

Laboratory Ethics and Data Integrity
Why should we care?

Oregon Technical Advisory Committee (OTAC)

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TNI Standard

2009 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”

Ethics and Data Integrity Training

Program Overview

Define Ethics

Define Improper Laboratory Practice

Define Laboratory Fraud

Why Act Ethically

Why is Ethical Behaviour Important

Real Cases, Examples and Case Studies

Ethics Defined

A system of moral principles governing the appropriate conduct for a person or group

Being honest and straightforward not lying or cheating

Doing the right thing

A code of conduct

- ACS web page "The Chemical Professional'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

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.

1. Omission – drop a point in a calibration to make the curve look better.
2. Manipulation – manual integration
3. Alteration - taking a pH reading before the probe has stabilized to get a better result even though the procedure says to wait.

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.

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 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

Why Talk about Improper Laboratory Practices and Fraud

The EPA takes these things very seriously

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

- Arizona 2006 – 20 cases of severe improper procedures, including fraud, during audits of over 140 laboratories seeking certification from the State (about 1 in 7 laboratories)
- Currently the OIG has 52 laboratories under investigation

Real Life Events

The Crime

An EPA investigation found that a wastewater treatment plant had committed fraud by falsifying MPN results to appear within control when they were not.

The investigation was initiated after a whistle blower reported that the plant manager appeared to be altering MPN results for plant discharge.

The EPA OIG found evidence of fraud and went to trial. The plant manager was found guilty and sentenced to 10 years in jail.

The Twist

The municipality hired a consultant to come in and fix the MPN problem

The consultant found that in fact the plant was **not in violation**, the discharge was fine, the plant manager had been sampling at a dirty port!

Real Life Events

The Crime

A municipality contracted a consultant to take wastewater monitoring samples. The consultant was responsible for taking samples, reviewing data and submitting reports.

The municipality did a random check and found, when they opened one of the manhole covers that the ISCO sampler was there but not running and taking samples. Several other discharge points were the same.

The consultant was a small independent run by a PhD. The EPA OIG found that there was fraud and the owner was convicted and sentenced to 10 years in jail and forced to repay \$250K in fees.

The Twist

During the course of the investigation the credentials of the owner were also found to be fraudulent, she was not a PhD.

Case Study

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 . He glances at the micro samples and does not see any positives as he runs out the door.

The next morning Max looks at the samples and two of them are yellow. The yellow color indicates a positive result.

He decides to go with his original observation.

Is this Fraud or Improper Practice?

Case Study

You saw Max running out the door in the afternoon and know that he should have recorded the results yesterday.

What should you do and why?

Examples

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.

What would you do?

You are the consultant, what do you say

The laboratory discovers that the BOD analyst has been filtering the Effluent sample before setting up the test. When queried, he is doing it because he wants to lower the BOD to avoid dealing with violations and having to do extra testing over weekends and especially, holidays. The analyst learned his lesson years ago that if he did not do this, it would be many long hours for the same pay.

Examples

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 even though the SOP says otherwise.

Is this an improper practice, why, why not.

What would you advise ?

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.

Case Study

During a review of a completed Chain of Custody during an EPA audit of a treatment plant, it was noted by the EPA auditor that the sampling time was exactly the same for five different locations sampled by the same operator. Is there a problem with this?

Examples

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.

What would you advise?

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Comprehensive Ethics and Integrity Training for
Environmental Laboratory Professionals, Quality
Assurance Solutions, LLC