



DISTRICT OF COLUMBIA

**DFS**

**DEPARTMENT OF  
FORENSIC SCIENCES**

Forensic Science Laboratory | Public Health Laboratory | Crime Scene Sciences

*Seeing the Error of Our Ways: Perspectives  
from Department of Forensic Science,  
Washington DC*

Jenifer Smith, PhD  
Director

International Symposium on Forensic Science Error Management  
July 25, 2017

# “A ROAD LESS TRAVELED”

BS in Biochemistry - Penn State

Internship at the NY OCME-  
1980

PhD in Physiological Chem -  
Ohio State (**The dark years**)

Post Doc-Harvard Med School  
Special Agent of FBI

1986-1990 Baltimore Field office

1990-2002 DNA Unit/ FBI Lab

2002-2006 Chief of CIA's Bio Tech Center

2006- 2009 Chief of FBI's WMD  
Intelligence & Analysis Section

2009-Retired

[Penn State Faculty](#) 2010-2015







# WASHINGTON DC

- Federal Territory (68.34 sq. mi.)
- Governed by
  - Mayor Muriel Bowser
  - City Council- 13 members
- Home to 670,000 people
- DC Budget = \$7.147 billion
- Crime Stats:

Offense	2016	2017	Percent Change
Homicide	70	62	-11%
Sex Abuse	180	176	-2%
Assault w/ a Dangerous Weapon	1,375	1,070	-22%
Robbery	1,715	1,180	-31%
Violent Crime-Total	3,340	2,488	-26%
Burglary	1,186	861	-27%
Motor Vehicle Theft	1,445	1,344	-7%
Theft from Auto	6,453	5,876	-9%
Theft (Other)	7,757	8,054	4%
Arson	4	2	-50%
Property Crime-Total	16,845	16,137	-4%
All Crime-Total	20,185	18,625	-8%



- Forensic analysis previously done by
- FBI Laboratory
  - MPD Laboratory

DEA continues to conduct analysis of controlled substances

# § 5–1501.02. Department of Forensic Sciences Act of 2011

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**(a)** There is established as a subordinate agency in the executive branch of the government of the District of Columbia, the Department of Forensic Sciences.

**(b)** The mission of the Department shall be to provide high-quality, timely, accurate, and reliable forensic science services with:

- (1)** The use of best practices and best available technology;
- (2)** A focus on unbiased science and transparency; and
- (3)** The goal of enhancing public safety.



# § 5–1501.06 - POWERS & DUTIES

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- (a)** Lists all of forensic services the Dept. shall provide
- (b)** The Dept. shall provide forensic services upon request to:
- (1)** District agencies including:
    - A. MPD
    - B. Office of Chief Medical Examiner (OCME)
    - C. Office of the Attorney General (OAG)
    - D. Dept. of Health (DOH)
    - E. Fire and Emergency Medical Services (FEMS)
  - (2)** The United States Attorney's Office for DC
- (c)** The Department also may provide forensic science services to other law enforcement or investigative agencies.

# § 5–1501.11 SCIENCE ADVISORY BOARD

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There is established a Science Advisory Board, which shall consist of 9 voting members to be appointed pursuant to § 1-523.01(f), as follows:

- (1) Five scientists with experience in scientific research and methodology, who have published in peer-reviewed scientific journals, and who are not currently employed by the Department or by a law enforcement laboratory or agency, including:
  - (A) One statistician; and
  - (B) One with expertise in quality assurance; and
- (2) Four forensic scientists not currently employed by the Department or by a law enforcement laboratory or agency that provides forensic science services to the District.



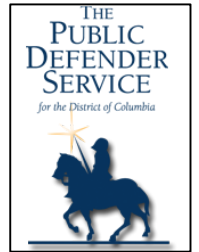
# § 5-1501.13 - STAKEHOLDER COUNCIL



There is established a Stakeholder Council, which shall consist of the following members:

- (1) The Deputy Mayor for Public Safety and Justice;
- (2) The Chief of MPD;
- (3) The Chief Medical Examiner;
- (4) The Attorney General;
- (5) The United States Attorney for the District of Columbia;
- (6) The Director of the Public Defender Service for the District of Columbia;
- (7) The Federal Public Defender for the District of Columbia;
- (8) The Director of the Department of Health;
- (9) The Chief of the Fire and Emergency Medical Services Department;
- (10) The Director of the Department; and
- (11) The head of any other government agency that regularly utilizes the forensic science services of the Department.

(b) The chairperson of the Judiciary Committee of the Council of the District of Columbia shall be an ex officio, non-voting member of the Stakeholder Council.



# FORENSIC SCIENCE AT DFS....

*“Application of scientific principals and technological practices to the purposes of assisting decision makers in matters of **criminal justice, national security and public health.**”*



# CONSOLIDATED FORENSIC LAB

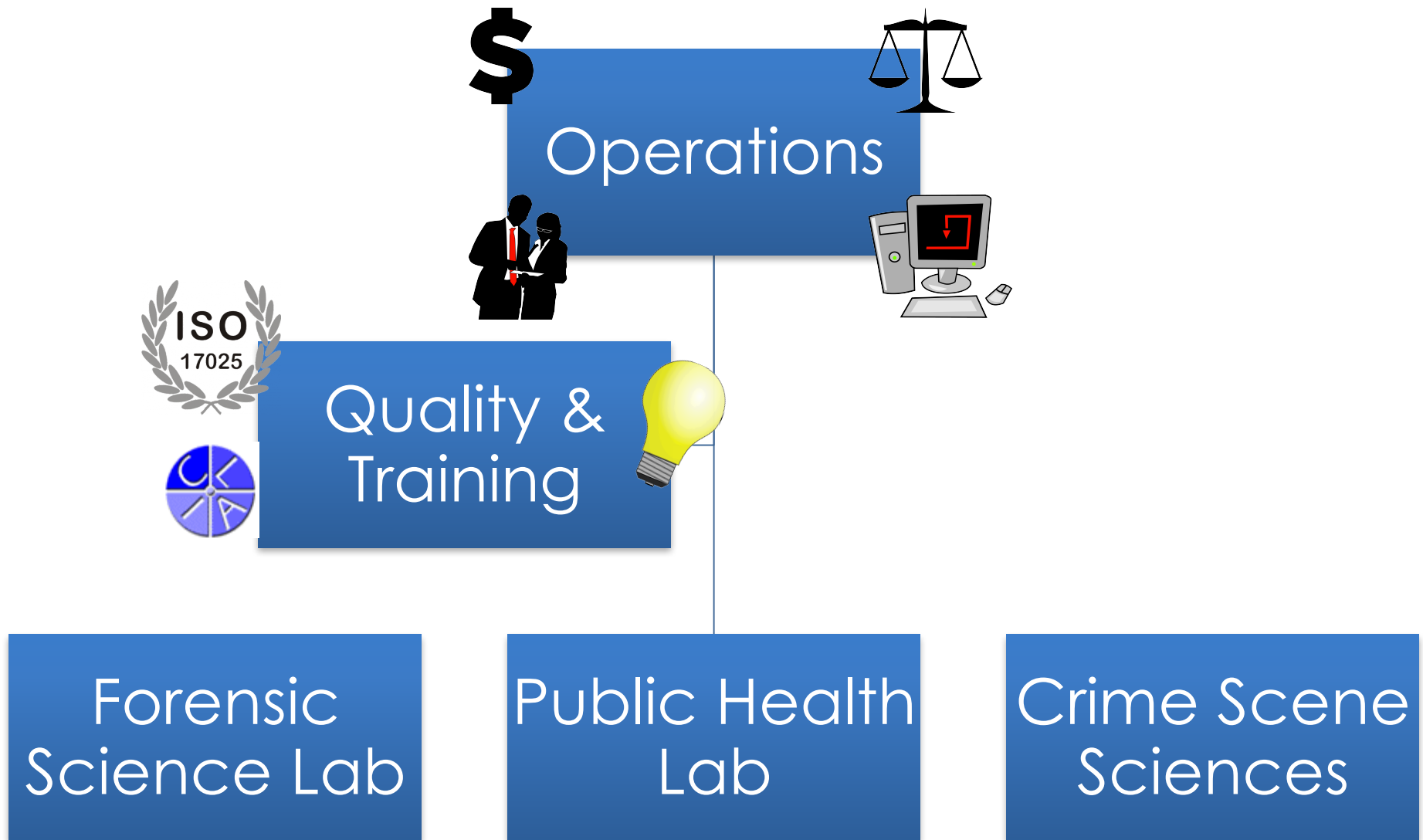
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## Medical Examiner's Office Department of Forensic Sciences (10/1/12)

- \$230 million building
- \$6 million of equipment
- 351,000 sq. ft.
- LEEDS Platinum
- DFS FY15 Budget
  - \$15,162,599
  - 136 FTEs
- DFS FY18 Budget
  - \$28,100,670 (↑ 13 million)
  - 219 FTEs (↑ 83 FTEs )



# DFS DIVISIONS







# QUALITY IS JOB ONE



DC Code 5-1501.07(d)(1) states:

*“The Department shall be accredited by an appropriate, bona fide national accrediting organization.”*

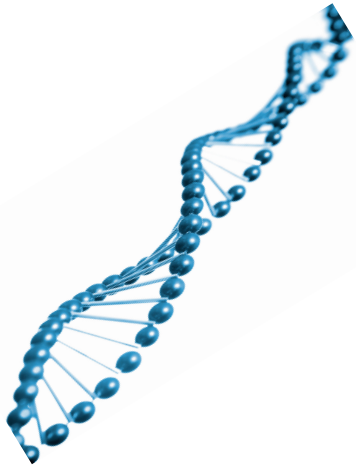


**C**linical  
**L**aboratory  
**I**mprovement  
**A**mendments



# FORENSIC SCIENCE LABORATORY

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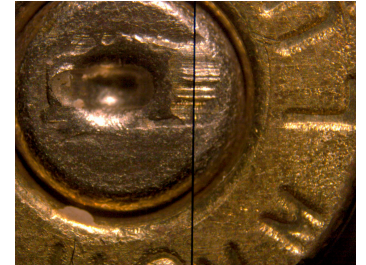


Forensic Biology Unit

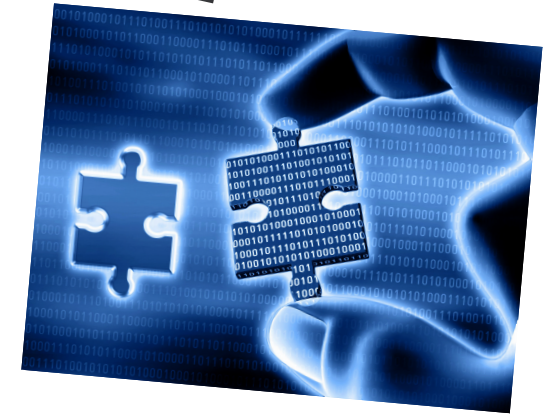


Latent Fingerprint Unit

Forensic Intelligence Unit



Firearms Examination Unit



Digital Evidence Unit



# CRIME SCENE SCIENCES

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DISTRICT OF COLUMBIA  
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DEPARTMENT OF  
FORENSIC SCIENCES

Central Evidence



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WE ARE  
WASHINGTON  
DC  
GOVERNMENT OF THE  
DISTRICT OF COLUMBIA  
MURIEL BOWSER, MAYOR

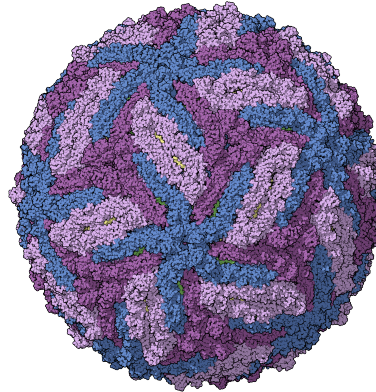


# PUBLIC HEALTH LABORATORY

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Microbiology Unit



Immunology & Virology Unit



Tier 1 BT Lab and Tier 2 CT Lab



Biomonitoring & Analytical Chemistry Unit



Accessioning Unit



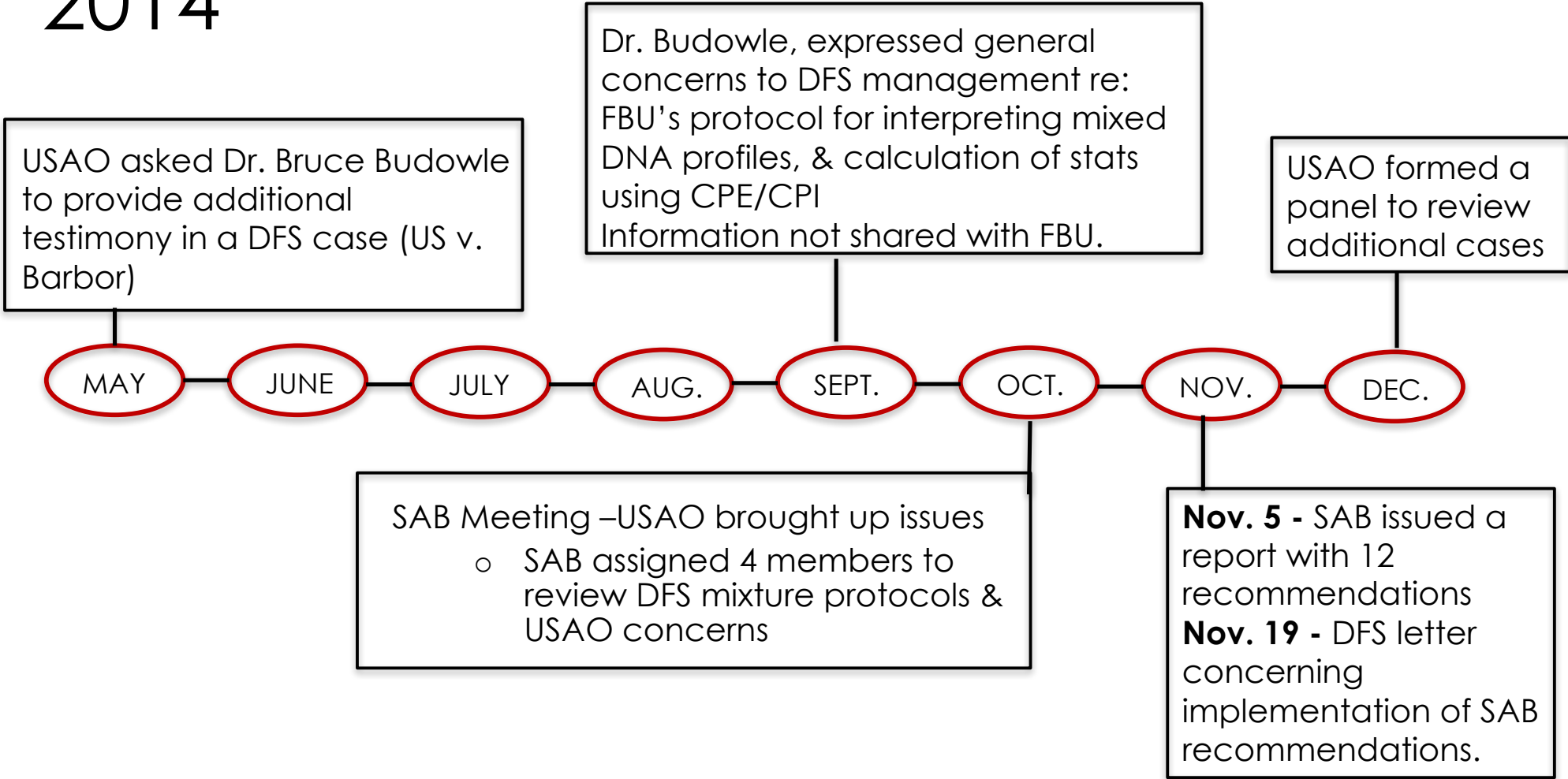
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# THREE YEARS AGO.....

2014



# Nov. 5, 2014 - SAB REPORT

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“The two standard operating procedures reviewed were found to be well written *but generic and quite limited in scope*. While they may provide minimal adequate guidance for the interpretation of high quality single-source or two-person mixed DNA profiles with no allele drop-out, *there is a lack of specificity and detail in several important areas relevant to current issues in the interpretation of low template DNA and DNA mixtures.*”

# SAB - 12 RECOMMENDATIONS

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1. State the AT & ST to be used and under which conditions
2. Address detection, analysis & interpretation of DNA profiles resulting from the amplification of single-source low template DNA, including criteria for the inclusion & exclusion of known individuals, & the appropriate method(s) for statistical frequency calculations.
3. Information for assessing the possible number of contributors in a mixed DNA profile & how to use that information in the interpretation of the profile & the generation of statistical frequencies.
4. Detailed explanation of how to interpret two-person mixtures, including criteria for determining a major/minor two-person mixture & how to resolve a mixture assuming the presence of one known contributor.
5. Detailed explanation of how to interpret mixtures of 3 or more contributors, whether a major contributor can be assessed from a complex mixture, & if so, when. Specific treatment of profiles with suspected low template DNA and the possibility of stochastic events affecting the profile should be clearly detailed.
6. Inclusion & exclusion criteria for two, three and more contributor DNA mixtures.
7. Criteria for making a statement of “inconclusive.”

# SAB - 12 RECOMMENDATIONS

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8. Statement of the software package(s) used with appropriate references for the software & associated validation studies.
9. Detailed explanation of how to calculate statistical frequencies incorporating the issues associated with low template DNA, stochastic effects and/or complex mixtures.
10. How & when to use the calculation of  $2p$  vs.  $p$ .
11. How to use the assumed number of contributors to assess the feasibility that all alleles from all contributors are present in the profile & when it is appropriate (and inappropriate) to use CPI/CPE
12. How to use the ST, stutter peak ratios, peak height ratios & mixture ratios in DNA mixtures & to incorporate possible stochastic effects, shared alleles, possible alleles in the stutter position that may be typical stutter vs. elevated stutter vs. stutter plus an allele from a minor contributor into the interpretation of the results and the calculation of statistical frequencies.



# Nov. 19, 2014 DFS RESPONSE

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*All of the recommendations from the SAB will be incorporated into DFS protocols that are estimated to be in place **by end of January 2015**. Any cases going to trial between the date of this report and the end of January that involve mixtures that require calculations of significance of inclusion will either require a request for continuance until the protocols are in place, and the calculations can be conducted under the new protocol, or, if no continuance can be obtained, reports will be issued under the current protocol."*



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# A NEW YEAR- A NEW MAYOR

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## 2015

USAO requested of the Mayor that their experts be allowed to meet with members of FBU at DFS

USAO also indicated that that they would not utilize DFS for DNA testing

JAN.

FEB.

MARCH

APRIL

MAY

JUNE

JULY

AUG.

DFS became aware of 6 cases disclosed to the Public Defender Service by USAO Report (12/30/14).

DFS issued a report on Jan. 29<sup>th</sup> after reviewing USAO report



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# USAO DISCLOSURE REPORT

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The disclosure report contained information & a summary statement outlining issues identified from the review of six cases selected by the USAO re: CPI

The expert panel from the USAO outlined five “thematic issues of concern”

1. the limitation of CPI calculations,
2. the application of CPI calculations,
3. the appropriateness of DNA mixture deconvolution,
4. the definition of “intimate samples”, and
5. the use of a stochastic threshold when interpreting DNA mixtures.

# Jan. 29, 2015 - DFS RESPONSE

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All of the reported issues fall under the general category concerning the DNA mixture interpretation guidelines within the Unit. On Jan. 27, 2015, the reported issues and related cases were **reviewed in depth by DFS personnel**. *The general finding of the review were ultimately seen as a difference of opinion between experts in regards to all five of the noted issues. The arguments and criticisms raised in the USAO report were not found to be persuasive. In all cases, it was seen that the Unit personnel issuing the reports adhered to the Unit's DNA mixture interpretation guidelines that were in place at the time the work was performed on the cases.*

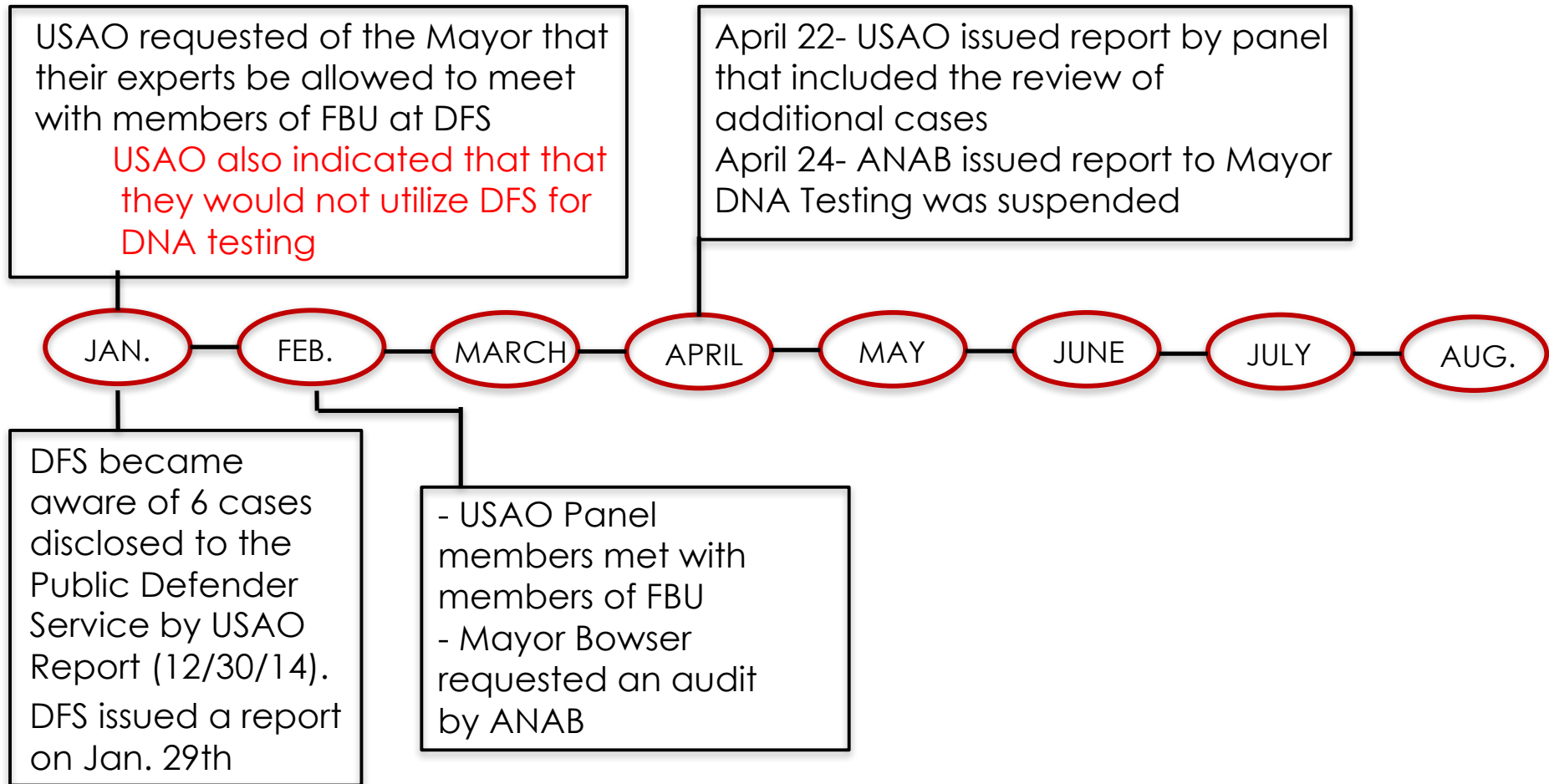


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# A NEW YEAR- A NEW MAYOR

## 2015





# ANAB Report

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- Issued 8 Major & 1 Minor Non Conformities

*“The laboratory’s DNA section **is not in compliance with the FBI QAS or the ISO/IEC 17025 standard**. The non-compliance is in two general areas: **technical and quality management system**. For the technical area, staff were not competent (lack of completed training) and were using inadequate procedures (not fully validated and/or inadequately written). For the quality management system, there was a failure to address these issues before any casework was performed and a failure of not stopping casework when a complaint was received and/or when management including the DNA technical leader became aware of these issues.”*

# NEXT STEPS

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- Mayor Muriel Bowser suspended FBU DNA testing
- Accreditation remained for other DFS Units
- Management changes to include departure of:
  - DFS Director
  - DFS Deputy Director
  - DFS General Council
  - FBU Technical Leader
- Appointment of Dr. Roger Mitchell ( DC Chief Medical Examiner) as Interim Director of DFS
  - Two consultants hired- Jenifer Smith and Kate Theisen



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# ROOT CAUSE ANALYSIS (RCA)

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- Arrived at DFS on May 7, 2015
  - Focused on issues raised concerning FBU
- Reviewed -
  - USAO Report (4/22/15)
  - ANAB Audit Document (4/24/15)
  - DFS reports/letters (11/14 & 1/15)
  - DFS SAB report (Appendix A: 11/14)
  - Internal FBU SOPs, training materials
- Interviewed
  - DFS Training Coordinator
  - DFS Quality Coordinator
  - FSL Quality specialist
  - FBU personnel

# RCA – DNA ISSUES

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- ANAB Report Review
  - All non conformities had merit with one exception
    - Technical leader was aware of USAO concerns
  - Twelve recommendations concerning mixture interpretation issues.
- USAO Report Review
  - Inappropriate use of CPI in mixtures by
    - inclusion of loci where allele drop out was highly probable
    - including individuals whose known alleles were not present, at those loci, in the evidence samples
  - Inappropriate calculation of two separate CPIs for the same forensic DNA mixture profile
  - Not using established stochastic thresholds to assess potential allele drop out
  - Inconsistencies and deficiencies in the technical review process of the DNA analysis pipeline

# RCA – DNA ISSUES

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- FBU analysts (13) were interviewed/surveyed
  - 8 have > nine years FS DNA experience
  - 5 with > five years FS DNA experience
  - 7 have a MSc degree
  - Experience at both private and public forensic DNA typing labs
- Suggestions from survey:
  - Unit manager was overwhelmed and not able to perform both Tech Leader and Manager responsibilities
  - Improve communication – **they had no knowledge of allegations until Feb visit by panel**
  - Implement LIMS
  - “Process/pipeline changes”



# INTERNAL REVIEW RESPONSE PLAN (DNA)

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- Empower FBU analysts
  - Four committees were formed within FBU to ensure involvement of FBU analysts in formulation of FBU procedures, practices & policies
    - SOP/QA
    - LIMS
    - Validation
    - Process ( Work Flow/Pipelines)
- Retrain FBU analysts
  - Competency Determination
- Implement STRmix
  - Validation
  - Create new SOPs
- Fix the DNA “Infrastructure”
  - Create Unit Manager position
  - Create Technical Leader position
    - Secure funding for FBU Technical Leader Continuing Education
  - Implement “DNA-LIMS”

# DNA MITIGATION RE-TRAINING

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- DNA Re-Training Plan (6 months)
  - Addressed quality issues
    - Knowledge and application of Corrective Actions, Preventative Actions, root cause analysis
    - Establish a Quality Culture
    - Strengthen Technical Review process
  - Provided a CODIS refresher
  - Mixture Deconvolution & Interpretation
  - STRmix Training
  - Testimony Training

# DNA MITIGATION RE-TRAIN ANALYSTS

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- Internal Review Response Training Plan
  - Address quality issues
    - Knowledge and application of Corrective Actions, Preventative Actions, root cause analysis
    - Establish a Quality Culture
    - Strengthen Technical Review process
  - CODIS refresher
  - Serology Refresher and Recertification
  - Mixture Deconvolution & Interpretation
  - Validation
  - SOP Development and Implementation



# RE-TRAINING MIXTURE INTERPRETATION



- Dr John Buckleton & Simon Gittleson (NIST)
  - Math refresher
  - Review of the CPI issue raised in the USAO's report concerning FBU's mixture interpretation practices and procedures.
  - Discussion of the "spectrum" of mixture interpretation systems to include CPI, RMP, LR Binary, Continuous models
  - Modeling PCR Behaviors
  - General Review of Relevant SWGDAM Mixture Interpretation Guidelines
  - Population Genetics and Relatedness
  - Likelihood Ratios (LR)
  - Proposition setting/verbalizing the LR, court questioning
  - Mixture Deconvolution/Number of and Assigning Contributors
  - Deconvolution of Mixtures and Low Level Template DNA

# RE-TRAINING WORKSHOPS

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- NIJ/USACIL Mixture Interpretation Training
  - 3 day workshop to discuss various mixture approaches and STRmix
- Review of cases outlined in USAO's disclosure document
  - Bruce Budowle – UTEP
  - Fred Bieber- Harvard
- STRmix Training – Niche Vision
  - 3 day immersion with STRmix
- DNA LIMS Familiarization Training
  - 5 day training with provider.



# RE-TRAINING OUTSIDE EXPERTS

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- Implementation/Validation of STRmix
  - USACIL
  - John Simich of Erie County
- CODIS Update
  - Doug Hares- FBI
- Quality Issues/ Quality Culture-
  - Kate Theisen- Quality Culture Training
  - Sorenson – Root Cause Analysis Training

# RE-TRAINING COMPETENCY

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- Written exercises/quizzes throughout modules
- Mock Question practice throughout modules
- Case Examples from other labs
- Competency testing
  - Written Exam
  - Oral boards - Dr. Gittleson, Dr. Coble, Dr. Buckleton
  - Moot Courts - Dr. Budowle & Dr. Bieber and Stakeholders
  - Qualifying Test

# DNA MITIGATION STRmix IMPLEMENTATION

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- Validation Studies
  - Part I: Parameters (approx. 321 samples)
    - Analytical Threshold
    - Stutter
    - Drop-In
    - Saturation
    - Model Maker
  - Part II: Internal Validation ( approx. 470 samples)
    - Sections (A-M) 4.1.1 – 4.1.14 of SWGDAM Guidelines
- DFS contracted with Niche Vision to utilize Dr. Jo Bright to help with the analysis of data. Without this help our validation would have taken at least 6-8 months.

# DNA MITIGATION FBU INFRASTRUCTURE

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- DNA Technical Leader – Susan Welti
  - MFS in Forensic Molecular Biology from the George Washington University
  - 15 years of experience in forensic DNA typing (OCME-NY and AFDIL)
  - FBI qualified DNA auditor
- Unit Manager – Andrea Borchardt
  - MS in Molecular and Cellular Biology from the Johns Hopkins University
  - 10 years experience in forensic DNA typing (Bode), 8 years experience in forensic DNA management (Bode), 2 years experience as adjunct instructor (VCU)
  - FBI qualified DNA auditor

# DNA MITIGATION PROCESS IMPROVEMENT

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- Implemented DNA specific case processing/tracking system (STACs DNA LIMS)
- Redesigned lab processing to improve efficiencies to increase productivity and reduce turnaround times
- New Tech. Lead reviewed all protocols and created three new protocols.



# DNA MEDIATION REVIEW PANEL



## Presentations by:

- Validation Committee
  - Review of internal validation studies
- Protocol Committee
  - Introduction of New SOPs
- Process Committee
  - Consolidated processes
- LIMS Committee
  - STACsDNA

## Esteemed Review Panel members:

- Dr. John Buckleton
- Dr. Bruce Budowle
- Dr. Michael Coble (SAB Member)
- Dr. Simon Gittleson
- Dr. John Simich
- Dr. Sandy Zabell (SAB Member)



# DNA MEDIATION

## CODIS Assistance to DFS

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- DFS stopped entry of CODIS cases at the end of April.
- Cases were sent to Contract Labs for DNA testing to continue
- Cases that had suitable profiles were uploaded into CODIS on behalf of DFS
- Two Labs provided critical assistance to DFS during this time of crisis
  - LA County, CA- Steve Renteria, CODIS Admin./TL
  - Erie Co. NY- Kristen Betker , CODIS Admin

# DNA TESTING REINITIATED

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- **FBU on-line- February 18, 2016**
  - 7<sup>th</sup> laboratory in the country to implement STRmix
  - Successful QAS Audits by ANAB
  - Recently implemented GlobalFiler and revalidated STRmix for use with Globalfiler
  - NO DNA Backlog of PERKS
  - Meeting TAT required by SAVRAA Law

# QUALITY SYSTEM ISSUES

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- FBU “canary in the mine shaft”; issues at DFS were systemic
- Director of Quality was not involved in making decisions
  - Quality decisions were handled by embedded QA Specialist within FBU
- Quality System was not “triggered”
  - No customer “complaint” was ever documented & no QCARs/QPARs
- Director of Training was not involved in FBU training.
  - Training inadequate for to cover new validation studies and protocol changes
  - Feb. training on new mixture approach was conducted but no competency testing
- Internal Communication weak
  - FBU analysts were unaware of the original concerns and had not been shown the cases
  - Decisions concerning the use/applications of the protocols was made by General Counsel, Deputy Director and FBU Technical Lead
- External Customer Communication weak
  - Concern about “Independence” created Detachment
  - DFS had a “No Communication” policy
- Operational infrastructure was weak
  - FBU Technical Leader overwhelmed- Need to split job
  - No LIMS infrastructure in DFS
    - Cases & performance metrics tracked by Excel Spreadsheets

# QUALITY SYSTEM MITIGATION

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- Back to ISO 17025 “basics”
  - Elevated Quality and Training Decisions to Director Level
  - Implemented Complaint/Inquiry Procedure
  - Implemented Communication policies and practices that ensured DFS remained independent but **not detached** from External customers and internal employees





# QA MANAGEMENT

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4.1.5 The Lab shall...

i) appoint a member of staff as management manager (however named) who, irrespective of other duties and responsibilities, shall have **defined responsibility and authority** for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;



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Exec. Assistant  
Herb Thomas

**Interim Director\***  
Roger Mitchell, Jr., MD

PIO  
(vacant)

**Interim General Counsel\***  
Robert Hildum, Esq.

**Deputy Director\***  
(vacant)

**Chief of Operations\***  
Yi-Ru Chen

Discovery

**Deputy Director Quality\***  
Karen Wiggins

**Deputy Director IT\***  
Michael Dyke

Operations

**Deputy Director Training\***  
Brittany Graham

**Director, Forensic Science Laboratory\***  
Paul Reedy (Interim)

**Director, Public Health Laboratory\***, Alpha Diallo, PhD  
**Director, Special Operations**, Jason Kolowski, PhD  
(Interim)

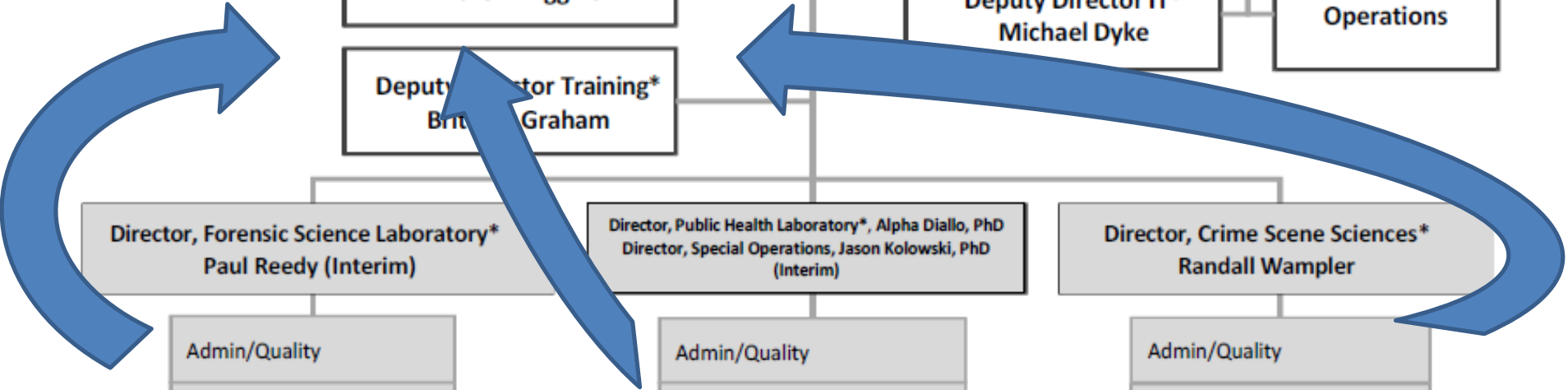
**Director, Crime Scene Sciences\***  
Randall Wampler

- Admin/Quality
- Forensic Biology Unit
- Fingerprint Unit
- Firearms Unit
- Digital Evidence Unit
- Materials Analysis Unit

- Admin/Quality
- Accessioning Unit
- Bioterrorism Unit
- Chemistry Unit
- Microbiology Unit
- Immunology & Virology Unit

- Admin/Quality
- Crime Scene Units
- Central Evidence Unit

\*Key managerial personnel





# COMMUNICATION

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## 4.1 MANAGEMENT

4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

## 4.2 QUALITY SYSTEM

4.2.4 Top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.





# CUSTOMER SERVICE

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## 4.7 SERVICE TO CUSTOMER

- 4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.

## 4.8 COMPLAINTS

- The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

# MEDIATION

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DFS had a “no communication” policy

- Stakeholders had difficulty finding out their case status.
- Created detachment from the Stakeholders
- Policy was discontinued
- Regular meetings with Customers (MPD, OAG, USAO).
  - Request expedited testing from FSL Units
  - Discuss general questions about evidence collection and processing with CSS
  - Forum to ask questions and for clarification about DFS policies and procedures



# CORRECTIVE ACTION

## 4.11 Corrective Action

### ○ 4.11.1- General

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

### ○ 4.11.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

### ○ 4.11.3 Selection & implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select & implement the action(s) most likely to eliminate the problem & to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude & the risk of the problem. The laboratory shall document & implement any required changes resulting from corrective action investigations



# MEDIATION

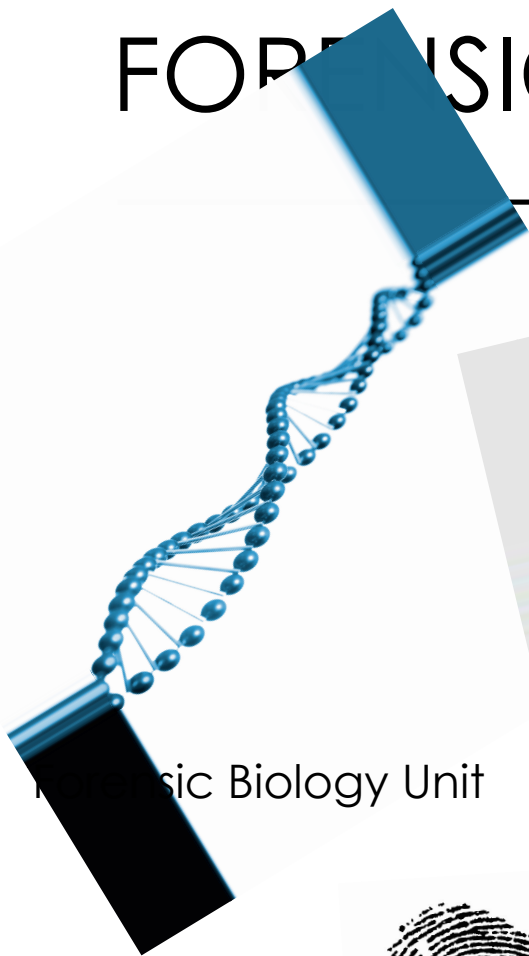
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- DFS Procedure for Complaints and Inquiries
  - Two days – Acknowledge receipt
    - Complaint/Inquiry Form
  - Five days – Assessment by Complaint/Inquiry Team for further action, response sent
  - Thirty days – Determination of course of investigation by C/IR Team, response sent
    - Advise of investigation
    - Explain procedures, timeline, documentation (eg Q-CARs, Q-PARs)
  - Sixty days – Completion of investigation by C/IR Team, draft response, draft report
  - Ninety days – Notification to complainant

QCARs/QPARs are opened and monitored by  
Deputy Director of Quality & Training



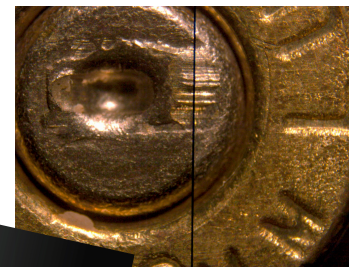
# FORENSIC SCIENCE LABORATORY



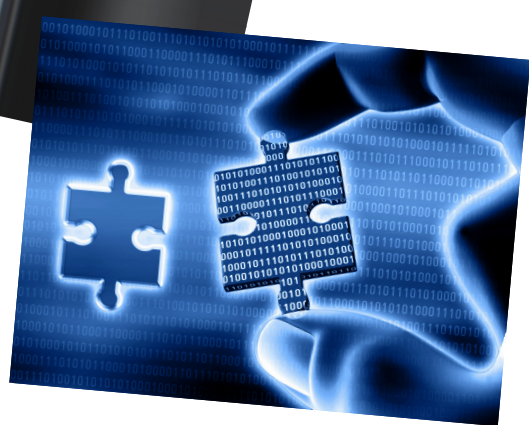
Forensic Biology Unit



Intelligence Unit



Examination Unit



Digital Evidence Unit



Latent Fingerprint Unit



# FIREARMS ISSUE OVERVIEW

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- Proficiency test error
- DFS Quality System triggered / action taken
  - QCAR
- Two credible errors detected in case review
  - QCARs
  - Review of FEU Protocols - Verification
- Relevant stakeholder notifications same time
  - Re-Work request to document differences
- DFS unaware “Discretionary Differences” terminology or notification by USAO to PDS
- Washington Post Article
  - public shaming of examiner

# FIREARMS

## PROFICIENCY TEST ERROR

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- External proficiency test (PT) error identified in Dec. 2016
  - Examiner immediately removed from casework prior to receipt of “Stat” report
  - QCAR initiated
  - Sample of work product identified for review since last successful proficiency test (20/120 cases reviewed)
  - Credible error detected in casework
  - Review expanded to all cases worked since last successful PT (120 cases)
  - Notification of PT and error to SAB
  - Notification of casework error, case review & DFS offer extended to re-work any relevant stakeholder requested cases issued

# VERIFICATION PROTOCOL REVIEW

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- A second credible error detected in case review
- Second QCAR initiated
- Notification of second error issued to Stakeholders- DFS offer re-extended to re-work any requested cases
- Two different verification examiners
- Verifiers successfully passed all external PTs
- Review of FEU casework protocols reveal 100% verification Policy effective 9/2015
  - No Mechanism Implemented To Ensure Transition from Sampling to 100% Verification
- Sample casework of Verifiers conducted since last PT identified for case review

# STRENGTHENING QA SYSTEM

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- Conducted Unit and FSL All-Staff Meetings
  - Shared Facts surrounding the incident
  - Reminded all that Proficiency Test Like Casework
  - Listened – Gathered their perspective
- Witnessing Verifications 60-day Implementation
  - April thru June to ensure 100% verifications occurring
- Reviewed FSL Issued Policies in Document Control System
- Additional Training Provided
  - PCAST Report Review
  - Mock Trial Court Testimony Training on issues
- Blind Proficiency Test Program



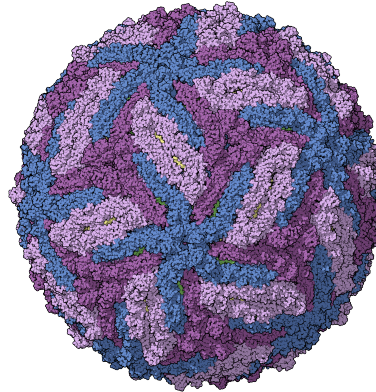


# PUBLIC HEALTH LABORATORY

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Microbiology Unit



Immunology & Virology Unit



Tier 1 BT Lab and Tier 2 CT Lab



Biomonitoring & Analytical Chemistry Unit



Accessioning Unit



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# ZIKA TIMELINE

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- January, 2016 Zika RT-PCR test implemented
- May, 2016- Verification of MAC-ELISA - Dr. Knuckles
  - 20<sup>th</sup> Century Science = MAC-ELISA
    - All Manual- Not a kit format
    - Issued as an Emergency Use Authorization (EUA) protocol- no deviations
  - CDC provided PT panel- DFS passed all results
  - Training conducted and PT testing of technical staff
  - Implemented with **2** positive controls and 1 neg. control
  - Controls performed – plates were interpreted
- July, 2016-MAC-ELISA testing started at DFS
- New PHL Director- Dr. Tran
  - Concerned about issues with test identified beginning in end of November ( last Positive test was 11/19)
  - Dec-Jan Dr. Tran conducted review & 2 mistakes found



# Zika MAC-ELISA ERRORS

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1. Wrong calculation in equation for P/N ratio to determine “positive” or “negative” result
  - Background calculation used instead of proper calculation
2. Over dilution of conjugate
  - Two options for commercial conjugate (1:100 or undiluted)
  - Diluted as if undiluted conjugate
  - Had not run appropriate titration studies

# NECESSARY SOLUTION

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- Recalculation of proper P/N ratio
  - None of the results changed from negative to equivocal or positive
- Retest all patient specimens affected by dilution error
  - 423 patients (449 specimens)
    - Pregnant women tested at CDC
    - All others tested at other PHLs

# ZIKA TIMELINE

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- January 25<sup>th</sup> notified DOH of need to do re-testing
  - Determine the number of samples
  - Arranged testing with CDC and other state PHLs and shipped samples
- Internal QCARS generated
- February 16- Providers advised of results
- February 27-28 CMS audit -CLIA compliance- MAC-ELISA only
  - Report provided on March 9<sup>th</sup>- 10 days to respond- 8 Deficiencies
    - Major deficiencies associated with Lab Technical Leader
    - Additional negative control for lab to be in compliance with CLIA
- Quality and PHL team responded to CMS Audit Findings
- April 11, 2017 - Final CMS acceptance of Allegation of Compliance and EOC
- July - SAB review of SOP, worksheets, titration & verification

# PHL QUALITY CHANGES

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- Extensive internal validation testing on all CDC issued protocols beyond what is recommended to verify that the tests work. Similar to what is done in Forensic community
- All protocols that involve a person embedding a calculation into a worksheet will be technically reviewed by at least one other individual for verification.
- Conduct verification studies using addition PT samples from PHLs in addition to CDCs panel of PT samples.
- Prior to implementation, all new tests will be technically reviewed and approved by a member of the DFS Scientific Advisory Board (SAB) who has the relevant expertise.

# FUTURE DIRECTION

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- Move Zika molecular testing to highly sensitive and fully automated platform
  - Study currently underway
- Add Dynex Agility to MAC-ELISA workflow
  - Fully automated EIA system
- Purchase DiaSorin Liaison XL
  - Zika NS-1 IgM antibody detection



# INDEPENDENCE & TRANSPARENCY

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[Jenifer Smith, PhD](#)

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[Brittany Graham, MFS](#)

[Troy Kelly](#)

[Herbert Thomas](#)

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### Department of Forensic Sciences



#### Office Hours

Monday to Friday, 9 am to 5:30 pm,  
except District holidays

#### Connect With Us

401 E Street, SW, Washington, DC  
20024

Phone: (202) 727-8267

### Open Government and FOIA - DFS

#### Open Government Material

The District is committed to a transparent, open form of government. District agency websites are required to make **certain records** available online to the public, if those records exist. In cases where these records exist but are not yet available online, agencies are working to provide them as soon as possible. If you have any questions, please contact the FOIA Officer.

- [Public Employee Salary Information](#) (Please note that this is the complete listing of District employees. Agency designation is located in column two.)
- [DFS' FY14 Budget](#)
- [DFS Organization Chart](#)
- [Agency Open Government Report 2014 \(PDF\)](#).

#### Administration

- See [DFS's Accreditation Documents 2016](#)
- View [the statute](#) that created and governs DFS (PDF).
- See [DFS's Accreditation Documents - March 2014 \(PDF\)](#).
- See [DFS's Accreditation Documents - June 2015 \(PDF\)](#).
- View [DFS Organization Chart \(PDF\)](#).

#### Financial

- See [DFS's FY 2014 Annual Report \(PDF\)](#).
- View [DFS's FY 2013 Annual Report \(PDF\)](#).
- See [DFS's Purchase Orders, Contracts for FY 2013 \(PDF\)](#).
- View [DFS's FY 2014 Budget \(PDF\)](#).
- See [DFS's FY 2015 Budget \(PDF\)](#).

# ACKNOWLEDGEMENTS

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## Executive Team

- Brittany Graham- Deputy Director
- Karen Wiggins- FSL Director
- Yi-Ru Chen- COO
- Troy Kelly- CSS Director
- Tony Tran- PHL Director
- LaShon Beamon-PIO
- Rashee Raj-GC

## Unit Managers

- Andrea Borchardt- FBU
- Susan Welti- FBU Tech Lead
- Jessica Beckman-LFU
- Jonathon Pope-FEU
- Tracy Walraven-DEU
- Abdel Maliky- FIU
- Grant Greenwalt- CSSU
- Luke Short-FCU &CT LRN
- Horng Kan- BT LRN
- Lindsey Stevenson- MU



# DON'T BE A STRANGER!

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Our YouTube channel: [DC Department of Forensic Sciences](https://www.youtube.com/DCDepartmentofForensicSciences)



Our Facebook page: [DC Department of Forensic Sciences](https://www.facebook.com/DCDepartmentofForensicSciences)



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# Extra Slides

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# ZIKA UPDATE

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- New COS-1 Antigen from CDC
  - Titration studies and verification studies
- New SOP
- New Worksheets
- Parallel Study
  - Consecutive samples collected 2/15/17 through 5/11/17
  - 105 samples total

# Zika MAC-ELISA Retest Results

## Re-test of Zika MAC-ELISA

Laboratory performing testing	Gender	Pregnancy status	Patients Tested	Samples Tested*	Laboratory performing testing	Gender	Pregnancy status	Negative	Zika Infection	Unspecified flavivirus	Grand Total
CDC			291	317	CDC			265	1	25	291
	Female		291	317		Female		265	1	25	291
		Pregnant	291	317			Pregnant	265	1	25	291
Lab 1			50	50	Lab 1			50			50
	Female		50	50		Female		50			50
		Non-Pregnant	50	50			Non-Pregnant	50			50
Lab 2			37	37	Lab 2			36	1		37
	Female		25	25		Female		24	1		25
		Non-Pregnant	25	25			Non-Pregnant	24	1		25
	Male		12	12		Male		12			12
		N/A	12	12			N/A	12			12
Lab 3			45	45	Lab 3			43	1	1	45
	Male		45	45		Male		43	1	1	45
		N/A	45	45			N/A	43	1	1	45
<b>Grand Total</b>			<b>423</b>	<b>449</b>	<b>Grand Total</b>			<b>394</b>	<b>3</b>	<b>26</b>	<b>423</b>

\*26 patients have duplicate samples sent due to having two different collection dates per CDC and DC DOH guidelines



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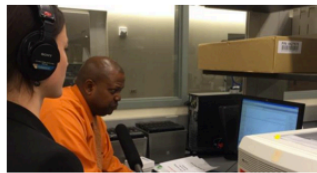
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### A Safer, Stronger DC

View Mayor Bowser's 'Safer, Stronger DC' legislative proposals that will help prevent and address violent crime in the District.



### DFS Tech, Cleveland Weeden Talks Zika Testing to NPR

DFS is among 30 national public health labs, sanctioned by the Centers for Disease Control and Prevention, to conduct Zika testing.



### Washington Post: DNA Testing

"We are no longer laggi field of forensic DNA te

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THANK YOU

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The DC Department of Forensic Sciences





# Why STRmix?

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- Looking for continuous probabilistic model
- Comprehensible training; in-house expertise is possible ( i.e. not a “black box”)
- STRmix allows for modeling either allele-specific or locus-specific stutter
- Faster computations
- PC-based- no need to buy additional