

Module 5

Environmental Lab & Sampling Ethics

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Disclaimer

- ❑ The following information is provided to assist with Environmental Lab & Sampling Ethics
- ❑ The information is for guidance only.



Overview

- Define Ethics
- Why is Ethical Behavior Important
- Define Fraud and Improper Laboratory Practice
- Clearly identify what constitutes unethical behaviour and the penalties that accompany such behaviour.
- Consequences of Improper Practices
- Identify the employees' responsibility
- Identify the employers' responsibility





Ethics Defined

- A system of moral principles governing the appropriate conduct for a person or group
- Doing the right thing
- Being honest and straightforward not lying or cheating
- A code of conduct
 - ACS web page “The Chemist’s Code of Conduct”
 - ACIL web page Code of Conduct for Laboratories
 - www.acil.org

Why Act Ethically

- Your personal reputation and the reputation of your organization or business depends upon it
- Decisions we make as chemists and environmental professionals affect the environment and the lives of others
- Acting ethically can enrich your work life as well as your home life
- The penalties for misconduct for you and your organization can be substantial

Definition of Improper Practice

- ❑ A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.

Definition of Laboratory Fraud

- ❑ The deliberate falsification of analytical or quality assurance results, where failed method requirements are made to appear acceptable during reporting.
- ❑ The intentional recording or reporting of incorrect information
- ❑ An intentional gross deviation from method specified analytical practices, combined with the intent to conceal the deviation.

Why Talk about Improper Laboratory Practices and Fraud

The EPA Office of the Inspector General (OIG) has shown increased interest in the investigation of laboratory misconduct.

- The number of fraud cases investigated by OIG has increased each of the last six years.
- Arizona – 20 cases of severe improper procedures, including fraud, during audits of over 140 laboratories seeking certification from the State (about 1 in 7 laboratories)
- EPA OIG Report, September 21, 2006
 - Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks
 - <http://www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf>

OIG – Areas of Concern

- Data manipulation
- Failure to follow SOPs/reference methods
- Falsifying existing data
- Improper calibration
- Inappropriate manual integrations
- Overwriting files: peak shaving, juicing/peak enhancing, deleting
- Inadequate training
- Inappropriate collection process
- Incomplete record keeping

OIG – Areas of Concern

- Mis-labeled sample
- No demonstration of competency
- No requirement for collector
- Reporting data for samples not analyzed ("dry labbing")
- Retention times not assured
- **Sample integrity unknown**
- Selective use of QC data
- Sequencing analysis
- Spiking samples after preparation
- Time travel (changing times and dates)

▫ **Source: EPA OIG expert panel**

Difference Between Fraud and an Improper Practice?

- Fraud is purposeful and intentional
- Fraud is not a mistake.
- Fraud is an intentional misrepresentation of lab data to hide known or potential problems.
- Fraud makes data look better than it really is, with the intent to deceive.
- Sometimes the difference between fraud, improper practice and honest mistake is simply lack of proper documentation.

Penalties for Fraud

Some Possible Legal Actions

- ◆ Suspension or Debarment
- ◆ Civil Prosecution
- ◆ Criminal Prosecution

Regulations or Statues that may be used for Fraud Prosecution

- ◆ False Claims - 18 U.S.C. 287
- ◆ False Statements - 18 U.S.C. 1001
- ◆ Mail Fraud - 18 U.S.C. 1341
- ◆ Wire Fraud - 18 U.S.C. 1343
- ◆ Conspiracy - 18 U.S.C. 371
- ◆ Misprision (Concealment) of Felony - 18 U.S.C. 4
- ◆ Obstruction of Justice - 18 U.S.C 1505

Penalties for Fraud

Penalties for Conviction of Fraud

- ◆ False Claims – up to 5 Years prison and/or \$500,000 fine
- ◆ False Statements - up to 5 Years prison and/or \$500,000 fine
- ◆ Mail Fraud - up to 5 Years prison and/or \$500,000 fine
- ◆ Wire Fraud - up to 5 Years prison and/or \$500,000 fine
- ◆ Conspiracy - up to 5 Years prison and/or \$500,000 fine
- ◆ Concealment of Felony - up to 3 Years and/or \$500,000 fine
- ◆ Obstruction of Justice - up to 5 Years prison and/or \$500,000 fine

Fraud Prevention

- Zero Tolerance
 - Fraud is grounds for immediate dismissal

- Be Proactive
 - Develop a Laboratory Data Integrity Program Plan
 - * QA Manual
 - Develop a Code of Conduct and/or Ethics Agreement
 - Write SOPs (manual integration, use of electronic audit functions, data review criteria)
 - Watch each other

Laboratory Responsibilities

- Continuously monitor data on a periodic but random basis – data audits
- Provide clear guidance and policies for ethical behaviour - code of conduct statement signed yearly
- Provide ongoing training to employees
- Perform confidential investigations if a problem is detected.
- Notify clients and reissue reports if data is negatively impacted.
- Eliminate undue pressure on analysts – quality ahead of TAT
- Provide mechanism for confidential reporting of abuse without recrimination – whistle blower policy

Employee Responsibilities

- Uphold the ethics policy and practices as demonstrated in their daily conduct.
- Seek help when the proper course of action is unclear or unknown to them.
- Remain alert and sensitive to situations that could result in actions by any employee that are improper, illegal, unethical, or otherwise in violation of the ethics policy and practices.
- Counsel fellow employees when it appears that they are in danger of violating the ethics policy and practices.
- Report violations of the ethics policy and practices to their supervisor.

How Do I Know a Practice is Improper

- Does it violate policy or procedure, SOP or QAPP
- Mom Test – would mom approve
- Would an auditor approve
- Gut check – Do I really feel this is right
- Would my son or daughter be proud
- Am I doing this so I can leave early
- Would my supervisor, lab director or QA manager disapprove



Why do Improper Practices Occur?

- **TO MAKE QC PASS!**

* (this is **WRONG!**)

- 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

An Ounce of PREVENTION:

- DOCUMENT, DOCUMENT, DOCUMENT!!- An 'outsider' should be able to re-create the entire analytical process, including data review decisions
- Talk with your Supervisor, QAO or Lab Chief if you have doubts or questions
- Follow the method / SOP as written- (or revise the SOP as necessary)

An Ounce of PREVENTION:

- ❑ If you miss a holding time or make a mistake, be honest about it. Covering it up can take it from honest mistake to fraud.
- ❑ Don't be clever be smart, in the long run it takes less effort to just follow policy than to find clever ways to circumvent it .
- ❑ QC is used to determine sample, equipment, or method issues, not how good you are at your job.
- ❑ Whatever the problem, it is not worth losing your job or going to jail!
- ❑ Talk with your Supervisor or QA Officer if you have questions

To Be Clear...

- It is **OK** to make a mistake
 - It is **NOT** OK to hide that mistake
- It is **OK** to have QC out of limits
 - It is **NOT** OK to hide QC that is out of limits or make it appear to be within limits when it is not.
- There are potentially **severe** consequences for scientific misconduct that can affect you and your lab.
- Good **communication** can be key to prevention of these problems!

Quick Review

- Lab Fraud / Scientific Misconduct
 - Has intent behind it
 - Is not an accident or mistake
 - Is not acceptable for any reason
 - Can destroy careers
- Prevention
 - DOCUMENT / Communicate problems immediately
 - Take time to do it right!
 - Don't take short cuts
 - Follow the SOP / Method
 - Expect some QC to fail on occasion

Acknowledgements

- USEPA Office of Inspector General (OIG) – Laboratory Fraud
- State of South Carolina DHEC – Improper Practices
- City of Portland, OR and City of Keene, NH – Ethics Training
- Laboratory Fraud Detection and Deterrence
Rick McMillin and David Stockton, USEPA Region 6
- Environmental Science Corporation Code of Ethics

QUESTIONS???

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