



Ethics and Data Integrity in Environmental Laboratories

Matthew Jones | August 2023

Objectives

- Why do we need to talk about ethics and data integrity?
- Develop basic understanding of ethics and how it relates to data integrity
- Understand the difference between fraud and improper laboratory practices
- Consequences of unethical laboratory behavior
- What is your role?

Why do we need to talk about ethics and data integrity?

- NELAC/TNI certification requires annual training
- State and Federal regulations/statutes
- EPA continues to be concerned
- Safety

Current Reasons for Discussing Ethics and Data Integrity

- Most lab workers have high standards of ethics, but...history shows us that:
 - Data integrity lapses do occur (even with highly trained staff)
 - Applicable to small, large, medium, commercial, governmental, etc.
 - The frequency of cases are not decreasing
- Save yourself time and money

Current Reasons for Discussing Ethics and Data Integrity

- Most lab workers have high standards of ethics, but...history shows us that:
 - Data integrity lapses do occur (even with highly trained staff)
 - Applicable to small, large, medium, commercial, governmental, etc.
 - The frequency of cases are not decreasing
- Save yourself time and money

Definitions

- Ethics: a set of moral principles : a theory or system of moral values
 - Consists of the rules of conduct recognized by a culture of humans and accepted by society
- What about Ethical Behavior? Does it relate to good character?
- What is Data Integrity?
 - The maintenance of, and the assurance of the accuracy and consistency of, data over its entire life-cycle

Scenario

- You need to drive to Sharon Springs
- You're running late
- You are guaranteed that there will be no police on the road for the entire trip
- How fast do you drive?

Laboratory Scenario

- You need to get sample results out by 2 p.m.
- The test you are performing takes 4-6 hours of prep, analysis and documentation
- You have an appointment in the afternoon
- You are guaranteed that there will be no supervisors, other analysts, or inspectors in the laboratory
- What do you do?

Data Integrity Application

Data integrity policies and procedures need to be incorporated into:

- all levels of responsibility
- training
- documenting and
- controlling and reporting results
 - 2003 NELAC 5.1.7 (2016 TNI Standard V1M2 5.2.7)

Fraud vs Improper Practices

- Both are violations of Ethical Behavior.
- Fraud is defined as intentional or deliberate falsification or fabrication.
- Types of Laboratory Fraud:
 - Falsification
 - Failure to Follow procedures

Examples of Improper Laboratory Practices

- Improper laboratory practice is usually due to improper training
 - Reading temperature from a piece of equipment instead of a thermometer
 - Obtaining data with an uncalibrated instrument
 - Unsuccessful calibration of instrument due to not knowing all the “buttons” that needed to be pushed, checked or clicked
 - Improper rounding of data/results
 - Reading burettes incorrectly (not using bottom of meniscus)

Examples of Fraudulent Actions

- Intentionally writing results without performing the test or procedure (dry lab)
- Intentionally reporting good QC results when they are bad
- Intentionally logging the wrong times/dates
- Shortcutting critical steps in sample prep
- “Juicing”– Spike manipulation
- Peak Dialing – manipulating controls

Why Fraudulent Behavior?

- Both are violations of Ethical Behavior.
- Fraud is defined as intentional or deliberate falsification or fabrication.
- Types of Laboratory Fraud:
 - Falsification
 - Failure to Follow procedures

Where can laboratory fraud occur?

- OIG report No. 2006-P-00036
- EPA and OIG identified the main areas of laboratory sampling and analysis that are vulnerable to laboratory fraud
- Focus on intentional errors

Error Type: U = Unintentional I = Intentional B = Both		Severity Rating: 5 = Most Severe 1 = Least Severe	
Description of Vulnerability		Error Type	Severity Rating
a) Sample Collection			
• Sample is mislabeled	B		4
• Sample not preserved/or no dechlorinating agent/adulteration of sample	B		4
b) Sample Tracking and Recording			
• Holding time/temp. exceeded	B		4
c) Adherence to Standard Operating Procedures (SOPs) for Analytical Methods			
• Adherence to SOP	B		4
• QA manager/lab mgmt. not knowledgeable about approved methodology	B		4
• Untrained/inexperienced analysts	B		4
d) Preparation of Samples and Standard Solutions			
• Incorrect preparations/inappropriate standards (i.e., no traceability; contaminated/expired)	B		4
e) Instrument Performance			
• Instrument response/sensitivity-needs documentation	B		4
f) Instrument Maintenance			
• Analyst/QA officer doesn't understand repair needs	U		4
• No repairs-maintenance log maintenance	U		4
• Repaired incorrectly	U		4
g) Instrument Calibration			
• Calibration curve incorrect-data biased high or low	B		4
• Calibration verification not performed	I		4
• Out of date reference materials	B		3
h) Lab Technician Performance			
• Trained analysts can falsify data	I		5
i) Adherence to Quality Assurance/Quality Control (QA/QC) Plan			
• Analysts can falsify/not performing QA/QC data	I		5
j) Data Validation and Verification			
• Not flagging data outside of acceptance criteria	I		5
• Selection of inappropriate QC acceptance criteria	I		4

Activity

- Everyone should have received five forms in a handout
- There may or may not be something wrong with each one of these sheets
- Does anything stand out?
- Are there examples of improper lab practice or fraud?

Activity

- Fraud or Improper Practice?
 - All Initial Calibration Verifications are identical
 - All the sampling and analysis times are identical
 - The temperature data for each week is identical (copy and paste)
 - Time travel: Dates are filled out that haven't come to pass yet

Consequences of Laboratory Fraud

- Loss of...
 - Time
 - Money
- Public health
- Prison (3613 criminal actions prosecuted in FY 2021)
- Fines (\$12 billion recovered in FY 2021)

Examples of Consequences

- Reliance Laboratories, Inc. (RLI) admitted to falsified data due to inoperable laboratory equipment for a municipal drinking water lab.
 - Jan 30, 2023, owner of RLI faces up five years in prison and a \$250,000 fine.

Examples of Consequences

- Post Rock Rural Water District (Ellsworth, KS)
 - Former Post Rock employee pleaded guilty to hacking and tampering with the water districts treatment computer system in 2019
- EPA and FBI have recommended a prison sentence of 12 months

Examples of Consequences

- Employee of Wamego Wastewater Treatment Facility knowingly discharged untreated or inadequately treated sewage into the Kansas River.
- Includes 19 counts of falsifying data in DMR reports.
 - Faces up to five years in prison and \$10,000 fine for each of the falsification counts
 - Potential health risks

What is your responsibility?

- **Everyone** is responsible for ensuring ethics in the workplace
- Annual Training on ethics and data integrity
 - Don't just check the box
- Do the right thing
 - The reputation of the company depends on it
 - Your personal and professional reputation depends on it
 - If you don't know what the right thing is, **ask**

What is your responsibility?

- 2003 NELAC 5.4.2.6 & 5.5.2.7 (2016 TNI 4.2.8.1 & 5.2.7)
 - Annual ethics and data integrity training
 - Signed data integrity documentation
 - In depth, periodic monitoring of data integrity
 - Data integrity procedure documentation
 - Organizational mission and its relationship to analytical reporting, data integrity and record keeping
 - Specific examples of ethical behavior breaches

In Depth, Periodic Monitoring of Data

- What is periodic monitoring of data?
- What does a review signature/initials mean?
- How does anyone else know what data has been monitored?
- How does anyone else know what data monitoring means in your laboratory?

Contact Information

- **ELIPO Office**
kdhe.elipo@ks.gov | 785-296-3811
- **Laboratory Improvement Specialist: Matthew Jones**
Matthew.Jones@ks.gov | 785-296-6918
- **Laboratory Improvement Specialist: Amy Suggitt**
Amy.Suggitt@ks.gov | 785-296-1196
- **Certification Program Manager: Carissa Robertson**
Carissa.Robertson@ks.gov | 785-291-3162

Questions and Thank You



Matthew Jones
Matthew.Jones@ks.gov
785-296-6198

kdhe.ks.gov/1117