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# Laboratory Ethics and Data Integrity

**Presented by**

Vicente Zuno

Biosafety Officer

# The Purpose of Data Ethics and Integrity

- To develop a proactive program for the prevention and detection of improper, unethical, or illegal actions
- To increase your awareness of Laboratory Ethics and related issues
- To ensure that you know the rules

The employees' personal reputation and the reputation of the Bureau depend on ethical actions. The decisions made by laboratory employees affect the environment in which they work, as well as the lives of others. Acting ethically can enrich employee work life, as well as their home life. Penalties can be substantial for the individual and the organization.

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# *TNI Standard

Applicable 2003 [2009] NELAC Standards
5.4.2.6 [V1M2, 4.2.8.1]

"The laboratory shall maintain and establish data integrity procedures. There are four required elements within the data integrity system:

1. Data integrity training
2. Signed data integrity documentation for all employees
3. In-depth, periodic monitoring of data integrity, and
4. Data integrity procedure documentation…"

# *TNI Standard

Applicable 2003 [2009] NELAC Standards
5.5.2.7 [V1M2, 5.2.7]

"Data integrity training shall be provided as a formal part of new employee orientation and must also be provided on an annual basis for all current employees. Topics covered shall be documented in writing and provided to all trainees..."

# Program Overview

- Define Ethics and Integrity
- Importance of ethical behavior
- Define laboratory fraud and improper lab practices
- Identify what constitutes unethical behavior
- Consequences of unethical behavior
- Identify the employees' responsibilities
- Identify the employers' responsibilities
- Examples of improper practices

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# * Definitions

## Ethics

* A system of moral principals governing the appropriate conduct for a person or group
* A Code of Conduct
* Doing the right thing, not lying, or cheating
* Being straightforward and honest

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## Integrity

* The laboratory's responsibility to meet general standards of objectivity, data quality, and ethical behavior in order to report accurate, complete, and valid information
* A highly ethical approach to testing
* Strict adherence to a standard of value or conduct

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# Why Act Ethically?

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

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# Improper Practice and Laboratory Fraud

## 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

## Laboratory Fraud

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

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# *Areas of Concern

- *Data manipulation or fabrication
- *Failure to follow SOP
- *Falsifying existing data
- *Improper calibration and verification of instruments
- *Inadequate training
- *Inappropriate data entry
- *Incomplete recordkeeping
- *Misrepresentation of QC sample results

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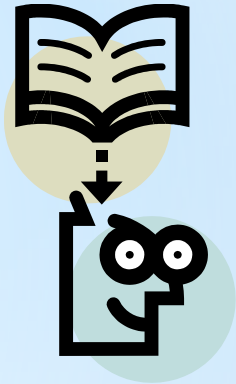
# Areas of Concern (continued)

- Improper manipulation of samples
- Mislabeled samples
- No demonstration of competency
- Improper treatment of Proficiency samples (sharing, referral, etc.)
- Reporting data for samples not analyzed (Dry Labbing)
- Selective use of QC data
- Changing times and dates (Time Travel)
- Unwarranted manipulation of computer software

# *Fabrication

- *Creating information that is not true
- *Creating data for an analysis that was not performed
- *Claiming ownership for work performed by external analysts, equipment, or facilities
- *Cutting and pasting reports and support data



## Examples:

- Subcontracting PT samples
- "Reappearing" QC results
- Recording data before starting the process

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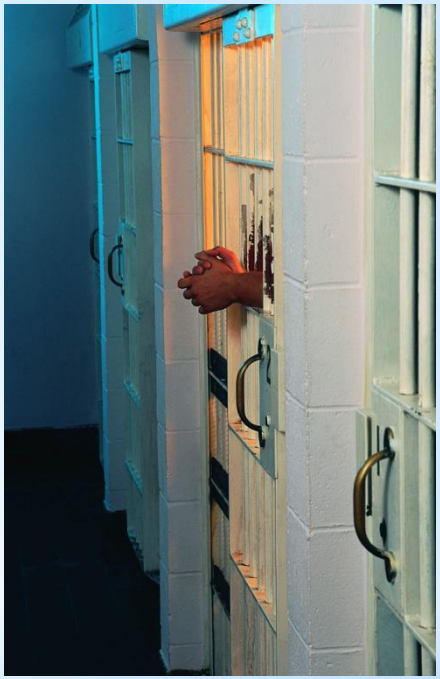
# What is Fraud?

- Fraud is purposeful and intentional
- Fraud is **not** a mistake or an accident
- 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

# What Are the Penalties for Fraud?

- Suspension or loss of Accreditation
- Civil Prosecution
- Criminal Prosecution
- Penalties can be up to 5 years in prison and/or a $500,000 fine



**Fraud has zero tolerance and is grounds for immediate dismissal**

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# Manager & Supervisor Responsibilities

- Continue to monitor data with periodic checks and audits
- Provide clear guidance and policies for ethical behavior
- Provide ongoing training
- Perform confidential investigations if a problem is detected
- Notify clients and reissue reports if data is negatively impacted
- Eliminate undue pressure on analysts
- Provide mechanism for confidential reporting of abuse without recrimination - Whistleblower Policy

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# Employee Responsibilities

- Uphold the ethics policy and practices as demonstrated in your daily conduct
- Seek help when the proper course of action is unclear or unknown to you
- 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

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# How Do I Know if a Practice is Improper?

- Does it violate policy or procedure? (SOP/QAPP)
- Mom Test – would Mom approve?
- Would an auditor approve?
- Gut check – Do I really feel this is right?
- Am I doing this so I can leave early?
- Would my Supervisor, Lab Director or QA Manager disapprove?

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# 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, QA/QC Officer, Lab Manager, or Lab Director if you have doubts or questions
- Follow the method/SOP as written or revise the SOP as necessary
- If you miss holding time or make a mistake, be honest about it - covering it up can take an honest mistake to fraud

# An Ounce of Prevention (continued)

- Don't be clever, be smart!
- In the long run it takes less effort to just follow policy than to find a clever way to circumvent it
- Don't take shortcuts
- QCs are 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
- Take your time and do it right

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* 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

# * To Be Clear…


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# Important Final Points and Summary

- It is really ***OK*** to make a mistake
- They do not lead to fraud *unless you try to hide them*
- Short term gains are not worth long term consequences
- ***Traceability*** is the operative word: everything you do must be able to be traced back from beginning to end and can be recreated
- Report inappropriate behavior, unethical or illegal practices to management
- ***Be Vigilant and Take Pride in What You Do***

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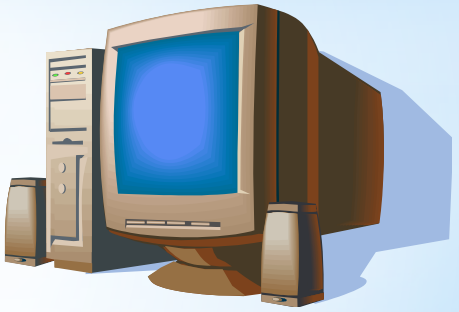
# * Examples of Improper Lab Practices



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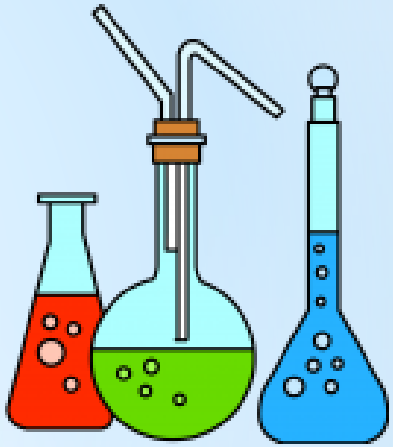
# Improper Lab Practices



* Treating batch QC different than samples
* Failing to follow SOP for prepping of sample
* PT sample not treated as a sample
* Failing to verify collection criteria (holding time, temperature, volume, etc.)
* Testing samples on an instrument that has not been calibrated
* Failure to calibrate an instrument as required by SOP
* Manipulation or deletion of data

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## Time Travel

* Altering the recorded times when samples were collected, extracted, or analyzed
* Resetting clocks on instruments or time clocks to make it appear as if samples were analyzed within holding time

## Dry Labbing

* Changing computer generated reports to represent results that were never generated
* Using results from one sample and applying them to others
* Manually entering random values for results never determined through analysis

# * Improper Analytical Procedures Data Modification/Manipulation/Selection

* The information contained in this training and the policy is not all-encompassing
* Other ethical or improper practice concerns may occur which are not specifically covered by the policy
* Each employee should try to be as honest and ethical as possible in every situation to avoid any possible problem for himself/herself or the Bureau

* **Improper practices <u>will not</u> be allowed in the Laboratory**

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# * Real Life Examples: What Would You Do?

*You notice that an instrument consistently fails to pass calibration and QC. What would you do?

A) Continue testing anyway

B) Report it to your supervisor

C) Copy and paste QC data from a previous batch run

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# * Real Life Examples: What Would You Do?

* You are taking a specimen out of the incubator and notice the temperature is out of range. When you look at the chart, the temperature has been out of range for several days, and there is no corrective action. What would you do?

A) You ignore it and return to process you specimen

B) Record that the temperature was within range

C) Report it to your supervisor

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Lab Fraud

Documentation

Integrity

Ethics

*Questions?

Prevention

Dry Labbing

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