Your ethical muscle grows stronger every time you choose right over wrong.

~ Price Pritchett

Ethics and Data Integrity For Small Laboratories

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Who am I?

Tambra Thomas

- Suburban Laboratories, Inc. in Hillside
- Environmental testing laboratory
- Quality Assurance Manager
- Human Resources Manager
- Background

  B.S. Chemistry - Loyola University 1993

  M.S. Organizational Development - Benedictine University 2010

I wear two hats!


Alien Song
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Do you sometimes feel like that poor alien?

Do you feel like there’s so many procedures to follow in your laboratories that it seems overwhelming?

Quality Assurance

Data Integrity

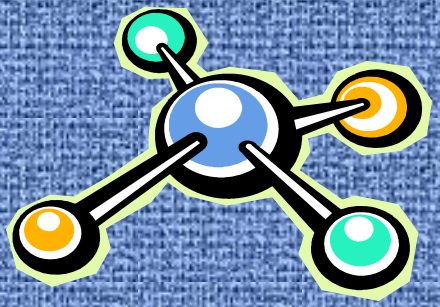
Documentation

QUALITY CONTROL

Manual Integration

Audit

Calibration



Overview

- Ethics
- Data Integrity
- Improper Practices
- Implementing a Program

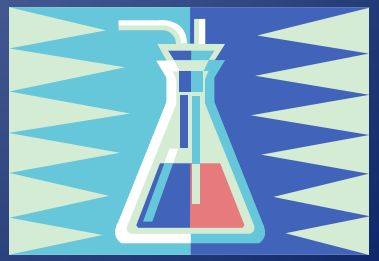
Ethics Defined

- 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

- Moral awareness/commitment



Why act ethically responsible?

- Your personal reputation and the reputation of your organization depends on 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 personal life

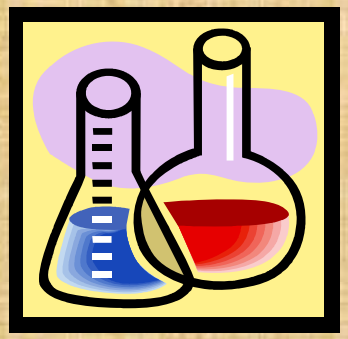
- The penalties for misconduct for you and your organization can be substantial

Benefits of an Ethics Program

- ✓ It protects the rights of the employee
- ✓ It protects the well being of the company, hence employee job security
- ✓ It clearly defines what behavior is expected of all employees
- ✓ It explains employee duties and responsibilities
- ✓ It clearly states what discipline measures the company may take if an employee commits an intentional improper practice

Goals of an Ethics Program

- ❖ Education – tool for knowledge advancement
- ❖ Motivation – what one person does can affect everyone in the lab.
- ❖ Questions can be addressed proactively



Data Integrity – Scientist's Golden Rule

- Validity of data
- Assurance that data is accurate and consistent
- Data is not breached in any way
- Quality data is produced

Another way of saying this is……

You should be able to document that the work:

- ❖Was performed
- ❖Can be authenticated
- ❖Can be reconstructed
- ❖Is traceable

How do Ethics and Data Integrity go together?

For laboratories, why do ethics and data integrity go hand in hand?

Think of it this way:

Is my data valid in all aspects? (This is data integrity)

If not, what should I do about it? (This is ethics)

NELAC Certification Requirements for Ethics and Data Integrity

- Section 5.4.2.6 of Quality Systems
- There are 4 required elements within a data integrity system:

  1. Data integrity training

  2. Signed data integrity documentation for lab employees

  3. In-depth, periodic monitoring of data integrity

  4. Data integrity procedure documentation

Fraud vs. 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 an honest mistake is simply lack of proper documentation.

Laboratory's Responsibility

- Continuously monitor data
- Provide clear guidance and policies for ethical behavior
- Provide ongoing training to employees
- Perform investigations if a problem is detected
- Eliminate undue pressure on analysts – quality before turn around time
- Provide mechanism for confidential reporting

Employees' Responsibility

- Uphold the ethics policy as demonstrated in their daily conduct.
- Seek help when the proper course of action is unclear or unknown to them.
- Be aware of situations that could result in actions that are improper, illegal, unethical, or otherwise in violation of the ethics and data integrity policy.
- Report violations of the ethics and data integrity policy to their supervisor.

Why do improper practices occur?

- To avoid rerunning samples
- To avoid instrument maintenance
- To avoid missing sample holding times
- To avoid getting in trouble
- To avoid looking bad

An Ounce of Prevention

Document, document, document! (very, very important)

Ask your supervisor if you have any questions or doubts.

Always follow the method/SOP as it is written…revise the SOP if needed.

Take the time to do it right; don't take short cuts.

Remember

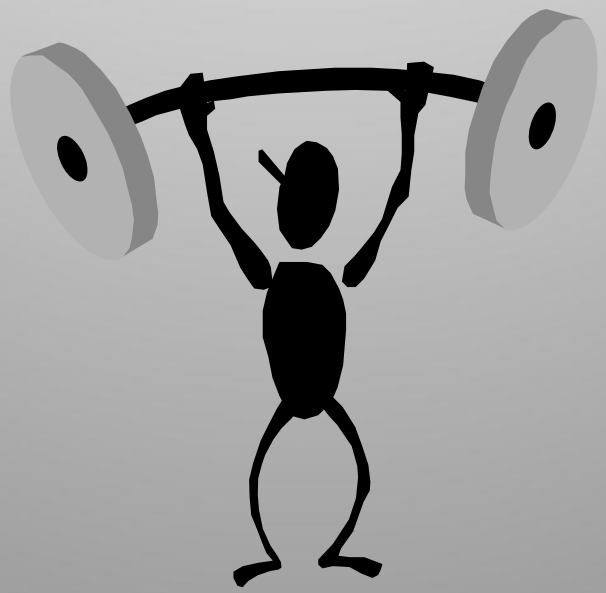
It is ok to make a mistake.
It is not ok to hide that mistake.

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.

Good communication is the key to prevention of problems.

Laboratory Fraud: Deterrence and Detection

A strong reinforced ethics training program is one of the key cornerstones to an effective "total ethical process."



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.

Examples of Improper Practice

- Dry Labbing
- Write overs
- Juicing
- Time Travel
- Improper manual integration
- Dropping calibration standards
- Inappropriate changes in concentrations of standards
- Improper GC/MS Tuning
- Unwarranted manipulation of computer software

Real examples – What would you do?

You're doing alkalinity analysis. You're in the process of standardizing the acid, and you just titrated past the endpoint. If you have to start all over it's going to take another hour of work. You know how much you overshot the mark by, you could estimate the number. Besides, it all comes out in the calculation, doesn't it?

Real example – What would you do?

The ICP instrument isn't working again. You just can't get the lead run to work. It's time to do the EPA report, and you know that the secondary effluent lead will be less than 5 ppb; it always is, always has been, and always will be. You'll run the test later when the instrument is working better. Just this one time, couldn't you report <5? You know that's what the value is.

Real example – What would you do?

When you're checking the morning temperatures, you realize that you forgot to record yesterday's TSS oven temperature in the book. You know you read it and that it was fine. Can you fill in the data now?

The goal is to train and sustain

- First, ***train*** employees on ethics and data integrity

- Then, ***sustain*** the program by following your guidelines and have annual refresher training

Sustaining is the key to a great ethics and data integrity program.

It’s more than just documentation. It’s the overall effort to strive to consistently follow the proper procedures.

Example: Missed BOD dilutions for a critical customer. As part of the corrective action, it was documented that project managers would communicate to the analyst any exceptions in setting up dilutions for this customer.

How do you sustain this? What happens if it’s not sustained?

What is the purpose of having a corrective action if it’s not sustained?

How do I implement a program for ethics and data integrity?

Remember NELAC requirements for implementing an Ethics and Data Integrity program:

1. Have a formal policy for ethics and data integrity (SOP with agreement form)

2. Train your employees

3. Periodically monitor data

4. Document the monitoring

How Ethics and Data Integrity training is done at Suburban Laboratories

- PowerPoint presentation
    1. One presentation is for new hires which is more detailed
    2. One presentation is for refresher training and is slightly shorter

- Yearly review of our Standard Operating Procedure

- If updates are made, revised SOP goes to all employees and they sign a training form

- Quarterly Ethics and Data Integrity monitoring

    1. Performed by the Quality Assurance Officer
    2. Consists of auditing notebooks, data packages, and possibly questioning analysts
    3. Documentation of monitoring noting what was audited and any inconsistencies noted

Remember this if nothing else….

Why again is it important to have an ethics and data integrity program?

Because it is critical to protect people and our environment. In the end, that's the ultimate goal.


The Office