Laboratory Ethics and Data Integrity

OREGON ENVIRONMENTAL LABORATORY ASSOCIATION ANNUAL CONFERENCE

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SALEM, OREGON

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BASED ON THE "TRAIN THE TRAINER" PRESENTATION DEVELOPED FOR THE ORELAP Technical Advisory Committee (OTAC)

TNI Standard

- 2016 TNI (NELAC) Standard 5.2.7:

- "Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis"

Case Study

- The following is a theoretical event:
- Max is scheduled to read some Collilert results in the afternoon, he gets very busy with an emergency in the plant which makes him late for his son's big game and he totally forgets about the micro samples.
- The next morning Max looks at the samples and they are all yellow. The yellow color indicates a negative result.
- Sure the 24 hour window has past but they are still negative why not write down yesterday's date and move on.
- What would you do and why?

Case Study

- You saw Max taking readings in the morning and know they should have been done yesterday
- What should you do and why?
- Is this an improper practice? Is this fraud?

Ethics and Data Integrity Training

Program Overview

- Define Ethics
- Why is Ethical Behaviour Important
- Define Laboratory 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
- Examples of Improper Practices
- Review correct integration procedures

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"
  - www.acs.org/careers search Code of Conduct
  - ACIL web page Code of Conduct for Laboratories
  - www.acil.org look under About Us

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.

What is the 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.

Example #1

- You're in a hurry because it's a short week. You started up the autoclave and forgot to check the pressure and temperature during the sterilization cycle as required by the SOP. Why not just check off the column in the log book. We have that positive bottle in there to determine sterility, right? It's just this one time.

- This practice is:

  A. An improper lab practice

  B. Lab fraud

-

Example #2

- Max is scheduled to read some Collilert results in the afternoon, he gets very busy with an emergency in the plant which makes him late for his son's big game and he totally forgets about the micro samples.
- The next morning Max looks at the samples and they are all yellow. The yellow color indicates a negative result.
- Sure the 24 hour window has past but they are still negative why not write down yesterday's date and move on.
- Is this Fraud or Improper Practice?

Example #3

- An analyst knows that the response to VOCs degrades over time on their GC/MS. The lab is slammed with VOCs and analyses will be going out of hold if they have to stop to recalibrate.
- When they prepare the samples they put just a little more standard into the LCS sample to make sure they get good results
- The results are almost always ND it really won't make a difference.
- This practice is:

A. **An improper lab practice**
B. **Lab fraud**

Example #4

- Julie is being pressured by her supervisor to get more metals digestions done in a shorter time due to rush turnaround times. She decides that she could turn up the temperature and digest in half the time to solve her dilemma.

- This practice is:

  A. An improper lab practice
  B. Lab fraud

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Ethics Scenario - Possible Solutions

- Discuss the situation with the supervisor (and possibly Quality Manager) and clearly define how many samples can be done correctly.
- Coordinate with the supervisor the possibility of extra shift work or weekend work to complete all the samples on time.
- If this is not possible, inform supervisor and Project Manager which clients need to be informed that their samples will not be completed on time.
- Document all actions taken on prep log.
- Propose her method performance improvements to management who may decide that the changes are method compliant and the SOP can be modified.

Why Talk about Improper Laboratory Practices and Fraud

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

- 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

What Are the 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

What Are the 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

OIG – Areas of Concern #1

- 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 #2

- Mislabeled 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
- Spiking samples after preparation
- Time travel (changing times and dates)

Source: EPA OIG expert panel

Fraud Prevention

Create effective policies:

- Zero Tolerance – fraud is grounds for immediate dismissal
- Be Proactive:
  - Develop a Laboratory Data Integrity Program Plan
  - Develop a Code of Conduct and/or Ethics Agreement
  - Write SOPs (manual integration, use of electronic audit functions, data review criteria)

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:

- 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

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)

Quick Review

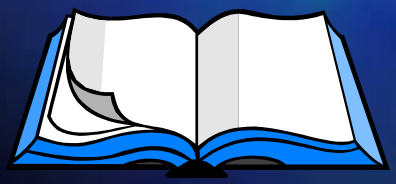
- Lab Fraud / Scientific Misconduct
  - Has intent behind it
  - Is not an accident or mistake
  - Is not acceptable for any reason
  - Can destroy careers
- Prevention
  - DOCUMENT / Communicate problems immediately
  - Take time to do it right!
  - Don’t take short cuts
  - Follow the SOP / Method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

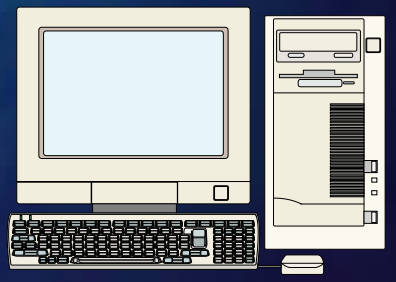
To Be Clear…

- 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!

Examples of Improper Lab Practices

Not a "How To" but a 'How Not To"





Improper Preparation Practices

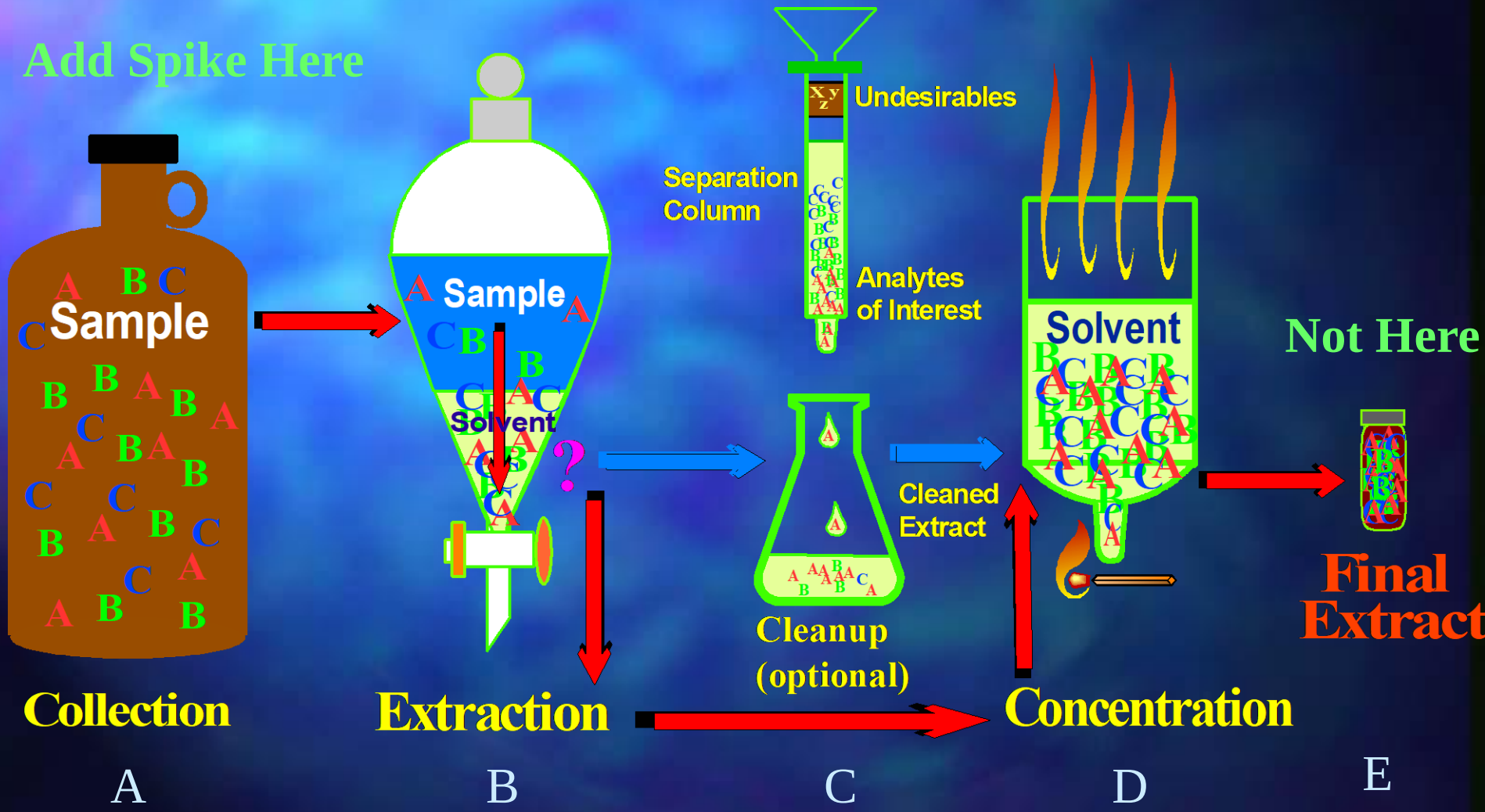
- Not prepping a PT sample before analysis (direct injection)
- Not prepping calibration standards when required by method
- Not adding surrogates or spikes until after prep – post spike
- Leaving out hydrolysis step in Herbicide analysis
- Not digesting samples for metal analysis when required by the method
  - organo-metalics give low or no reading

Treating Batch QC Different than Samples

- Not treating batch QC samples in the same way as the rest of the batch
  - Not extracting or digesting method blank or laboratory control sample (LCS).
  - Must use same clean-up techniques on QC samples as regular samples
- Reserving special glassware for blanks
  - blank may appear cleaner than samples would
  - may report sample results that are blank related

Improper Spiking Procedure

Testing for Analytes A, B, and C



Improper Calibration Procedures

- Using calibration procedures that are not allowed by the required method
  - Second order curves
- Selective removal of bad points to avoid re-running standards
  - sometimes allowed (upper, lower, statistical cause)

Data Deletion

- Removal of existing data to give the appearance of non-detect results
  - e.g. You run this station every week and it always is non-detect….
- Selective removal of MDL data points
  - e.g. Analyze eight and choose the best seven
- Raw data packages not containing all data, should include failed data.

Improper Use of QC Data

- Selective use of QC data
  - Running extra QC in case some results don't 'work out' and not using the 'bad' data
  - Running QC samples without documented evaluation criteria
    - This can lead to inconsistent evaluation of the results.

Improper Analytical Procedures

- Data Modification / Manipulation / Selection
  - modification of existing data to represent values different from actual
  - Dry labbing of data
  - time travel
  - Improper manual integration

Examples of Dry Labbing (fabrication)

- Changing a computer generated report to represent sample results which were never generated
- 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
  - e.g. pH of this station is always 7.5.....

Manual Integration (MI)

- Operator decides everything. Big potential for fraud. Big **RED** flag.
- Sometimes very necessary to use MI for accurate results, not always wrong.
- Can be very difficult to determine proper integration method.
  - Co-elutions
  - Bad baselines

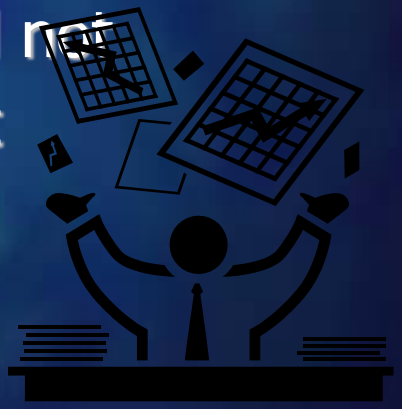
- **Protect yourself:** always document how and why MI done!

Reasons for Improper Manual Integration

- Biggest reason: **TO MAKE QC PASS!**
- Curve does not pass response criteria
  - minimum response or linearity
- Continuing Calibration response does not match curve (% difference >)
- Internal Standard areas out
- Surrogates out
- Matrix spikes out

Results of Poor Integration

- Sample results too high (calibration or ISTD area)
- Sample results too low (calibration or ISTD area)
- Data appears better than it is:
  - Curve looks good, when should not
  - Continuing Cal passes, when should not
  - Internal Standards match, when should not
  - Surrogates appear ok, when should not
  - Spikes appear to ok, when should not



Acknowledgements

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