

**ACIL / DoD  
Panel  
Discussion**

*Ethics, Data Integrity,  
ACIL and DoD  
Initiatives*

# Agenda

- *ACIL Environmental Laboratory Data Integrity Initiative*
- *NELAC - Ethics and Data Integrity*
- *USEPA / ACIL Agreement*
- *EPA MDL Procedure*
- *PBMS and NELAC*
- *DoD Initiatives*
- *Environmental Testing Industry Perspectives*
- *Discussion and Questions*

# **Environmental Laboratory Data Integrity Initiative**

ELDII

# The Objectives

- Regulators and data users will view data generated by an ELDII Signatory with confidence in the underlying integrity and ethical practices used to produce the results.
- The frequency of data integrity problems will be substantially reduced in ELDII signatory laboratories.
- Those data integrity problems found in ELDII laboratories will be isolated situations where individuals violated clear, established policies.
- Implementation of ELDII will protect data users, the public, and responsible laboratories.

The ELDII has been developed  
based on a foundation of 15 basic  
principles

# Basic Principles

- **The environmental laboratory industry is ethically and morally obligated to the public at large to provide data that are precise, accurate, and of known and documented quality.**
- **ACIL is committed to promoting the self-policing of the operations of its member laboratories to maintain data user confidence in the fundamental integrity of the environmental testing process and the results generated from such testing.**
- **Environmental laboratories that voluntarily become signatories to the Environmental Laboratory Data Integrity Initiative commit themselves to establishing and maintaining an effective self-governance program to prevent, identify, and rectify any data integrity problems.**

# Basic Principles

- Essential elements of the Environmental Laboratory Data Integrity Initiative and any self-governance program include a business ethics and data integrity policy; an ethics and compliance officer; a training program; enforcement of the business ethics and data integrity policy through disciplinary action; a confidential mechanism for anonymously reporting alleged misconduct and a means for conducting internal investigations of all alleged misconduct; procedures and guidance for recalling data if necessary; and an effective external and internal monitoring system.

Management and employee commitment will be memorialized in an annual, signed code of business ethics and data integrity that reflects the essential elements of the Environmental Laboratory Data Integrity Initiative and states that the signers will not violate any provisions of the policy nor will they tolerate any violations by others.

- The self-governance program will include the appointment of an individual as the Ethics and Compliance Officer to be responsible for compliance within the laboratory.

# Basic Principles

- The self-governance program will include an effective training program that ensures that management and all employees are fully aware of their respective duties with respect to the self-governance program.
- The self-governance program will include procedures to effectively enforce the business and data integrity policy through disciplinary action.
- The self-governance program will include a confidential mechanism for anonymously reporting alleged misconduct and will require full investigation of all alleged misconduct.

# Basic Principles

- The self-governance program will include procedures and guidance for recalling data if and where necessary.
- The self-governance program will provide for adequate internal and external audits of the laboratory systems, practices, and procedures to detect data integrity problems. Audits will include detailed source data review.
- Laboratory implementation of the Environmental Laboratory Data Integrity Initiative, particularly internal data integrity investigations, will be thoroughly documented with the documentation maintained in a confidential manner and as prescribed by law and regulation.

# Basic Principles

- **Signatory laboratories agree to voluntarily disclose to appropriate individuals or organizations any significant data integrity violations that are discovered, investigated, and substantiated.**
- **It is the goal of the Environmental Laboratory Data Integrity Initiative to eliminate data integrity problems; however, it is recognized that even in the most committed and organized laboratory organization, data integrity problems may occur. However, with a conscientious and rigorous effort, it is possible to minimize or significantly lower the frequency of these occurrences.**
- **ACIL will continuously initiate and pursue efforts to reduce all underlying causes that contribute to data integrity problems.**

# **The 7 Elements of Technical & Administrative Conformance**

The Essentials  
of the Initiative Guidance

# 1. Business Ethics & Data Integrity Policy

- Contains the basics of the Organization's data integrity plan
- Code of Ethics & Conduct
- Overview of laboratory's systems approach to ethical performance
- Senior management involvement critical
- Communicated to all employees

## 2. Ethics and Compliance Officer

- Senior individual
- May hold other positions
- Communicate directly to highest levels of management
- Authority to direct actions to uphold conformance to Company's integrity plan and ELDII

## 3. Effective Training

- Technical, business ethics, and data integrity
- Organization's ethics and integrity policies
- Special Areas of Concern
- All functions or responsibilities used in the generation of results and reports
- Both initial and refresher training

## 4. Effective Enforcement of Self-Governance Program

- Policy versus Platitude
- Documented Disciplinary Action Policy
- Zero Tolerance
- Management Commitment
- Corrective Actions and Follow Up

## 5. Internal Investigations and Reporting of Misconduct

- Confidentiality (hotline or similar system)
- Timely (Immediate)
- No Retaliation for Reporting
- Comprehensive
- Objective
- Documented and Maintained
- Senior Management Involvement
- Notification of Results and Actions

## 6. Internal and External Monitoring Systems

- Internal & External Surveillance Techniques
- Quarterly Electronic Data Audits
- Semi-Annual Comprehensive Data Audit
- On-going Data Review & Reduction Process (Multi-levels)
- Annual Systems Audit including ELDII Requirements
- Objective Evidence to verify Thorough Implementation

## 7. Data Recall Policy & Procedure

Recall due to potential defects or errors is an accepted and recognized procedure in the manufacturing and service world.

# Current Status

- Contractors ready to accept applications
- 10% on site audits
- Application forms and instructions available at [www.acil.org](http://www.acil.org)

# **NELAC - Ethics and Data Integrity**

# Data Integrity Procedures

Effective June 2004 revisions to Chapter 5  
Quality Systems includes updated Ethics and  
Data Integrity Procedures

These new procedures were proposed  
through the efforts of ACIL.

# NELAC 2002 Chapter 5

## Chapter 5 Scope

5.1.7 An integral part of a Quality System are the data integrity procedures. The data integrity procedures provide assurance that a highly ethical approach to testing is a key component of all laboratory planning, training and implementation of methods. The following sections in this standard address data integrity procedures:

Management Responsibilities	5.4.2.6 , 5.4.2.6.1 and 5.4.2.6.2
Training	5.5.2.7
Control and Documentation	5.4.15

# **NELAC 2002 Chapter 5 Management Commitment**

5.5.2.7 Senior managers acknowledge their support of these procedures.....

# Summary of Data Integrity Procedures

## The Four Elements of Data Integrity

- Employee Training
- Employee Training Documentation
- Data Integrity Reviews and Procedures
- Data Integrity Procedures Documentation

# NELAC 2002 Chapter 5

## ➤ **Employee Training**

5.5.2.7 Data Integrity training shall be provided.....

## NELAC 2002 Chapter 5

### ➤ **Employee Training Documentation**

5.5.2.7 Topics covered shall be documented in writing and have a signature attendance documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

# NELAC 2002 Chapter 5

## ➤ Data Integrity Reviews and Procedures

5.4.2.6.1 Laboratory Management shall provide a mechanism for confidential reporting of data integrity issues

5.4.2.6.2 In instances of ethical concern, the mechanism shall include a process whereby Laboratory Management are to be informed of the need for any further detailed investigation.

5.4.15 The laboratory, as part of their overall internal auditing program, shall insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity.

# NELAC 2002 Chapter 5

## ➤ Data Integrity Procedures Documentation

5.4.15 All investigations that result in finding of inappropriate activity shall be documented....

5.4.2.6 The laboratory shall establish and maintain data integrity procedures....

# USEPA / ACIL Agreement

An agreement has been signed that will recognize areas of mutual interest for the Environmental Protection Agency and the American Council of Independent Laboratories.

The goal of this agreement is to provide increased opportunity for EPA and ACIL to work together to promote a national dialog on environmental monitoring issues

This agreement has specific goals to make tangible improvements in the following areas:

*Improve* communication between EPA and the environmental laboratory community on changes in business, policy, and technical standards at all levels of operation in a manner that fosters trust and understanding.

*Foster* the adoption of a recognized national environmental laboratory accreditation program characterized by nationally accepted standards for environmental laboratory accreditation, uniform standards for laboratory accreditation, and reciprocity across the states.

*Promote* the performance based measurement approach to environmental monitoring.

*Eliminate* barriers that stand in the way of increasing confidence in the quality of our nation's environmental testing laboratories and the credibility of the data emanating from these laboratories.

*Improve* the professionalism of the monitoring community by jointly developing and presenting training necessary to increase the expertise of both government and private sector scientists, engineers and technicians.

To these ends, EPA and ACIL agree to:

*Establish* a series of periodic meetings between our organizations to discuss technical issues and business practices and options to address any issues that emerge; these meeting would be held in conjunction with the ACIL Annual and Mid-Winter Meetings, at a minimum.

*Cooperate* in education and training efforts in order to increase organizational effectiveness, efficiency and overall quality of the nation's environmental testing.

*Establish* links between the EPA and ACIL Web sites to help members of ACIL keep better informed about Agency activities impacting the monitoring community and members of the greater environmental monitoring community keep abreast of ACIL initiatives to improve data quality

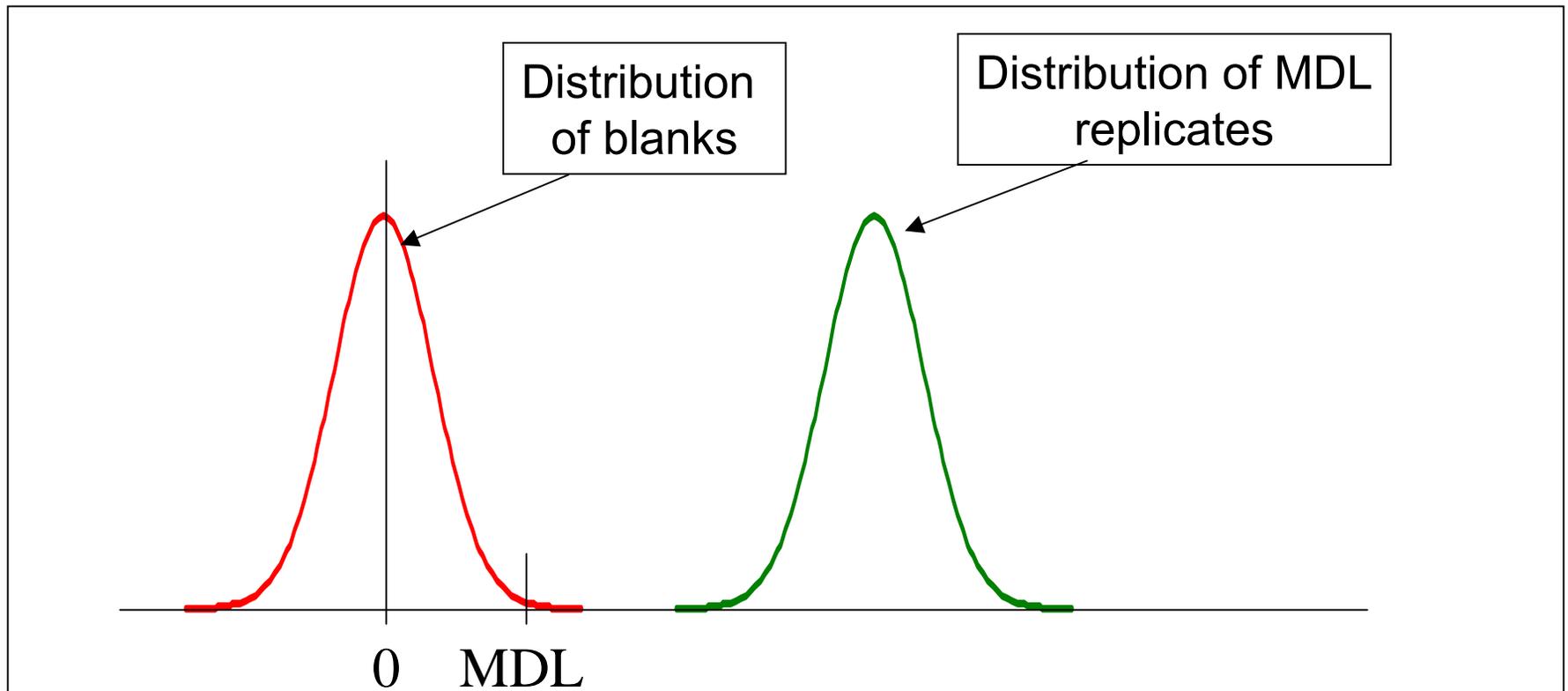
## *Next Step*

*A team made up of representatives of both organizations will meet to develop a plan to implement this agreement.*

# Sound Science and the MDL

- Procedure is under review, final decision by September 2004
- Current procedure and proposed procedure are both seriously flawed
- ACIL position and proposed option at [www.ACIL-MDL.org](http://www.ACIL-MDL.org)

# MDL assumes:



# Proposed EPA MDL Procedure

- Blank is centered around zero
- Population variance can be estimated with seven replicates run over short period of time
- Qualitative identification is not addressed
- False positives and negatives

# List of Principles

- The detection limit procedure must:
  - Control false positives and false negatives
    - $L_D$  and  $L_C$
    - $L_D$  is the lowest true quantity that can be reliably detected
    - $L_C$  is the lowest result that can be reliably distinguished from a blank
  - Consider the blank
  - Incorporate long term variability
  - Include a demonstration of qualitative identification capability

# Office of Water MDL

	Accurate $L_C$	Accurate $L_D$
Mean blank = 0 $LT_{SD} = ST_{SD}$ No censoring	✓	⊗
Mean blank $\neq 0$	⊗	⊗
$LT_{SD} \neq ST_{SD}$	⊗	⊗
Censoring	⊗	⊗

# ACIL proposal

- MDL based on both variance and mean of long term blanks for measurements that always give a result in the blank
- MDL based on qualitative identification for measurements that normally give no response in blank.
- [www.ACIL-MDL.org](http://www.ACIL-MDL.org)

**Performance Based Measurement  
Systems (PBMS) as part of the  
NELAC 2002 and 2003 Quality  
Systems Chapter**

**ACIL supports PBMS approaches that provide flexibility while ensuring sound science. ACIL supports the NELAC approach to PBMS.**

# Agenda

- Performance Based Measurement Systems
  - ✓ NELAC 2002 Chapter 5
  - ✓ NELAC 2003 Chapter 5
- Roadblocks to Performance Based Measurement Systems (PBMS)

# NELAC 2002 Chapter 5

## Performance Based Measurement Systems

The NELAC 2002 Chapter 5 addresses  
PBMS under both management and  
technical requirements

# PBMS Management Requirements

## 5.4.4 Review of Requests, Tenders and Contracts

- Establish and maintain procedures....
- the methods to be used, are adequately defined, documented and understood....

# PBMS Management Requirements

## 5.4.4 Review of Requests, Tenders and Contracts

- Records shall be maintained....
- the appropriate environmental test method is selected....

# PBMS Technical Requirements

## 5.5.4 Environmental Test Methods and Method Validation

- The laboratory shall use methods which meet the needs of the client....
- The introduction of environmental test methods developed by the laboratory for its own use shall be a planned activity....

# PBMS Technical Requirements

## 5.5.4 Environmental Test Methods and Method Validation

- When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test.

# PBMS Technical Requirements

## 5.5.4 Environmental Test Methods and Method Validation

- The laboratory shall validate....
- Validation is the confirmation by examination and the provision of objective evidence.....

# NELAC 2003 Chapter 5

## Performance Based Measurement Systems

The NELAC 2003 Chapter 5 addresses  
PBMS method validation procedures

# NELAC 2003 Chapter 5

- Validation of Methods
  - ✓ The minimum requirements shall be the initial test method evaluation requirements given in Appendix C.3 of this chapter.

# NELAC 2003 Chapter 5

- C.3 INITIAL TEST METHOD EVALUATION
  - ✓ C.3.1. Limit of Detection (LOD)
  - ✓ C.3.2. Limit of Quantitation (LOQ)
  - ✓ C.3.3. Evaluation of Precision and Bias
  - ✓ C.3.4. Evaluation of Selectivity
  - ✓ Handout Appendix C.3, LOD, and LOQ

# Roadblocks to PBMS



# Roadblocks to PBMS



## Project Pre-Planning

What Question?

The Shotgun Approach

# Roadblocks to PBMS



Regulators

I want to compare apples to apples

SW846 as a promulgated method

# Roadblocks to PBMS



## Government Procurement

Laboratory Services as a contributing member to  
pre-project planning?

Best Value vs. Low Price Procurement

# Roadblocks to PBMS



NELAC Accrediting Authorities

How to include a PBMS method on a certificate?

I won't recognize a PBMS method if I'm not the primary AA.

# Industry Perspective

- Cost of compliance increasing
- Assumption of risk
- Detached from end user
- Proliferation of hardcopy and electronic reports
- Performance criteria that are not verified to be either relevant or possible
- Contracting vehicles
  - Fixed unit price
  - Design and optimization costs absent, perhaps it should be mandatory
- Bid process and award criteria