Data Integrity and the Deterrence of Laboratory Fraud

Presented by Don LaFara, Manager Laboratory Certification Program Nevada Division of Environmental Protection

Acknowledgements':

Ted Pass Ph.D. K.L.C.P. and the USEPA Office of the Inspector General





About 34 Million 700 Thousand Hits

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How to spot a romance scammer? Top 10 Worst Scams of 2015

AARP Fraud Fighters

www.aarp.org/Foundation -

4.5 ★★★★★ advertiser rating Recognize the scam and take action to stay smart!

lab test fraud - The Hesch Firm LLC

laboratories. If you have information about lab fraud, contact VS&G.

pubs.acs.org/subscribe/archive/tcaw/10/i11/html/11regs.html -

commercial and academic settings. When the data used to gain ...

Cases of laboratory fraud have rocked the scientific world from time to time, occurring in both

Regulations and You: The long arm of the lab laws

What are Ethics ?

Ethics has to do with what my gut feelings tell me what is right what is wrong

A moral philosophy that recommends concepts of conduct

> Ethics consists of the the Rules of Conduct recognized by a culture of humans accepted by society

What is Integrity?

Adherence to moral and ethical principles

Soundness of character, honesty

Integrity is a concept of consistency of actions, values, principles and expectations

What is Data Integrity?

Data that is Technically Sound, Legally Defensible and of Known and Documented Quality

Data that is Representative, Comparable & Complete

Data that is Acquired, Validated and Meets All Quality Control Requirements

Ensuring Data Integrity

New Employees Must Receive Ethics Training

Current Employees Must Receive Annual Ethics Training Refresher

Signed Attestation on file with Training records Which Lessens the Liability of the Employer

Everyone associated with the Production of Data from Sample Collection, Final Report, Disposal Archive must Attest that they have Read and Understood their **Ethical Responsibilities**

What is Laboratory Fraud?

Intentional Mis-representation of Data to Hide Known or Potential Problems

As defined by the USEPA

Fabrication of data

Not Reporting Fraudulent Activity

Deletion of Non-Compliant Data

Falsification of Analytical Equipment Records

Misrepresentation of Any Material Fact

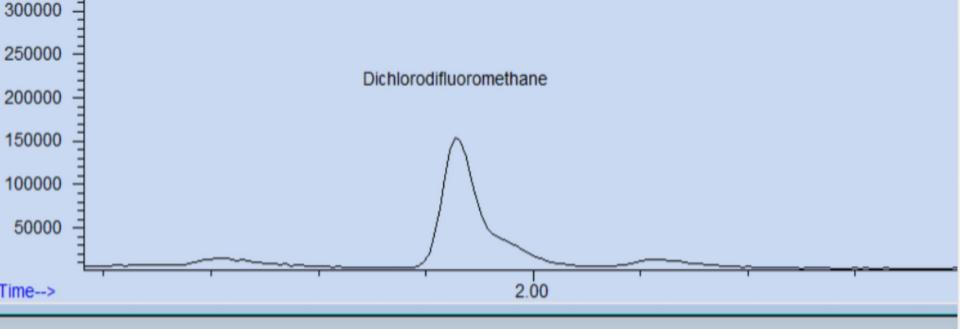
Time travel (Mint Miner)

Sometimes all it takes is an Investigation for a Lab to Lose their Reputation, Lose Business or Completely Closedown

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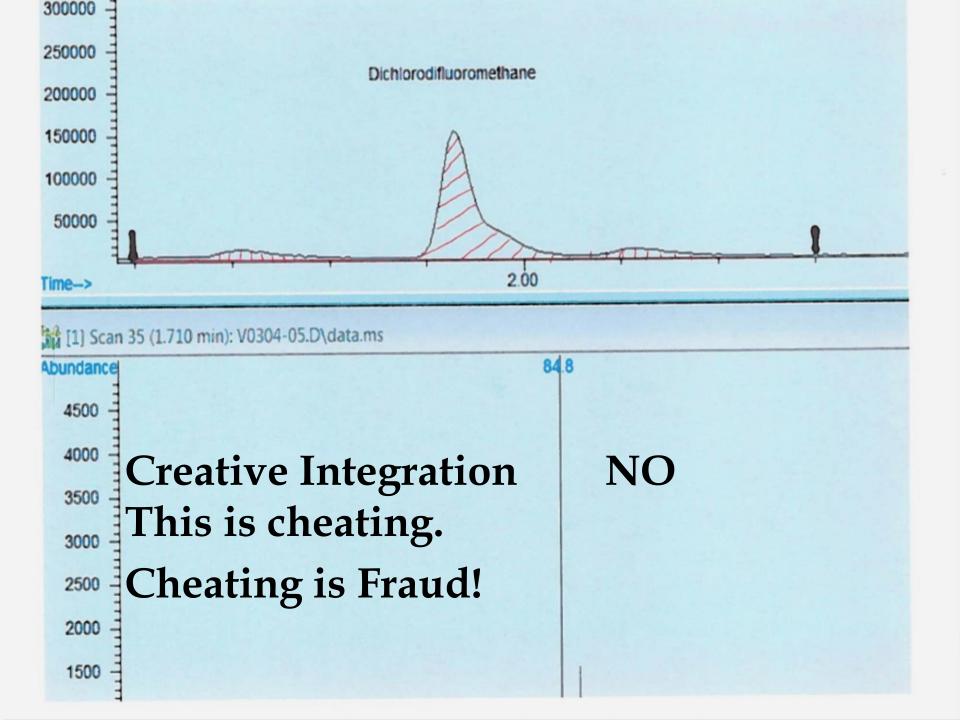
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2	Report Generation	Generated Report using option:		Mar-04-15 11:32:54	V150303S.RES
3	Quantitation	Calculation using initial calibration	V150303S.RES	Mar-04-15 13:00:02	V150303S.RES
4		Changed peak amount for Dichlorodifluoromethane from 3.53203ug/L to 3.94355ug/L	Dichlorodifluoromethane	Mar-04-15 13:00:12	V150304W.RES
5	Manual	Changed peak amount for Trichlorofluoromethane from 1.4462ug/L to 5.01462ug/L	Trichlorofluoromethane	Mar-04-15 13:00:23	V150304W.RES
6	Integration	Changed peak amount for Trichlorofluoromethane from 5.01462ug/L to 5.03369ug/L	Trichlorofluoromethane	Mar-04-15 13:00:28	V150304W.RES
7		Changed peak amount for tert-Butanol (TBA) from 24.0195ug/L to 20.8141ug/L	tert-Butanol (TBA)	Mar-04-15 13:00:45	V150304W.RES
8	State Change	From Not Reviewed to QT Reviewed		Mar-04-15 13:01:58	V150304W.RES
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Data Integrity Violations

A Breech of Ethics occurs when an Analyst or Data Reviewer Intentionally Manipulates Data improperly.

Honest Mistakes can Appear to be Fraud if they go Unreported or Covered Up **What is Laboratory FRAUD?** The deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable.

Intentional Misrepresentation of Lab Data to Hide Known or Potential Problems.

Make Data Look Better Than it Really is, With the Intent to Deceive. Usually for monetary gain.

Lying, Cheating and Stealing

Improper Laboratory Practices

Manual integrations, peak shaving, peak juicing

Manipulation of internal standards

Older instrumentation without digital print out or retrievable file generation

Improper Laboratory Practices

Intentionally mis-labeling sample collection information (NAC445A.0636) Sampler's Attestation of Authenticity

Time travel, changing the computer clock to make it appear samples were analyzed within holding time

Microbiology, hand written records

Improper Laboratory Practices

Dry Lab Results Generating Results Without Analyzing the Samples

Cherry Picking Choosing what Standards to drop or what Results not to Report

Deterrence of Laboratory Fraud The Laboratory's Values are Communicated through the Laboratory's Ethics Policy **The Ethics Policy Must be Strictly Enforced Ensure the Employee knows the Difference Between Making a Mistake and Improper Laboratory Practices**

Deterrence of Laboratory Fraud Proactive Approach Training, Documentation

I have Read, Understood and Will Abide By the Laboratory's Ethics Policy Deterrence of Laboratory Fraud Establish the Laboratory's Values and Their Commitment to Quality Ensure that All Analyst are on Board Zero Tolerence

Clarify Consequences, possible Legal Action against the Employee

Dismissal?

Deterrence of Laboratory Fraud Emphasize the Company's "Culture of Integrity"

What are the Consequences?

Fines, Incarceration?

Deterrence of Laboratory Fraud Educate, what Constitutes an Ethics Violation?

Attest to Follow SOPs, QAM and the Ethics Policy

Deterrence of Laboratory Fraud

Encourage Open Communication Open door Policy **Explain the Goals of the Organization**

What Specific Actions Constitute a Violation?

When in Doubt Ask a Supervisor

When it comes to Laboratory Fraud, one Incident can taint the Entire Organization

Types of Improper Laboratory Practices

Unintentional through ignorance or lack of training, lack of communication

Intentional with a Minor Impact on Public Health or the Environment

Intentional Jeopardizing the Public Health The EPA defines laboratory fraud as "the deliberate falsification of analytical and quality assurance results." Any number of laboratory practices may constitute fraud, including:

- Fabricating data.
- Intentionally calibrating equipment using other than accepted procedures.
- Modifying samples to alter characteristics.
- Manipulating analytical results.
- Substituting samples, files or data.
- Falsifying records of analytical instrumentation
- Deletion of non-compliant data
- Improper handling of data errors, equipment failures
- Lack of reporting unethical behavior of co-workers.

EPA Has Not Implemented Adequate Management Procedures to Address Potential Fraudulent Environmental Data EPA Office of the Inspector General (OIG)

Report No. 14-P-0270 May 29th 2014 The EPA is not ensuring that fraudulent laboratory environmental data is being communicated to appropriate program offices and data users, reviewed, and analyzed for its impact on human health and the environment. Further, the EPA Does Not Consistently Notify the States when Laboratory Due Diligence Activities can begin during a Fraud Investigation that affects a State Environmental Program. The Agency (EPA), Does Not have a Policy on Communicating Case Information to the States and other Regulating Parties during Investigations.

As a result, Laboratory Fraud Cases May Not include a Due Diligence Review. In such cases, Potentially Negative Impacts to Human Health and the Environment Due to Fraudulent Laboratory Data could go Undetected. Ineffective Oversight of laboratory data, has been Identified by the EPA OIG on many occasions. The Agency (EPA) Does Not give Fraud Prevention and Detection Adequate Attention.

Some Industry Officials point to the Declining **Market for Environmental Testing Laboratories** as a primary reason for some Laboratories to **Focus on Production Versus Quality.** When a laboratory focus is on Production rather than Quality, and is influenced by **Monetary Circumstances**, the Data Quality Suffers.

Another factor is the "One Size Fits All" approach to QA/QC was cited by Government as contributing to Lab Fraud. This approach occurs in Situations where **Specific QA/QC is defined in a Project Plan.** Labs are Aware of the Requirements yet Choose to Ignore or Intentionally Overlook the Requirements because they are viewed as too Stringent or too **Expensive and Decide to Cut Corners to Save Money.**

Cases of Laboratory Fraud have Rocked the Scientific World occurring in both Commercial and Academic settings. When Fraudulent Data is used to Make Environmental Decisions regarding Discharges into Environment, our Faith in the **Regulatory System (EPA, NDEP etc.) becomes** Questionable.

Monitoring Observations what we look for... The Use of Consumables, 100 micro results and only 50 Media Packets Used

Perfection, QC always passes

Instrument performing flawlessly, continuously with no maintenance performed

Instrumentation that Does Not Produce a Record, Printout or a Retrievable File are Problematic

Monitoring/Surveillance

Have an Open Door Policy

Encourage Analysts to Come to Management with Problems or Concerns

Don't ask the Impossible Analyst only Want to Please

Continuous in-depth Monitoring of Laboratory Activities

Spend Time in the Laboratory Make Observations

Audits Internal and External

Does it Make Sense

Consumables

Does it Add up?

Anion Cation Balance

You are judged by numbers in the lab

There is a culture of pressure to get it done with no new resources But there is no excuse for cheating at the end of the day

Lisa Jackson

Former Administrator USEPA

Case Study

Blue Marsh and McKenna caused environmental test reports to be prepared and mailed to customers which falsely stated that the proper EPA methods for analysis were being performed when, as the defendants knew, the EPA Methods for testing and analysis were not being followed and the results were false, inaccurate and unreliable. For example, it is alleged that from approximately September 2005 through October 2005, the defendants prepared and mailed false and fraudulent test results for Hurricane Katrina flood water samples which were required by EPA to be tested for contamination by various pollutants, including, among others, cyanide, and herbicides

There is no kind of dishonesty into which otherwise good people more easily and frequently fall than that of defrauding the government **Ben Franklin**

Case Study

On August 26, 2013, Tennie White, the owner and operator of an environmental laboratory located in Jackson, Mississippi, was sentenced to forty (40) months in prison with three years of supervised release thereafter, a \$1,000.00 fine and a \$100.00 special assessment, by U.S. District Judge Henry T. Wingate, in connection with her conviction for faking laboratory testing results and lying to federal investigators.

Case Study

Tanknology-NDE International, of Austin, Texas, was ordered to pay \$29 million in fines and restitution for false testing of underground storage tanks The nation's largest underground-storage tank testing company admitted the fraud at postal facilities, military bases and a NASA facility, among other sites "Knock, knock." "Who's there?" a familiar childhood refrain But When the Answer from the other side of the lab door is "Open Up, U.S. Marshals!", the day has probably taken a turn for the worse.



The Most Infamous Case of Fraud occurred at a **Toxicology laboratory in the 1970s and involved the** firm Industrial Bio-Test (IBT). IBT was a leading contract Toxicology Lab for the Safety Testing of **Pesticides, Food additives, and Drugs. At the time, IBT** conducted approximately 40% of all U.S. toxicological tests. As a result of the Fraud **Investigation**, Thousands of Industrial Chemicals had to be Re-Analyzed. 3 Company Officers were **Found Guilty of Mail Fraud and Making False** Statements to the Government. After a 6 month trial, 1 defendant was sentenced to a year in prison followed by 4 years probation; 2 others were sentenced to 6 months in jail and 2 years probation.

Things you Should Not Do if You Work in a Lab

• Mislabel Samples - Time, Date Collected - Preservatives

- Censor Information Only Report Data that Looks Good
- Manipulate Data Massage the Muscles not the Data
- Improper Calibration Dropping Points off the Curve
- Inappropriate Manual Integrations Moving base lines (IS) Deleting peaks, Run the same sample twice & calling it a duplicate, Peak
 - Shaving, Peak Juicing,
- Overwriting Files Instrument Tuning, Dirty blanks, Failed QC
- Falsifying Records The Standard Prep/QC Records
- Temperature Records, Balance Calibrations, Maintenance Records etc.
- Report Data when the Sample Was Never Analyzed
- Take Shortcuts Skip steps to save time, run more samples
- Make False Statements in a Narrative

Things you Should Do if you Work in a Lab

• Always Tell the Truth, The Analyst's Integrity is Paramount

- If You Make a Mistake Tell the Supervisor or Start Over
- Don't Take on More than you Can Handle
- Follow the SOP and Ensure the SOP Follows the Method
- If You Need Help Ask for it
- Uphold the Company's Core Values,
- Maintain Competence and Proficiency as an Analyst
- Take Pride in your Work
- Maintain your Equipment, Document Maintenance Activities
- Conduct yourself in a Professional Manner
- Create a Working Environment Conducive to Ethical Conduct and Professionalism
- Ensure that employees feel free to Express any Ethical Concerns
- Work to create an Environment Free From Harassment or Coercion of any kind, especially to perform illegal or unethical acts and discrimination on the Basis of Race, Creed, Color, Sex, Ethnic Origin, Age or Disability

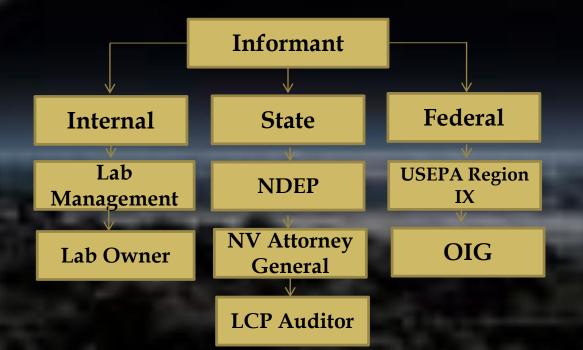
If You Commit Lab Fraud What Criminal Charges can you Expect?

- If the Results of your Fraudulent Data are Sent through the US Mail or by a Commercial Interstate Carrier, the Charge is Mail Fraud (30 yrs 1 million)
- If Your Results are sent via Facsimile, you Will be Charged with Wire Fraud (20 yrs 1 million)
- If You Results are Presented to the US Government You will be Charged with Attempting to Defraud the US Government (10 yrs. 5 million or both)

In Addition to the Charges just cited, You can also be Charged with Making False Statements, Concealing a Material Fact, Obstruction of Justice. (10-40 yrs. Fines are based om the severeity of the Crime) Think About the Possible Consequences Before you Act If there is the Slightest Doubt What Your Doing Could be Considered Improper Laboratory Practice Ask Your Supervisor And Get Their Response in Writing If they Don't want to Put it in Writing Use Your Chain of Command

How to Report Suspected Laboratory Fraud

USEPA OFFICE of the Inspector General (OIG)



Report Fraud Waste and Abuse

Report Fraud waste and Abuse

Nevada Division of Environmental Protection (NDEP) 901 S. Stewart Street STE 4001 Carson City NV 89701 Telephone: (775) 687-9491 Fax: (775) 687-5699

Las Vegas Office: Office of the Attorney General Grant Sawyer Building 555 E. Washington Avenue, Suite 3900 Las Vegas, NV 89101 Telephone: (702) 486-3420 Fax: (702) 486-3768

Carson City Office: Office of the Attorney General 100 North Carson Street Carson City, NV 89701 Telephone: (775) 684-1100 Fax: (775) 684-1108

US EPA

Pacific Southwest, Region 9 75 Hawthorne St. San Francisco, CA 94105 Telephone: (415) 947-3553 Fax: (415) 947-3553

Office of Inspector General 1200 Pennsylvania Avenue, N.W. (2410T) Washington, DC 20460 Telephone: (202) 566-2391 Fax: (202) 566-2549

US EPA Enforcement and Compliance Assurance (OECA) Mail Code 2231A 1200 Pennsylvania Ave Washington, DC. 20460 Telephone: (202)-564-2440

Questions?