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**Environmental Testing Data Integrity Issues  
and Prevention Programs**

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# Abstract

When you have an environmental decision pending, whether it's a determination for regulatory compliance, extent of contamination, remediation status, or background characterization, you depend on a qualified and ethical environmental laboratory for your analytical test results.

Are all environmental laboratories equivalent and to be treated as a commodity? In a world driven by better, faster and cheaper, you need to be confident that your laboratory's quality and data integrity systems provide data suitable for making the correct decision.

This presentation provides an overview of environmental laboratory quality assurance systems and data integrity programs. It provides background information on data integrity issues seen in the industry over the years and how to detect, deter and prevent them. Finally, it will be a guide for evaluating your risks in a laboratory selection decision.

# Outline

- Historical context: Why do we need a data integrity program
- Types of Data Integrity Issues
- Potential Causes or Red flags
- Prevention and Deterrence
- Consequences for unethical behavior
- Lab selection

# Historical Context:

- 1980's: emergence commercial environmental laboratory industry
- First convictions and sentencing of laboratory owners and analysts for falsification, fabrication and inappropriate manipulation of environmental data and reports.
- New Lingo for familiar fraudulent practices surface:
  - Time traveling
  - Juicing
  - Peak shaving
  - Dry-Labing

# Historical Context:

- 1990's Rapid consolidation of the commercial laboratory industry
- Electronic processing, instrument automation advances, competition stiffens, and analytical prices drop.
- FBI raids on laboratory facilities become more frequent and common.
- Numerous arrests, convictions, fines resulting in jail sentences and laboratory closures.

# Historical Context

- 1990's fraud uncovered at Government Laboratories
  - Greed alone doesn't explain why people resort to unethical behavior



***September 5, 2001***

***EPA OIG Open Letter to the  
Environmental Laboratory Community***

# EPA OIG Open Letter

In an open letter, EPA Inspector General requests the laboratory community to strengthen Data Integrity programs and quality systems.

- An open call to help stamp out unethical behavior, and
- Build confidence in the environmental laboratory industry.

# EPA's 2001 OIG Letter Key Points

- Draw everyone's attention to misconduct or unethical practices in analytical laboratories
- The EPA OIG has seen an increase in the number of allegations that environmental laboratories inappropriately manipulate laboratory data.

# EPA's OIG Letter Key Points

- To deter these practices EPA-OIG is working closely with EPA's Criminal Investigations Division, other federal investigative organizations, and the Department of Justice to investigate and, as appropriate, prosecute all allegations of laboratory fraud.
- These efforts to date have resulted in substantial fines, penalties, incarcerations, federal suspension and debarment actions, and laboratory closures.
- A laboratory's best protection against fraudulent activity is the effective implementation of strong, proactive, and independent ethical practices and Quality Systems.

# EPA's OIG Letter: Request of the Environmental Laboratory Community

- Create a corporate environment conducive to quality operations, ethical standards, personal integrity, and accountability.
- Plan for routine “down-time” to perform instrument maintenance and repairs to meet method quality control requirements.
- Acknowledge that improving quality promotes profits and an *increase* in business because a reputable laboratory *attracts* business.

# Historical Context

- 2000's -Today: Continued consolidation, mergers, acquisitions and bankruptcies.
  - Continued ethical lapses, inappropriate data manipulation, fraud and criminal actions, penalties and settlements.

# Causes of Unethical Behavior

The root causes for data integrity problems are very complex; simplistic views are often erroneous:

- Greed
- Undue Pressure
- Stupidity
- Ignorance
- Arrogance
- Laziness

***It goes beyond this!***

# Pressure Points

The environmental laboratory industry is highly complex, sophisticated and regulated with daily pressures:

- Demanding Client Programs and Regulations
- Compressed Turn Around Time (TAT)
- Meeting Holding Times
- Passing Stringent Quality Controls and Method Requirements
- Competition
- Cyclical Workload
- Revenue Goals
- Business Sustainability

# Questions to Ponder

- Is environmental testing a commodity?
- What's the cost of an ethical breach and is it considered in the procurement decision?
- Does laboratory certification protect you from the liabilities of an ethics breach?
- What factors should be considered in your Laboratory selection beyond the \$?

# What to Look for in your Laboratory beyond the \$

- Demonstrates strong commitments to ethics and data integrity
- Invests in people, technology and facilities to drive quality and efficiency improvements
- Willing to admit mistakes and makes corrections even when difficult, embarrassing or painful
- Participation in the industry's communities: ACIL, TNI, EDQW, etc.
- Certification and data quality and integrity systems
- **What else?**

# NELAC Key Data Integrity Elements

- Four required elements:
  - ~ Data Integrity Training
  - ~ Signed Data integrity documentation for all staff
  - ~ In-depth Periodic Monitoring of data integrity
  - ~ Data integrity procedure documentation
- Plus:
  - ~ Laboratory management shall provide a mechanism for confidential reporting of integrity issues in the laboratory.

# **Data Integrity and Unethical Practice Deterrence**



# Organize for Ethics and Quality

- ✓ Ethical leadership begins with the Owner, CEO and Senior Managers
- ✓ Ethics Policy with clearly defined do's and don'ts
- ✓ Annual ethics training and continual communication on appropriate behavior and expectations for all staff
- ✓ Signed ethics agreement and commitment from all staff
- ✓ Provide alternative chain-of-command reporting routes for reporting unethical behavior
- ✓ Create “Hotlines” for confidential & anonymous reporting of data integrity issues available to staff

# Data Integrity Leadership

## Express Core Values

***Integrity*** - We adhere to the highest moral and ethical principles **in all that we do.**



# Leadership Messaging

*“Data quality and legal defensibility are critical factors for our clients and for TestAmerica. Compliance with data integrity rules supersedes all other requirements and is the cornerstone of our reputation.”*

– *Rachel Brydon Jannetta, CEO*



# Create a Good Work Environment

- ✓ Create an atmosphere where problems are brought forward and addressed rather than hidden
- ✓ Prevent “Undue Pressure”, or pressure without relief or recourse.
  - ❖ Report Narrative
  - ❖ Stop work authority for all employees
  - ❖ Data integrity line available to all staff
  - ❖ Data recall notification process
  - ❖ Out-side of chain-of-command reporting process

# Organize for Ethics and Quality

- ✓ Employ independent and uninhibited quality assurance staff for observing, assessing and reporting on operational activities
- ✓ Data authenticity assessments of analyst work product and instrument raw data
- ✓ Electronic data monitoring
- ✓ Electronic audit trail monitoring for being turned on
- ✓ Monitor compliance with manual integration policies

# Develop Policies and Procedures

- ✓ Have detailed up-to-date standard operating procedures (SOPs) describing analytical methods
- ✓ Automate methodologies
- ✓ Secondary data verification reviews and supervision
- ✓ Document analytical decisions in run logs, maintenance logs, case narratives, corrective action reports
- ✓ Data qualification and data recall procedures
- ✓ Record retention, archival and disposal practices
- ✓ Policy for appropriate manual integration

# Peak Integration Examples

- ✓ All employees working on chromatographic data systems must be trained in “acceptable manual integration practices”
- ✓ The Training must include examples of appropriate and inappropriate integrations.
- ✓ Supervisors and/or peers review manual integrations

# Notify or Potential Punishments and Penalties for Improper, Unethical or Illegal Actions

- Any person in violation of the Data Integrity is subject to disciplinary action, which can include termination.
- In addition, any wrongdoing which relates to work under a government contract or subcontract could also subject you to the potential for prosecution under federal **law**.

# Communicating Consequences

- Possible downward spiral
- Damaged reputation
- Loss of business
- Less than desirable financial performance
- Potential loss of jobs
- Potential lab closures
- Potentially huge financial penalties,
- Impact on our clients, environment and Public Health.
- All bad things!



***People that have falsified data have received both civil and criminal convictions. Some are convicted felons, and some are serving jail time.***

# Key Take Away Messages

- Data Integrity is vital for the Environmental Industry.
- All Laboratories must have Ethics Policies and data integrity programs.
- All labs must ensure reported concerns are fully investigated.
- Look for companies that:
  - Train all employees in ethics and data integrity practices
  - Require employees to sign Ethics Statements
  - Have strong independent Quality Assurance staff.



# The Risk of Relying on Accreditation alone

- Accreditation audits occur every 2 or 3 years with surveillance assessments in-between
- Some States, Agencies or Accreditation Bodies dig deeper than others
- Accreditation verifies the required minimal elements of the Quality Standard, and not necessarily the effectiveness or efficiency
- Audits are a snap-shot in time, lab conditions can change and deteriorate rapidly

# Conclusion



- Have you been in your laboratory lately; beyond the sample receiving doors?
- Is your laboratory meeting your needs?
- You deserve to have your samples analyzed by trained and qualified professionals at modern facilities with quality and ethics that you can trust!

# QUESTIONS?