



Laboratory Ethics and Data Integrity

Association of Public Health
Laboratories

September 2014

Outline

- What is Lab Fraud or Scientific Misconduct?
- Potential Areas of Deception or Abuse
 - Procedural deception
 - Measurement deception
- Detection and Deterrence
 - Consequences

Primary Goals

- To understand the concepts of scientific misconduct and lab fraud, not to go over all possible forms these could take
- To understand the difference between a mistake and misconduct
- NOT to cover all general ethics issues



Why Should We Be Concerned?

- Jail time is possible
- Many may lose their jobs – not just the guilty
- The integrity, dependability and known quality of our data are our most important commodities



Lab Fraud or Scientific Misconduct?

- Same type of behavior can be found in both
- Scientific Misconduct:
 - based on **violation of scientific ethical or conduct rules** which may have potential to damage the organization or affect the ability to conduct business when broken; consequences are internal (though may include removal) unless determined to also be fraudulent
- Lab Fraud:
 - **legal term with legal consequences**, for the individual and/or the organization; usually a type of misconduct which is associated with a perceived harm (victim)
- **NEITHER IS A MISTAKE or ACCIDENT!**
 - Has purpose or intent behind it

Definitions of Lab Fraud

EPA Definition, 1999 OIG memo and 2006 Evaluation Report

- **1999:** “The **deliberate falsification** of analytical and quality assurance results, where failed method and contractual requirements are made to **appear** acceptable.”
- **2006:** “The **deliberate falsification during reporting** of analytical and quality assurance results that failed method and contractual requirements to make them **appear to have passed requirements**.”



Ethics - Definitions, Webster's 9th Edition

➤ Ethic:

- the discipline dealing with what is good and bad and with moral duty and obligation
- a set of moral principles or values

➤ Ethical:

- of or relating to ethics
- involving or expressing moral approval or disapproval
- conforming to accepted professional standards of conduct



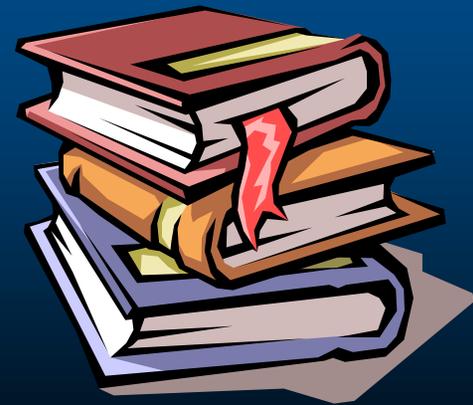
Codes of Conduct



- Violation of Professional Ethics can reflect badly on ALL members of that profession (*especially others within the immediate organization!*)
- ACS (American Chemical Society) “The Chemical Professional’s Code of Conduct”:
(www.acs.org/content/acs/en/careers/profdev/ethics/the-chemical-professionals-code-of-conduct.html)
- AIC (American Institute of Chemists) Code of Ethics:
(http://www.theaic.org/about_ethics.html)
- ASM (American Society for Microbiology) Code of Ethics:
(<http://www.asm.org/ccLibraryFiles/FILENAME/000000001596/ASMCCodeofEthics05.pdf>)

Laboratory Ethics Policy *(example)*

- “It shall be the policy of the XXXX Laboratory to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of each staff member and each manager to hold to the highest ethical standard of professional conduct in the performance of all duties.”



Ethics

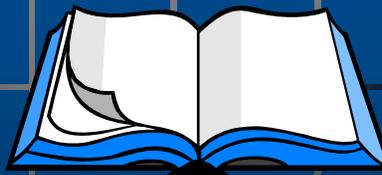
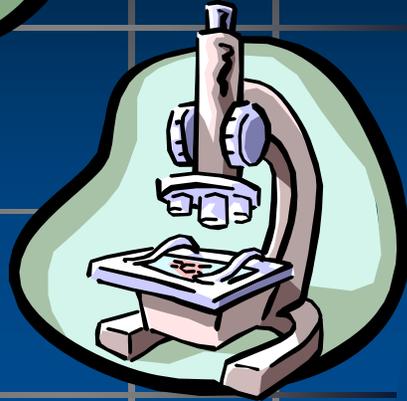
- What if our Scientists didn't have them ?
 - Enforcement Actions
 - Criminal prosecutions could fail or be overturned
 - Risk Assessments
 - Drinking Water – would you want to drink water that had been deemed safe based on false data????
 - Waste Water – our lakes and streams...
 - Superfund Sites – our next play ground???



Potential Areas of Deceptive Practice in the Laboratory

or... Things You Should **NOT** be Doing in a Laboratory

Descriptions & Examples



2006 EPA OIG Top 20 Vulnerabilities

- Censoring of information based on reporting limits
- Data manipulation
- Failure to follow SOPs/reference methods
- Falsifying existing data
- Improper calibration
- Inappropriate manual integrations
- Overwriting files: peak shaving, juicing, deleting
- Inadequate training
- Inappropriate sample collection process
- Incomplete record keeping

2006 EPA OIG Top 20 Vulnerabilities cont.

- Mislabeled sample
- No demonstration of competency
- No requirement for collector
- Reporting data for samples not analyzed (dry lab)
- Retention times not assured
- Sample integrity unknown
- Selective use of QC data
- Sequencing analysis
- Spiking samples after preparation
- Time travel (warping)

Potential Areas of Lab Deception

➤ **Procedural Deceptions:** Deviations from standard procedures that make the final reported data appear to represent something other than what it really is.

- Sample prep, calibration procedure, sample analysis, instrument settings??
- **SHORT CUTS**
- **“Fixing” Problems**
- **Very difficult to prove or detect**



➤ **Measurement Deceptions:** Direct physical measurements which have been altered so as not to reflect true values, but appear to.

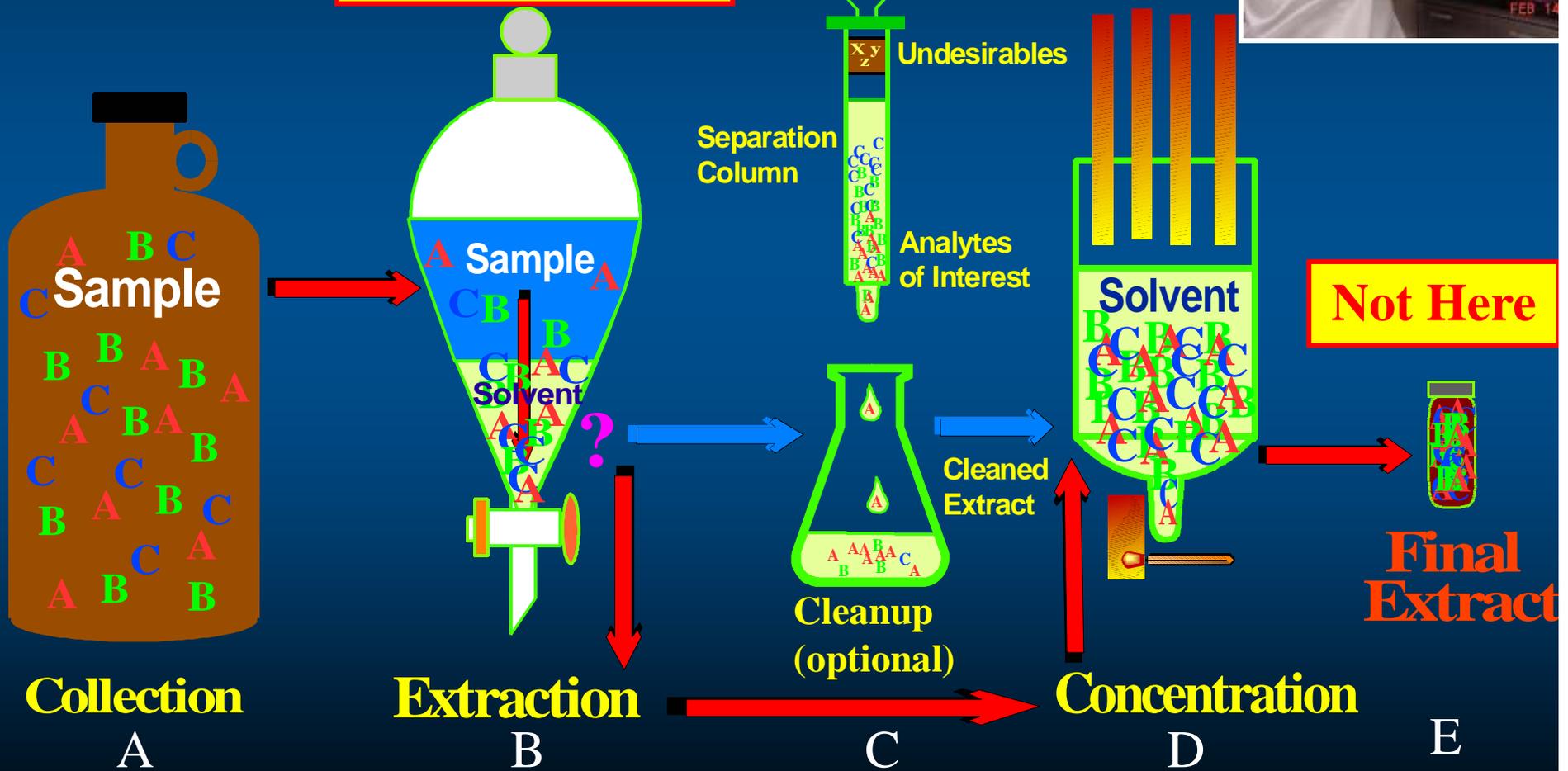
- Time and date, temperature, weights (%), volume, pH, calibration, QC, intermediate results, final results



Procedural Deception (harder to prove intent or detect)

Testing for Analytes A, B, and C

Add Spike Here



Examples of Procedural Deception

Misrepresentation of analysis

- Leaving out hydrolysis step in herbicide sample prep.
 - Only acids will be detected. Some esters (2,4-D) will not be detected in samples, but unless stated in reports, will be expected to be.
 - QC or sample results will not be obviously affected - gives appearance everything ok. Is this fraud????

- Not preping the PE (PT) sample before analysis (direct injection) **
 - Will not reflect a true analysis since sample is not in the same form and sample prep is eliminated, but results appear to reflect sample prep was performed.
 - Easier to meet PE criteria without sample prep losses (DW). Is this fraud???
 - NELAC requirements for PT samples strict

- Not digesting samples for metal analysis
 - organo-metalics give low or no reading

Examples of Procedural Deception

(continued)

- Not extracting or digesting method blank per method
 - blank appears cleaner than samples would
 - may report sample results that are blank related

- Spiking samples after extraction or digestion
 - easier to make criteria (surrogate or spike)
 - not reflective of sample analyte recoveries

- Using extra spiking solution to compensate for low recoveries or lost sample

An Ounce of PREVENTION:

- DOCUMENT, DOCUMENT, DOCUMENT!!
 - Write down any deviations from standard procedures
- COMMUNICATE, COMMUNICATE, COMMUNICATE!!
 - Talk with your Supervisor or Team Leader, especially about new things you want to try
- Be conservative, if messed up – then just start over, don't try to “fix” it
- Follow the method / SOP as written!!
- Reliability of your data is extremely important!

Measurement Deception Includes:

➤ Data **Deletion**

- removal of existing data to give the appearance of negative results
 - to please a big client, self reporting

➤ Data **Creation** (**fabrication**)

- creation of unsupported data without scientific measurement or determination
 - dry lab, to make easy money or deadlines

➤ Data **Modification** / **Manipulation**

- modification of existing data to represent values different from actual
 - time travel, peak integration, falsification

Examples of Dry Labbing (data creation)

- Generating report to represent sample results which were never completed
- Using the result from one sample and applying it to others as an accurate determined value for each sample
- Manually entering random values for results never determined through analysis
- PE result used from another lab

Examples of Time Travel (data modification)

- Computer dates are set back to show analysis within holding times
- Computer times are set back to show analysis within calibration or tune time limits
- Log book dates are written with earlier dates to show sample prep or analysis within holding times
- Entries of samples prepared or analyzed past holding times written in with those prepared within holding times to make them appear within holding times
- Amended reports without the date of amendment, or without any indication that the report is amended

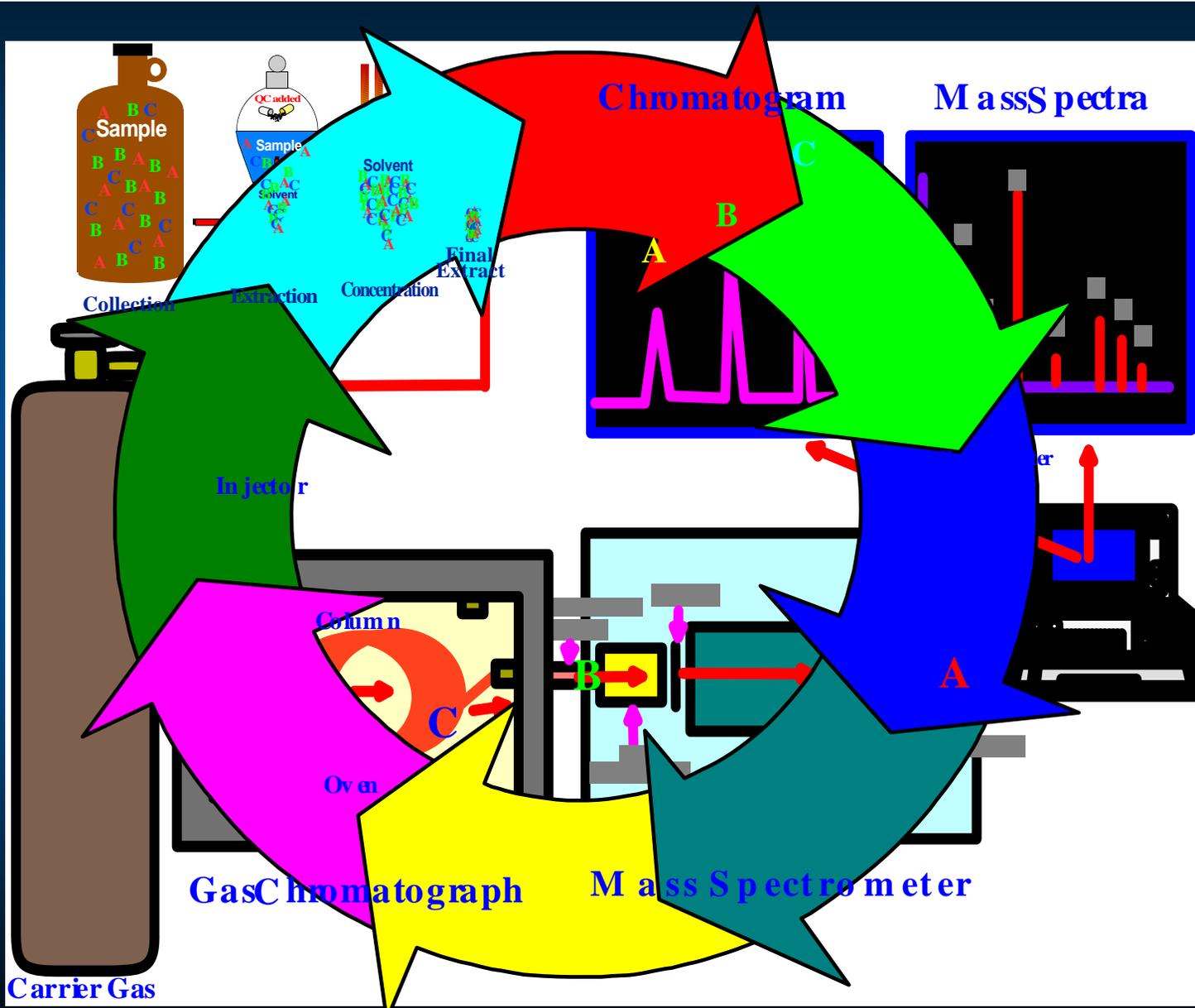
Reasons for Data Manipulation/Falsification

- Biggest reason: **TO MAKE QC PASS!**

- Bench Reasons:
 - to avoid re-running sample
 - to avoid instrument maintenance
 - to avoid missing sample holding times
 - to avoid getting in trouble with boss

- Management Reasons:
 - to avoid looking bad to upper management
 - to avoid financial penalties on contract
 - please client

The Final Data is only as good as the weakest link



An Ounce of PREVENTION:

- Don't over pressure staff on deadlines, make sure they aren't pressured to cheat. Let them know that Quality and reliability of the data comes first.
- Let the staff know that if they need help – ask for it! You can find a way to help them out.
- QC is used to determine sample, equipment, or method issues, not necessarily how good the staff is.
- What ever the problem, it is not worth losing your job or going to jail!

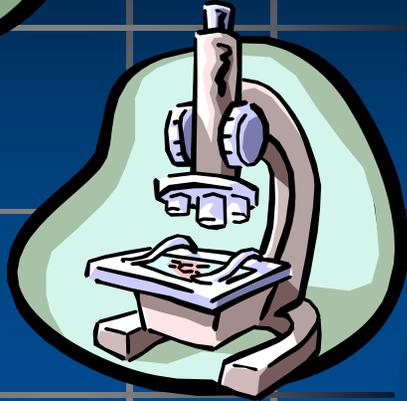


Make it Clear...

- It is **OK** to make a mistake
 - It is **NOT** OK to hide mistakes
- It is **OK** to have QC out of limits
 - It is **NOT** OK to hide QC that is out of limits
- There are potentially **severe** consequences for scientific misconduct that can affect the entire facility.
- Good **communication** can be key to prevention of these problems!



Detection and Deterrence



Detection

- Data Review (internal detection)
 - best line of defense for many problems
 - analyst, peer, team leader, outside source, QA officer
 - make checks for deception part of data review SOP
 - if QC looks too perfect for bad matrix - double check it
 - random calculation verifications by hand
 - walk sample through lab (data audit)
- Compare written logs to computer logs
 - check for time travel or dry labbing (dates match?)
- Random spot checks at the bench
 - best for more sophisticated users

Detection (continued)

- Electronic audit trail checks
 - look for multiple manual integrations on one peak
 - other suspicious changes
 - make sure this feature is always turned on!
- Unannounced Audits
 - internal technical and / or data audits
 - independent outside source audits
 - blind check samples, spikes, or surrogates
 - split samples with outside lab
- Voluntary disclosure or whistle-blower
 - make convenient means of disclosure available

Deterrence, Ask the basic question: Why?

- Need to understand the fundamental reasons this occurs before implementing prevention
- **Why?**
 - **pressure** to perform or please?
 - don't realize the **purpose of the QC** data since the QC process is often by-passed by these actions
 - pressure to make **deadlines**, no time for maintenance?
 - don't know better? **How was taught?** Everyone else is doing it? Reflection on schooling or training?
 - **penalties** for QC out of criteria (monetary for private lab)
 - **focus on production** rather than proper level of Quality
 - taking a **short cut!**

Deterrence (continued)

EPA OIG Suggestions:

- **Provide training** for auditors and data reviewers on fraud detection
- Promote ethics through **outreach and training**
- Provide fraud contacts (hotlines, etc.)
- Quality system demonstration / accreditation made mandatory for all programs

Deterrence, Legal



- Criminal Conviction (jail time &/or fine)
 - mail fraud, 18 USC 1341
 - wire fraud, 18 USC 1343
 - false statements, 18 USC 1001
 - conspiracy to defraud, 18 USC 371
 - concealment of a felony, 18 USC 4 (misprision)
 - false claims, 18 USC 287
 - obstruction of justice
- Civil Conviction (monetary)
- Administrative Action
 - suspension and debarment



Consequences *(Reputation and Career destroyed for you and others!)*

- “Pace to **close** Tulsa lab after finding improper analytical practices”, *Environmental Laboratory, Wash. Reporter*, Vol 15, issue 8, April 22, 2004
 - Management allegedly knew, culture too wide spread
 - Trust broken, reputation damaged
 - Deviations from “established lab practices”, not peak shaving
- “Mold testing company owner charged with testing, cleanup fraud”, *Environmental Laboratory, Wash. Reporter*, Vol 15, issue 15, August 12, 2004
 - Schongar allegedly generated false positive laboratory mold tests
 - Offered services to remediate the allegedly fake problems
 - Generated allegedly false laboratory results showing no more mold
 - In our public schools (Connecticut)!!
 - **Up to \$250,000 and 5 years imprisonment per count**

Consequences (continued)

- “Former lab owner sentenced for test fraud scheme”, *Environmental Laboratory, Wash. Reporter*, Vol 16, issue 6, March 24, 2005
 - Kilgarlin sentenced to 46 months in federal prison
 - **\$13,359 fine** for mail fraud and obstruction of justice
 - Dry-labbing results and false statements
- “Former Manager of Milford Water Company Found Guilty, Sentenced for Tampering with Drinking Water Samples”
(<http://www.mass.gov/ago/news-and-updates/press-releases/2013/2013-05-17-papuga-sentence.html>)
 - Papuga sentenced to 1 year plus five years probation and 250 hour community service.
 - Tampered with samples during a boil-water order

Consequences (continued)

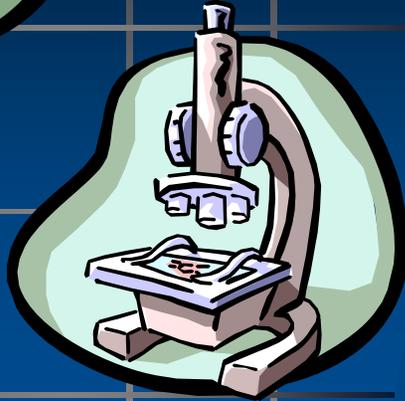
- “Dookhan pleads guilty in drug lab scandal”
(http://www.bostonglobe.com/metro/2013/11/22/annie-dookhan-former-state-chemist-who-mishandled-drug-evidence-agrees-plead-guilty/7UU3hfZUof4DFJGoNUfXGO/story.html?p1=ArticleTab_Article_Top)
 - Dookhan sentenced to 3-5 years
 - Three levels of management terminated or resigned
 - Drug lab shut down
 - Evidence integrity in more than 40,000 cases possibly tainted

References

- EPA OEI Quality Systems Web Site:
<http://www.epa.gov/quality/bestlabs.html>

Quick Review

- Lab Fraud / Scientific Misconduct
 - Has intent behind it
 - Is not an accident or mistake
 - Is not acceptable for any reason
 - Can destroy lives
- Prevention
 - **DOCUMENT / COMMUNICATE** problems immediately
 - Don't play around with data / procedures
 - Take time to do it right!
 - Don't take short cuts
 - Follow the SOP / Method
 - Expect some QC to fail on occasion
- **The dependability and known quality of our data are our most important commodities**



If you get caught at this, you could lose your job, destroy careers, and possibly go to jail.

IS IT WORTH IT?

Questions?