Forensic Services staff were informed of the identified issues in Woods' cases on 11/8/23 and divided into teams to assist with the projects associated with the quality investigation. The quality investigation was a full review of quant data in all cases worked by FS Woods and a risk assessment of the impact to evidence outlined below in projects 2 and 7.

The following projects were set in motion:

1-Staff Support
Provide support and resources to staff during this time
Engagement by supervisors and entire management team
2-Quality Case Review of all Woods cases
Review all 10,787 known cases worked by Woods during her CBI career
2008 - 2023 - Electronic files located in Laboratory Information Management System (LIMS)
1994 - 2007 - Paper files located in a secure off-site location
Phase 1
Step 1- Download of all versions of each Excel batch note file from all cases within each batch.
Step 2A & 2B: Verify step 1 for completeness and manually calculate the quant values in one batch note file to determine if the values in each case are the true values.
Step 3: Apply an Excel macro to compare all versions of the batch notes from all cases in each batch. This is to determine if any one case had a different value than the rest.
Step 4: Review GMID-X projects to determine if samples where no DNA was detected, reagent blanks and negative controls all contained the expected primer peak.
Step 5: [redacted] conducted a risk analysis of all potential issues identified in steps 1-4.
Phase 2

CODIS Review- All 89 CODIS no match dispositions made by Woods were reviewed for accuracy. These 89 no match dispositions to the CBI-Arvada ORI would not have previously been reviewed by another internal or external LDIS. These dispositions were seen as a potential risk to casework. This review was a recommendation of the External DNA Advisory Panel.
Review of technical and batch reviewers- A summary of all batch and technical reviewers of Woods' casework was reviewed for trends.
Review FS Woods' computer and personal drives in order to determine if additional versions of workbooks exist in these locations
Evaluate FS Woods' previous Quality Incident Reports (QIR's) and LIMS Correction Requests in Ideagen Quality Management (IQM)
Review of Issues found in paper case file review - See Project 8.
3-Case Review Retesting
Work with Law Enforcement Agencies, DA offices and Defense Counsel as applicable to coordinate retesting of cases based on inquiries and court proceedings
Prioritize cases scheduled for trial
Address testing of pending cases in backlog and work to outsource to private laboratories or assign as appropriate for completion
4-Case Information Gathering
Utilize state databases to research each case worked by FS Woods
Data identified: SID#, FBI#, Court Case#, County, Judicial District, Hearing or Trial Held, Court Disposition, Charge Class, Sentenced to Jail or DOC, Currently Incarcerated, Is Suspect Deceased
5-Identification of Individuals in Prison
Incorporated into 4-Case Information Gathering
6-Search for Subpoenas and Testimony
Reviewed FS Woods' personal testimony record and recorded testimonies in FA to best determine the scope of her court appearances. We understand that this is not a comprehensive list, however, the CoCourts database does not have a way to pull this information.
Cross referenced known testimonies with the affected case list
Comparison to the list of individuals in prison
Continual monitoring of incoming subpoenas
7-Immediate Quality Control Measures Implemented
The Technical Leader for each forensic discipline led a discussion with the Technical Working Group to identify quality control measures to implement.
See Corrective Action section
8-Requesting Archived Paper Case Files and Paper Case File Review
FS Woods' 1994-2007 cases are paper file cases
Request a sampling of (399) cases to establish process
Assemble paper file review team
Create a review outline for analysts to follow to promote a uniform review process
Established a timeline for DNA quantification at CBI
Established that FS Woods did not begin DNA casework until 2000, however, all cases back to 1994 will still be reviewed for additional DNA work completed in subsequent evidence submissions.
9-Triage calls and questions from Law Enforcement Agencies, District Attorneys and Defense Counsel
Inquiries from entities will be received by [redacted] to determine the reason for the call
Tracking requests to ensure inquiries are addressed
Coordinating meetings as applicable on a case to case basis to determine next steps in particular case inquiries
10-Formation of an external advisory panel consisting of DNA technical experts from across the country
DNA technical experts from Idaho, Utah, Texas, and Georgia agreed to assist CBI as an external advisory panel
Review CBI policy and procedures
Review CBI investigation of FS Woods' work
Provide input and recommendations
11-Quality review of other analysts work
Review of other BIO Analysts- The quality investigation needed to determine if this unethical behavior was a systemic or an individual issue; therefore, all DNA scientist's casework will be reviewed.

This has been an extensive investigation including most members of the CBI-FS staff helping to review Woods' cases from 1994-present. Please see attached documents for the Quality review plan, notifications to ANAB and summary of affected cases.

Purpose and result of Investigation Projects To Date:

1-Staff Support
Peer support program
Chaplain program
Situational Debrief with contracted psychologist
2-Quality Case Review of all Woods cases
2008 - 2023 - Casework review is complete
1994 - 2007 - Paper case file review is in-progress. Woods did not perform DNA analysis until 2000. Pre-2000 cases will still be reviewed holistically, but no quantitative data exists to review.
Update (4/15/24): It was determined that all of Wood's serology only paper case files will also be reviewed. Initial paper case file review is approximately 2/3rd complete. However, after initial review, a final review will need to occur to verify any potential issues identified in the initial review.
Phase 1
654 affected cases were identified through phase 1 reviewing the DNA workbooks of FS Woods. Completed on 12/26/23.
Anomaly frequency timeline was created to assess data alteration trends over time. See attached timeline.
Update (4/15/24): 56 amended reports will be issued to correct incorrect information on original reports. Agencies and DA's offices will be contacted prior to issuing these reports.
Phase 2
CODIS Review- One instance was found in which Woods' dispositioned a match as a no match. The match was two profiles from a staff member that hit to one another. The issue was corrected by another LDIS. This correction included agency notification, new CODIS letters issued, profile removal from CODIS and proper documentation of the incident in a QIR. Completed on 1/3/24.
Update (4/15/24): Two additional issues were identified during this review. The first issue involved an incorrect initial match disposition (it was marked as a no-match and should have been a match). The second issue involved a profile that should not have been uploaded and searched in CODIS but was. However, the report indicated that it was not searched. An amended report will be issued to clarify this. For additional information, please refer to QIR's 81756 and 82089.
Review of technical and batch reviewers- A summary of all batch and technical reviewers of FS Woods' casework was reviewed for trends. No significant trends were observed.
Review FS Woods' computer and personal drives is in-progress
Review of Quality Incident Reports (QIR's) and LIMS Correction Requests revealed her practice of avoiding these workflows. No significant trends were observed, see corrective action relating to LIMS requests. Review completed on 11/30/23.
Review of Issues found in paper case file review- See Project 8.
3-Case Review Retesting
Re-analysis and continued analysis of Woods' open lab records have been outsourced to an external DNA laboratory.
Reports were written to reflect the analysis that had been partially completed, and explained that additional analysis and testing would be outsourced to another DNA laboratory. Completed on 3/5/2024.
Additional analysis of Woods' cases has been completed on an as needed basis. Only by request from LEAs, DA offices and Defense Counsel or pending subpoena at this time.
See attached Re-analysis spreadsheet
4-Case Information Gathering
See attached Case List
5-Identification of Individuals in Prison
See attached Case List
6-Search for Subpoenas and Testimony
Continual monitoring of active subpoenas and need for substitute testimony.
See attached Re-analysis spreadsheet
Compiled a list of all known testimonies in Colorado by FS Woods
FS Woods' testimony list added to attached Case List
7-Immediate Quality Control Measures Implemented
See Immediate Actions and Corrective Action sections
8-Requesting Archived Paper Case Files and Paper Case File Review
Initial review of 399 cases from 1994-2007 complete
This was done to assess the contents and scope of work for each year.
Risk analysis of potential issues by [redacted] is in-progress
9-Triage calls and questions from Law Enforcement Agencies, District Attorneys and Defense Counsel

See Re-analysis spreadsheet
A dedicated phone line was established to receive inquiries into this investigation.
10-Formation of an external advisory panel consisting of DNA technical experts from across the country
Meetings to date: 11/17/23, 11/27/23, 12/15/23, 1/8/24, 2/5/24 and 3/4/24.
Panel reviews the status and scope of the investigation and gives recommendations for continued investigation.
Recommendations and suggestions received from panel since November:
Implemented:
Go into Gene Mapper and print primer peak. This is part of the initial corrective action plan, but with the whole electropherogram.
Have technical reviewer upload the batch note file to the case after review (initial corrective action)
Look to see what FS Woods uploaded to CODIS (not needed based on workflow) and her work on assessing hits (completed in Phase 2)
Review to see if any EDS files were "spot deleted" from 2019 to present. This is in-progress.
11-Quality review of other analysts work
All current and past DNA scientists who performed casework in our quality system since 2008 were included in the review, 40 analysts in total. Ten batches for each analyst were selected at random in order to span the analyst's tenure. The quant data from one case in each batch was manually calculated. All batches in which another analyst ran samples for FS Woods were included in the review for that analyst. FS Woods altered data in one of these instances. As a result of that alteration, additional reviews were conducted for that analyst. No anomalies of any kind were found.
See CAR# 81009 for [redacted] anomalies found.
No anomalies were found for any other CBI-FS DNA analysts past and present. Completed on March 7th.

**CAR - Corrective Action**
Describe the corrective actions selective and how they were implemented. Include why these actions were taken.
CAR - BIO Corrective Actions

DNA Discipline Operation Manual updates as outlined in 'Immediate Actions Taken' represent the corrective actions that have been implemented to date.

Corrective Action: Additional Technical Review training by the Technical Leader.
Anticipated completion date/responsible party: September 2024 by [redacted]
Identified Risk: Based on the procedural requirements of the technical and batch review process (DNA 12-03), there is a varied interpretation among analysts on the specifics of what needs to be reviewed. This variability could have contributed to Woods' actions going undiscovered, if the actions were done prior to review.
Expected outcome: Additional uniformity will decrease the spectrum of interpretation of how to perform technical and batch reviews.
Completion: This training was conducted on 4/24/24 during a BIO Technical Working Group (TWG) Meeting.

Corrective Action: All no match determinations that do not require another agency/lab to confirm will be reviewed by another LDIS.
Anticipated completion date/responsible party: September 2024 by [redacted]
Identified Risk: 89 no match determinations of CBI Arvada to CBI Arvada potential CODIS hits were only reviewed by Woods. This review did find that two profiles from a staff member had hit to one another, but Woods dispositioned it as a no match. Since the root cause of issues discovered in Woods' work are integrity related, this unverified no match disposition posed potential risk.
Expected outcome: Analysts will now have a 2nd analyst's opinion of the no match disposition to reduce the possibility of human error.

CAR - System Corrective Actions

Corrective Action: Current ethics training involves an annual review of ANAB Guiding Principles as well as a separate ethics training assigned through our SABA platform. Under this corrective action, the CBI-FS will begin to engage in more direct conversations and training around the consequences of integrity issues and the importance of ethical behavior throughout the year. This will be a large part of the annual in-service starting in 2024, but will be added to all future training plans as well.
Anticipated completion date/responsible party: September 2024 by CBI Management
Identified Risk: FS Woods' actions have wide spread and very serious consequences. The staff needs these

consequences to be plainly stated on a regular basis to ensure they stay top of mind. Additionally, scientists are not trained to understand the laws violated by unethical behavior in the workplace.
Expected outcome: The staff will be routinely reminded in a multitude of ways that the obligation of continuous ethical behavior is of the utmost importance.

Corrective Action: Improve the Quality Incident Review (QIR) and Corrective Action report (CAR) process to include a more detailed risk assessment (which includes level of impact and probability of recurrence), timely documentation, and increased accountability.
Anticipated completion date/responsible party: July 2024 by [redacted]
Identified Risk: In 2018 an alteration of data by FS Woods was identified during review. A QIR was initiated and the quality incident was investigated. The QIR process failed to identify the scope and extent of these non-conformances which led to recurrence. Woods went on to alter data in 11 additional instances before she was removed from casework in 2023.
Expected outcome: The new process will increase accountability among Forensic Services employees, make documentation and review of incidents more timely, and ensure objective assessment of risk. These improvements will lead to more effective results in identifying and addressing quality issues within the laboratory setting.
Completion: Update (4/15/24): A new risk matrix was developed and implemented. This includes new risk categories, definitions, and a requirement for the applicable technical leader to also perform a risk assessment for QIR's. These changes were implemented in the new version of QP11, published on 3/21/24 (revision #5).

Corrective Action: All LIMS correction requests must be documented in a tracked workflow.
Anticipated completion date/responsible party: July 2024 by [redacted]
Identified Risk: Since the workflow was recommended, but not required, it has been more difficult to track Woods' actions.
Expected outcome: The quality unit will have a better understanding of the breadth and types of LIMS corrections that are occurring and can track trends.
Completion: A new procedure document was published on 4/23/24 (EP Appendix A - LIMS Corrections). This appendix provides requirements for correcting data in LIMS. The purpose of this new document is to make our LIMS Corrections more transparent, consistent, and trackable. The LIMS Correction request # and summary will be placed into the case file by the LIMS Committee members. Corrections that require a LIMS Correction Request workflow cannot be made by the requestor. This document can be viewed on the CBI-FS website.

PAR - Preventive Actions

Preventative Action: Within the latent discipline, documentation of the # of latents observed by the reviewer during the suitability review in LIMS. The technical reviewer will then verify that the number of latents of value in the case and those identified by the suitability reviewer(s) are the same.
Anticipated completion date/responsible party: This was completed in January 2024 by [redacted]; the ACE-V DOM has been updated to reflect this new requirement.
Identified Risk: A possibility that the number of latent prints that were observed by both parties on an item could be different then what was photographed, analyzed and potentially compared in the case.
Expected Outcome: This will ensure that the number of latents of value that are retained in the case are the same number that the suitability reviewer has also agreed are of value for comparison.

Preventative Action: A screenshot of all latents entered into the AFIS database will be uploaded to the lab record to be technically reviewed.
Anticipated completion date/responsible party: January 2024 by [redacted]
Identified Risk: That actual entry and disposition of latents in AFIS and NGI could be different from what the analyst reported in the worksheet/report.
Expected outcome: This will ensure that the number of latents entered into a database is accurately reflected in the worksheet and report.

Preventative Action: Technical leaders assess their discipline's data retention practices to see if there is room for improvement and longer retention times.
Anticipated completion date/responsible party: April 2024 by [redacted]
Identified Risk (in DNA): An inability to ensure that the data imported into case files is identical to the raw data.

Expected outcome: The ability to compare raw instrumentation data to data used and imported into case files in order to confirm the integrity of the data.

Preventive Action: The implementation of a more comprehensive case re-analysis program and an expansion of case reviews during the internal audit to include full audit trails of selected cases.
Anticipated completion date/responsible party: October 2024 by [redacted] and [redacted]
Identified Risk: The intentional deletion and/or alteration of data.
Expected outcome: Full audit trail reviews and comprehensive re-analysis of completed casework will aim to look at cases from a different perspective. Re-analysis of casework can catch deletion and/or alteration of data that may have been done after review. These additional reviews will help to deter and identify these actions in the future.

Preventive Action: The addition of a suitability review for projectiles and cartridge cases determined to be of no value. In addition, mandating that photographs be taken of all firearms comparisons that result in an identification conclusion.
Anticipated completion date/responsible party: August 2024 by the [redacted] and [redacted]
Identified Risk: The potential for projectiles and cartridge cases that are of comparison quality to be deemed not suitable.
Expected outcome: More accurate suitability determinations for projectiles and cartridge cases. In addition, more objective documentation to support conclusions.

Preventive Action: The quality unit or supervisors will select cases for the case review portion of internal audits in the future. This was previously done by scientists.
Anticipated completion date/responsible party: October 2024 by [redacted] and [redacted]
Identified Risk: The potential for scientists to choose cases based upon those they feel have the least risk of error.
Expected outcome: Implementing a system where cases for review are selected by a quality unit rather than by individual scientists could indeed enhance transparency and mitigate the risk of bias, including the potential for cherry-picking cases. This transparency can increase trust in the review process and allow for better scrutiny by peers.

**CAR - Root Cause Analysis**
Identify the root cause of the problem
The non-conformances detailed above appear to be intentional acts of altering data, deleting data, not retaining all technical records, and not reporting conclusions accurately.
FS Woods was never interviewed or participated in a root cause analysis discussion with the quality management team due to her resignation from CBI on November 6, 2023. Based on the data obtained during the quality investigation, the root cause of these non-conformances appears to be a lack of integrity which resulted in the intentional acts described above. There is no evidence that Ms. Woods falsified DNA profiles. The observed theme of Woods' actions appears to be evading additional work or documentation. However, these additional steps are required by the quality system in order to maintain the integrity of CBI's work product. The corrective actions detailed in this report are designed to mitigate the risk and prevent a recurrence of similar intentional acts in the future.

**CAR - Additional Audits**
Additional Audits if necessary
CBI-FS intends to voluntarily submit to an on-site assessment in 2024.

**CAR - Monitor Corrective Action**
Describe the planned method or means for monitoring
Describe the planned method or means for monitoring

To ensure the effectiveness of the corrective actions outlined in this report, a comprehensive monitoring

plan will be implemented following the completion of the corrective actions. These monitoring activities may include:

Routine Re-analysis of Cases:

Currently routine re-analysis occurs in our toxicology and drug chemistry disciplines. This monitoring plan may include case re-analysis of all staff in the biological sciences unit as well as all other laboratory disciplines as well. Regular re-analysis may help to identify any recurring issues and ensure ongoing compliance with established procedures.

Blind Proficiency Testing:

A blind proficiency testing plan may be implemented in order to evaluate staff's continued competence and adherence to laboratory procedures accurately and consistently. Blind testing involves providing samples or scenarios without the staff's prior knowledge of their contents, allowing for unbiased assessment of competence and adherence to established procedures.

Periodic Detailed and Specific Case Reviews:

Detailed and specific case reviews will be conducted periodically to assess the quality of work and adherence to protocols in previously worked cases. These reviews will involve in-depth analysis of individual cases, focusing on the accuracy of results, documentation practices, and overall compliance with established standards. By examining specific cases, any deviations or deficiencies can be identified and addressed promptly.

*This document serves as an ongoing record of the investigation and corrective actions implemented. As progress is made, additional information will be appended to this CAR document.

**Assign** [redacted]

Assign next stage to [redacted]

**Attach Supporting Documentation**

[redacted]