



Massachusetts Water Resources Authority



A Lab Director Looks at Lab Ethics

Michael F. Delaney

May 3, 2016



My Final Mission...

When I find something I don't agree with, work to improve it.



- Standard Methods committees on Control Charts, Solids, and Cyanide.
- MassDEP Lab Advisory Committee.
- Independent Testing Lab Association (ITLA)
- EPA Environmental Laboratory Advisory Board. (ELAB)

EPA Environmental Laboratory Advisory Board (ELAB)



United States Environmental Protection Agency

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Environmental Laboratory Advisory Board



The Environmental Laboratory Advisory Board (ELAB) is established in compliance with the Federal Advisory Committee Act (FACA) to provide consensus advice, information, and recommendations on issues related to:



What's New

- [*Monitoring work group minutes](#)
- [*Register for Environmental Measurement Symposium](#)

Board Work

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Laboratory Ethics – Part 28

“The Year of Detection” Edition

OR...what will they call Ununpentium?



Labs Behaving Badly

CRIME

A BLOG ABOUT MURDER, THEFT, AND OTHER WICKEDNESS.

JAN. 14 2012 3:45 PM

Slate



The Unsettling, Underregulated World of Crime Labs

By Justin Peters



A forensic scientist prepares blood samples for DNA extraction.

Photo by Mario Villaluna/Getty Images

On Friday, the *New York Times* reported that the NYC medical examiner's office is reviewing more than 800 rape cases in which DNA evidence may have been mishandled by an incompetent technician. Joseph Goldstein writes:

Supervisors have so far found 26 cases in which the technician failed to detect biological evidence when some actually existed, according to the medical examiner's office. In seven of those cases, full DNA profiles were developed—in some instances, evidence that sex-crime investigators did not see for years, hampering their ability to develop cases against rape suspects.

The piece goes on to note that, in the course of her job handling the DNA evidence collected in "rape kits," the technician—identified by the *Times* as Semita Mitchell—also

Lab Ethics...
In the middle...
(because it wasn't the beginning)...

...there was Annie...

Little Awful Annie

ARF!



A WBUR SPECIAL REPORT

BAD CHEMISTRY

Annie Dookhan And The Massachusetts Drug Lab Crisis



Annie Dookhan And The Massachusetts Drug Lab Crisis



news

WRITTEN BY

In August 2012, Massachusetts officials [closed the Hinton state drug lab](#) in Jamaica Plain because a then -obscure chemist allegedly “failed to follow testing protocols” while testing drugs related to criminal cases. That chemist is no longer obscure: Annie Dookhan is now frequently mentioned by lawyers,

A WBUR SPECIAL REPORT

BAD CHEMISTRY

Annie Dookhan And The Massachusetts Drug Lab Crisis



Dookhan Pleads Guilty, Gets 3-5 Years In Prison

news

WRITTEN BY
Deborah Becker

PUBLISHED
November 22, 2013

Update:

Disgraced former state chemist Annie Dookhan is now behind bars, after she pleaded guilty Friday to all 27 counts against her related to the drug lab crisis.

Dookhan showed little emotion and spoke softly as she pleaded guilty.



WBUR

Embed

Deb Becker On Sentencing:

0:00 / 0:00

Download this story



She was recently released
from prison.

Seeking Balance...

Have we achieved the proper balance between taking bad acts seriously versus creating the culture of telling management the issues?



MWRA Actions on Lab Ethics...

- ✓ One full day of training by Marlene Moore.
- ✓ QA Audits of methods and procedures.
- ✓ Supervisor audits.
- ✓ Signed Ethics Statement Pledge.
- ✓ Putting link to QAMP Ethics section, and SOPs on the LIMS visual workflow.
- ✓ Annual Ethics training. This will likely be required by MassDEP in 2016.

INTERNAL AUDIT OF LAB QA PROGRAM

MASSACHUSETTS WATER RESOURCES AUTHORITY INTERNAL AUDIT DEPARTMENT

To: Michael Hornbrook, Chief Operating Officer
From: John Mahoney, Director Internal Audit *JM*
Brian Rozowsky, Assistant Director Internal Audit *BR*
Date: July 11, 2014
Subject: Department of Laboratory Services Quality Assurance Program
(Report 14-1-07)

Introduction

The Department of Laboratory Services' (DLS) goal is to provide high quality and responsive services in support of MWRA's water and wastewater programs and to provide services to the Department of Conservation and Recreation (DCR) and the MWRA member water and wastewater communities. This includes timely and cost effective laboratory tests to meet the strict testing guidelines by all regulatory programs and permits, including the Safe Drinking Water Act (SDWA), Clean Water Act, and National Pollutant Discharge Elimination System (NPDES) permits.

INTERNAL AUDIT OF LAB QA PROGRAM

Results of Review

The DLS QAMP program is well documented. It contains the elements of a QA plan recommended by the Environmental Protection Agency (EPA). The QAMP, SOPs and other procedural documents are readily available on the MWRA Intranet.

- Updating the Ethics Statement in the QAMP to include language suggested by the EPA dealing with fraud, waste and abuse.
- Developing a report from the Laboratory Information Systems (LIMS) that summarizes each type of analysis performed by an analyst in a year. This will facilitate review by laboratory supervisors during the re-certification process.
- Increasing the frequency of rolling audits to ensure that auditable activities are reviewed at least once every three years.
- Instituting a program of having lab supervisors observe each analyst perform an analysis at least once a year to ensure compliance with the SOP and the reference test method. The frequency of observation should be increased to at least biannually and be documented.
- Assigning QA responsibilities to additional staff on either a full time or rotating basis to ensure the QA rolling audit schedule is maintained and that back-up staff is available in the absence of the QAC.

Data Integrity Training



Data Integrity - Preventing Improper Practices

**Advanced
Systems
Inc.**



Presented: June 2013

Do's and Don'ts

- Don't Pull the number out of the air!



- Do document all you do and why!



Statement of Responsibilities for Laboratory Employees

I acknowledge that I have certain responsibilities as a laboratory employee at the MWRA. I agree to the following guidelines:

1. I will observe the MWRA Code of Conduct, policies, procedures, practices and protocols that apply to laboratory work.
2. I will observe the Ethics Statement as stated in section 1.5 of the Department of Laboratory Services' Quality Assurance Management Plan.
3. ***I will report apparent data integrity or ethical issues to management if I become aware of them.***

I understand that this is a serious obligation and that I need to follow these guidelines to be best of my ability.

Name/Date/Signature:

1.5 DLS ETHICS STATEMENT

- Supervisory personnel are required to provide DLS staff members with guidelines and an understanding of the ethical and quality standards required to work in the laboratory and to operate the laboratory in a safe and efficient manner that complies with generally accepted laboratory and safety practices.
- All staff members of the DLS are expected to adhere to the ethics policy of the MWRA as set forth in the Authority's Code of Conduct handbook.

1.5 DLS ETHICS STATEMENT (Cont.)

- In addition the DLS staff are required to utilize their best professional efforts to:
 - Produce results that are accurate and defensible, including qualifying results when necessary, and to report any observations of apparent data integrity issues.
 - Present services in a confidential, honest and forthright manner.
 - Have a clear understanding with the client as to the extent and the kind of service to be rendered, especially in fields where different grades or characters of services are offered.
 - Perform laboratory duties in a manner that protects the environment and the health and safety of employees and the public.
 - Oppose and refrain from incompetent and fraudulent inspection, sampling, analysis, testing, consultation, development and research work.

Supervisor Audits

MASSACHUSETTS WATER RESOURCES AUTHORITY MEMORANDUM

To: Richard P. Trubiano, Deputy Chief Operating Officer
From: Michael F. Delaney, Director, Laboratory Services *Michael F. Delaney*
Date: January 13, 2014
Subject: A Proposed Laboratory Auditing Procedure

Request: Every supervisor will perform an annual “methods and procedures” audit of each of their analysts to verify that analyses are being performed and documented properly.

Supervisor Audits

To tighten up the gap between constant data audits on lab results and infrequent compliance audits, we propose to institute a new auditing requirement by supervisors, with oversight and review by the managers and QAC. These audits will be “methods and procedures” audits, focusing on how we do things, including the following questions:

1. Does the test have an approved SOP? Is the SOP in the process of being modified? If so, does it need to go through the review process?
2. Is the analyst or supervisor in possession of the reference method?
3. Is the most up-to-date approved SOP available at the bench?
4. Do the observed analysis practices correspond to approved SOP procedures? Are any modifications to SOPs needed?
5. Do the observed analysis practices correspond to the reference method requirements?
6. Does the SOP have an appropriate level of specificity on calibration and quality control procedures?
7. Is standard/reagent preparation performed and recorded correctly? Are standards/reagents properly labeled?
8. Are all data processing steps appropriate and well-documented?

DEP TO REQUIRE ETHICS TRAINING...

(6) On an annual basis, certified laboratories and laboratories seeking certification shall require all personnel to participate in a laboratory ethics training program. Training shall include the following topics: proper procedures to ensure data integrity, recognition and prevention of improper laboratory practices, the promotion of objectivity and impartiality in the generation and reporting of analytical data, and procedures for confidential reporting of data integrity concerns to a laboratory supervisor, director, or owner, as appropriate. The laboratory must document the content of the training and the date of participation in the training for each staff member and shall make this documentation and the materials used in the training available for review during an inspection.



**MWRA Labs...No
Significant
Ethical Issues
uncovered in...22
months!**



The Glossary of Fraud

- Dry Labbing
- Time Travel
- Peak Shaving
- Juicing

DRY- LABBING...



5.2



7.6



9.3

The Glossary of Fraud, also includes...

- Improper GC/MS tuning
- Improper calibration / QC analysis
- Misrepresentation of QC samples
- File substitution
- Unwarranted manipulation of computer software
- Improper alteration of analytical conditions
- Over dilution of samples or misrepresentation of detection limits
- Deletion of non-compliant data
- Concealment of a known problem

Where Fraud Occurs

Organics – 54%

Entire Lab – 17 %

Inorganics- 14 %

Microbiology – 6%

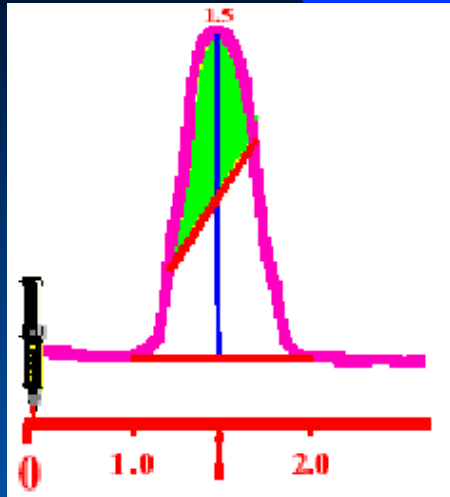
Other – 9 %

Manual Integration

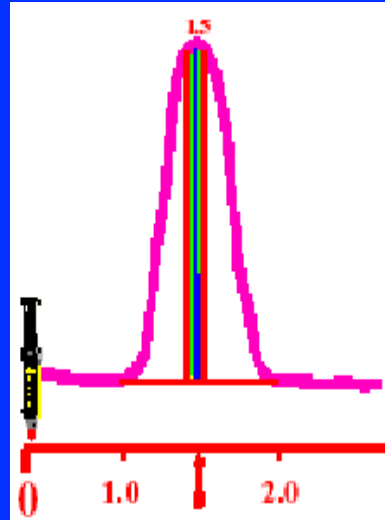
- e. When integrating chromatography peaks, either automatically or manually, each laboratory must ensure that integrations are performed in a correct and consistent manner for standards and samples, including quality control samples. Each laboratory must maintain documentation of manual integrations that includes the following:
- i. The laboratory's written procedure for manual integration;
 - ii. The original chromatogram and the manually integrated chromatogram;
 - iii. The analyst's initials, date of manual integration, and the reason(s) for the manual integration.

Peak Shaving: Less Area

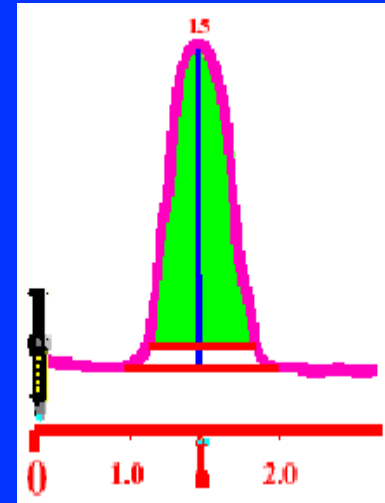
Std Area = 100,000
Sample Result = 1,000 ug/Kg



Std Area = 40,000
Sample Result = 2,500 ug/Kg



Std Area = 5,000
Sample Result = 20,000 ug/Kg

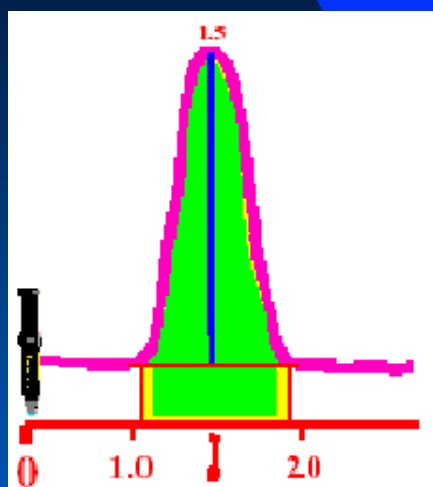


Std Area = 90,000
Sample Result = 1,111 ug/Kg

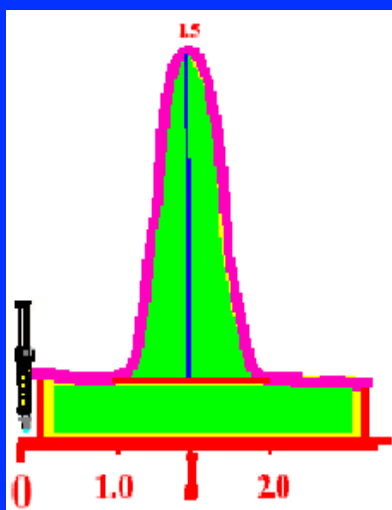
Name	RT	Area	Amount
Target Compounds			
5) Phenol	7.02	94 79878m	62.71 ug/L

Peak Addition: More Area

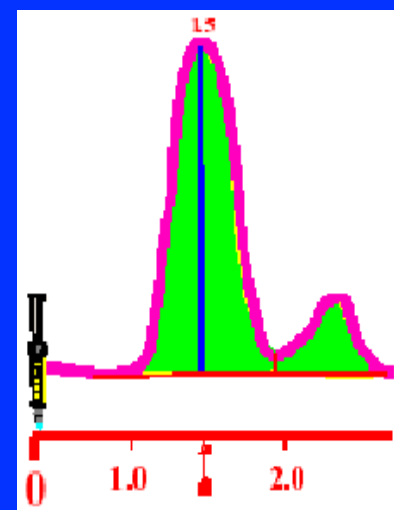
Std Area = 100,000
Sample Result = 1,000 ug/Kg



Std Area = 130,000
Sample Result = 769 ug/Kg



Std Area = 200,000
Sample Result = 500 ug/Kg



Std Area = 130,000
Sample Result = 769 ug/Kg

Name	RT	Area	Amount
Target Compounds			
5) Phenol	7.02	94 79878m	62.71 ug/L

Who ya gonna call?



- Supervisor, manager, me.
- Or, Internal Audit.
- Remember, there is a Massachusetts Whistleblower Law

Massachusetts Whistleblower Law



THE 188TH GENERAL COURT OF
THE COMMONWEALTH OF MASSACHUSETTS

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PART I	ADMINISTRATION OF THE GOVERNMENT	▶
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TITLE XXI	LABOR AND INDUSTRIES	◀ ▶
		PREV NEXT
CHAPTER 149	LABOR AND INDUSTRIES	▶
		NEXT
Section 185	Retaliation against employees reporting violations of law or risks to public health, safety or environment; remedies	◀ ▶
		PREV NEXT

MWRA on Lab Ethics...

Only a few incidents in 20+ years resulting in lengthy suspensions or terminations.

Concern: Have we achieved the proper balance between taking bad acts seriously versus creating the culture of telling management the issues.

Let's look at 3 examples...

Anonymous Lab Person = ALP

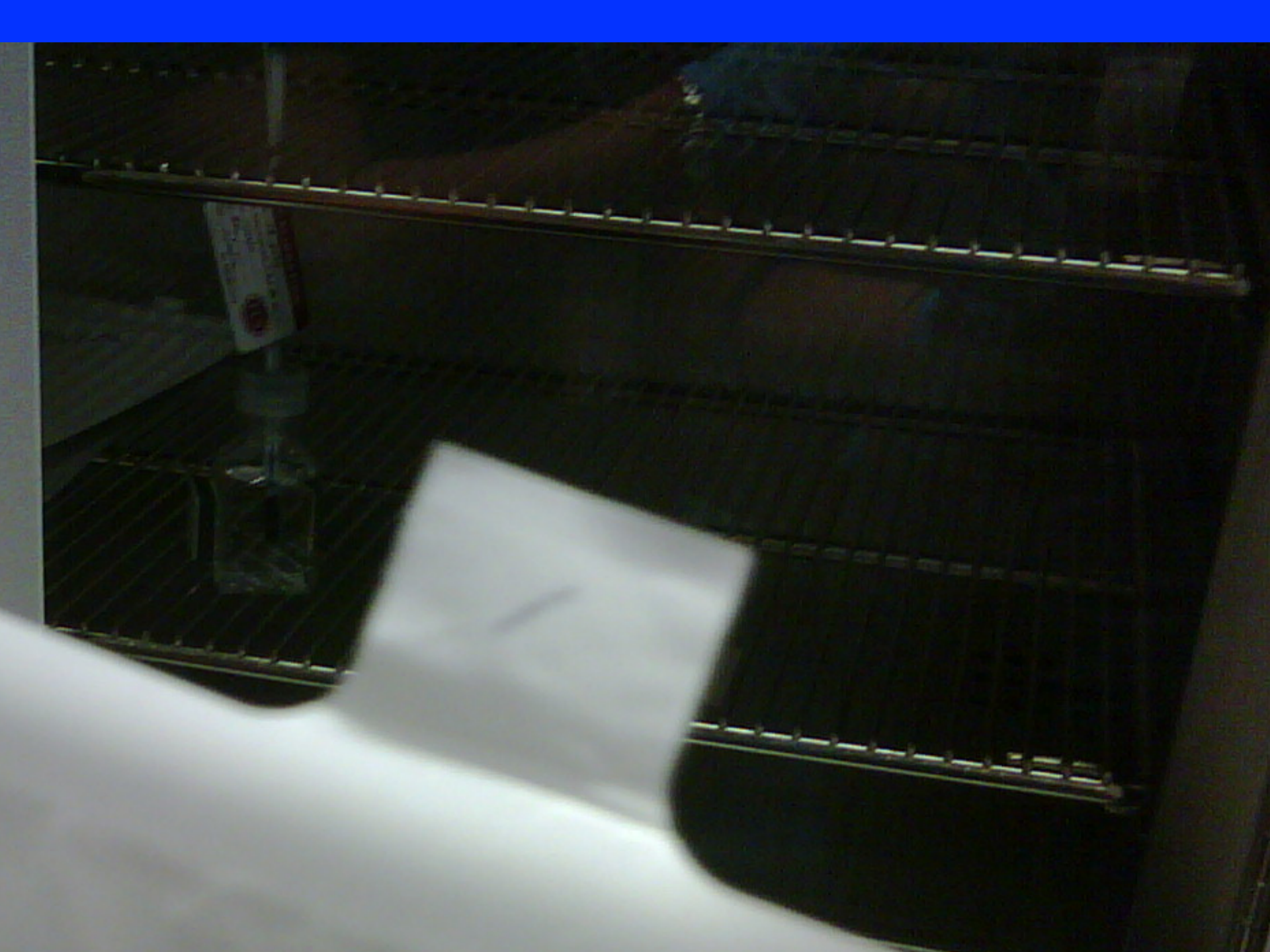
Invoking the “Cone of Silence” / “Cone of Science”.



Anonymous Lab Person #1

Carry over the QC samples from one day (batch) to the next.





Anonymous Lab Person #2

Excessive amount of personal emailing instead of performing the assigned work.



Subject	Received	S... C...	Flag
G... Frwd, RE: New Insights Into How Antibiotics Damage Human Cells Suggest Novel Strategi...	Mon 7/29/2013 4:54 PM	30...	Flag
G... RE: Dr. Gudrun Lange Reviews Neuropsychological Testing for CFS and FM 2013 via MA C...	Mon 7/29/2013 4:54 PM	41...	Flag
G... frwdd, RE: Just a Heads-Up To The Lefties Pretending to "Work" the 'Other Side' of the M...	Mon 7/29/2013 4:53 PM	26...	Flag
G... frd, RE: Concerns raised about voter eligibility 7/23/13 WMUR, Critics say NH law open to ...	Mon 7/29/2013 4:53 PM	21...	Flag
G... RE: Concerns raised about voter eligibility 7/23/13 WMUR, Critics say NH law open to abu...	Mon 7/29/2013 4:53 PM	21...	Flag
G... Mick, RE: The Report on Gov't Cybersecurity Causing 'Major Concerns' That You Might No...	Mon 7/29/2013 4:52 PM	34...	Flag
G... frwd, RE: The Report on Gov't Cybersecurity Causing 'Major Concerns' That You Might No...	Mon 7/29/2013 4:52 PM	32...	Flag
... FW: The Report on Gov't Cybersecurity Causing 'Major Concerns' That You Might Not Ha...	Mon 7/29/2013 4:52 PM	30...	Flag
G... frwd, RE: Congress to probe lethal crash that killed SEAL Team 6 members 7/24/13 The Hill	Mon 7/29/2013 4:51 PM	39...	Flag
... FW: Congress (GOP) to probe lethal crash that killed SEAL Team 6 members 7/24/13 The ...	Mon 7/29/2013 4:51 PM	38...	Flag
G... Frwd, RE: UNSUNG BLACK PEOPLE 7/24/13 by Ann Coulter	Mon 7/29/2013 4:51 PM	31...	Flag
... FW: UNSUNG BLACK PEOPLE 7/24/13 by Ann Coulter	Mon 7/29/2013 4:51 PM	30...	Flag
G... Frwd, RE: Congress Bogs Down, But Is That a Bad Thing? 7/24/13 RCP	Mon 7/29/2013 4:50 PM	39...	Flag
... FW: Congress Bogs Down, But Is That a Bad Thing? 7/24/13 RCP	Mon 7/29/2013 4:50 PM	38...	Flag
G... Link and dylan?, RE: In the Land of Opportunity 7/24/13 By Michael Busler	Mon 7/29/2013 4:49 PM	34...	Flag
... FW: Arctic Ice Scare — Climate Price Tag Claim Melts Under Scrutiny 7/26/13 The New A...	Mon 7/29/2013 4:48 PM	43...	Flag

est Novel Strategi...	Mon 7/29/2013 4:54 PM	30...	
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hat You Might No...	Mon 7/29/2013 4:52 PM	34...	
hat You Might No...	Mon 7/29/2013 4:52 PM	32...	
ou Might Not Ha...	Mon 7/29/2013 4:52 PM	30...	
rs 7/24/13 The Hill	Mon 7/29/2013 4:51 PM	39...	
pers 7/24/13 The ...	Mon 7/29/2013 4:51 PM	38...	
	Mon 7/29/2013 4:51 PM	31...	
	Mon 7/29/2013 4:51 PM	30...	
	Mon 7/29/2013 4:50 PM	39...	
	Mon 7/29/2013 4:50 PM	38...	
er	Mon 7/29/2013 4:49 PM	34...	
6/13 The New A...	Mon 7/29/2013 4:48 PM	43...	

Anonymous Lab Person #3

Inappropriately zeroing the spectrophotometer to hide the effect of instrument drift.

	A	B	C	D
1	Instrument Action	Date/Time	Comment	
2				
3	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 14:36	Prior to closing 1cm check blank	
4	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:55	Prior to 1cm filter blank	
5	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:51	Prior to initial 1cm check blank	
6	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:51	Prior to initial 1cm check blank	
7	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:47	Prior to closing 5cm check blank	
8	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:28	Prior to initial 5cm check blank	
9	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:16	Prior to closing 10cm check blank	
10	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 12:06	Prior to DLC standard in 10cm cell	
11	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 11:48	Prior to 10cm filter blank	
12	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 11:42	Prior to initial 10cm check blank	
13	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/24/2014 10:51	Prior to initial 10cm check blank	
14				
15	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 15:01	Prior to 1cm LCS at 15:02	
16	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 14:52	Prior to 1cm filter blank at 14:52	
17	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 14:47	Prior to initial 1cm check blank	
18	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 14:33	Prior to initial 1cm check blank	
19	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 14:29	Prior to closing 5cm check blank at 14:30	
20			Missing baseline check prior to initial 5cm check blank at 13:44	
21	Baseline - range: 300.0 nm - 200.0 nm; slit width: 2.0	6/20/2014 13:42	Prior to closing 10cm check blank at 13:43	

Jan_Jun2014 Sheet1 Sheet2 Sheet3

Ready 100%

6/24/2014 14:36	Prior to closing 1cm check blank
6/24/2014 12:55	Prior to 1cm filter blank
6/24/2014 12:51	Prior to initial 1cm check blank
6/24/2014 12:51	Prior to initial 1cm check blank
6/24/2014 12:47	Prior to closing 5cm check blank
6/24/2014 12:28	Prior to initial 5cm check blank
6/24/2014 12:16	Prior to closing 10cm check blank
6/24/2014 12:06	Prior to DLC standard in 10cm cell
6/24/2014 11:48	Prior to 10cm filter blank
6/24/2014 11:42	Prior to initial 10cm check blank
6/24/2014 10:51	Prior to initial 10cm check blank
6/20/2014 15:01	Prior to 1cm LCS at 15:02
6/20/2014 14:52	Prior to 1cm filter blank at 14:52
6/20/2014 14:47	Prior to initial 1cm check blank
6/20/2014 14:33	Prior to initial 1cm check blank
6/20/2014 14:29	Prior to closing 5cm check blank at 14:30
	Missing baseline check prior to initial 5cm check blank at 13:4

These were fraud, not mistakes.

So, progressive discipline was invoked.

Summary of Lab Ethics

- ❖ Call 'em as you see 'em. (Tell the truth.)
- ❖ Follow the rules (e.g. SOPs, QAMP)
- ❖ See Something – Say Something (not...
See Something – Shoot Something.)
Report questionable practices.
- ❖ Stuff Happens (Mistakes were made.)

Seeking Balance...

Have we achieved the proper balance between taking bad acts seriously versus creating the culture of telling management the issues?



The End...



If time allows...

**You may recall the
“Delaney Clause”**

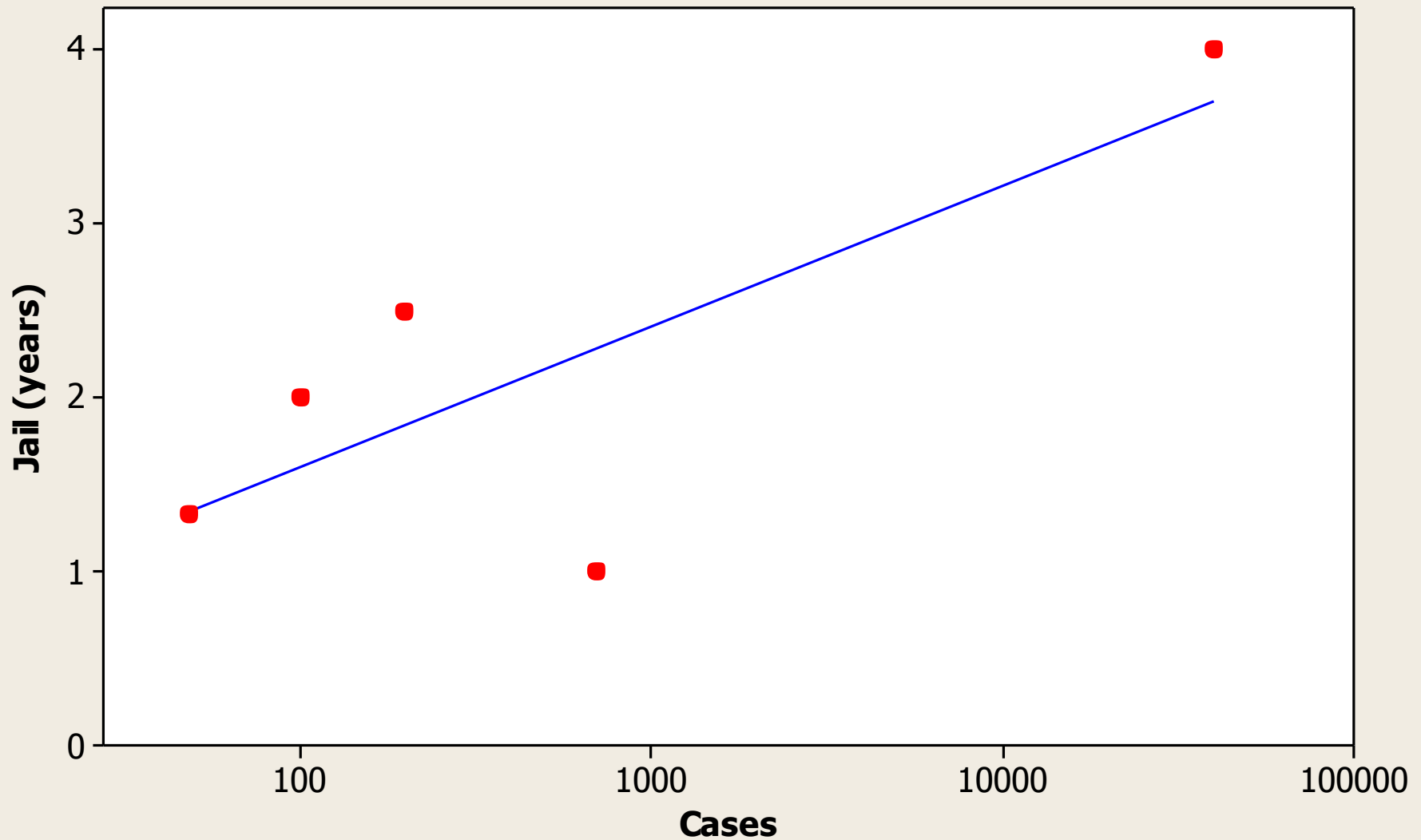
**but my research has
discovered the
existence of the
“Delaney Curve”**

“Delaney Curve”

I conducted an exhaustive search of the internet to compile a list of instances of crime lab fraud to see how the size of the crime was related to the magnitude of the punishment.

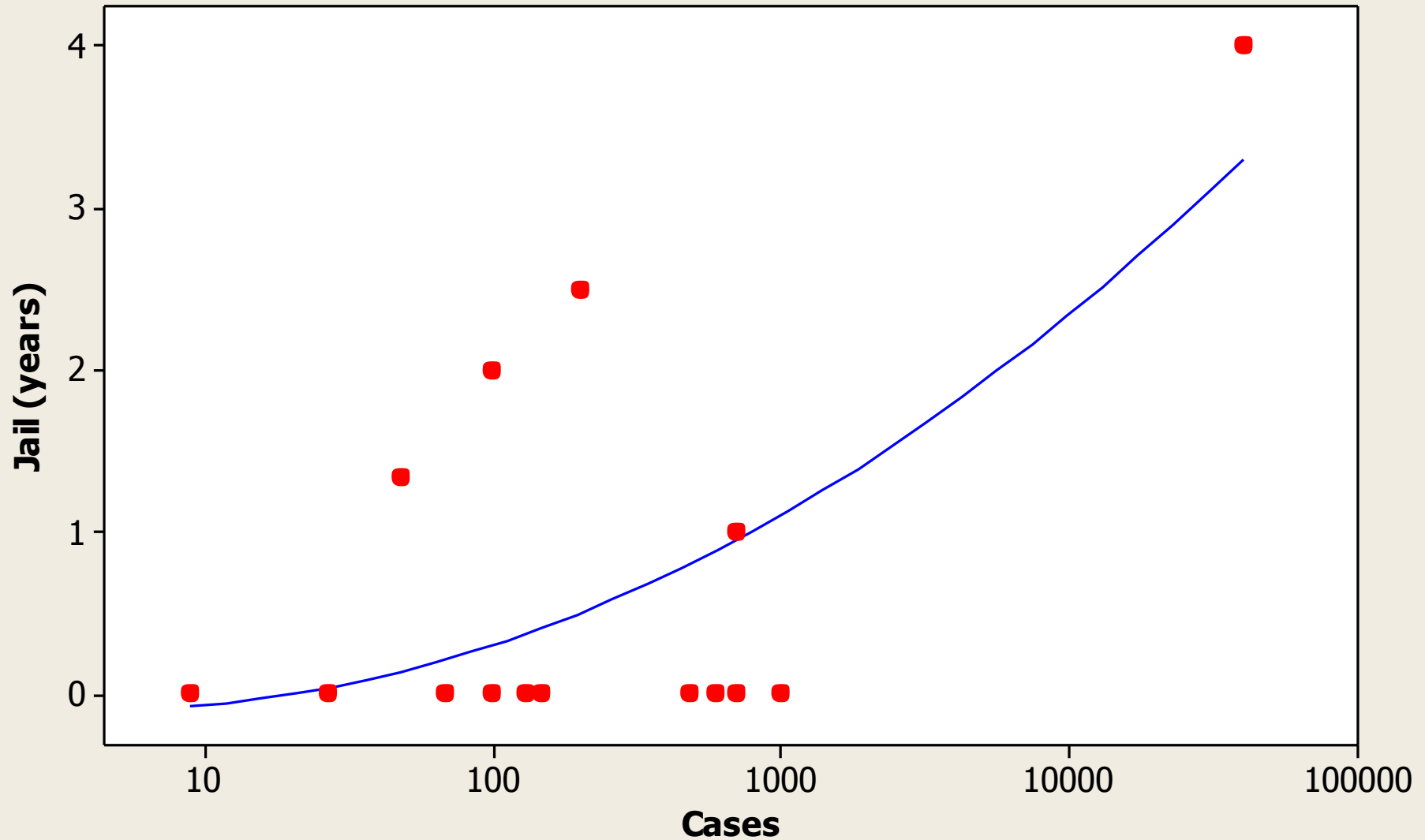
“Delaney Curve”

Jail (years) vs Cases



“Delaney Curve”

Jail (years) vs Cases





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Set Weather ▾

Every 8 minutes, we respond to disaster.



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115

Lab tech allegedly faked result in drug case; 7,827 criminal cases now in question



65

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By [Justin Zarembo](#) | NJ Advance Media for NJ.com

[Email the author](#)

on March 02, 2016 at 5:23 PM, updated March 03, 2016 at 12:29 PM

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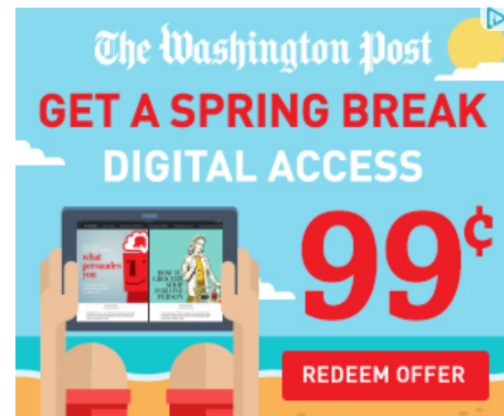
PASSAIC COUNTY — A lab technician for the State Police allegedly faked results in a drug case, and has drawn into question 7,827 criminal cases on which he worked, according to state officials.

Kamalkant Shah worked as a laboratory technician for the State Police laboratory in Little Falls and was found to have "dry labbed" suspected marijuana, according to [a Feb. 29 memo to Public Defender Joseph Krakora from](#)



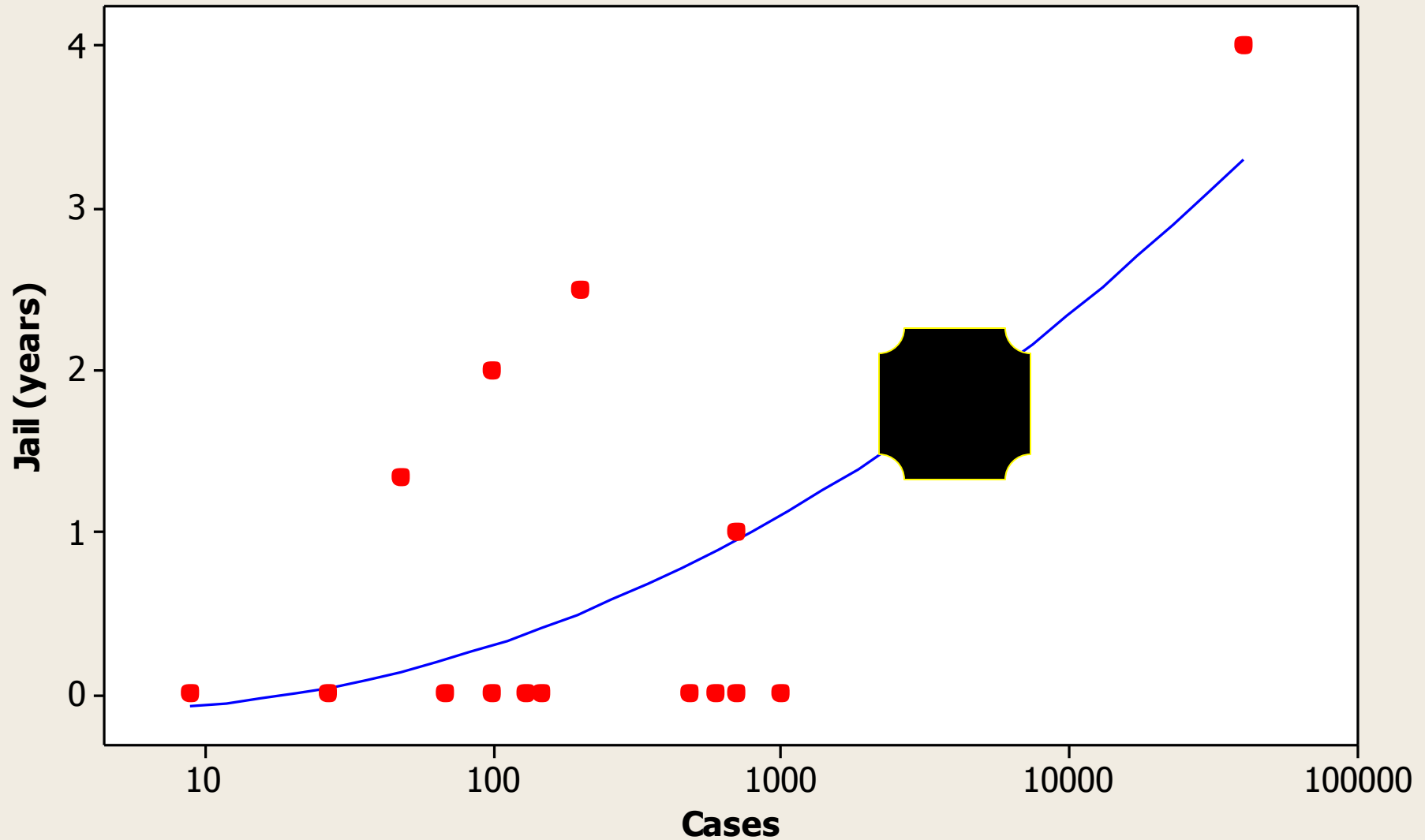
A lab technician for the State Police allegedly faked results in a drug case, according to a memo from the Public Defender's Office.

Sponsored by:



“Delaney Curve”

Jail (years) vs Cases



The End



Moon Over the Digesters

