



Department of Health  
*Legal Counsel*

June 10, 2011

David C. Sleigh, Esq.  
Sleigh & Gary  
364 Railroad St., Ste. E  
St. Johnsbury, VT 05819-1688

Re: Supplemental Discovery  
DataMaster

Dear David:

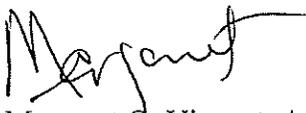
In response to your e-mail request, dated May 24, 2011 for supplemental materials in connection with the pending DataMaster litigation, I enclose the following records in response to the specific questions you posed, as follows:

- a. List of all previous investigations either initiated by Ed Luce, or involving his participation, in addition to the three investigations that were explicitly requested by DOH management.  
*Mr. Luce did not initiate or conduct any other investigations. In his deposition he did testify that the BAC datamaster investigation was initiated by him.*
- b. A copy of the complete investigation file, including any final reports and conclusions, for the investigation of the Calibration of BAC DataMasters (December 2008).  
*See records attached marked as "B." All other records were previously provided to you.*
- c. An organization chart with reporting relationships, titles, and individuals identified, for DOH laboratories as it was in effect on 1/28/2010; and an organization chart with reporting relationships, titles, and individuals identified for DOH laboratories as it exists today.  
*See records attached marked as "C."*
- d. A copy of all available documentation for all Corrective Action Reports related to activities identified during or as a result of the ethics investigation.  
*These records were previously provided to you.*
- e. A copy of all available records documenting the scope and delivery of annual ethics training to laboratory personnel during the period 2007-2011.  
*See records attached marked as "E."*
- f. A copy of records documenting the composition of the Laboratory Ethics Committee during the period 2010-2011.  
*There is no named committee.*
- g. A copy of meeting minutes for each of the Ethics Committee meetings, scheduled to be held on Jan. 2010, Apr. 2010, Jul. 2010, Oct. 2010, Jan. 2011, and Apr. 2011.  
*There were no committee meetings held on Jan. 2010, April 2010 or July 2010..*

- The procedure was rewritten in September of 2010 and an Ethics Committee was no longer in the procedure so there were no meetings held.*
- h. Records identifying the laboratory's Ethics and Compliance Officer(s) during the period 2010-present.  
*See records attached marked as "H."*
- i. A copy of any available documentation related to the post-investigation meeting between management and Darcy Richardson and Amanda Bolduc.  
*These records were previously provided to you.*
- j. A complete copy of the complete investigation file, including records reviewed during the course of the investigation, and all records generated during the course of the investigation.  
*These records were previously provided to you.*
- k. A copy of Approval History sheets showing signatures indicating current approvals for each of the procedures provided by the DOH that were ever formally implemented (the required approval history sheets were not provided for any of the procedures provided to date; in the absence of these records, they must not be considered to have been formally implemented).  
*See records attached marked as "K."*
- l. A copy of all correspondence and records of DOH communication (e.g., phone logs, maintenance log entries) with NPAS during the period 2010 – present.  
*A CD is attached and the e-mails are from January 2011 –present pursuant to your voice mail of June 8, 2011*
- m. A copy of all available training and qualification records regarding Mr. Luce's assignment as a Quality Systems Specialist.  
*These records were previously provided to you.*
- n. A copy of all available training and qualification records regarding Mr. Harnois' competence to perform his assigned duties.  
*See records attached marked as "N."*

The enclosed records should satisfy this supplemental request. Please let me know if there is anything else you require.

Sincerely,



Margaret O. Vincent, Assistant Attorney General  
Vermont Department of Health

Enclosures

Cc: Stuart Schurr

10/10/08 ~ 3:30 pm

- discussion w/ AB about data confidence
- discussed w/ AB & DR about my responsibilities in this situation

10/14/08 E. Chem Meeting

- New Kit C w/  $\text{F}^-$  (now in effect)
- Add Fluoride to Kit C in LIT F (last det.)
- enter QC materials as samples into LITS/STARLIMS

3

10/23/08 - continued discussion  
w/ AB & DR

□ Set-Up Corrective Action Training  
for 10/31/08

10/24/08

□ Cal Std (vs) Calibration Check  
Std (vs) Field Sim Sol'n

□ TSTI - tech support inquiry  
like instrument  
maintenance logs.

□ DMT will not have 1<sup>st</sup>  
issue b/c cal w/ 0.101  
and check w/ 0.02, 0.08,  
~~0.04, 0.08~~ 0.16, 0.40

□ Acetone check in field

~~Bob share info  
then Steve.~~

10/28/09 Meeting w/ Stella & Bob about  
Data Integrity in DataMaster Program  
& discussions w/ AB & DR

□ per Bob - procedure was followed  
correctly for setting-up, calibration,  
linearity check and field installation  
of DataMaster Ser # 881109

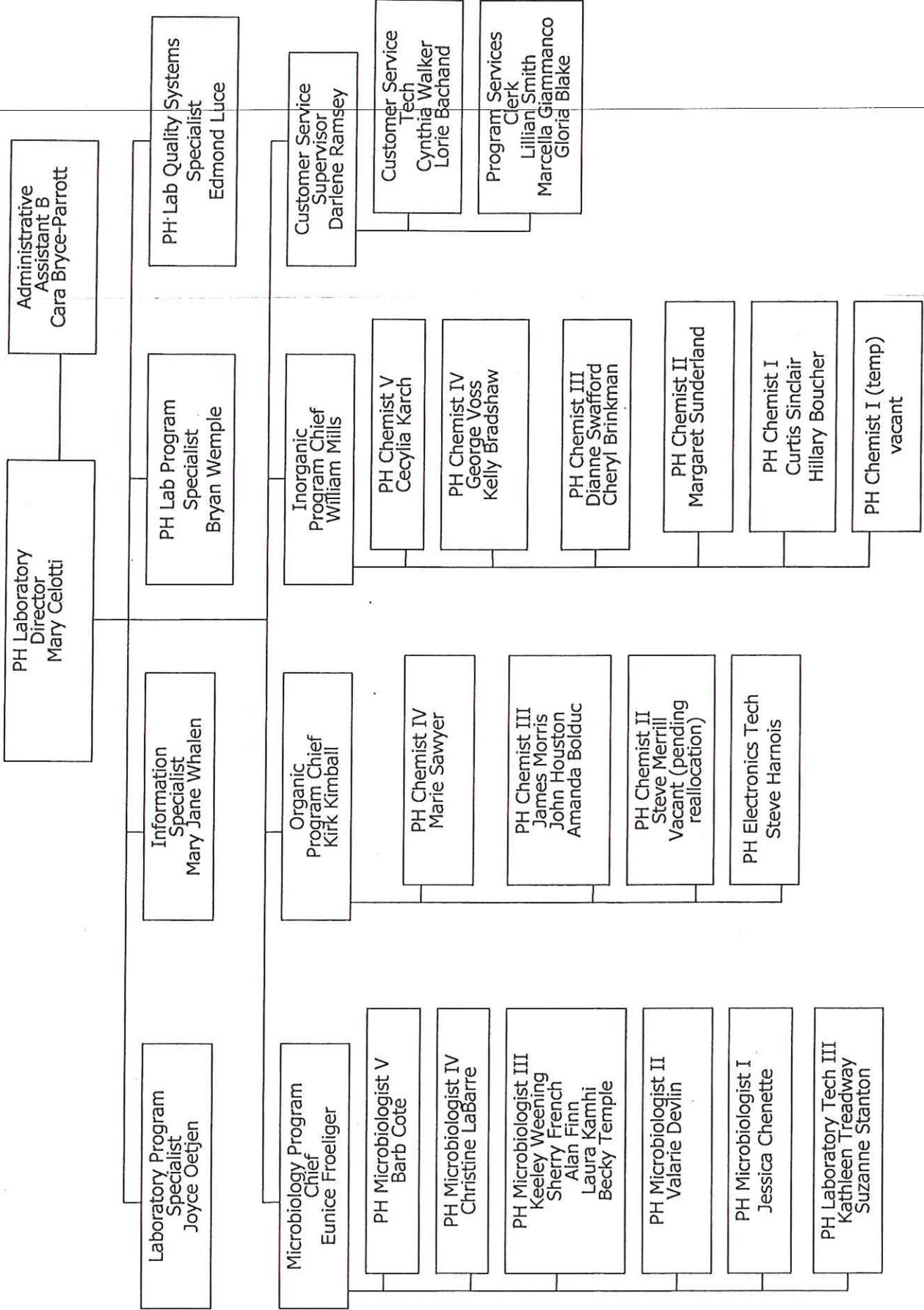
□ Bob will research documentation  
in procedures

□ I will write summary of investigation  
to be shared w/ Bob & Stella.

10/29/08 Supervisor's Meeting

877-777-8540

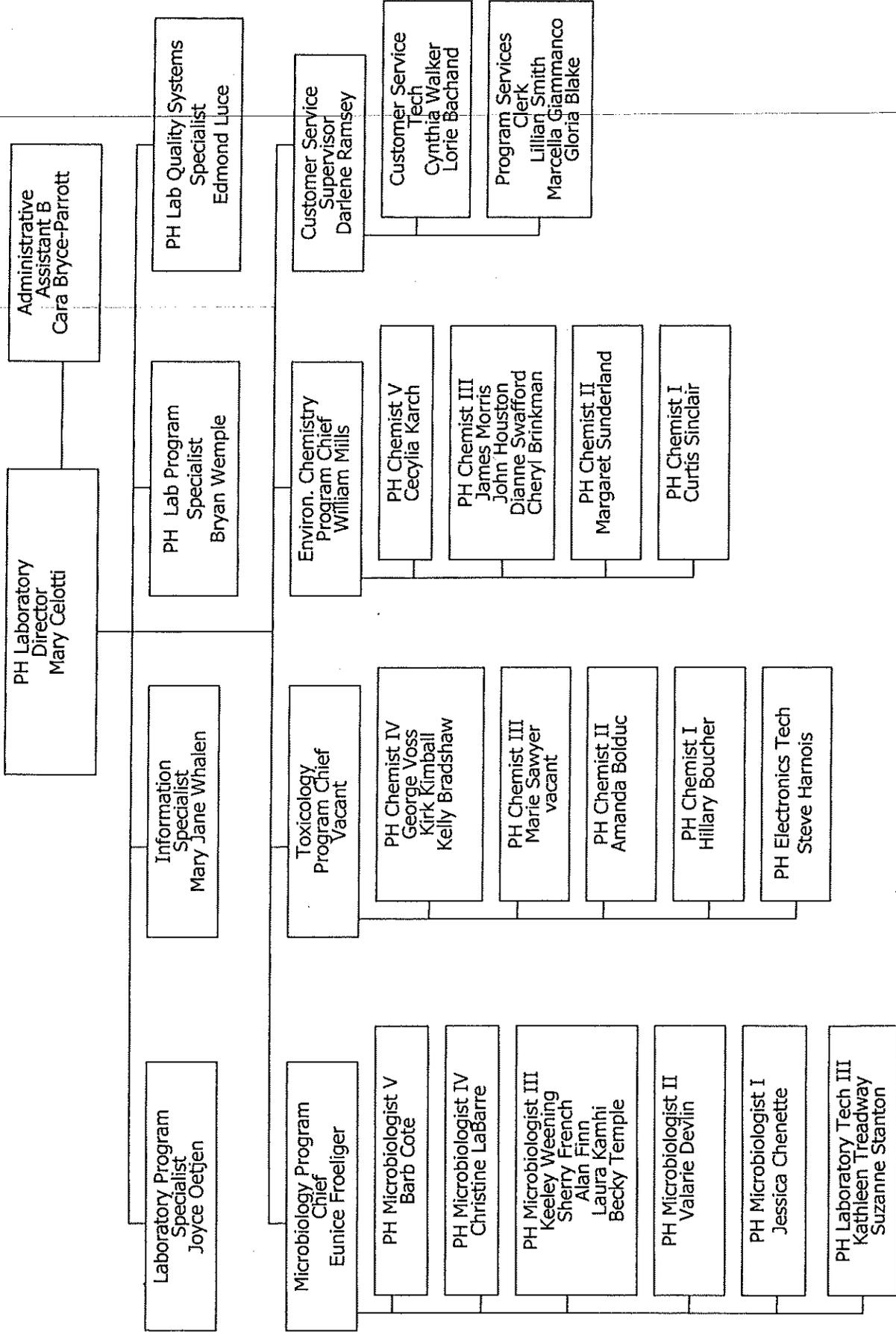
Vermont Department of Health  
 Organizational Chart  
 DIVISION OF HEALTH SURVEILLANCE – PUBLIC HEALTH LABORATORY



Vermont Department of Health  
Organizational Charts

CURRENT

DIVISION OF HEALTH SURVEILLANCE – PUBLIC HEALTH LABORATORY



Preventing Improper Environmental Lab Practices and Advanced Topics in QA  
October 16, 2007 Burlington, VT 588-415-07

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October 16, 2007 Burlington, VT 588-415-07

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Preventing Improper Environmental Lab Practices and Advanced Topics in QA  
October 16, 2007 ..... Burlington, VT- 588-415-07

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**Preventing Improper Environmental Lab Practices and Advanced Topics in QA**  
**October 16, 2007** **Burlington, VT 588-415-07**

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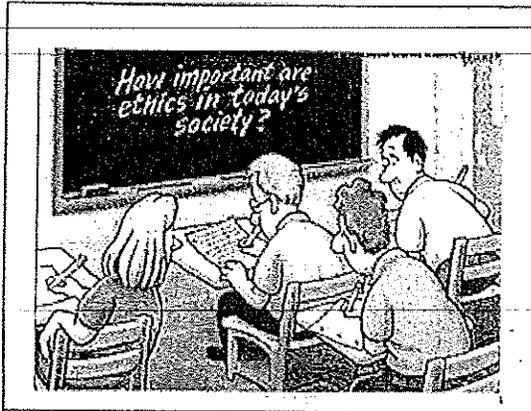
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Vermont Department of  
Health Laboratory Ethics  
& Data Integrity Training

January 4<sup>th</sup>, 2008

© 2008 Vermont Department of Health

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Introduction

- Ethics
- Data Integrity

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### Ethics

- Set of Moral Principles
- Recognized Rules of Conduct
- "Do the Right Thing"

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### Data Integrity

- Sample Identity
- Conditions
- Analyze in a Controlled & Documented Manner
  - Traceability
  - Historical Reconstruction

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### Why Do We Need an Ethics & Data Integrity Program?

- Current Events & Environment
- Current Customer Expectations
  - Quality
  - Confidence
  - Trust
- Accreditation & Regulatory Authorities
  - American Council of Independent Laboratories (ACIL)
  - National Environmental Laboratory Accreditation Conference (NELAC)

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### Pre-Requisites for Ethics Program

- Mission Statement
- System of Administrative Policies
  - Quality Systems Manual
  - Business Ethics & Data Integrity Policy
- Clearly Defined Procedures
  - Accessioning & Sample Acceptance
  - Analytical SOPs
- Training

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### Requirements for Ethics Program

- Self-Governance
- Ethics & Compliance Officer
- Training
- Enforcement
- Anonymous & Confidential Reporting of Alleged Misconduct
- Procedure for Investigation
- Documentation ...

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### Requirements for Ethics Program

- Documentation of Alleged Misconduct
- Documentation of Summary Report
- Procedure & Guidance for Recalling Data
  - Amended Reports
- Corrective Actions
- Internal & External Monitoring Systems

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## Consequences

- External
  - Loss of Accreditation or Certification
  - Criminal Charges
  - Financial Repercussions
- Internal
  - Oral or Written Admonishments
  - Suspension or Termination

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## Examples

- Fabricating Data or Falsifying Laboratory Records
- Misrepresentation of QC Results
- Manipulations of Calibration Data
- Substituting Sample Files or Data
- Conflict of Interest
- Fraud – Deliberate Deception Practiced to Secure Unfair or Unlawful Gain

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## Summary

- VDHL's Business Ethics & Data Integrity policy applies to every laboratory activity
- Both Clinical & Environmental Laboratory Accrediting Authorities are incorporating policies to increase the credibility of laboratory results
- If "Something" does not feel right, then ask for assistance or guidance

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### Conclusion

- It is difficult to cover every ethical situation that may arise
- High Ethical Standards are Critical to the Maintenance the Public's Trust & Confidence
- Each one of us is Responsible to Conform to this Policy & Legal Regulations
- Framework of Honesty, Integrity, Dignity, and Loyalty

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### Where to Get More Information

- Seagull/Public/Document Control/General/QS Manual/QS Manual April 2006/QA108 Ethics & Integrity
- *The Environmental Laboratory Data Integrity Initiative Policy Statement* by The Data Integrity Committee of the Environmental Science Section of the American Council of Independent Laboratories, January 2003 at [http://www.acil.org/associations/1304/files/Data Integrity158668.pdf](http://www.acil.org/associations/1304/files/Data%20Integrity158668.pdf)
- NELAC Standard 2003 (cleaned-up) at <http://www.nemc.us/epa12/pdfs/NELAC%20Standard032406.pdf> in section 5.5.2.7

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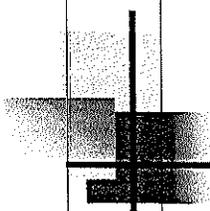
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# Annual Ethics Training for Environmental Labs

Presented by: Marlene Moore  
mmoore@advancedsys.com

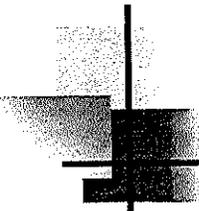
March 12, 2009



# Objectives

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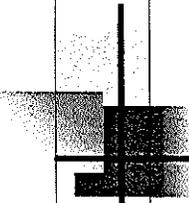
- List the elements of data integrity training
- Review laboratory vulnerabilities



# This Training

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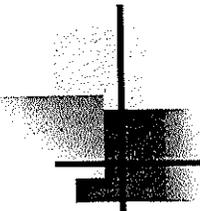
- Organizational mission and its relationship to the critical need for honesty
- Full disclosure in all analytical reporting
- How and when to report data integrity issues
- Recordkeeping



# Mission of Laboratory

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- Be Honest and Impartial
- Strive to Increase the Competence and Prestige of Their Profession
- Promote Ethics in the Lab by Discouraging Improper Conduct and Encouraging Proper Conduct
- Promote a “Culture of Integrity”

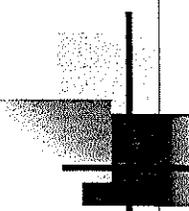


# Data Integrity Elements

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- Data integrity procedures in quality manual
  - Signed and dated by senior management
- Four required elements:
  - 1) data integrity training,
  - 2) signed data integrity documentation for all laboratory employees,
  - 3) in-depth, periodic monitoring of data integrity,
  - 4) data integrity procedure documentation

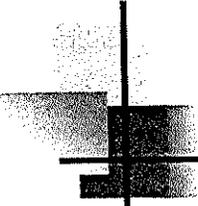
2003 NELAC Standard



# Training

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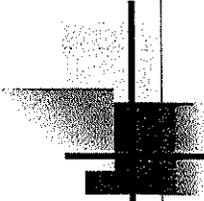
- All Staff – At least once per year
  - Review policy for laboratory
  - Present examples of improper conduct
  - Describe how to report improper practices
- Data Review Staff
  - Review data review procedure
  - Describe identification of vulnerabilities
  - Present how to document the data review



# Responsibilities

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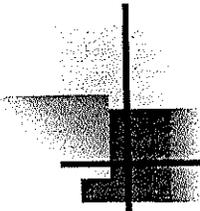
- Employee
  - Report any known or suspected unacceptable practices to QAO or as directed by program
- QAO or Ethics Officer
  - Perform preliminary investigation
  - Report to Ethics Committee and Lab Management



# Responsibilities

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- Ethics Committee (if formed)
  - Review internal audit findings
  - Review reports and make recommendations
- Management
  - Review recommendations from committee
  - Develop plan of action
  - Disciplinary action if appropriate
  - Notify client(s) of any significant data quality affects on reported data.



# Corrective Action

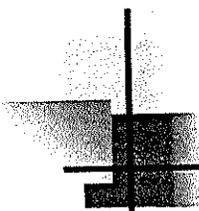
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- Document problems, method deviations
  - Corrective action form
  - Failed QC
  - Data manipulations
- Corrective actions process
  - Identify
  - Root cause
  - Implement change
  - Verify effectiveness of change

# Reporting Unacceptable Practices

- Report to Lab QAO or Ethics Officer
  - How do you report any unacceptable practices?
    - Defined in Lab procedure
    - Documented

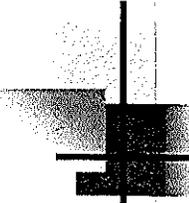
*Just because it is questionable practice,  
does not make it an improper practice or  
data integrity issue*



# Records or Data Review

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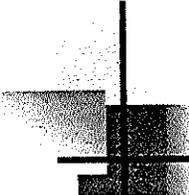
- Historical Reconstruction
- Changes - manual & electronic
  - Single line, date, initial
  - Reason why
- Complete
  - without vulnerabilities



# Quality System Vulnerabilities

---

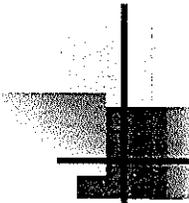
- Weaknesses in the following areas:
  - Management commitment to data integrity
  - Resources
  - Qualifications and training
  - Supervision and oversight
  - Preventive and corrective actions
  - Document control



# Fabrication

---

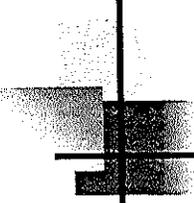
- Creating information that is not true
- Creating data for an analysis that was not performed
- Creating information for a sample that was not collected
- Claiming ownership for work performed by external analysts, equipment, facilities
- Cutting and pasting reports and support data



# Fabrication

---

- Examples:
  - Subcontracting PT samples
  - Creating CoCs without sample possession
  - Filling in logbooks for audits
  - “Reappearing” QC results
  - Recording instrument conditions before starting the process



# Misrepresentation of QC Results

---

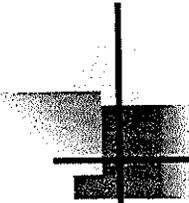
## ■ Examples:

- Representing QC samples as digested or extracted when they were not
- Adding surrogates after sample extraction
- Adding more than the prescribed amount of spikes
- Reporting post-digested spikes as predigested
- Failing to prepare blanks, spikes, PT samples or standards in the same manner as samples

# Improper Date/Time Setting

- Examples:
  - Resetting instrument clocks to make it appear that a sample was analyzed within holding time
  - Altering dates/times on printouts and/or screen printing to make analyses appear to meet 12-hour windows

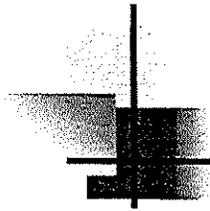




# Improper Peak Integration

---

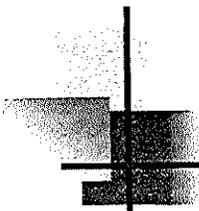
- Examples:
  - Adding or subtracting peak area to make QC results appear to meet criteria
  - Artificially reducing the height of peak responses
  - Failing to manually subtract an interfering peak because doing so would result in a QC failure



# Improper GC/MS Tuning

---

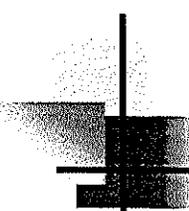
- Examples:
  - Choosing non-representative scan(s) for evaluation
  - Performing incorrect background subtraction
  - Injecting incorrect amounts (BFB surrogate in CCV)
  - Copying and renaming files and screen printing
  - Adding spectra from two different files



# Improper Calibration

---

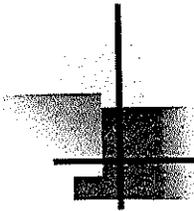
- Examples:
  - Recording results for pH meter calibrations that are not performed
  - Performing multiple calibration runs or QC analyses
  - Representing previous initial calibration data as current
  - Inserting calibration levels or CCVs run well after initial calibration
  - Discarding analyte responses from the center of the calibration curve without technical justification



# Data File Substitution

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- Examples:
  - Reusing historical initial calibration data and representing it as current
  - Changing sample IDs in the data files
  - Using data files for QC or tunes from acceptable runs performed on other days



# Unwarranted Sample Dilution

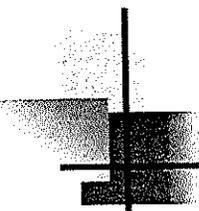
---

- Examples:
  - Diluting a sample to reduce laboratory contamination below the method detection limit (MDL)
  - Reporting result as non detected at the reporting limit (RL)

# Deletion of Data

- Examples:
  - Deleting common laboratory contaminant results from method blanks
  - Recording only those assays that work in the laboratory notebook





# Improper Alteration

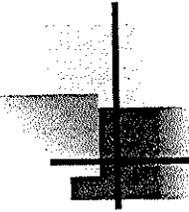
---

- Examples:
  - Adjusting electron multiplier voltage on a GC/MS
  - Increasing gain
  - Failing to run samples and standards under the same conditions

# Software Manipulation

- Examples:
  - Removing data qualifying flags (R)
  - Removing the "M" flag to hide the fact that a manual integration was performed
  - Redrawing baseline

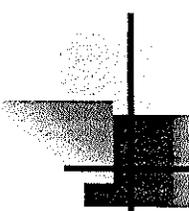




# Concealment

---

- Examples:
  - Failure to discuss surrogate or CCV failures in the case narrative
  - Failure to report and resolve equipment malfunction issues



# Laboratory Environment

---

- Minimize Undue Pressures
- Open Discussion of Technical Issues
- Open Door Policy

What to do when things:

- ❖ *Go wrong*
- ❖ *Can't get done*
- ❖ *Just don't seem right*



OFFICE OF INSPECTOR GENERAL

*Catalyst for Improving the Environment*

# EPA IG Report

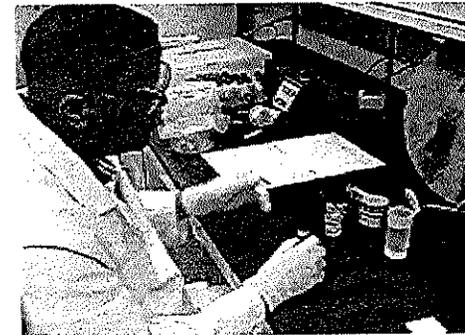
## Evaluation Report

**Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks**

Report No. 2006-P-00036

September 21, 2006

*EPA IG Report Expert  
Panel - Appendix E*



[www.epa.gov/oig/reports/2006/  
20060921-2006-P-00036.pdf](http://www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf)



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**EPA** Guidance on Environmental  
Data Verification and  
Data Validation

EPA QA/G-8

- [www.epa.gov/quality](http://www.epa.gov/quality)
- Training
- Documents

QUALITY

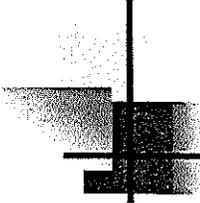
Chapter 4  
Data Integrity

# Any Questions?

*Why do we look  
for  
vulnerabilities?*

***Question !***





# Summary

---

- Develop Training Program
  - That is right for your laboratory
- Review Data Records
  - Document review and be critical
  - Look for vulnerabilities

# End Teleconference



*Have a Nice Day  
Good Bye!*

*Thank you !!*



# APHL

## Association of Public Health Laboratories Teleconference Series

### ENVIRONMENTAL ETHICS TRAINING

5/10/2011

1:00-2:00 PM ET

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**Speaker**

**Susan Kon, BS Chemistry, ACS Certified, Analytical Technical Lead / Data Reporting & Processing, RJ Lee Group Inc.**

Ms. Kon's career spans over twenty-one years of working in the commercial environmental laboratory industry. During this time she has held key positions including Laboratory Manager, Laboratory Director and Quality Assurance Manager. She is familiar with laboratory regulations for several ISO based certification programs including, NELAC, AIHA and NQA-1. In these roles she had developed and supported quality systems according to regulatory guidelines. She has been actively involved with the Pennsylvania Association of Accredited Environmental Laboratories, where she is currently serving as president. She has written ethics programs for her current company, RJLG, and the PAAEL.

**Jonathan Kon, WSCF IH QA Manager**

Jon Kon has 20 years of experience in the commercial laboratory industry. He has held the following positions: Technical Director, Quality Assurance Manager and Vice President of Laboratory Operations. In addition Jon is a licensed drinking water and waste water operator.

**Objectives**

At the conclusion of this program, participants will be able to:

- Explain the importance of ethics training in the laboratory.
- Summarize the annual ethics training requirements required for NELAC and AIHA (American Industrial Hygiene Association) certification programs.

**Continuing Education Credit**

The Association of Public Health Laboratories (APHL) is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. Participants who successfully complete this program will be awarded 1 contact hour of continuing education credit. Florida CEU credit will be offered based on 1 contact hour.  
Continuing education credits are available to individuals who successfully complete the program and evaluation by 6/10/2011.

**Archived Program**

The archived streaming video will be available within two weeks. Anyone from your site can view the Web archived program and/or complete the evaluation and print the CEU certificate for free. To register for the archive program go to [www.aphl.org/courses/Pages/590-942-10.aspx](http://www.aphl.org/courses/Pages/590-942-10.aspx) and use the complementary discount code 942qx in the discount box during registration.

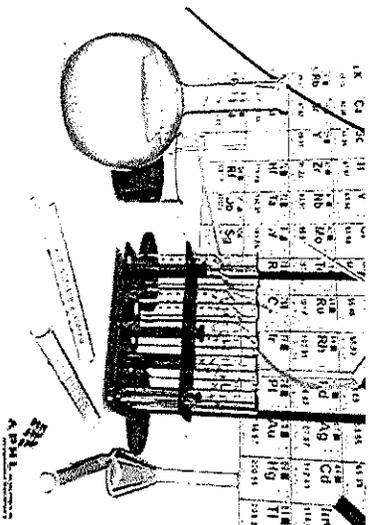
Comments, opinions, and evaluations expressed in this program do not constitute endorsement by APHL. The APHL does not authorize any program faculty to express personal opinion or evaluation as the position of APHL. The use of trade names and commercial sources is for identification only and does not imply endorsement by the program sponsors.

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Detailed directions for completing the evaluation and printing your certificate are on the last page of the handouts. Evaluation password: chair

The Association of Public Health Laboratories (APHL) sponsors educational programs on critical issues in laboratory science.  
For more information, visit [www.aphl.org/courses](http://www.aphl.org/courses)

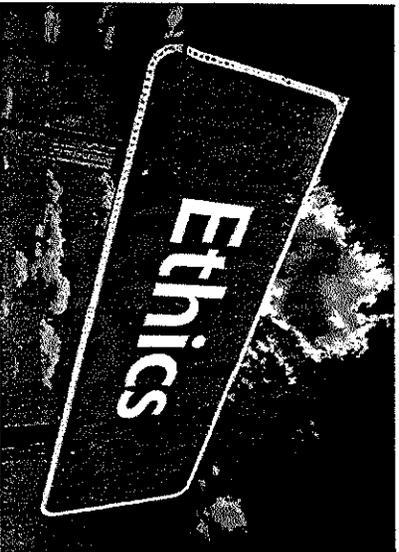
# Applying Ethics in the Laboratory



## A Few Words from Einstein :



- "Most people say that it is intellect which makes a great scientist. They are wrong: It is character."
- "Relativity applies to physics, not ethics."



## Goals of Ethics Training

- To understand that a commitment to ethics education is a fundamental obligation of every business to supply to their employees.
- To identify that ethics education rather than being just an obligatory programmatic add-on can be both intellectually and personally challenging and satisfying.
- To realize that ethics education is not only about teaching a body of knowledge, it is also concerned with decision-making, problem solving, and critical thinking.



## Why Is It Necessary?

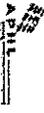
- As professionals, it is our moral responsibility to comply to ethical business practices.
- Ethics training for employees is a requirement by many certification programs; including NELAP and PA Chapter 252.
- The laboratory must maintain appropriate evidence that each employee understands their ethical responsibilities in relation to their job function.



## Our Responsibility



- As analytical laboratories that are providing regulatory agencies information pertaining to the evaluation of public health risks; it is our responsibility to ensure that the data we provide is legally defensible.
- To remember that our daily activities effect decisions being made regarding public health and the environment.



## Definitions

### Ethics



- 1) A system of moral principles
- 2) The rules of conduct recognized in respect to a particular class of human actions; such as professional conduct.
- 3) Moral principles, as of an individual

## Definitions

### Integrity

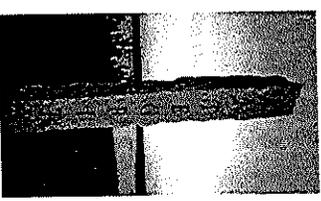
- 1) Adherence to moral and ethical principles; soundness of moral character; honesty
- 2) The state of being whole, entire, or undiminished
- 3) A sound, unimpaired or perfect condition



## Definitions

### Data Integrity

...refers to the legal defensibility of the data, which is supported and proven by all relevant aspects of the Quality System. A breach of data integrity occurs when an analyst or other responsible person intentionally manipulates or distorts data and submits the results of that data as valid.



## Definitions

### Morals

- 1) Relating to, dealing with, or capable of making the distinction between right and wrong in conduct.
- 2) Relating to, serving to teach, or in accordance with the principles of right and wrong
- 3) Good or right in conduct or character

## Code of Ethics

- Every corporation should establish their own Code of Ethics as it relates to their business practices.
- The Code of Ethics sets forth the principles and standards by which laboratory professionals practice their profession.



## Laboratory Code of Ethics Example

1. **Duty to the Client**
  - a) Laboratory professionals are accountable for the quality and integrity of the laboratory services they provide. This obligation includes maintaining individual competence in judgment and performance and striving to safeguard the client from illegal practice by others.
  - b) Laboratory professionals maintain high standards of practice. They exercise sound judgment in establishing, performing and evaluating analysis.
  - c) Laboratory professionals maintain strict confidentiality of client information and testing results.

## Laboratory Code of Ethics Example (continued)

13

- ii. **Duty to Colleagues of the Profession**
- Laboratory professionals uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of professional reliability, honesty, and integrity.
  - Laboratory professionals actively strive to establish cooperative and respectful working relationships with other laboratory professionals with a primary objective of ensuring a high standard of customer service to our clients.



## Laboratory Code of Ethics Example (continued)

14

- iii. **Duty to Society**
- Laboratory professionals comply with relevant laws and regulations pertaining to the practice of analytical testing, and actively seek, within the dictates of their conscience, to change those who do not meet the high standards of practice to which their profession is committed.
  - As custodians of information used to evaluate risk assessment to mankind and the environment, laboratory professionals have the responsibility to ensure that laboratory data is legally defensible.



## Top Reasons for Lab Fraud

15

- FORCE QC TO PASS!!!
- Holding & Turnaround Time Pressure
- Lab over-capacity
- Lack of qualified personnel
- Lack of ethical personnel management
- Poor supervision by management
- Not wanting to admit you don't understand a problem
- Laziness

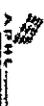


## Two Basic Types of Lab Fraud #1

16

Fraud committed by the lab in conjunction with, or at the behest of, its client.

- In order to obtain and/or keep the clients' business, the lab agrees to participate in a conspiracy to falsify analytical results



## Two Basic Types of Lab Fraud #2

17

The labs' clients are the victims of the fraud.

- Lab wants to maximize its profits and accepts work it cannot accomplish
- Lab cannot meet contractual obligations and so cuts back on quality, not quantity, of work performed.



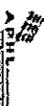
"I was a victim of fraud"



## What do you notice about the preceding page?

18

- It only makes reference to "the Lab" as a whole, not individual employees.
- Unethical behavior of one person is a bad reflection on everyone.
- Frequently, many people or the company as a whole is punished, not just the individual.



## Two Basic Types of Analytical Lab Fraud

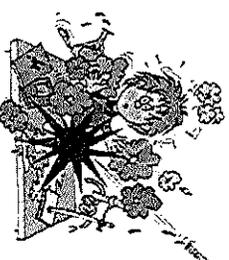
- **Procedural Fraud**
  - Shortcuts or deviations from the method that often occur in:
    - Sample Prep
    - Spiking
    - Dry Labbing
- **Measurement Fraud**
  - Altering or forging direct physical measurements, most often found in:
    - Improper Manual Integrations
    - Improper Calibrations
    - Time Traveling
    - Deleting non-Compliant Data



19

## What is Procedural Fraud?

- Procedural fraud occurs when a person deliberately deviates from the standard operating procedure and/or established Quality System.



20

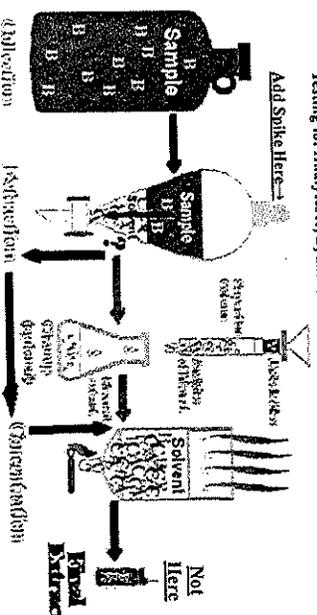
## Procedural Fraud

- Procedural fraud occurs when an analyst does not follow the method in regards to the sample preparation and matrix spiking.
- The following page is an example of incorrect spiking procedures during an organic extraction procedure.

21

## Illustration of Procedural Fraud

Testing for Analytes A, B, and C



22

## Other Examples of Procedural Fraud

(NOTE: Procedural Fraud is harder to detect)

- Not prepping a Proficiency Test sample prior to analysis
- Not digesting metals samples
- Spiking samples after preparation; illustrated on previous page.
- Adding extra spike to compensate for low recoveries
- Using improper calibration procedures
- Recalling older calibrations when current calibration does not pass.
- Using second-order curves if not allowed by required method.

23

## What is Measurement Fraud?

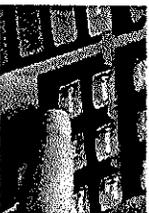


- Measurement fraud occurs when an analyst deliberately manipulates data to make it appear that all quality control samples pass acceptance criteria.
- Dry labbing occurs when analyst does not perform the requested analysis and makes up the results.

24

## Examples of Measurement Fraud

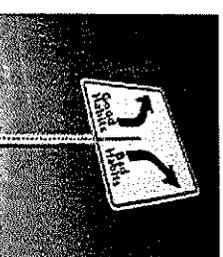
- > Deletion of data, often to give the appearance of negative results
- > Data modification or manipulation
- > Improper Integrations
- > Time travel
- > Creation of false data
- > Dry labbing



25

## Developing Habits

AT THE CROSSROADS:  
We need to decide if we want to develop good or bad laboratory practices.



26

## Establishing Good Habits

- Habit means: "The perfection of an activity through its practice".
- Good Habits must be established and reinforced by an employee's Direct Manager or Supervisor.
- Ethics, or lack thereof, is supported by the daily decisions made by Management and witnessed by Employees.

27

## Issues Which Assist in Cultivating Bad Habits

- > Working Conditions – unsafe lab conditions, lack of space, faulty equipment
- > Personnel Conditions – lazy, ignorance, lack of integrity, overly ambitious
- > Management Conditions – uninformed management, demeaning, use of ultimatums, ignorant, weak

28

## Where Fraud Occurs



- Organics – 54%
- Entire Lab – 17%
- Inorganics – 14%
- Microbiology – 6%
- Air – 3%
- Asbestos - 3%



29

## Role of Analyst vs. Management

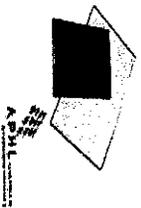
- > Analyst – generate data of known and documented quality. May involve delay to client if required quality of data cannot be produced.
- > Management – interface between the analyst and the customer. Verifies data is of known quality. Handles any issues with client data to arrive at a conclusion that is satisfactory to customer, analyst and regulatory bodies. Ensures that laboratory personnel are properly trained.

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## Importance of Analyst Narration

a.k.a. Document, Document, Document!

- > Records observations and information relevant to analysis at time of analysis, so events and thoughts do not need to be recreated at a later time.
- > Helps evaluate data for deficiencies.
- > Clarify an issue where it would otherwise appear unethical or fraudulent. (C.Y.O.A.)
- > Dispel appearance of red flags.....



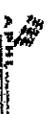
31



## Red Flags



- > Odd, unwarranted data manipulations.
- > Failure to follow procedure
- > Analysis dates and times don't match
- > Perfect control charts
- > Weaknesses in internal corrective action system
- > Failure to sustain corrective actions
- > High staff turnover in specific areas
- > Employees unclear on roles and responsibilities
- > Incomplete training records
- > Too few QC records to support data output



32

## Common Improper Laboratory Practices

- ✦ Improper peak integration (improper manual integration)
- ✦ Misrepresentation of QC sample
- ✦ Improper GC/MS Tuning
- ✦ Improper Date/Time Setting
- ✦ Improper Calibration/Verification
- ✦ Improper Removal or Calibration Points
- ✦ Data File Substitution/Modification
- ✦ Unwarranted Sample Dilution
- ✦ Deletion of Non-Compliant Data
- ✦ Unwarranted Software Manipulation
- ✦ Concealment of a Known Problem



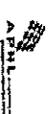
33

## Improper Practices

### Improper Peak Integration

*Altering the area of a chromatographic peak to avoid QC failures*

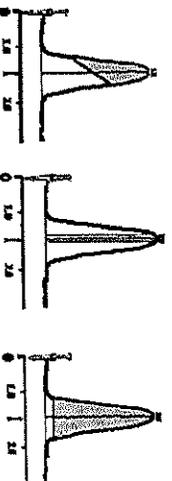
- > Adding or subtracting peak area to make QC results appear to meet criteria
- > Artificially reducing the height of peak responses
- > Failing to manually subtract an interfering peak because doing so would result in a QC failure



34

## Basic Examples of Improper Manual Integrations

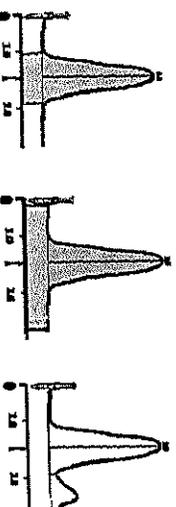
### Peak Shaving - Deleting Area



35

## Basic Examples of Improper Manual Integrations

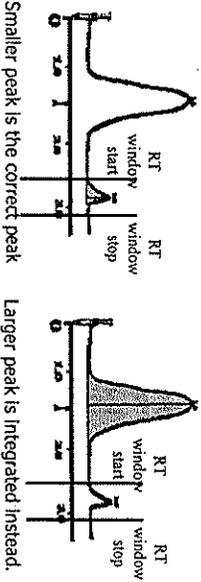
### Peak Juicing



36

## Basic Examples of Improper Manual Integrations

### Peak Substitution



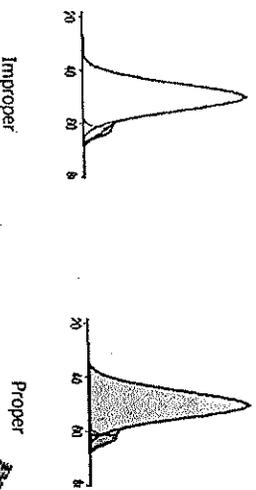
Smaller peak is the correct peak

Larger peak is integrated instead.

37

## Basic Examples of Improper Manual Integrations

### Co-Eluting Peaks



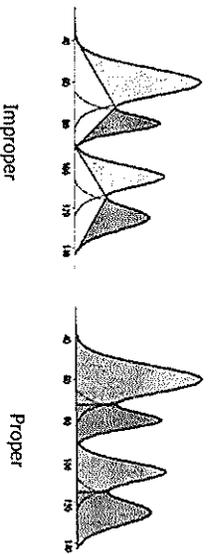
Improper

Proper

38

## Basic Examples of Improper Manual Integrations

### Co-Eluting Peaks



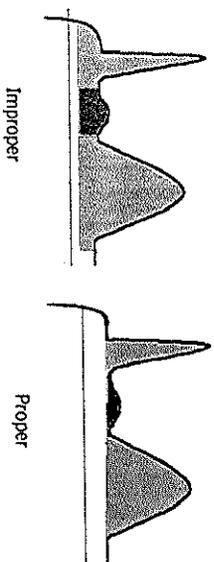
Improper

Proper

39

## Basic Examples of Improper Manual Integrations

### Raised Baseline



Improper

Proper

40

## Improper Practices

### Misrepresentation of QC Results

*Improperly processing or reporting QC samples.*

- Representing QC samples as digested or extracted when they were not
- Adding surrogates after sample extraction
- Adding more than the prescribed amount of spikes
- Reporting post-digested spikes as pre-digested
- Failing to prepare blanks, spikes, PT samples or standards in the same manner as samples

41

## Improper Practices

### Improper GC/MS Tuning

*Manipulating ion abundance of MS tune verification to cause abundance to appear to meet criteria*

- Choosing non-representative scan for evaluation, contrary to method specifications
- Performing incorrect background subtraction
- Injecting incorrect amounts of tune std (BFB, DFTPP)
- Copying and renaming files
- Adding spectra from two different files

42

## Improper Practices

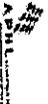
Improper Date/Time Setting



43

*Altering the recorded time that samples were collected, extracted, or analyzed*

- Resetting instrument clocks to make it appear that a sample was analyzed within holding time
- Altering dates/times on printouts and/or screen printing to make analyses appear to meet 12-hour windows



45

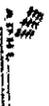
## Improper Practices

Improper Removal of Calibration Points

Removal of points from the middle range of the calibration curve is strongly discouraged. The following are the only reasons for omitting calibration points from the middle of the calibration curve:

1. Obvious instrument failure, such as empty sample vial, mistiming, or high deviation between replicates indicating an automatic sampler issue
2. Removal of point to minimize concentration range of the samples.
3. Samples in the analytical batch were not detected at or near the calibration point in question.

Removal of points from the calibration curve are to be documented in all cases.



47

## Improper Practices

Unwarranted Sample Dilution



*Diluting samples or blanks without explanation, often to the point of eliminating target analyte responses*

- Diluting a sample to reduce laboratory contamination below the MDL



## Improper Practices

Improper Calibration/Verification

- Recording results for instrument calibrations that are not performed
- Performing multiple calibration runs or QC analyses
- Representing previous initial calibration data as current
- Inserting calibration standards or CCVs run well after the initial calibration
- Discarding analyte responses from the center of the calibration curve without technical justification.



44

## Improper Practices

Data File Substitution/Modification

*Substituting previously generated analyses for non-compliant calibration, QC or sample runs*

- Reusing historical initial calibration data and representing it as current
- Changing sample IDs in the data files



46

## Improper Practices

Deletion of Non-Compliant Data



*Failing to record, or deleting, non-compliant analytical results for calibrations, QC samples or blanks*

- Deleting common laboratory contaminant results from method blanks
- Recording only those analyses that work in the laboratory notebook



48

## Improper Practices "Out & Out Fraud"



- Failing to run samples and standards under the same conditions
- Forging another's name or initials
- Reporting results without having actually analyzing the sample (dry labbing)
- Signing for review of data that was not performed.
- Spiking "a little extra" to improve recoveries



50

## Improper Practices Unwarranted Software Manipulation

- Removing operational codes to eliminate or hide manipulations
- Performing inappropriate background subtractions
- Adjusting baselines
- Removing data qualifiers (i.e. to hide the fact that a manual integration was performed)



52

## If You Suspect a Mistake..



- > Alert your Supervisor
- > Initiate proper corrective action procedures. According to your businesses' practice
- > Determine the "Root Cause" of the problem.
- > Use mistake as a learning opportunity for all analysts.
- > If mistake is a result of lack of proper training, document that training - or retraining – has been done.



## Improper Practices



### Concealment of a Known Problem

*Concealing a known sample problem or QC failure or concealing an unethical or improper practice*

- Failure to discuss surrogate or QC failures in case narrative or properly qualify on final report
- Failure to report and resolve equipment malfunction issues
- Failure to report known or suspected unethical behavior by fellow analysts



51

## Data Integrity Advisor

- > Your facility may consider having a data integrity advisor independent from direct management.
- > Keeps all discussions confidential.
- > Has the authority to contact appropriate personnel capable of conducting a more in-depth investigation.



54

## If you Suspect Unethical Behavior...

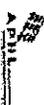
- > Address concern with either supervisor or technical director
- > May consider contacting QC Manager for anonymous reporting.



53

## Data Integrity Advisor

- > Your facility may consider having a data integrity advisor independent from direct management.
- > Keeps all discussions confidential.
- > Has the authority to contact appropriate personnel capable of conducting a more in-depth investigation.



50

## Potential Consequences for Breaching Data Integrity

- > If discrepancies are a result of genuine mistakes:
  - > Documented retraining where knowledge is deficient
  - > Full disclosure to client with re-analysis of samples, if possible or qualifying data in final report.



55

## Potential Consequences for Breaching Data Integrity

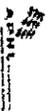
- > If discrepancies are a result of unethical behavior:
  - Depending on the degree and severity of the infraction and the results of the investigation, the consequences may range from:
    - > A discussion with the employee and notation in their employment record
    - > Fines and/or imprisonment
    - > Termination of employment.



56

## Long-Term Consequences of Unethical Behavior

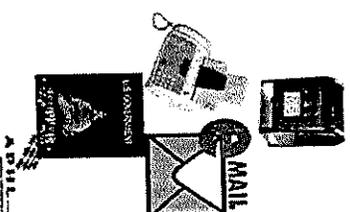
- INACCURATE DATA IS REPORTED TO THE CLIENT AND GOVERNMENT AGENCY**
- > Results are inaccurate; the reported results are too high or too low
  - > The quality of the data is poor and not supported by the laboratory's quality system
  - > End user of data is making decisions and taking action based on faulty data
    - > Unnecessary and very expensive remediation may be performed
    - > Contamination may not be revealed which, over time, may affect the health of many people



57

## If The Results of Fraudulent data are....

- Sent through the US Mail or other commercial interstate carrier
  - The charge is mail fraud.
- Sent via facsimile or e-mail
  - The charge is wire fraud.
- Data is presented to the US government, its agencies or departments
  - The offense is attempting to defraud the US government.



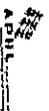
58

## Data Integrity



Procedures that ensure your data is legally defensible

When proper data integrity procedures are compromised, this should raise a red flag. Are ethics also being compromised?



59

## Data Integrity Training



- > Training must be a formal part of all new employee orientation
- > All current employees must be re-trained on an annual basis.
- > Attendance must be documented (sign-in sheet, email confirmation for on-line training, etc.)
- > All employees, after receiving training, must attest to understanding their obligations (signed agreement, electronic acknowledgement, etc.)



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## Data Integrity



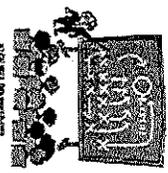
### Training MUST include:

- > The company's organizational mission and its relationship to the critical need for honest and full disclosure in all analytical reporting
- > How and when to report issues of data integrity (very similar to ethics)
- > Record Keeping

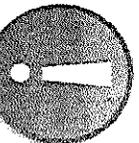
## Data Integrity

Training should include discussion regarding the specific laboratory's data integrity procedures.

- > SOPs, QC criteria, data review, audits, PT samples, all QA parameters etc.
- > Consequences for infractions



## Data Integrity



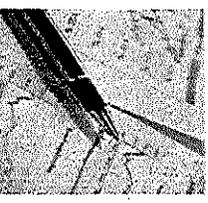
Very important.....

Management must demonstrate their support of these procedures by not only 'talking the talk' but also by 'walking the walk'.  
"Lead By Example!!!!"

## Analyst Responsibility in Recordkeeping



- > All analyst records must be properly initialed and dated.
- > Must be able to provide historical recreation of events.
- > Indelible ink must be used. Do not use pencil. It is recommended that gel link pens are not used in the laboratory.
- > Corrections and changes to records must be performed ONLY using a single-line cross out with the initials of person making the correction, the date of the correction and an explanation of the error. NO OBLITERATING, WHITE-OUT OR SCRIBBLES.



## Proper Procedures for Making Corrections

PROPER PROCEDURE

IMPROPER PROCEDURE

~~4112205~~ <sup>RR</sup> 4/12/06  
~~ASBESTOS~~ <sup>RR</sup> ASBESTOS

4112205 4/12/06  
~~ASBESTOS~~ ASBESTOS  
8260 TCL

## Sample Records Must be Kept for:

- > Preservation, container, and holding time compliance
- > Sample ID, accept/reject at log-in
- > Storage and tracking, including shipping receipts, transmittals and internal records
- > Procedures for receipt, retention and safe disposal

## Laboratory Must Retain:

- > All original raw data, whether hard copy or electronic
- > Reference to test method used
- > Copies of final reports
- > Archived SOPs
- > All correspondence relating to a project
- > Corrective Action reports, including audit and follow-up
- > PT results and all raw data
- > Records of data review and cross-checking



## Strip Charts, Computer Data, Notebooks and Logbooks Must Include:

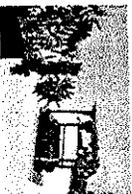
- > Sample ID
- > Date (and time if appropriate) of analysis
- > Instrument ID
- > Analysis method
- > All calculations (automatic and manual)
- > Analyst's initials
- > Sample Prep, including: clean-up and separation protocols, container codes, volumes or weights, instrument print-outs, meter readings, calculations, reagents used
- > Sample analysis data
- > Standard / Reagent receipt, prep and use
- > Calibration criteria
- > Data & calculations, review, confirmation interpretation, reporting
- > QC acceptability
- > Electronic data security



## Laboratory must maintain a record management system for all logbooks and analytical records.



## Scenario #1



Mike returns from vacation to find out that while he was gone samples were received by the laboratory for an analysis that is rarely requested. Since he is considered to be the primary analyst for this test, samples were stored until he returned from vacation. Sample hold time will expire in two days, when Mike discovers that he has not completed annual demonstration of capabilities. He does not think he can complete the DOCs and samples within two days. He knows that client services gets upset when they have to contact a client for sample out of hold time issues. Should he attempt to run the DOC along with samples and hope they pass? Should he inform client services that he cannot analyze the samples within hold time? How should he proceed?



## Administrative Records

- > Personnel qualifications, experience and training records
- > Initial and continuing DOC for each analyst
- > Log of names, initials and signatures for all analysts



## Scenario #2



Ellen hated this time of year: proficiency test studies. She knew if she failed the cyanide PT, the laboratory would lose certification; which would affect the company's relationship with one of their largest clients. To ensure that the numbers she would turn into her supervisor were correct, Ellen decided to analyze the sample in triplicate and at different dilutions. This would enable her to verify her numbers on the final run that she would submit for management review. Did Ellen do anything wrong?



## Scenario #3

The laboratory has serviced ABC Company for 10 years as a drinking and wastewater client. For the past year, ABC has had intermittent problems with their drinking water from their well. They have been warned by the PADEP to install a permanent treatment system to eliminate the bacteria problems. Instead of installing a chlorinator, they decided to use a UV light. The laboratory received a sample for total coliform analysis which has obviously had chlorine added. Client services called the customer and informed them that they were going to reject the sample. The client asked them to analyze the sample as is and report the results to the state. If the laboratory was unwilling to do this, they knew of other laboratories that provided the same services. What should the laboratory do in this situation? It had taken years to establish a working relationship with ABC and they were a very good customer.

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## A Spoonful of Sugar.....



75

- > Never pressure staff to produce results. Quality and reliability of the data is most important.
- > Constantly offer to help be part of the solution when problems arise.
- > QC is not a measure of the staff – It's a measure of the data.
- > No problem is worth losing your job – or fines and jail time!



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"It is curious – curious that physical courage should be so common in the world, and moral courage so rare."

-Mark Twain



## Scenario #4



74

Jill was recently hired to assist with the analysis of volatile organics. Upon completion of her initial demonstrations of capabilities, she begins to analyze client samples. She notices that the other VOA analyst is not performing the pH and chlorine residual checks on customer samples. Instead he is just checking off in the daily run log that they are completed. When she questions the analyst, he informs her that the organics supervisor told him not to waste his time doing the checks since the laboratory purchases the VOA vials pre-preserved. Jill feels uncomfortable and goes to her supervisor, who confirms what the VOA analyst stated. She is new and does not want to 'rock the boat', what should she do?



## Make it Clear.....



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- ✦ It is OK to make a mistake.  
It is not OK to hide mistakes.
- ✦ It is OK to have QC out of limits.  
It is not OK to hide QC that is out of limits.
- ✦ There are potentially severe consequences for scientific misconduct that can affect the entire facility.
- ✦ Good communication (and documentation!) can be the key to prevention of these problems!



78

## References

- "EPA Lab Fraud" presented by Michael Daggett, Director Lab Fraud Investigations, USEPA
- "Laboratory Fraud: Investigation and Prosecution" by Stacy Mitchell, USDOJ
- "Manual Integration & Ethical Issues" by Richard McMillin, USEPA Region VI
- "RJ Lee Group Inc. Ethics Training" by Susan Kon



Association of Public Health Laboratories Continuing Education Credit

588-942-11

Program	Environmental Ethics Training
Evaluation Password	chair
CEU Deadline	6/10/2011

APHL offers both PACE® (is accepted in all states including CA except Florida) and Florida CE credit. To obtain a certificate, participants must complete a program evaluation. After completing the evaluation you will be able to print your own PACE® certificate. If you request Florida credit, your information will be forwarded to CE Broker and you will receive a certificate by email within a month.

**Creating an Account**

If you have never registered for an APHL or NLTN program you must first create an account in the system. Once you create an account, the information will remain in the system for future programs.

1. Go to [www.aphl.org/courses/Pages/Login.aspx](http://www.aphl.org/courses/Pages/Login.aspx)
2. Select Not a registered user? Create an account here
3. Complete steps 1-3 on the online form
4. Remember to save your login name (email address) and password

***For participants who have already created an account in the APHL/NLTN registration system.***

How to do the evaluation and print your certificate

1. Go to [www.aphl.org/cec](http://www.aphl.org/cec) (log-in if necessary using the same email address and password that you used to register. If you have forgotten your email address or password select: [Forgot account info](#) and follow the instructions.).
2. Select **PROCEED**
3. On the **HOME** page click on 
4. Under **TELECONFERENCE EVALUATIONS** find the appropriate evaluation
5. Click on the title of the program evaluation
6. The teleconference evaluation information will appear on the bottom of the page, select **REGISTER**
7. On the next screen, confirm that this is the correct evaluation and select **SUBMIT**
8. Next screen, **ACTIVITIES DETAILS**, click on the **START** button to begin the evaluation (if the evaluation does not open you will need to turn off your pop-up blocker or set it to always accept pop-ups from this site- contact your IT department if you need help doing this)
9. After completing the evaluation, the page will ask "Have You Completed This Activity," select **YES** (if you did not complete the evaluation and wish to return to it at another time say **NO**)
10. On the next screen, **ACTIVITIES DETAILS**, click on the **CERTIFICATE ICON**  located next to the teleconference title to open the certificate
11. When the certificate opens, select the **PRINT** button to print the certificate.



**APHL**

**Association of Public Health Teleconference Series  
ANNUAL ETHICS TRAINING FOR ENVIRONMENTAL  
LABS**

**MARCH 9, 2010 1:00-2:00 PM ET**

**Speaker**

Marlene O. Moore President, Advanced Systems, Inc., Newark, DE  
Ms. Moore co-founded Advanced Systems Inc. in February 1992. Advanced Systems, Inc. is an environmental consulting company specializing in quality systems for laboratory and sampling operations. She brings together the needs of quality system management operations and regulatory compliance.

**Objectives**

- At the conclusion of this program, participants will be able to:
- Explain the code of conduct for environmental analysts.
  - Discuss data integrity procedures and documentation.

**Disclosure Statement**

Comments, opinions, and evaluations expressed in this program do not constitute endorsement by APHL. The APHL does not authorize any program faculty to express personal opinion or evaluation as the position of APHL. The use of trade names and commercial sources is for identification only and does not imply endorsement by the program sponsors.

**Continuing Education Credit**

The Association of Public Health Laboratories (APHL) is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. Participants who successfully complete this program will be awarded 1 contact hour of continuing education credit. Florida CEU credit will be offered based on 1 contact hour.

Continuing education credits are available to individuals who successfully complete the program and evaluation by **September 9, 2010**.

**Evaluation**

Each individual who registers and completes the evaluation will earn 1.0 PACE credit and can print a PACE certificate for their files.

1. Register for the program evaluation at [www.aphl.org/courses/Pages/200-920-10.aspx](http://www.aphl.org/courses/Pages/200-920-10.aspx).
  - a. Students who are new to APHL/NLTN will need to set up a personal profile and create a user name and password. Returning students should log in with their existing user name and password. There is **no charge** to register and take the evaluation to receive your certificate, as the registration fee was covered by the original site registration.
2. After registration you will receive a confirmation by email with the specific instructions on entering the Continuing Education Center (CEC).
3. Enter the CEC and complete the evaluation of the program.
4. Print your PACE certificate
5. For **detailed directions to complete the process, visit [www.directionCEC.aspx](http://www.directionCEC.aspx)**. For Florida CEUs, enter your information at the end of the evaluation survey. We will email your Florida CE certificate within a month.

Why the change to the Continuing Education Center?

The CEC will allow you the ability to receive your certificate immediately and manage your training record of programs completed with APHL/NLTN. Lost a certificate? You have access to training transcript and certificates at anytime for no additional cost.

The Association of Public Health Laboratories (APHL) sponsors

educational programs on critical issues in laboratory science.

For more information, visit [www.aphl.org/courses](http://www.aphl.org/courses)

# Annual Ethics Training for Environmental Labs

Martene Moore  
Advanced Systems, Inc.  
mmoore@advancedsys.com

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## Objectives

- Meet the needs of annual ethics training
- Review ethical code of conduct
- Discuss
  - data integrity procedures
  - data integrity training documentation
  - in-depth data monitoring
  - data integrity procedure documentation

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## 2003 NELAC Data Integrity

- Management Responsibilities
  - Procedures - 5.4.2.6
- Training
  - Topics, documentation - 5.5.2.7
- Control and Documentation
  - Auditing/Investigations - 5.4.15

*When are these procedures?*

3

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## 2009 TNI Requirement

- Standard References V1M2
  - 4.2.8.1 and 4.2.8.5 Additional Management System Requirements
  - 4.2.8.3.h Quality Manual
  - 4.16 Data Integrity Investigations
  - 5.2.7 Data Integrity Training

[www.nelac-institute.org](http://www.nelac-institute.org)

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## Code of Conduct

- Will be honest and impartial and will serve with devotion their employer, customers, and the public.
- Will strive to increase the competence and prestige of their profession.
- Will promote ethics in the lab by discouraging improper conduct and encouraging proper conduct.
- Will promote data integrity principles.”

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## Code of Conduct

- Will not condone nor participate in fraudulent practices including, but not limited to:
  - fabricating data
  - misrepresenting QC results
  - unacceptable equipment calibrations
  - altering samples
  - manipulating sample results
  - substituting samples/files/data
  - falsifying records
- Will report any discoveries of misconduct to their immediate supervisor

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## Code of Conduct

7

- Act in professional matters as a faithful agent or trustee for the Company/Organization and all other customers.
- Inform the Company/Organization of any business connections, interests, or affiliations that might influence their judgement or impair the equitable character of their services.
- Indicate to the Company/Organization the adverse consequences to be expected if their professional judgement is overruled.

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## Principles

8

- Do not disclose information concerning the business affairs or technical processes of the Company/Organization or former employer or customer without the employer's or customer's consent.
- Engage in supplementary employment or consulting practice of a like nature to current job responsibilities only with the consent of the Company/Organization.

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## Data Integrity Procedures

9

- Confidential Reporting of Data Integrity Issues
  - Private discussion of ethical issues
  - Report items of ethical concern
  - Investigation of potential ethical lapses
- Data Monitoring
  - Manual
  - Electronic

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## Data Integrity Procedures

10

- Written ethics agreements
- Examples of improper practices
- Examples of improper chromatographic manipulations
- Requirements for external ethics program training
- Any external resources available to employees

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## Procedure Review

11

- Data Integrity Procedures
  - Annual Review
  - Signed by Top Management
- Evaluation of Effectiveness by Management
  - Not just a checklist
  - Heart/sole review
  - -- or else consequences

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## Training Content

12

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting.
  - how and when to report data integrity issues, and record keeping
- Training, including discussion regarding all data integrity procedures
- Data integrity training documentation

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### Training Content (Cont'd)

13

- In-depth data monitoring and data integrity procedure documentation
- Specific examples of breaches of ethical behavior such as
  - Improper data manipulations,
  - adjustments of instrument time clocks, and
  - inappropriate changes in concentrations of standards

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### Training Documentation

14

- Signed Data Integrity Documentation
  - All Staff – not just analysts
    - Don't forget IT, HR and Purchasing Depts.
  - Understand obligations related to data integrity
- Personnel
  - New employee
  - Annual – All staff

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### Requirement

15

- *Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution.*

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## Training

- All Staff – At least once per year
  - Review policy for laboratory
  - Present examples of improper conduct
  - Describe how to report improper practices
- Data Review Staff
  - Review data review procedure
  - Describe identification of vulnerabilities
  - Present how to document the data review

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## Requirement

- *Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient.*

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## In-Depth Data Monitoring

- Audit by person external to that operation
  - Outside party if deemed necessary by management
- Check paper, final report to raw data
  - Include sample receiving
- Sampling of past records
- Look for Vulnerabilities

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## Procedure Documentation

19

- Records to Maintain
  - Complete Data
  - Changes to Data
  - Data Not Usable
  - ALLI (Be a pack rat)

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## Records or Data Review

- Historical Reconstruction
- Changes - manual & electronic
  - Single line, date, initial
  - Reason why
- Complete
  - without vulnerabilities

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## EPA OIG Report

21



Protecting Technology Investments in  
Improving Drinking Water Laboratory  
Sampling and Testing Procedures  
November 2006



[www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf](http://www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf)

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22

EPA Guidance on Environmental Data Verification and Validation  
EPA 820-R-1

**Quality**

- [www.epa.gov/quality](http://www.epa.gov/quality)
- Training
- Documents

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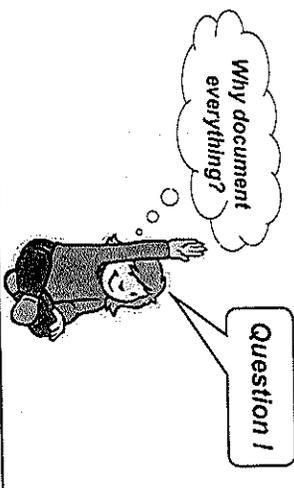
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23

Any Questions?

Question 1

Why document everything?



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24

End Teleconference

Have a Nice Day Good Bye

Thank you !!



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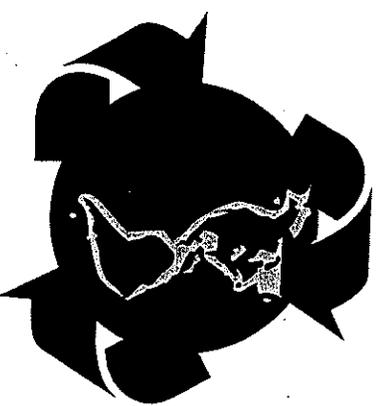
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# Preventing Improper Environmental Laboratory Practices & Advanced Topics in Quality Assurance

**Advanced  
Systems  
Inc.**



Presented: October 2007

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P.O. Box 8032 ♦ Newark, Delaware 19714 ♦ (800) 598-9984 ♦ Internet: [mnoore@advancedsys.com](mailto:mnoore@advancedsys.com)

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# Preventing Improper Environmental Lab Practices and Advanced Topics in QA

## Agenda

7:30 AM	Registration
8:00	Welcome and Introduction
8:15	Ethics
9:00	Data Integrity
9:45	Break
10:00	Preventing Improper Practices
11:00	Writing Procedures
12:00 PM	Lunch (on your own)
1:00	Overview of QA
1:15	Data Quality Indicators
2:00	Calculations
2:45	Break
3:00	Evaluation
4:45	Question and Answer and Course Evaluation
5:00	Adjourn

## Course Objectives

At the conclusion of this program, the participants will be able to:

- ❖ outline the process for developing a laboratory ethics and quality assurance programs.
- ❖ list examples of different types of electronic data handling of records including some background on the Good Automated Laboratory Practices (GALP) and data archiving.
- ❖ define the terms and formulas used for measurement performance indicators in the chemistry laboratory.
- ❖ list the methods of evaluation of quality control trends.

## Faculty

Marlene O. Moore, President  
Advanced Systems, Inc.

Marlene O. Moore co-founded Advanced Systems, Inc. in February 1992 as an environmental consulting company specializing in quality systems for laboratory and sampling operators. She brings together the needs of quality system management, measurement operations, and regulatory compliance. Ms. Moore has managed environmental sampling and testing laboratories for over 20 years before entering the consulting field. She currently serves as an ISO 9000 auditor and an assessor for ISO/IEC 17025. She was trained as an auditor under the EPA Safe Drinking Water Program for state auditors for inorganic, organic, and microbiology.

*This Course is Sponsored by*

**Vermont Department of Environmental  
Conservation Laboratory**

**Vermont Department of Health**

**and**

**National Laboratory  
Training Network**



# **Preventing Improper Laboratory Practices**

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## **Advanced Topics in QA**

October 2007

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### *Disclaimer*

The material is presented for the attendee to receive a basic understanding of the quality systems approach to preventing improper laboratory practices for environmental testing laboratories and learn about the more common calculations used for data quality indicators. The information includes items from a combination of reference sources and practical experience. The information is not presented as the sole method, procedure or information for preventing improper practices and laboratory QC topics.

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ACRONYMS .....	5
DEFINITIONS OF TERMS .....	7

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## Objectives

- Outline Process For
  - Laboratory Ethics Program
  - Quality Assurance Program
- Types of Electronic Data Handling
  - Background and Data Archiving
  - Good Automated Laboratory Practices (GALP)
- Define Terms for Measurement Performance Indicators
- List Methods of Evaluation of Quality Control Trends

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## Why do we need an ethics program?

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## EPA IG Report

EPA IG Report Expert  
Panel - Appendix E



[www.epa.gov/oig/reports/2006/  
20060921-2006-P-00036.pdf](http://www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf)

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### What is Ethical Behavior?

- Ensuring an Ethical Environment
- Laboratory Policies
  - Legal and human resources review



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### Laboratory Environment

- Minimize Undue Pressures
- Open Discussion of Technical Issues
- Open Door Policy

What to do when things:

- ❖ Go Wrong
- ❖ Can't get done
- ❖ Just don't seem right

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### Laboratory Ethics Policy

- Conflict of Interest
- Independence
- Confidential Information
- Unwarranted Privileges
- Appropriate Transactions
- Undue Influence
- Financial Interests

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## Principles

- Be Honest and Impartial
- Strive to Increase the Competence and Prestige of Their Profession
- Promote Ethics in the Lab by Discouraging Improper Conduct and Encouraging Proper Conduct
- Promote a "Culture of Integrity"

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## Principles

- Do not condone nor participate in fraudulent practices including, but not limited to:
  - fabricating data
  - misrepresenting QC results
  - unacceptable equipment calibrations
  - altering samples
  - manipulating sample results
  - substituting samples/files/data
  - falsifying records

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Do not discard "bad" data - this is evidence that when data fails - no results reported.

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## Definitions

- The "F" Word
- Improper Practices
- Data Assessment
- System Vulnerability

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## Fraud

- A deliberate deception practiced so as to secure unfair or unlawful gain
- Reminder: A determination of fraud is the conclusion of a legal process which must evaluate the elements of both "intent" and "unlawful gain". Until that point, the practice in question is an allegation of misconduct.

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## Improper Practice

- A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required QC parameters, making the results appear acceptable
- Any alteration of data such that the data are unauthentic or untrue representations of the experiment or test performed

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## Data Assessment

- An in-depth review and reconstruction of data from raw/source data through final reporting
- Includes sample collection
- Includes laboratory
- Includes final project report

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## Vulnerabilities

- No Training for sample collection
- Wrong location or identity
- Improper preservation
- Chain of custody errors
- Lack of sample collection procedures
- Wrong sampling equipment
- No temperature controls
- Presumption that lab is in control of collection

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EPA IG Report Expert Panel - Appendix E

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## Vulnerabilities

- Misplacing or mislabeling sample
- Sample condition not checked
  - Lack of uniformity
- Date entry errors
- Inappropriate storage of sample
- Vague requirements for LIMS security and entry
- Inadequate procedures for sample handling

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EPA IG Report Expert Panel - Appendix E

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## Vulnerabilities

- Adherence to SOP (Laboratory)
- SOP not followed
- SOP not consistent with required method
- Lack of SOP review
- SOP has ambiguities
- Not using current version of SOP or method
- Lack of meaningful ethics training and testing
- Lack of training staff on inappropriate procedures

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## Vulnerabilities

- Spiking samples after preparation
- Spike adjusting or double spiking
- Backdating
- Recordkeeping errors
  - Missing calibration or standards logs
- Not performing verifications (balance, pipettes, temperature)
- Reagent tracking including water
- Sample preparation logs not reviewed

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EPA IG Report Expert Panel - Appendix E

include maintenance logs

## Vulnerabilities

- Improper calibration
- Inadequate training (sensitivity loss)
- Rerunning QC without rerunning samples
- Indiscriminate use of software to correct problems
- Referral to instrument mfg instructions without defining conflicts
- Instrument maintenance not performed
- Lack of clarity for checks
- Failure to review data, records
- Backups not timely or secured

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EPA IG Report Expert Panel - Appendix E

## Ethical Program Elements

- Self Governance Policy
- Ethics and Compliance Officer
- Training Program
- Enforcement
- Internal Investigations
- Data Recall
- External Monitoring
- Best Practices

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[www.asi.org](http://www.asi.org)

### Continued Vigilance

- Training of all including management
- External and internal review for adherence to the quality program
- Open discussion of technical issues
- Short-cuts not allowed
- Complete records with time allowed to document observations

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### Support of Procedures

- Senior Managers
  - upholding the spirit and intent of the organization's data integrity procedures and
  - effectively implementing the specific requirements of the procedures

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### Develop Rules and Policy

- Preventive practices
  - Define improper conduct
  - Establish peer review
  - Reporting improper practices
  - Define policy for laboratory
- Be sure rules are clear and concise*

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## Training

- Data integrity procedures in quality manual
  - Signed and dated by senior management
- Four required elements:
  - 1) data integrity training,
  - 2) signed data integrity documentation for all laboratory employees,
  - 3) in-depth, periodic monitoring of data integrity,
  - 4) data integrity procedure documentation

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## Auditing Program

- Documentation of finding of inappropriate activity include:
  - any disciplinary actions involved,
  - corrective actions taken, and
  - all appropriate notifications of clients
- All documentation of investigation and actions taken maintained for at least five years

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## Records

- Historical Reconstruction
- Changes - manual & electronic
  - Single line, date, initial
  - Reason why

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*if more than transcription*

*REVIEW.*

## Improper Practices

- Causes, factors
- Production pressure
- Conflicts of Interest
- Lack of awareness
- Lack of communication
- Misinterpretation of method requirements
- Personality and attitude
- Financial stability

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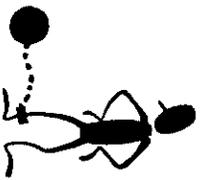
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## BREAK

*Course Resumes  
in 10 Minutes*



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## Prevent Improper Practices

- Quality System Elements
- Corrective Action Program
- Internal Audit
- Data Review

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### Corrective Action

- Corrective action is

the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence (NELAC 2003 Glossary)

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### Corrective Action

- Document differences
- Corrective actions underway
- Timeframe for completion identified

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Quintin from procedure  
CC/PT issues  
Internal Audits

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### Corrective Action

- Corrective action activities include
  - Departures from policies and procedures
  - Quality control failures
  - Documenting when things need to be changed
- Corrective action is not just a correction
  - Permanent fix to problem -- does not reoccur
- Corrective action is documented throughout the process

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### Corrective Action Steps

- Identify problem, concern, etc.
  - May include Client Complaints
- Investigate the problem
  - Perform cause analysis
- Follow-up to ensure the problem is fixed
- Evaluate process to ensure that the fix prevents recurrence of problem

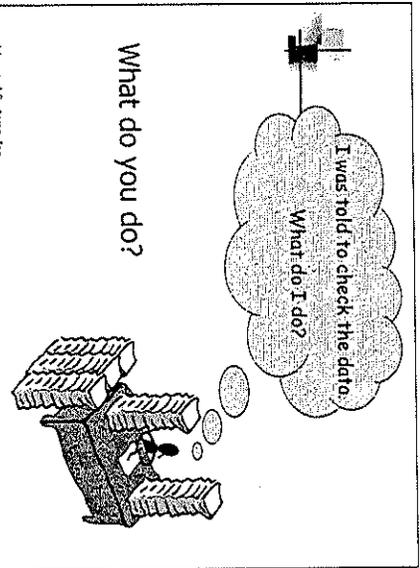
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*- use corrective action as part of follow-up audit*

### Technical Review

- Read SOP
- Read regulation or mandated method
- Read checklist
- Make list of questions
- Interview personnel
- Review data
- Identify findings or conformance
- Record information

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I was told to check the data.  
What do I do?

What do you do?

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## Review Records

- Define personnel responsible
- Review the records, data, etc.,
  - Factual
  - Complete
  - In compliance with SOPs, SAP, or QAPP
- Identify errors or omissions

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## SOP

- Clear Instructions
- Details Activity
- Specific to Function
- Handling Routine Problems
- Assessing Data Integrity



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## Six Principles

GALP  
[www.epa.gov](http://www.epa.gov)

- Integrity of data
- Appropriate formulas and algorithms
- Track entry, modification and recording
- Change control – software and operations
- Documented procedures
- Minimize and manage LIMS failure

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## Computer QA Elements

- Control of electronic documents
- Record keeping
- Software validation
- Maintenance of equipment
- Procedures for protecting data
  - Confidentiality, integrity
- Procedures for data security
  - Access control and authorization for changes

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## Data Integrity

- If it doesn't seem right –
  - Discuss it with management
- Laboratory quality programs require
  - Diligence
  - Procedures
  - Discussion

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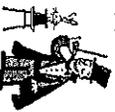
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## Do's and Don'ts

- Don't Pull the number out of the air!
- Do document all you do and why!



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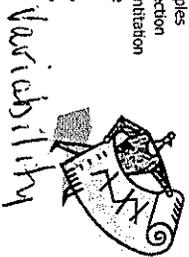






## Laboratory Performance

- Contamination Monitors
- Blanks
- Response Monitors
- Control Samples
- Limit of Detection
- Limit of Quantitation
- Critical Value
- Other
- Repeatability
- Reproducibility
- Uncertainty



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## Blanks

- Types
- Method
- Reagent
- Instrument
- Calculations
- Depends on Technology
- Method
- Manufacturer's Program

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prep batch (US analytical)  
batch

## Control Samples

- LCS, LOD, LOQ, CV
- MS, MSD
- Surrogates
- Internal Standards
- External Standards
- Second Source
- Technology specific control samples

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## Other

- Repeatability (Precision)
  - Same person, instrument, sample, lab, etc
  - Different person, instrument, sample, lab, etc.
- Reproducibility (Bias/Accuracy)
  - Same person, instrument, sample, lab, etc
  - Different person, instrument, sample, lab, etc.
  - Same true value - National standard (?)

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## Sources of Imprecision

- Instrumental instability
- Environmental fluctuations
- Operator skill
- Reagent control
- Variability of blank, sample
- Variable contamination, losses
- Faulty technique
- Maintenance of tolerances

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## Sources of Bias

- Calibration
- Operator bias
- Uncorrected blank
- Inefficiencies or losses
- Tolerances adjustments
- Interference resolution
- Contamination gains
- Instrumental shifts
- Matrix effects
- Theoretical

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### Combined Standard Uncertainty

$$u_c(y) = \sqrt{\sum_{i=1}^N u_i^2(y)}$$

$(y)$  = estimate of the measurand  $Y$ , output estimate

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### Expanded Uncertainty

$$U = k u_c(y)$$

$u_c(y)$  = Combined Standard Uncertainty

$k$  = Coverage Factor

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### Estimation of Uncertainty

$$\bar{X} \pm U \quad 95\% \text{ confidence level, } k=2$$

Where,

$\bar{X}$  = the mean of  $n$  measurements

$U$  = the uncertainty

$k$  = the coverage factor for a confidence level of approximately 95%

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\* use percent recovery not true value.

## Uncertainty Procedure

- Specify the measurand
- Determine measurement conditions
- Identify Uncertainty sources
- Consolidate Uncertainty components
- Quantify Uncertainty components
- Convert components to Standard Uncertainty
- Calculate Combined Uncertainty and Expanded Uncertainty

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9300 421a 029  
www.aaivds.com

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## Methods of Calculation

- Precision
- Bias/Accuracy
- Demonstration of Capability
- Detection Limits
- Control Limits



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## Precision

- Range  
$$\bar{R} = \frac{R_1 + R_2 + \dots + R_n}{n}$$
- Standard Deviation

$$s = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

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## Precision

- Relative Standard Deviation

$$RSD = 100 * \frac{\sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}}{\bar{x}}$$

%RSD

- Coefficient of Variation

$$CV = \frac{\sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}}{\bar{x}}$$

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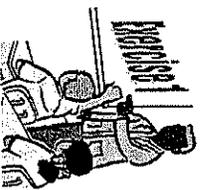
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## Let's Practice

$$? = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

$$? = \frac{|x_1 - x_2|}{(x_1 + x_2)/2} * 100$$



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## Bias/Accuracy

- Percent Recovery or Percent Bias

$$\%R = \frac{|x_1 - x_2|}{x_1} * 100$$

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11111 KENNEDY AVENUE

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### Demonstration of Capability

- QC Sample Outside Source
  - Four aliquots
  - concentration 1-4 times the LOQ
- Same day or over several days
- All results to be used
- Compare mean recovery and standard deviation to method or lab acceptance criteria to evaluate performance

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Appendix C NELAC 2003

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### LOD

- MDL - 40CFR 136 or Lab Defined
- Verification required if results reported to LOD
  - Initial and Annual
  - All steps of method
  - 2-3 times the reported LOD - must be measured
- Each instrument

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Appendix C NELAC 2003

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### LOQ

- Reporting Limit or Quantitation Limit
  - Lab procedure defines how LOQ determined
  - Reporting results only to LOQ
  - Must have procedure to define relation of LOD with LOQ
- Confirm validity (Annual if not done for LOD)
  - Spike 1-2 times claimed LOQ
  - Recovery must be within method or client or lab acceptance criteria

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Appendix C NELAC 2003

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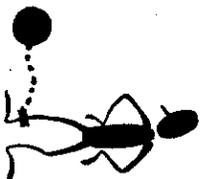
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## BREAK

*Course Resumes  
in 10 Minutes*



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## Methods of Evaluation

- Sampling QC
- Equipment Blanks
- Field Blanks
- Trip Blanks
- Cooler Temperature
- Field Duplicate Pairs
- Collocated Samples
- Field Splits



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## Methods of Evaluation

- Analytical QC
- Method Blank (MB)
- Laboratory Control Sample (LCS)
- Reagent Blank
- Storage Blank
- Internal Standards
- Second Source Standard
- Proficiency Testing (PT)
- Surrogates
- Lab Duplicate
- Lab Matrix Spike
- Matrix Spike Duplicate



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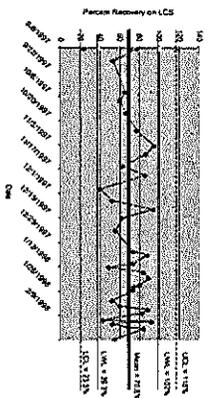
## Control Charts

- Mean Chart
  - Standard Deviation, Average
  - Warning Limits ( $\pm 2\sigma$ ), Control Limits ( $\pm 3\sigma$ )
  - Number of points for calculating  $\bar{x}$ 
    - Centered, 1:1:1:1:1
- Range Chart
  - Standard Deviation, Average
  - Upper WL and CL only
  - Baseline = zero
  - Factor used for duplicates =
    - 1.128 mean
    - 3.267 control limit

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SM 20th edition

## Control Chart



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## Control charts

- Evaluation
  - 1 measurement > CL
  - Analyze another
  - Stop test if > CL
  - 2 of 3 successive point > WL
  - Analyze another
  - Stop test if > WL evaluate bias and correct
  - 4 out of 5 points exceeds 1 $\sigma$  or decreasing or increasing order on same side of the central line
  - Analyze another
  - Stop test if exceeds 1 $\sigma$  or same pattern and correct
  - 7 successive points on same side of central line
  - Stop test and correct

SM 20th edition

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Std Methods 20th ed.

### Significant Figures

- Digits known definitively, except for last digit - last digit is in doubt
- Do not carry more than one doubtful digit in the final result
- Use standard deviation (or uncertainty) as guide for number of significant figures.
- Round only at the end of all operations
- How do you deal with zero?

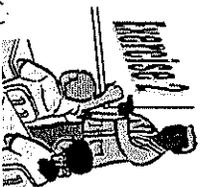
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SM 20th edition

define std. in OSM

### Let's Practice

0.0007
12.065
4.078
25.9
4885



(2.3)  $? = (56 * 0.025233 * 58.56 / 2.3)$

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### Rules for Rounding

- Drop off digits that are not significant
  - If digit > 5 increase preceding digit
  - If digit < 5 do not alter preceding digit
  - If digit = 5, round preceding digit to even number

- Practice: (Round to two sig figs)
- 2.77 = ?      2.30 = ?      2.25 = ?
  - 2.73 = ?      2.35 = ?      2.89 = ?

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SM 20th edition



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# **ATTACHMENT 1**

## **Reference Documents**

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**RELATED REFERENCE DOCUMENTS***Quality Programs*

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# **ATTACHMENT 2**

## **Information**

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**ACRONYMS**

A2LA	American Association of Laboratory Accreditation
ANSI	American National Standards Institute
ARAR	Applicable or Relevant and Appropriate Requirements
ASQ	American Society for Quality
ASTM	ASTM Standards
CBI	Confidential Business Information
CCV	Continuing Calibration Verification
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CoC	Chain of Custody
CRDL	Contract Required Detection Limit
CRQL	Contract Required Quantitation Limit
CRM	Certified Reference Material
CV	Coefficient of Variation
CVAA	Cold Vapor Atomic Absorption
CWA	Clean Water Act
DQA	Data Quality Assessment
DQO	Data Quality Objective
DQI	Data Quality Indicators
EPA	United States Environmental Protection Agency
EU	European Union
FDA	United States Food & Drug Administration
GC	Gas Chromatograph
GC-MS	Gas Chromatography - Mass Spectrometer (interfaced together)
GPC	Gel Permeation Chromatography
GFAA	Graphite Furnace Atomic Absorption (Spectroscopy)
HPLC	High Performance Liquid Chromatography
ICB	Initial Calibration Blank
ICP	Inductively Coupled Plasma (Atomic Emission Spectroscopy)
ICP/MS	Inductively Coupled Plasma/Mass Spectrometry
ICV	Initial Calibration Verification
ILAC	International Laboratory Accreditation Conference
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
LC	Liquid Chromatograph
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
LIMS	Laboratory Information Management System
MB	Method Blank
MDL	Method Detection Limit
MQL	Method Quantitation Limit
MRL	Method Reporting Limit
MS	Matrix Spike
MSD	Matrix Spike Duplicate
NACLA	National Cooperation of Laboratory Accreditation
NEELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NIST	National Institute of Standards and Technology
NVLAP	National Voluntary Laboratory Accreditation Program
OSHA	Occupational Safety and Health Administration
PDS	Post Digestion Spike
PT	Proficiency Testing
PBMS	Performance Based Measurement System
QA	Quality Assurance

QM	Quality Manual
QAP	Quality Assurance Plan
QMS	Quality Management System
QC	Quality Control
R	Recovery
RCRA	Resource Conservation and Recovery Act
RAB	Registrar Accreditation Board
RL	Reporting Limit
RSD	Relative Standard Deviation
RPD	Relative Percent Difference
S (p)	Standard Deviation of the Population (n)
S	Standard Deviation of the Sample (n-1)
SAP	Sampling and Analysis Plan
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SOP	Standard Operating Procedure
SOW	Statement of Work
TCLP	Toxicity Characteristic Leaching Procedure
TIC	Tentatively Identified Compounds
UKAS	United Kingdom Accreditation Service
WP	Water Pollution
WS	Water Supply

**DEFINITIONS OF TERMS**

The definitions presented here have been compiled using the definitions developed by the National Environmental Laboratory Accreditation Conference (NELAC- June 5, 2003). The source of each definition is noted.

Terms may have more than one definition due to the multiple documents used for project planning. Each project should define the term as used for the site specific project.

**Acceptance Criteria:** specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC) (NELAC)

**Accreditation:** the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

**Accrediting Authority:** the Territorial, State, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC)[1.4.2.3]

**Accrediting Authority Review Board (AARB):** five voting members from Federal and State Accrediting Authorities and one non-voting member from USEPA, appointed by the NELAP Director, in consultation with the NELAC Board of Directors, for the purposes stated in 1.4.7.e. (NELAC)[1.4.7.]

**Accuracy:** the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

**Assessor Body:** the organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews proficiency testing results, performs on-site assessments, etc., whether EPA, the State, or contracted private party. (NELAC)

**Analyst:** the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

**Applicant Laboratory or Applicant:** the laboratory or organization applying for NELAP accreditation. (NELAC)

**Assessment:** the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

**Assessment Criteria:** the measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

**Assessment Team:** the group of people authorized to perform the on-site inspection and proficiency testing data evaluation required to establish whether an applicant meets the criteria for NELAP accreditation. (NELAC)

**Assessor:** one who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested. (NELAC)

**Audit:** a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

**Batch:** environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same NELAC-defined matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

**Blank:** a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

**Equipment Blank:** a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

**Field Blank:** blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA-OSWER)

**Instrument Blank:** a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

**Method Blank:** a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)

**Reagent Blank:** (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

**Blind Sample:** a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

**Calibration:** Calibration: set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (VIM: 6.11)

- 1) In calibration of support equipment the values realized by standards are established through the use of Reference Standards that are traceable to the International System of Units (SI).
- 2) In calibration according to test methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

**Calibration Curve:** the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

**Calibration Method:** a defined technical procedure for performing a calibration. (NELAC)

**Calibration Standard:** a substance or reference material used to calibrate an instrument. (QAMS)

**Certified Reference Material (CRM):** a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

**Chain of Custody Form:** record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. (NELAC)

**Clean Air Act:** the enabling legislation in 42 U.S.C. 7401 *et seq.*, Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and to enforce them. (NELAC)

**Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund):** the enabling legislation in 42 U.S.C. 9601-9675 *et seq.*, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601*et seq.*, to eliminate the health and environmental threats posed by hazardous waste sites. (NELAC)

**Confidential Business Information (CBI):** Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality. (NELAC)

**Confirmation:** verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

- Second column confirmation
- Alternate wavelength
- Derivatization
- Mass spectral interpretation
- Alternative detectors or
- Additional cleanup procedures. (NELAC)

**Conformance:** an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994) (NELAC)

**Contributor:** a participant in NELAC who is not a Voting Member. Contributors include representatives of laboratories, manufacturers, industry, business, consumers, academia, laboratory associations, laboratory accreditation associations, counties, municipalities, and other political subdivisions, other federal officials not engaged in environmental activities, and other persons who are interested in the objectives and activities of NELAC. (NELAC)

**Corrective Action:** the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

**Critical Finding:** a finding or a combination of findings that results in a significant negative effect on data quality or defensibility, if not corrected. (NELAC)

**Data Audit:** a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

**Data Reduction:** the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

**Deficiency:** See Finding and Critical Finding

**Delegate:** any environmental official of the States or the Federal government not sitting in the House of Representatives, who is eligible to vote in the House of Delegates. (NELAC)

**Demonstration of Capability:** a procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

**Denial:** to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application. (NELAC)[4.4.11]

**Detection Limit:** the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (NELAC)

**Document Control:** the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

**Environmental Laboratory Advisory Board (ELAB):** a Federal Advisory Committee, with members appointed by EPA and composed of a balance of non-state, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. (NELAC)

**Environmental Monitoring Management Council (EMMC):** an EPA Committee consisting of EPA managers and scientists, organized into a Policy Council, a Steering Group, *ad hoc* Panels, and work groups addressing specific objectives, established to address EPA-wide monitoring issues. (NELAC)

**Federal Insecticide, Fungicide and Rodenticide Act (FIFRA):** the enabling legislation under 7 U.S.C. 135 *et seq.*, as amended, that empowers the EPA to register insecticides, fungicides, and rodenticides. (NELAC)

**Federal Water Pollution Control Act (Clean Water Act, CWA):** the enabling legislation under 33 U.S.C. 1251 *et seq.*, Public Law 92-50086 Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (NELAC)

**Field Measurement:** The determination of physical, biological, or radiological properties, or chemical constituents; that are measured on-site, close in time and space to the matrices being sampled/measured, following accepted test methods. This testing is performed in the field outside of a fixed-laboratory or outside of an enclosed structure that meets the requirements of a mobile laboratory. (NELAC)

**Field of Accreditation:** (previously Field of Testing) NELAC's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a matrix-technology/method – analyte/analyte group combination or for an updated/improved method are required to submit only that portion of the accreditation process not previously addressed (NELAC)

**Field of Proficiency Testing:** NELAC's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

**Finding:** an assessment conclusion, referenced to a NELAC Standard and supported by objective evidence that identifies a deviation from a NELAC requirement. See Critical Finding. (NELAC)

**Governmental Laboratory:** as used in these standards, a laboratory owned by a Federal, state, or tribal government; includes government-owned contractor-operated laboratories. (NELAC).

**Holding Times (Maximum Allowable Holding Times):** the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

**Inspection:** an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4-1994)

**Interim Accreditation:** temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment which has been delayed for reasons beyond the control of the laboratory. (NELAC)

**Internal Standard:** a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

**International System of Units (SI):** the coherent system of units adopted and recommend by the General Conference on Weight and Measures. (CCGPM) VIM 1.12)

**Laboratory:** a body that calibrates and/or tests. (ISO 25)

**Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample):** a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)

**Laboratory Duplicate:** aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

**Legal Chain of Custody Protocols:** procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory. (NELAC)

**Limit of Detection (LOD):** an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte-and matrix-specific and may be laboratory-dependent. (NELAC)

**Limits of Quantitation (LOQ):** The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. (NELAC)

**Manager** (however named): the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

**Matrix:** the substrate of a test sample.

**Field of Accreditation Matrix:** these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation).

**Drinking Water:** any aqueous sample that has been designated a potable or potential potable water source.

**Non-Potable Water:** any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

**Solid and Chemical Materials:** includes soils, sediments, sludges, products and by-products or an industrial process that results in a matrix not previously defined.

**Biological Tissue:** any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

**Air and Emissions:** whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

**Quality System Matrix:** These matrix definitions are an expansion of the field of Accreditation matrices and shall be used for purposes of batch and quality control requirements (see Appendix D of Chapter 5). These matrix distinctions shall be used:

**Aqueous:** any aqueous sample excluded from the definition of Drinking Water matrix of Saline/Estuarine source. Includes surface water, ground water effluents, and TCLP or other extracts.

**Drinking Water:** any aqueous sample that has been designated a potable or potential potable water source.

**Saline/Estuarine:** any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

**Non-aqueous Liquid:** any organic liquid with <15% settleable solids.

**Biological Tissue:** any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

**Solids:** includes soils, sediments, sludges and other matrices with >15% settleable solids.

**Chemical Waste:** a product or by-product of an industrial process that results in a matrix not previously defined.

**Air and Emissions:** whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

**Matrix Spike (spiked sample or fortified sample):** a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of Target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

**Matrix Spike Duplicate (spiked sample or fortified sample duplicate):** a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

**May:** denotes permitted action, but not required action. (NELAC)

**Measurement Quality Objectives (MQOs):** the desired sensitivity, range, precision, and bias of a measurement. (NELAC)

**Measurement System:** a test method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s). (NELAC)

**Method:** 1. see Test Method. 2. Logical sequence of operations, described generically, used in the performance of measurements. (VIM 2.4)

**Method Detection Limit:** one way to establish a Limit of Detection, defined as the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (NELAC)

**Mobile Laboratory:** A portable enclosed structure with necessary and appropriate accommodation and environmental conditions as described in Chapter 5, within which testing is performed by analysts. Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel. (NELAC)

**Must:** denotes a requirement that must be met. (Random House College Dictionary)

**National Accreditation Database:** the publicly accessible database listing the accreditation status of all laboratories participating in NELAP. (NELAC)

**National Institute of Standards and Technology (NIST):** an agency of the US Department of Commerce's Technology Administration that is working with EPA, States, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

**National Environmental Laboratory Accreditation Conference (NELAC):** a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

**National Environmental Laboratory Accreditation Program (NELAP):** the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

**National Voluntary Laboratory Accreditation Program (NVLAP):** a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (NELAC)

**Negative Control:** measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

**NELAC Standards:** the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference. (NELAC)

**NELAP Recognition:** the determination by the NELAP Director that an accrediting authority meets the requirements of the NELAP and is authorized to grant NELAP accreditation to laboratories. (NELAC)

**Non-Governmental Laboratory:** any laboratory not meeting the definition of the governmental laboratory. (NELAC)

**Performance Audit:** the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

**Positive Control:** measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

**Precision:** the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (NELAC)

**Preservation:** refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (NELAC)

**Primary Accrediting Authority:** the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (NELAC)

**Procedure:** specified way to carry out an activity or a process. Procedures can be documented or not (ISO 9000:2000 and Note 1)

**Proficiency Testing:** a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC)[2.1]

**Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA):** an organization with technical expertise, administrative capacity and financial resources sufficient to implement and operate a national program of PT provider evaluation and oversight that meets the responsibilities and requirements established by NELAC standards. (NELAC)

**Proficiency Testing Program:** the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (NELAC)

**Proficiency Testing Study Provider:** any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC PT samples, evaluate study results against published performance criteria and report the results to the laboratories, primary accrediting authorities, PTOB/PTPA, and NELAP. (NELAC)

**Proficiency Test Sample (PT):** a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

**Protocol:** a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed. (EPA-QAD)

**Quality Assurance:** an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

**Quality Assurance [Project] Plan (QAPP):** a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

**Quality Control:** the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS) (NELAC)

**Quality Control Sample:** a sample used to assess the performance of all or a portion of the measurement system. QC samples may be Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking. (NELAC)

**Quality Manual:** a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (NELAC)

**Quality System:** a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

**Raw Data:** any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)

**Recognition:** previously known as reciprocity. The mutual agreement of two or more parties (i.e., States) to accept each other's findings regarding the ability of environmental testing laboratories in meeting NELAC standards. (NELAC)

**Reference Material:** a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

**Reference Standard:** a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

**Reference Toxicant:** the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results (see Chapter 5, Appendix D, section 2.1f). (NELAC)

**Replicate Analyses:** the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

**Requirement:** denotes a mandatory specification; often designated by the term "shall". (NELAC)

**Resource Conservation and Recovery Act (RCRA):** the enabling legislation under 42 USC 321 *et seq.* (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (NELAC)

**Revocation:** the total or partial withdrawal of a laboratory's accreditation by the accrediting authority. (NELAC)[4.4.3]

**Safe Drinking Water Act (SDWA):** the enabling legislation, 42 USC 300f *et seq.* (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

**Sample Tracking:** procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

**Secondary Accrediting Authority:** the Territorial, State or federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority. See also **Recognition and Primary Accrediting Authority.** (NELAC)

**Selectivity:** (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

**Sensitivity:** the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (NELAC)

**Shall:** denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI)

**Should:** denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

**Spike:** a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

**Standard:** the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASQC)

**Standard Operating Procedures (SOPs):** a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

**Standard Method:** a test method issued by an organization generally recognized as competent to do so. (NELAC)

**Standardized Reference Material (SRM):** a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

**Statistical Minimum Significant Difference (SMSD):** the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased. (NELAC)

**Supervisor** (however named): the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/ quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (NELAC)

**Surrogate:** a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (QAMS)

**Suspension:** temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six months, to allow the laboratory time to correct deficiencies or area of non-compliance with the NELAC standards. (NELAC)[4.4.2]

**Technical Director:** individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

**Technology:** a specific arrangement of analytical instruments, detection systems, and/or preparation techniques. (NELAC)

**Test:** a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

**Test Method:** an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority. (NELAC)

**Testing Laboratory:** a laboratory that performs tests. (ISO/IEC Guide 2-12.4)

**Test Sensitivity/Power:** the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis (see Chapter 5, Appendix D, section 2.4.a). (NELAC)

**Tolerance Chart:** a chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radiobioassay laboratories). (ANSI)

**Toxic Substances Control Act (TSCA):** the enabling legislation in 15 USC 2601 et seq., (1976), that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (NELAC)

**Traceability:** the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

**United States Environmental Protection Agency (EPA):** the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

**Validation:** the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. (NELAC)

**Verification:** confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

**NOTE:** In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

**Voting Member:** officials in the employ of the Government of the United States, and the States, the Territories, the Possessions of the United States, or the District of Columbia and who are actively engaged in environmental regulatory programs or accreditation of environmental laboratories. (NELAC)

**Work Cell:** a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented. (NELAC)

**Working Range:** the difference between the Limit of Quantitation and the upper limit of measurement system calibration. (NELAC)

**Definition Sources:**

- 40CFR Part 136
- American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996
- American National Standards Institute (ANSI), Style Manual for Preparation of Proposed American National Standards, Eighth Edition, March 1991
- ANSI/ASSOC E4, 1994
- ANSI N42.23-1995, Measurement and Associated Instrument Quality Assurance for Radiobiassay Laboratories
- International Standards Organization (ISO) Guides 2, 30, 8402
- International Vocabulary of Basic and General Terms in Metrology (VIM): 1984. Issued by BIPM, IEC, ISO and OIML
- National Institute of Standards and Technology (NIST)
- National Environmental Laboratory Accreditation Conference (NELAC), July 1998 Standards
- Random House College Dictionary
- US EPA Quality Assurance Management Section (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95
- US EPA Quality Assurance Division (QAD)
- Webster's New World Dictionary of the American Language

**National Patent Analytical Systems, Inc.**

certifies that

***Steven Harnois,***  
***Electronics Technician***

of the

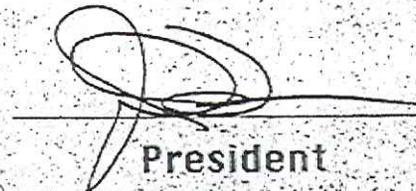
**Vermont Department of Health**

Attended a training course on the Theory of Operation, Supervisory functions and Maintenance and Repair as it pertains to the BAC DataMaster Infrared Breath Alcohol Analyzer and is authorized to use, maintain and perform repairs on the BAC DataMaster in accordance with the instruction received from National Patent Analytical Systems, Inc.

June 4, 2003

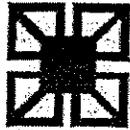


Instructor



President





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Hereby certifies that

Steven Harnois

of the

Vermont Department of Health

Has attended a training course on Advanced Maintenance and Repair as it pertains to the DataMaster family of Infrared Breath Alcohol Analyzers and is authorized to maintain and perform complex repairs on and educate others in the repair of the DataMaster in accordance with the instructions received from National Patent Analytical Systems, Inc.

Instructor

September 17, 2004

President

National Patent Analytical Systems, Inc.

certifies that

*Steven Harnois,*

*Electronics Technician*

of the

Vermont Department of Health

Attended a training course on the Theory of Operation, Supervisory  
Functions and Maintenance and Repair as it pertains to the  
DataMaster DMT

and is authorized to use, maintain and perform repairs on  
the DataMaster DMT in accordance with the instruction  
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January 3, 2008



Instructor

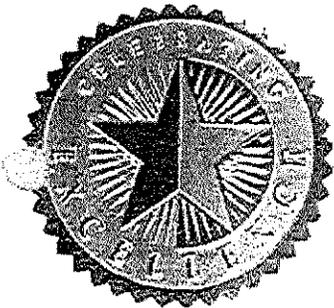


President

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CERTIFICATE OF  
**ACHIEVEMENT**

This certificate is presented to  
**Steven E. Harnois**  
for successfully completing the  
**Instructor Development – Basic Level**  
held at the VT Police Academy from  
November 28<sup>th</sup> – December 2<sup>nd</sup>, 2005



*Unless you try  
to do something  
beyond what you  
have already mastered,  
you will never grow.*

*R. J. Elrick*  
RJ Elrick, Executive Director

December 2, 2005