Quality System Overview

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Director of Technical Services
July 19, 2023

What is a Quality System?

- Also referred to as a Quality Management System
- Encompasses quality, administrative and technical operations that govern the activities of the laboratory

- Includes Quality Assurance (QA) and Quality Control (QC)

Figure 1: Quality System, Quality Assurance, and Quality Control Relationships

asq.org/quality-resources/quality-assurance-vs-control

Quality Assurance v Quality Control

Quality Assurance (QA) – “a documented system of protocols to assure the accuracy and reliability of analytical results”

Quality Control (QC) – “documented laboratory operations that ensure that the data generated are of known accuracy to a stated quantitative degree of probability”

Simply stated, QA is a system.

QC is a component of the system.

Christian, Donnell R. and Stephanie Drilling. “Implementing Quality in Laboratory Policies and Processes : Using Templates, Project Management, and Six Sigma.” (2009)

Quality Management System

- Statement of Quality Policy
- Document Control
- Personnel and Training
- Service to the Customer
- Evidence Handling
- Records and Case Files
- Reagents, Equipment & Supplies
- Reporting
- Technical & Administrative Review
- Nonconforming Work & Corrective Actions
- Complaints
- Continuous Improvement - Risk Management
- Audits & Management Review
- Testimony Monitoring
- Facilities, Security & Safety
- Proficiency Testing

Statement of Quality Policy

"The Department of Forensic Science (the Department, DFS) is responsible for providing scientific analysis of evidential material and breath testing equipment, training and calibration services upon the request of its customers, the criminal justice agencies of the Commonwealth. The Department is dedicated to providing a defect-free product in a professional manner to those agencies. To this end, the Department is committed to good professional practice and to the quality of its testing and calibration in servicing its customers via:

- The performance of forensic analyses and examinations that are accurate, relevant, reliable, thorough, timely and meets the need of the customer,
- Interpretation of analytical results without bias and free of internal and external influence,
- The presentation of the results of analyses and examinations in reports and testimonies that are clear, objective, balanced and easily understood by its customers,
- The ongoing development of the skills and expertise of its personnel…"

Document Control

Centralized electronic repository for the Quality Manual and Technical Procedures Manuals

Printed copies are “uncontrolled”

Employee is responsible for verifying they are using the current version

Issued by the applicable Director or Manager

Responsible for content – current and generally accepted in the forensic science community

Changes are tracked

Reviewed by Technical Resource Team

Approval process includes Document Custodian and Reviewer

Annual Review for completeness and continued suitability

DFS Quality System Documents

- Quality Manual
- Section Technical Procedures Manuals
- Section Training Manuals
- Regional Operating Procedures (ROPs)
- Safety Manual
- Administrative Policies and Procedures
- Information Technology Policies
- Human Resource Policies and Procedures
- Forms and Worksheets

Personnel and Training

- Education Requirements – Bachelor's Degree at a minimum
  - Discipline specific
- Documented Training Programs
  - Completion length varies from 3 months to 2 years depending on discipline requirements and Knowledge, Skills and Abilities (KSAs)
- General Training
  - Topics include Laboratory Information Management System (LIMS), the criminal justice system in Virginia, general knowledge of forensic science, ethics, safety and chemical hygiene
- Competency Exam
  - Technical Final, Practical Test, Mock Trial
- Work Authorization
  - Specifies casework/calibration duties, which include evidence handling, performing testing/calibration, evaluation of results, issuing of Certificates, testimony, and performance of technical and administrative reviews

Code of Professional Responsibilities and Ethics

All DFS employees shall:

1. Demonstrate the highest standards of honesty, truthfulness, and integrity in all their work activities and professional relationships in order to inspire public confidence and trust in the Department.
2. Maintain the highest standards of professional practice and competence.
3. Commit to the highest ideals in the stewardship of public resources.
4. Commit to private and professional activity that demonstrates independence between their personal interests and the interests of the Department.
5. Comply with the laws of the Commonwealth and Department policies and procedures.
6. Treat all persons in a professional, respectful, and courteous manner.
7. Strive to provide performance of the highest quality.

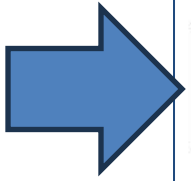
Additional criteria for scientific staff.

https://dfs.virginia.gov/wp-content/uploads/101-D004-Code-of-Professional-Responsibilities-and-Ethics-3155-4.pdf

Service to the Customer

- The Request for Laboratory Examination (RFLE) is used for evidence submission and represents the contract between the customer and DFS

- Initial review by the Forensic Evidence Specialist
  - Ensure RFLE is accurate and complete
  - Confirm appropriate exams are requested and proper items are submitted
- If clarification is needed, documented on the RFLE, a Memorandum for Record in the case file or within the LIMS
- Written Chain of Custody (CoC) between customer and DFS



Virginia Department of Forensic Science
Request for Laboratory Examination

Gray Areas are for DFS Use Only
Revised 12/1/2022

Investigating Officer(s): Investigator William E. Jones

Telephone #: (804) 555-2222
Email Address: joneswe@midcitypd.org
Agency and Address: Mid City Police Department
1000 E. Main Street
Mid City, VA 23007

Agency Case Number: 20220620-1234

FS Lab #: Sub #:

TRAINING FORM ONLY

Previous Submission? If yes, previous FS Lab #:

Names of Victims (Last, First, Middle): JOHNSON, Edward, W. (Friendly Loan Company) DOB: 2/6/1981 Race/Sex: N/A

Names of Suspects (Last, First, Middle): MEAN, Joe, B. DOB: 12/9/1980 Race/Sex: W/M

Date/Type of Offense: 6/30/22 Burglary

Court Date: October 3, 2022
☐District ☐ Circuit ☐ Juvenile ☐Federal

Brief Statement of Fact (continue on separate page if necessary):
One or more persons entered the Friendly Loan Co. at 1 N. Main Street. Entry was gained through a glass window in the rear alley. A lockbox had been pried open. A large amount of cash and checks were taken.

Jurisdiction of Offense: Mid City, VA

Specify manner of return of evidence: ☐ Mail ☒ Personal Pick-up

Container	Evidence Submitted: Itemize and Describe Evidence and Designate Requested Examinations
	Item 1. Swabs of red stain from carpet, air dried: Forensic Biology - analyze for DNA, compare to item 24. Item 2. One (1) cigarette butt: Forensic Biology - analyze for DNA, compare to item 24. Latents - analyze for latent prints, compare to item 20. Item 4. Lockbox: Latents - analyze for latent prints, compare to item 20. Firearms - examine for toolmarks, compare to item 26. Item 6. Two (2) blank checks: Latents - analyze for latent prints, compare to item 20. Item 15. Known glass samples from scene: Trace - use for comparison. Item 20. Known inked fingerprints and palm prints of Joe B. Mean: Latents - use for comparison. Item 21. Suspects clothing, one (1) brown shirt and one (1) pair gray pants. Trace - examine for glass, compare to item 15. Item 24. Known buccal swabs from Joe B. Mean, air dried: Forensic Biology - use for comparison. Item 26. Screwdriver: Firearms - use for comparison.

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This evidence is being submitted in connection with a criminal investigation and has not been examined by another laboratory. Tests performed utilize methods which are available on the Department website.

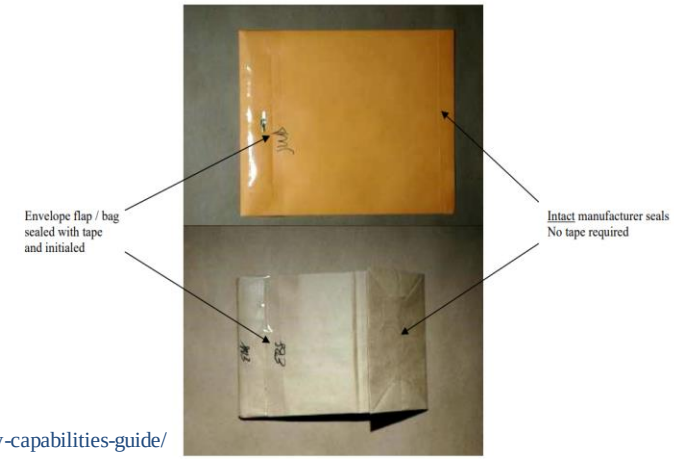
Submitting Officer (print): William E. Jones	**Relinquished by (print):**
Sign: *William E. Jones* **Date:** 7/01/22	**Sign:** **Date:**
Received by (print):	**Received by (print):**
Sign: **Date:**	**Sign:** **Date:**

Request for Laboratory Examination
Issued by: Deputy Director
Issue Date: 14-August-2008

DFS Document 100-F100
Revision Number 0
Page 1 of 1

Evidence Handling

- Evidence shall be sealed on receipt, while in long term storage, during transfer between laboratories and for return
  - Acceptable seal prevents escape of evidence and will be clearly damaged or altered if broken to permit entry
  - Personnel sealing evidence will place their initials on, across or under the seal
- Evidence must be stored in a manner to prevent loss, contamination, degradation, damage while maintaining the custody of the evidence
- Internal transfers of evidence – official CoC is the LIMS unless otherwise specified
- Evidence is either in personal or administrative custody
- Case is assigned to a qualified examiner and they will take custody of the evidence

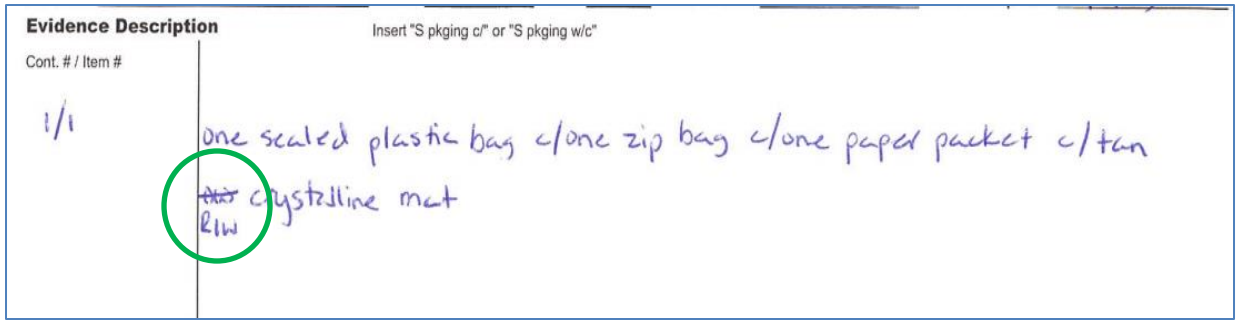


https://dfs.virginia.gov/documentation-publications/evidence-handling-and-laboratory-capabilities-guide/

Records and Case Files

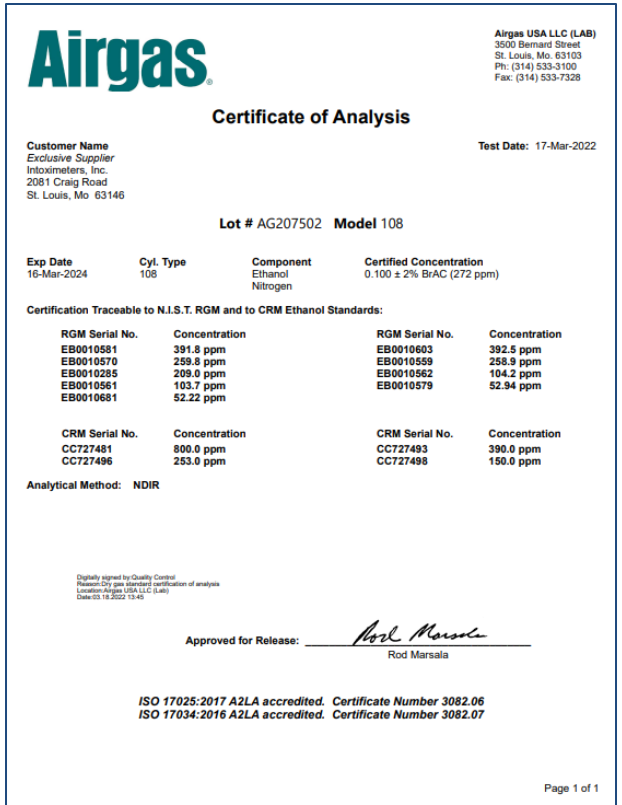
- Examination Documentation includes
  - tests conducted
  - standards and controls used
  - diagrams
  - printouts
  - photographs
  - spectra
  - chromatograms
  - observations
  - handwritten notes
  - other material used by the examiner to reach a conclusion
- Examination documentation must contain sufficient detail to allow another examiner, in the absence of the initial examiner, to evaluate the data and interpret the data that was the basis for the conclusion.

- Notes shall be
  - made contemporaneously
  - of a permanent nature (e.g., ink)
- When handwritten corrections are necessary, the text shall be crossed out, not erased, made illegible or obliterated
- Changes, alterations and additional notations, including interlineations shall be initialed by the person making the change
- Some disciplines utilize electronic notes



Reagents, Equipment & Supplies

- Reference Materials and Calibrated Equipment must meet specified requirements



Airgas

Airgas USA LLC (LAB)
3500 Bernard Street
St. Louis, Mo. 63103
Ph: (314) 533-3100
Fax: (314) 533-7328

Certificate of Analysis

Customer Name
Exclusive Supplier
Intoximeters, Inc.
2081 Craig Road
St. Louis, Mo 63146

Test Date: 17-Mar-2022

Lot # AG207502 **Model** 108

Exp Date	Cyl. Type	Component	Certified Concentration
16-Mar-2024	108	Ethanol Nitrogen	0.100 ± 2% BrAC (272 ppm)

Certification Traceable to N.I.S.T. RGM and to CRM Ethanol Standards:

RGM Serial No.	Concentration	RGM Serial No.	Concentration
EB0010581	391.8 ppm	EB0010603	392.5 ppm
EB0010570	259.8 ppm	EB0010559	258.9 ppm
EB0010285	209.0 ppm	EB0010562	104.2 ppm
EB0010561	103.7 ppm	EB0010579	52.94 ppm
EB0010681	52.22 ppm		

CRM Serial No.	Concentration	CRM Serial No.	Concentration
CC727481	800.0 ppm	CC727493	390.0 ppm
CC727496	253.0 ppm	CC727498	150.0 ppm

Analytical Method: NDIR

Digitally signed by:Quality Control
Reason:Dry gas standard certification of analysis
Location:Airgas USA LLC (LAB)
Date:03.18.2022 13:45

Approved for Release: Rod Marsala

ISO 17025:2017 A2LA accredited. Certificate Number 3082.06
ISO 17034:2016 A2LA accredited. Certificate Number 3082.07

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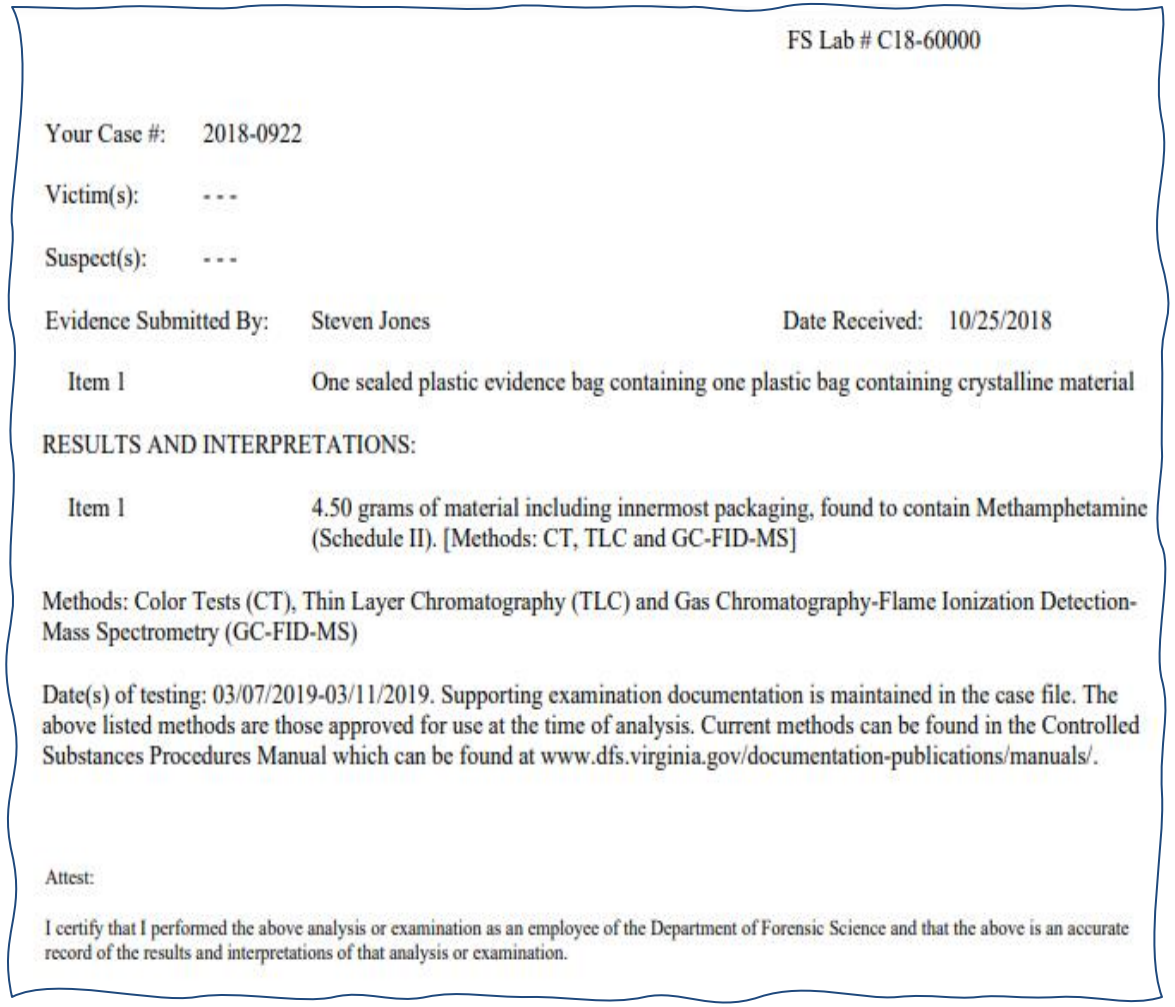
- Standards
- Calibrators
- Controls
- Balances
- Pipettes
- Rulers
- Thermometers
- Barometers

Reporting – Certificate of Analysis



FS Lab # C18-60000

Your Case #: 2018-0922

Victim(s): - - -

Suspect(s): - - -

Evidence Submitted By: Steven Jones Date Received: 10/25/2018

Item 1 One sealed plastic evidence bag containing one plastic bag containing crystalline material

RESULTS AND INTERPRETATIONS:

Item 1 4.50 grams of material including innermost packaging, found to contain Methamphetamine (Schedule II). [Methods: CT, TLC and GC-FID-MS]

Methods: Color Tests (CT), Thin Layer Chromatography (TLC) and Gas Chromatography-Flame Ionization Detection-Mass Spectrometry (GC-FID-MS)

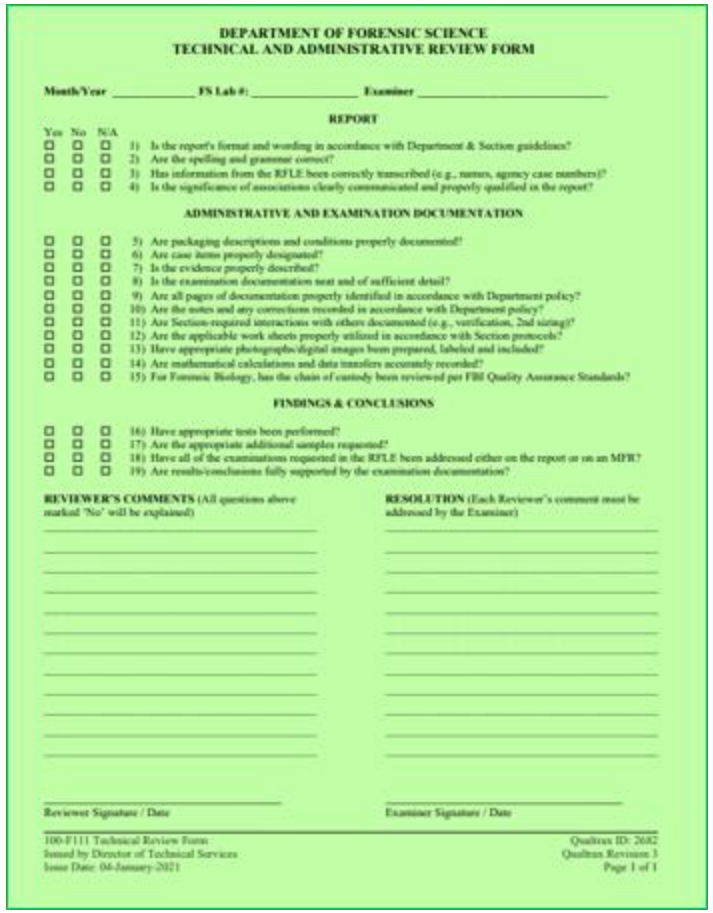
Date(s) of testing: 03/07/2019-03/11/2019. Supporting examination documentation is maintained in the case file. The above listed methods are those approved for use at the time of analysis. Current methods can be found in the Controlled Substances Procedures Manual which can be found at www.dfs.virginia.gov/documentation-publications/manuals/.

Attest:

I certify that I performed the above analysis or examination as an employee of the Department of Forensic Science and that the above is an accurate record of the results and interpretations of that analysis or examination.

- Methods
  - Published on website
  - Method Validations
    - Scientific Advisory Committee
- Technical & Administrative Review – 100%
  - Ensure the proper use of appropriate technical procedures (test methods) and applicable Department policies and procedures
  - Ensure the accuracy of reports to include spelling and grammatical correctness
  - Ensure the data supports the results and/or conclusion in the reports
  - Ensure that associations are properly qualified in the report
  - Ensure the report contains the required information
  - Ensure that the administrative and examination documentation is properly and uniquely identified
  - Check manual calculations and data transfers

Nonconforming Work & Corrective Actions



DEPARTMENT OF FORENSIC SCIENCE
TECHNICAL AND ADMINISTRATIVE REVIEW FORM

Month/Year _____ FS Lab #: _____ Examiner _____

REPORT

Yes	No	N/A	
☐	☐	☐	1) Is the report's format and wording in accordance with Department & Section guidelines?
☐	☐	☐	2) Are the spelling and grammar correct?
☐	☐	☐	3) Has information from the RFLE been correctly transcribed (e.g., names, agency case numbers)?
☐	☐	☐	4) Is the significance of associations clearly communicated and properly qualified in the report?

ADMINISTRATIVE AND EXAMINATION DOCUMENTATION

☐	☐	☐	5) Are packaging descriptions and conditions properly documented?
☐	☐	☐	6) Are case items properly designated?
☐	☐	☐	7) Is the evidence properly described?
☐	☐	☐	8) Is the examination documentation neat and of sufficient detail?
☐	☐	☐	9) Are all pages of documentation properly identified in accordance with Department policy?
☐	☐	☐	10) Are the notes and any corrections recorded in accordance with Department policy?
☐	☐	☐	11) Are Section-required interactions with others documented (e.g., verification, 2nd sizing)?
☐	☐	☐	12) Are the applicable work sheets properly utilized in accordance with Section protocols?
☐	☐	☐	13) Have appropriate photographs/digital images been prepared, labeled and included?
☐	☐	☐	14) Are mathematical calculations and data transfers accurately recorded?
☐	☐	☐	15) For Forensic Biology, has the chain of custody been reviewed per FBI Quality Assurance Standards?

FINDINGS & CONCLUSIONS

☐	☐	☐	16) Have appropriate tests been performed?
☐	☐	☐	17) Are the appropriate additional samples requested?
☐	☐	☐	18) Have all of the examinations requested in the RFLE been addressed either on the report or on an MFR?
☐	☐	☐	19) Are results/conclusions fully supported by the examination documentation?

REVIEWER'S COMMENTS (All questions above marked 'No' will be explained)

RESOLUTION (Each Reviewer's comment must be addressed by the Examiner)

_____ Reviewer Signature / Date

_____ Examiner Signature / Date

100-F111 Technical Review Form
Issued by Director of Technical Services
Issue Date: 04-January-2021

Qualtrax ID: 2682
Qualtrax Revision 3
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- Level I or Level II
- Corrective Action – Team and Report
  - The nonconformity
  - Event(s) which identified the nonconformity
  - Extent of the nonconformity
  - Effect(s) of the nonconformity on the quality of work and/or integrity of evidence
  - Response
  - Root cause of the nonconformity
  - Course of action
  - Follow-up activities, if applicable

Complaints

- Any staff member receiving a complaint should resolve the complaint at the time of receipt or as soon as practicable if within their authority and notify the appropriate individuals.
- An effort will be made to get all pertinent details from the complainant that could assist in the investigation of the complaint.

- Nature of the complaint
  - Case examination nonconformity
    - Corrective Action
  - Ethical violation, professional negligence, or professional misconduct
    - Director will review and make a determination; may assign an internal team to investigate, refer to SAC, FSB, OSIG, VSP or take other appropriate action
    - Notifications made as appropriate
  - Quality-related aspects
    - Employees encouraged to bring to the attention of appropriate individual as soon as practicable

Continuous Improvement - Risk Management

- Identifying Risks - The Department may identify risks through multiple quality assurance processes including, but not limited to: method validations, preventive action requests (i.e., Laboratory System Improvement submissions), corrective actions, internal audits and management review

- Assessing Risks - Risk assessment may be accomplished by analyzing historical data or by calculating the Risk Priority Number

- Mitigating Risks - Appropriate action(s) to address the risk may include Preventive Action, Corrective Action, halting of work, or no action due to an acceptable level of risk

Additional Monitoring (but not limited to…)

- Testimony Monitoring
  - At least once per calendar year
  - Direct Observation
  - Transcript Review
  - Input from Officers of the Court
- Facilities, Security & Safety
  - Adequate, appropriate, safe and secure facilities for its employees, equipment, supplies and evidence
- Proficiency Testing
  - Objective assessments of the staff's ability to perform examinations in a scientifically defensible and legally admissible manner and to follow Department and Section policies and procedures
  - At least one proficiency test per calendar year in each discipline

References

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- Accreditation Requirements for Forensic Testing and Calibration (2023) - ANAB anab.qualtraxcloud.com/ShowDocument.aspx?ID=12371
- asq.org/quality-resources/quality-assurance-vs-control
- https://blog.ansi.org/anab/reference-material-rm-vs-certified-crm/#gref

QUESTIONS?