

US EPA ARCHIVE DOCUMENT



Laboratory Ethics and Data Integrity

Association of Public Health
Laboratories

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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



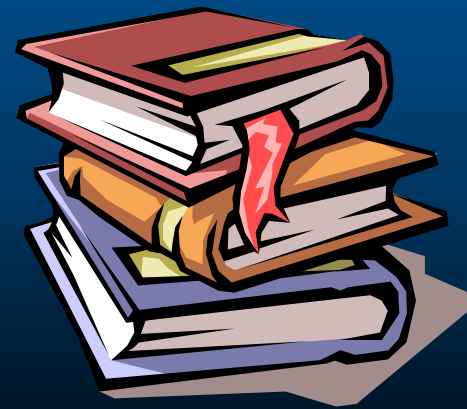
Codes of Conduct



- 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)*

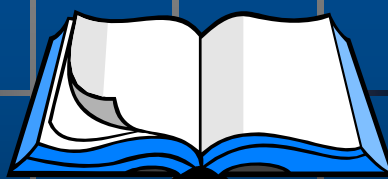
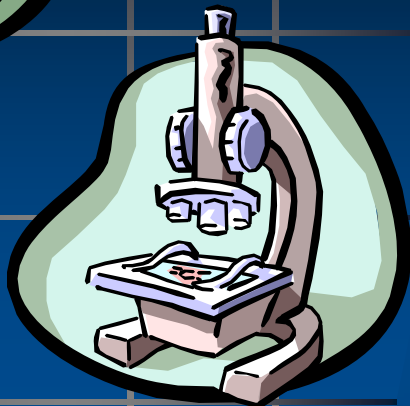
- “It shall be the policy of the XXXX Laboratory to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of each staff member and each manager to hold to the highest ethical standard of professional conduct in the performance of all duties.”



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???

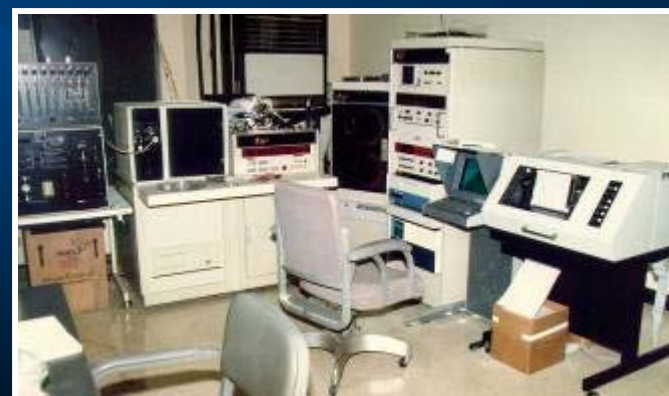




Potential Areas of Deceptive Practice in the Laboratory

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

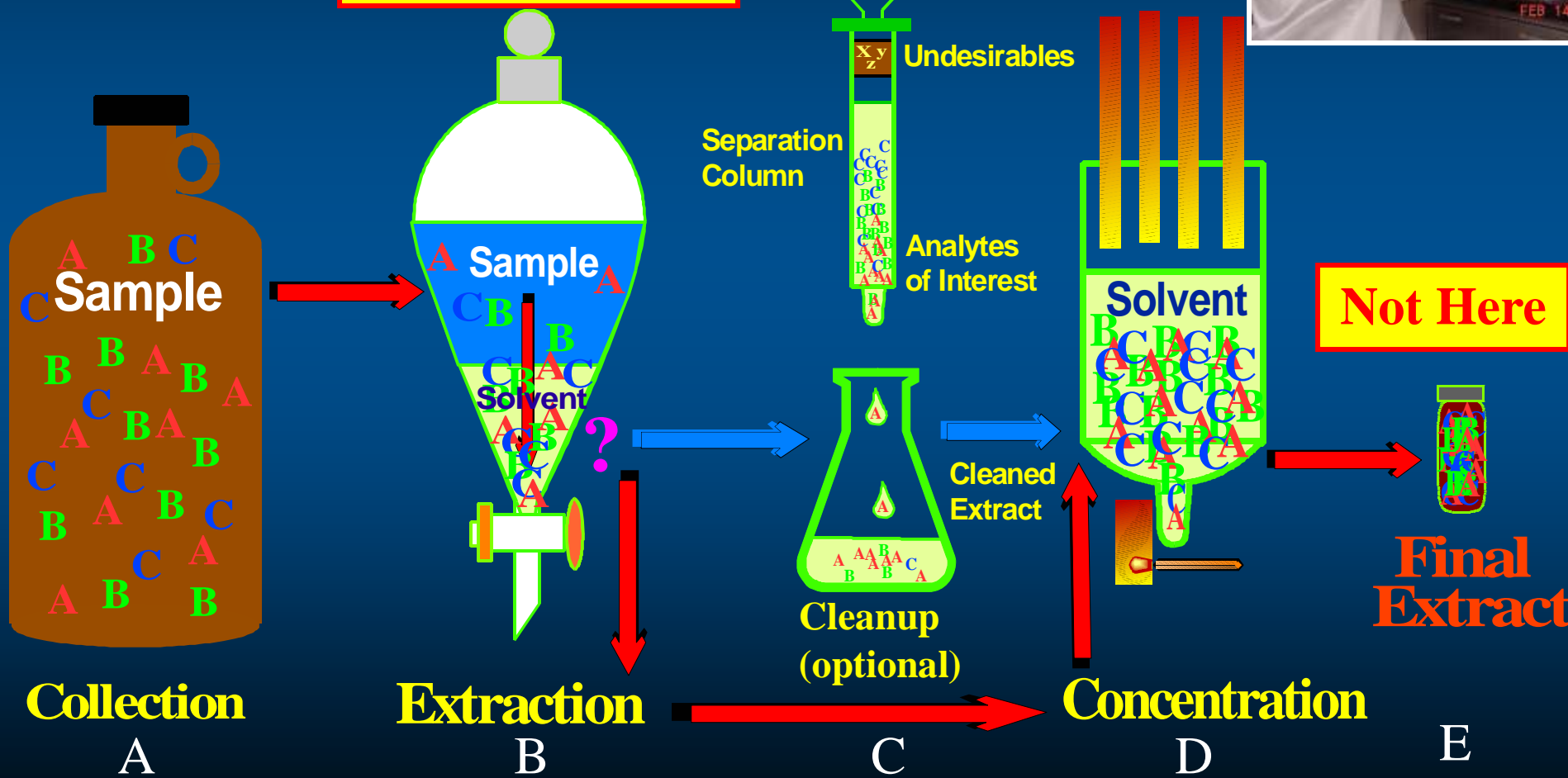


Procedural Deception (harder to prove intent or detect)

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

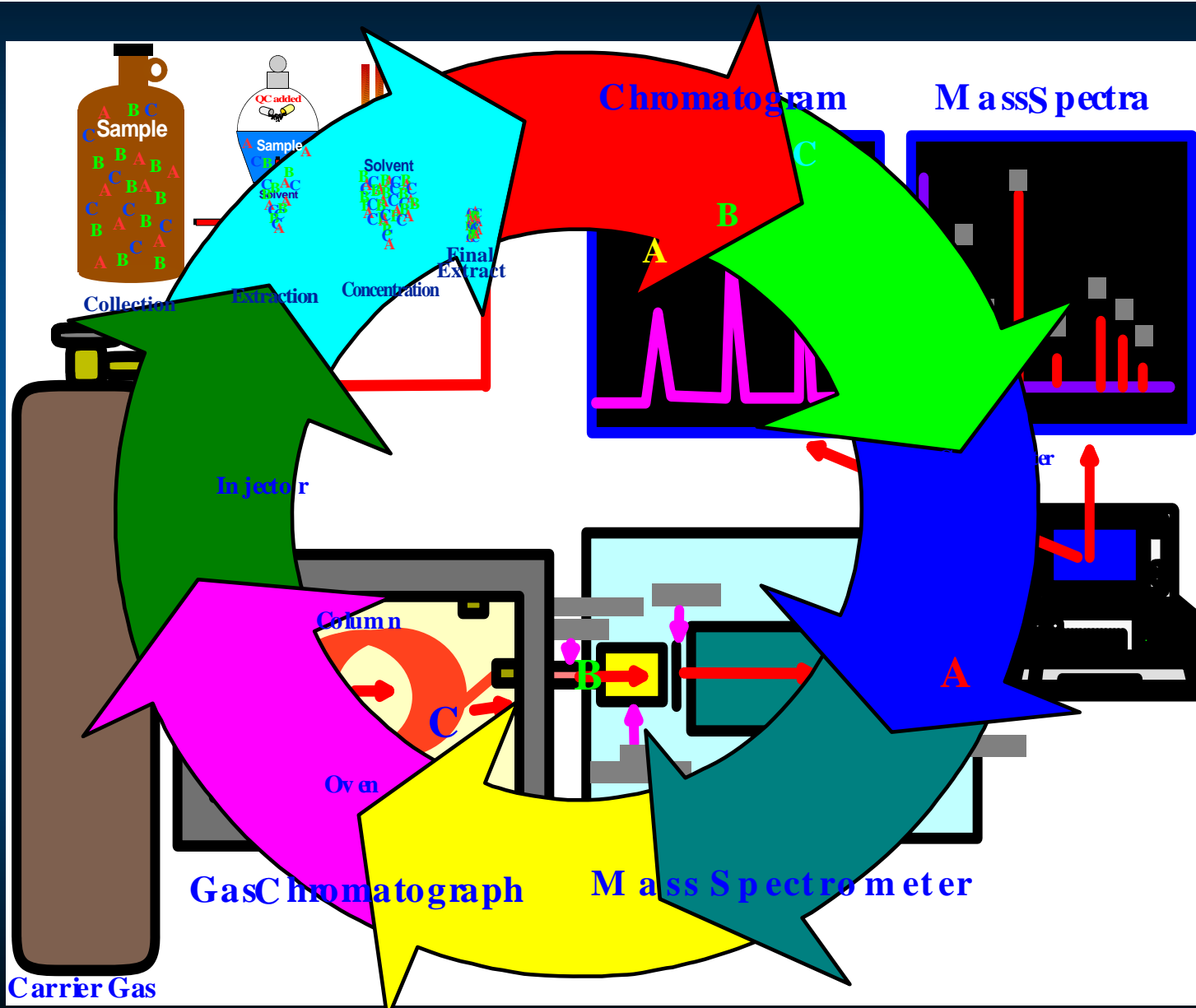
Reasons for Data Manipulation/Falsification

- 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?