



**The ACIL Environmental
Laboratory Data
Integrity Initiative
(ELDII)**

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Topics

- Background
- Principles
- Specific Requirements
- Signatory Process and Application
- Current Status
- Objectives

Background

- ELWR
- State, Federal, Municipal, Academic, and Commercial laboratories
- Serious damage to Federal programs
- 32 investigations ongoing
- Still a problem!

ACIL Response

- Years of involvement
- Everyone knew what we were not supposed to do
- What are we supposed to do?
- ELDII – what a responsible laboratory organization should do to minimize the frequency and impact of data integrity problems

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 and 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.

Signatory Process

- Documents available on ACIL web site
 - ELDII Policy Statement
 - ELDII Guidance Document
 - Signatory Application Checklist
 - Signatory Application Form and Instructions
- www.ACIL.org under “publications” followed by “Environmental Sciences”



Application

- Review policy statement, guidance document, checklist, and application
- Application includes detailed objective evidence that ELDII requirements have been implemented
- Application form, attached documents, and fee are submitted to Mrs. Janet Allen, ACIL, 1629 K Street, Suite 400, Washington, DC 20006



Annual Applicant Fees

- ACIL member lab with $<$ \$3M in revenues, \$1250
- ACIL member lab with $>$ \$3M in revenues, \$1650
- Government lab - \$1650
- Non-ACIL commercial lab - \$2350



Application Review and Approval

- Two application review contractors
 - Analytical Excellence, Inc.
 - Advanced Systems, Inc.
- Confidentiality procedures
- One in ten labs will have a site visit
- Contractors make recommendation to ACIL Data Integrity Committee
- Successful applicants receive Signatory Status Certificate good for one year

Current Status

- First Applications Received
- Verbal commitments from 70 laboratories to participate
- Reviewed with EPA, OIG, and others.

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.

Future Activities

- EPA OIG 2001 open letter
- Increase the population of ELDII Signatory Laboratories
- Include ELDII requirements or participation in contract criteria

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