



# **Guidance Document for Annual Data Integrity and Ethics Training**

For Environmental Laboratories accredited by the New  
York State Department of Health (NYSDOH)  
Environmental Laboratory Approval Program (ELAP)

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# Purpose

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- This presentation is to assist (guide) your environmental laboratory in meeting the annual data integrity and ethics training as indicated in both the 2003 and 2009 NELAC Standards.
- Your laboratory can use the information provided in this presentation to create your own training course.
- **Statements in 'blue' should be addressed to reflect your own lab's policies.**



# Definitions

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## **In·teg·ri·ty** n.

1. Strict adherence to a standard of value or conduct.
2. Personal honesty and independence.
3. Completeness: unity
4. Soundness

Source: Webster's II New Riverside Dictionary, Based on the Webster's II New College Dictionary (1996)



# Definitions (continued)

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## **Eth·ic** n.

1. A principle of right or good conduct.
2. A system of moral values.
3. **ethics** The branch of philosophy dealing with the rules of right conduct.

Source: Webster's II New Riverside Dictionary, Based on the Webster's II New College Dictionary (1996)



# Applicable 2003 [2009] NELAC Standards

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- 5.4.2.6 [V1M2, 4.2.8.1]

“The laboratory shall maintain and establish data integrity procedures...There are four required elements within the data integrity system. These are **1) data integrity training**, 2) signed data integrity documentation for all employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation...”



# Applicable 2003 [2009] NELAC Standards

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- 5.5.2.7 [V1M2, 5.2.7]

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



# What topics are to be covered?

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- 1. Organizational mission;
- 2. Emphasis on importance of proper written narration by the analyst;
- 3. Data integrity procedures;
- 4. How and when to report data integrity issues, and record keeping;
- 5. In-depth data monitoring and data integrity procedure documentation;
- 6. Specific examples of ethical 'breaches'; and
- 7. Consequences



# 1. Organizational Mission

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- The laboratory's mission must relate "to the critical need for **honesty** and **full disclosure** in all analytical reporting" (5.5.2.7) [V1M2, 5.2.7].

Note: Honesty is an integral part of Integrity.  
(See definition on previous slide.)

**What is your laboratory's mission statement?**

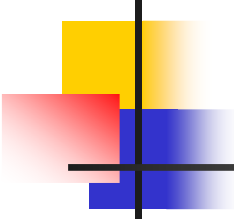




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## 2. Emphasis on importance of proper written narration **by the analyst**

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- Any deviations from standard procedures must be documented.
- Analyst notations must be recorded in “those cases where analytical data may be useful, but are in one sense or another partially deficient.” [V1M2, 5.2.7].
- “Raw Data” also includes field notes and handwritten records. [V1M2, 3.1]



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## 3. Data Integrity Procedures

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- How can a lab document that the data reported was obtained via good/honest conduct?
  - Are the bench sheets initialed and dated by analysts?
  - Are the bench sheets reviewed, signed off, and dated by upper management (e.g., Supervisor, Technical Director, QA Officer)?
  - Are a certain number of data packages (e.g., minimum number or percent) reviewed on a periodic basis (e.g., monthly, quarterly)?



## 3. Data Integrity Procedures (continued)

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- Are narratives/comments, footnotes, or qualified statements included on final reports? Examples:
  - “J” - The reported value was less than the Limit of Quantitation but greater than or equal to the Limit of Detection (or MDL).
  - \* - Duplicate analysis was not within control limits.
  - Comment - Laboratory is only responsible for the analysis of the sample; sampling was performed by the client.



## 3. Data Integrity Procedures (continued)

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- How can a lab document that reported data may have been compromised?
  - Does the sample receipt person include comments on the chain of custody? e.g., "VOA vial was cracked upon receipt."
  - Does the analyst include comments on the bench sheets? e.g., "The sample foamed and overflowed after addition of acid."
  - Does the analyst/QAO request a corrective action (CA) report be initiated & does this report include dates, follow-up activities, summary statement, root cause, etc.?



## 3. Data Integrity Procedures (continued)

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- **Does your lab have an “Ethics Statement” that all staff must sign?**
- **Is there a policy to minimize ‘undue pressure’ on staff?**
- **Is workload controlled to prevent ‘short-cuts’ ?**



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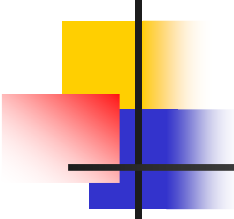


## 4. How and when to report data integrity issues

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- What are data integrity issues?
  - Any outcome or activity that may affect the soundness of the data
    - dirty glassware, cracked beakers
    - air bubbles in volatile samples, foaming
    - incubator stability, leaking sample bottles
    - spilled samples, emulsions
    - mixed matrices, oily substances

**What types of activities could effect the data integrity of the samples in your own lab?**

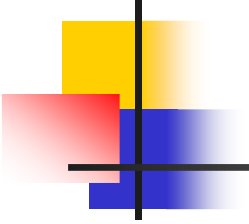


## 4. How and when to report data integrity issues (continued)

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- These issues also include improper practices.
  - Changing the time on computers (time traveling)
  - 'over-dosing' surrogates or LCS concentrations
  - Recording incorrect volumes or incubation times
  - Signing someone else's initials or name
  - Back-dating analysis
  - Manufacturing blank and QC sample data
  - Making up results (dry-labbing)

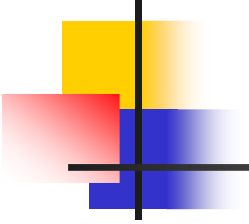
It's usually 'improper' when it doesn't feel right or if it goes against good conduct.



## 4. How and when to report data integrity issues (continued)

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- **What is the reporting policy for your lab?**
- **Where and how are sample integrity issues documented?**
- **Where and how are deviations from SOPs recorded?**
- **How are “improper practices” handled?**

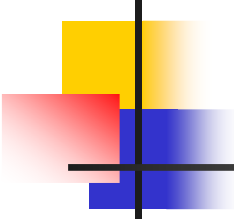


## 4. How and when to report data integrity issues (continued)

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### **What record keeping procedures does your lab use for potential or confirmed data integrity issues?**

- Corrective action forms
- Documented communication with the Project Manager and/or client or regulatory agency
- Bench log books
- Electronic tracking
- Documented employee counseling



## 4. How and when to report data integrity issues (continued)

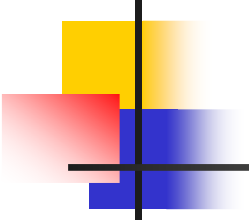
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A confidential mechanism for reporting data integrity issues must be made available to the employees:

### **What is your laboratories' mechanism?**

Examples:

- Anonymous comment box, phone call, or email
- Confidential meeting with supervisors, QAOs or directors



## 4. How and when to report data integrity issues (continued)

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If the data integrity or ethics issue is with upper management, New York State may be contacted:

**NYSDOH Laboratory Investigative Unit**

- **Hotline 1-800-682-6056**

Or US EPA may be contacted:

**US EPA Office of Inspector General**

- **Hotline 1-888-546-8740**



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## 5. In-depth data monitoring

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### **How does your lab perform “in-depth” data monitoring?**

Examples:

“Cradle to grave” sample evaluation

Evaluations of lab SOPs vs. the reference methods

Critical assessment of analysts’ bench performance

Review of analytical software performance and calculations





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## 4. Specific examples of ethical 'breaches' and improper practices

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Specific examples are provided on the following slides and cover laboratories involved in one and/or all of the following areas:

- a) Radon
- b) Asbestos
- c) Microbiology
- d) Chemistry

# a) Radon



Radon test kit  
Source: NYSDOH Bureau of Environmental  
Radiation Protection

## ■ Scenario 1

- *Sally is a home inspector. It's 10:00 AM on February 10th. She deploys a single charcoal canister with a 2-day measurement period specified by the manufacturer's instructions. She places the canister on the fireplace mantle in the home's living room. She retrieves the canister on February 13<sup>th</sup> at 11:00 AM. She sends the canister off to be analyzed on February 14<sup>th</sup>.*
- What's unethical and/or improper with this scenario (according to EPA Indoor Radon and Radon Decay Product Measurement Device Protocols, EPA 402-R-92-004, July 1992)?
  - Canister was not retrieved at the end of the 2-day measurement period.
  - Canister was placed near a source of excessive heat and ventilation.
  - A duplicate (collocated) detector was not deployed.



# a) Radon

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- Scenario 2
  - *Ed, a home inspector, rents a calibrated CRM from an ELAP-certified lab. It's May and severe weather with high winds is predicted for the week. He deploys the CRM in the home's basement with the windows open. He notes the start time & date on the field sheet. He programs the CRM to run continuously for 72 hours with measurements taken every 4 hours. Before he leaves, he closes the windows.*
  - *Ed returns 72 hours later. The windows are open. He only notes the end time & date on the field sheet and submits his field sheet and data from the CRM back to the certified lab. The lab produces the final report.*
- What's unethical and/or improper with this scenario (according to EPA Indoor Radon and Radon Decay Product Measurement Device Protocols, EPA 402-R-92-004, July 1992)?
  - The short-term test was conducted during severe storms with high winds or rapidly changing barometric pressure during the measurement period.
  - The deployment location was not specific. Enough detail is required to demonstrate the CRM was not within 3 feet of a window or placed on the floor. The CRM was not taking hourly measurements.
  - The closed building conditions were not in effect. These conditions were not documented on the field sheet.

## b) Asbestos



Asbestos fibers  
Source: Wikipedia

- Scenario 1
  - *Jane is an PCM analyst who works 8:00 AM to 5:00 PM . It is approaching 4:30 PM, and Jane is under pressure to get a result to her manager for a certain project. She has already analyzed 100 PCM samples today. She decides to dry lab the next few samples. She does not cut the quarter wedge from the filter to make a slide. She reports a fibers/cm<sup>3</sup> without analyzing the sample.*
- What's unethical and/or improper with this scenario?
  - Analyst is under undue pressures.
  - Analyst is dry labbing.
  - Analyst is analyzing more samples than industry maximum of 10 samples per hour.

## b) Asbestos



Blue asbestos (crocidolite)  
Source: Wikipedia

- Scenario 2
  - *John is the sample receipt person at a PLM lab. Lately, he has been receiving resilient floor tile samples and asphalt shingles. He logs these samples in as friable samples. Joe, the PLM analyst, analyzes the sample by point-counting methods listed in ELAP Certification Manual Item 198.1. He does not perform any matrix modifications to the samples.*
- What's unethical and/or improper with this scenario?
  - Samples are not being logged in correctly. It should be logged in as a non-friable organically bound (NOB) sample.
  - Samples are not being gravimetrically matrix reduced and tracked following methods listed in *ELAP Certification Manual Item 198.6*.

# c) Microbiology



- Scenario 1
  - *Fred is an analyst who works 7:30 AM to 4:00 PM analyzing drinking water samples for total coliform using IDEXX Colilert®. Once each day he records the temperature of the incubator and refrigerator. The lab's SOP states the use of the Colilert® comparator. He pours "snap packs" into a series of 120-mL sample bottles containing 100-mL of sample. He gently shakes the bottles and places them into a 35°C incubator at 9:00 AM. He continues to process samples throughout the afternoon and places them into the incubator.*
  - *24 hours later, he removes the bottles placed in the incubator at 9:00 AM. He notices some of the samples are faint yellow and others are bright yellow. He records all the faint yellow samples as negative and the bright yellow as positive for total coliform.*
- What's unethical and/or improper with this scenario?
  - Temperature of incubators must be recorded twice daily separated by at least 4 hours.
  - Colilert® SOP and method requires the use of a comparator. Samples should be compared against it.
  - If the yellow color is faint (less yellow than comparator) after 24 hours, it should be incubated for an additional 4 hours.



## c) Microbiology

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- Scenario 2
  - *Jenny receives a non-potable total coliform water sample from a client for a membrane filtration method at 9:45 AM. The only sample information contained on the chain of custody is the collection date, location, sampler's name, and sample ID. She fills in the collection time as 9:45 AM and gives the sample to John who preps the sample following SM 9222B. He places the sample into the incubator at 5:30 PM.*
- What's unethical and/or improper with this scenario?
  - The actual collection time is unknown. Non-potable water samples have a maximum holding time of 8 hours which includes the time elapsed from collection of the sample to placement into the incubator.



# d) Chemistry



## ■ Scenario 1

- *Joe is a wastewater operator. He never sees changes in the refrigerator's temperature. It is always 4°C. He reads a thermometer that does not have a correction factor indicated and is divided into 2°C. He decides to fill out the temperature log sheet for the entire month of April on April 1<sup>st</sup>.*
- What's unethical and/or improper with this scenario?
  - Refrigerator temperatures should be checked each workday.
  - The correction factor for the thermometer used to take the temperature is not incorporated.
  - Refrigerator thermometers should have graduations of no greater than 1 °C.



## d) Chemistry

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- Scenario 2
  - *Molly analyzes drinking waters for UV-absorbing organics using SM 5910 B. She filters the sample through a Gelman type GN-6 plastic polymer filter. She then places the sample on the spectrometer following the manufacturer's instruction.*
- What's unethical and/or improper with this scenario?
  - SM 5910B requires the use of glass fiber filter without organic binder (e.g., Whatman grade 934AH; Gelman type A/E; Millipore type AP40; ED Scientific Specialties grade 161; or other products that give demonstrably equivalent results).



## d) Chemistry

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- Scenario 3

- *Malcolm analyzes a homogenous non-potable water sample for total suspended solids using SM 2540 D. He assembles the filtration apparatus, wets the filter with a small amount of reagent water (RW), pipettes sample from the midpoint of the container, and washes filter with 3 successive 10-mL volumes of RW. When he transfers the filter to the aluminum weighing dish with tweezers, he tears the filter.*
- *Before he places the sample into the oven for drying at 103°C, he preps several other samples. All samples go into the oven at 11:45 AM. He goes to lunch and returns to remove the samples at 12:30 PM. He lets the samples cool to room temperature on the counter, then weighs the samples. He records only the sample weights and times on his bench sheets.*

- What's unethical and/or improper with this scenario?

- The filter was torn for the first sample he prepped. No comment was included on the bench sheet regarding this issue.
- The samples must dry for at least an hour. They were only dried 45 minutes.
- The samples should be cooled in a desiccator.
- The samples were not re-dried, re-cooled, re-desiccated, and re-weighed to make sure a constant weight is obtained.



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## 7. Consequences of breaches of ethical behavior or improper practices

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- Internal Risks:
    - Refresher Training
    - Loss of Job Responsibilities
    - Probation
    - Immediate Termination
  - When initiated by ELAP after an onsite assessment is conducted:
    - Proposal for Suspension for Repeat Deficiencies
    - Suspension
    - Denial
    - Revocation
- NYS Public Health Law, Section 502,  
NYCRR Subpart 55-2.6



## 7. Consequences of breaches of ethical behavior or improper practices (continued)

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- **NYS Criminal and Civil Penalties**

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.**



# NYS Criminal and Civil Penalties

## **NYS Public Health Law, Article 5, Title I, Section 502 –**

Environmental laboratories; examinations; certificates of approval

*"A person who intentionally violates or refuses or omits to comply with subdivision two of this section ... is guilty of a misdemeanor, punishable upon conviction, by imprisonment for not more than one year or by a fine of not more than \$1000 or by both such fine and imprisonment. A second or subsequent conviction shall be punishable by imprisonment for not more than one year or a fine of not more than \$2500 or by both such fine and imprisonment."*

## **NYS Public Health Law, Article 1, Title II, Section 12 –**

Violations of health laws or regulations; penalties and injunctions -

Deals with civil penalty

*"1. Any person who violates, disobeys or disregards any term or provision of this chapter or of any lawful notice, order or regulation ... shall be liable to the people of the state for a civil penalty of not to exceed \$2000 for every such violation."*



# Useful References

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- Oregon Environmental Laboratory Association, Laboratory Ethics and Data Integrity “Train-the-Trainer” Presentation
  - <http://www.oelaonline.com/power.php>
- New York Association of Approved Environmental Laboratories, Online Ethics Training
  - <http://www.nyaael.org/wordpress/on-line-training/>
- US Environmental Protection Agency, Training Courses on Quality Assurance and Quality Control Activities, Detecting Improper Laboratory Practices
  - <http://www.epa.gov/quality/trcourse.html#detectlab>