

**THE ENVIRONMENTAL LABORATORY
DATA INTEGRITY INITIATIVE
POLICY STATEMENT**

**THE DATA INTEGRITY COMMITTEE OF THE
ENVIRONMENTAL SCIENCES SECTION OF THE
AMERICAN COUNCIL OF INDEPENDENT LABORATORIES**

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I. PURPOSE

The Environmental Sciences Section (“ESS”) of the American Council of Independent Laboratories (“ACIL”) understands the fundamental importance of environmental testing data to nearly every significant public health and environmental management decision made. Because of this, ACIL is the sponsor and administrator of the Environmental Laboratory Data Integrity Initiative (“ELDII” or the “Initiative”). The purpose of the Initiative is to ensure that participating environmental laboratories meet strict ethical standards in the performance of analytical procedures and reporting of analytical results. The Initiative calls for a systems approach to ensuring that data is of known and documented quality. This approach consists of a number of elements including: 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.

II. BACKGROUND

Quality control programs alone have not been sufficient in some laboratories to avoid serious data integrity issues. As a result, data integrity issues have surfaced in a number of commercial and public sector laboratories, and this has seriously undermined the public’s

confidence in the environmental testing industry and in the precision and accuracy of the environmental testing data provided by the laboratories. Currently, the environmental testing industry faces a fundamental crisis in trust. While it is generally true that as the years have passed, the sensitivity, precision, and accuracy of environmental testing data have generally improved, there is a growing perception among the data user community that legally defensible data is frequently not being provided by the laboratories. This situation can only be remedied by a fundamental change in the manner in which laboratories face their responsibilities to the community at large. The environmental testing industry needs generally accepted guidance on the elements of a comprehensive ethics program, a means to share best practices for implementing ethics programs, a commitment from participating laboratories that they will abide by the requirements of an ethics program, and a mechanism to verify that the ethics programs have been implemented.

ACIL, as the national representative of the commercial environmental testing industry, requires that member laboratories sign and conform to its Code of Ethics. In 1996, ACIL's Environmental Sciences Section initiated the Seal of Excellence Program, which emphasizes a specific approach to ethics requiring participating laboratories to implement an internal system of ethics training and surveillance. In July 2002, ACIL was successful in encouraging the National Environmental Laboratory Accreditation Conference ("NELAC") to adopt new language in its standards requiring a systems approach to data integrity. This language is similar to the ethics system of the Seal of Excellence Program. This systems requirement will become a mandatory standard for all participating laboratories in July 2004.

As the ACIL Environmental Sciences Section looks forward to the future and as we consider new strategic initiatives for our members' benefit, we recognize that much more needs to be done to bring our member laboratories and, hopefully, all environmental laboratories to a point where production of data of known and documented quality is assured and where such data become a fundamental product of our industry. We view the Environmental Laboratory Data Integrity Initiative and its signatory process as the primary task in achieving this position.

III. BASIC PRINCIPLES

The Environmental Laboratory Data Integrity Initiative is based upon the following principles:

1. 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.
2. 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.
3. 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, deter, identify, and rectify any data integrity problems.
4. 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.
5. 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.

6. 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.
7. 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.
8. The self-governance program will include procedures to effectively enforce the business and data integrity policy through disciplinary action.
9. The self-governance program will include a confidential mechanism for anonymously reporting alleged misconduct and will require full investigation of all alleged misconduct.
10. The self-governance program will include procedures and guidance for recalling data if and where necessary.
11. 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.
12. 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.
13. Signatory laboratories agree to voluntarily disclose to appropriate individuals or organizations any significant data integrity violations that are discovered, investigated, and substantiated.
14. 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.
15. ACIL will continuously initiate and pursue efforts to reduce all underlying causes that contribute to data integrity problems.

IV. **SIGNATORY PROCESS**

The Data Integrity Committee of the Environmental Sciences Section of ACIL (the “Committee”) will administer the application and signatory process of the Environmental Laboratory Data Integrity Initiative. The 15 Member Board of the Environmental Sciences Section of ACIL appoints the Committee Chair and Members and oversees the activities of the Committee. The Committee will provide a detailed information packet and questionnaire to those laboratory organizations interested in participating in the Initiative. The purpose of these materials is to verify that potential signatories fully understand the requirements of the Initiative and are prepared to fully commit to the Initiative requirements. Following review, which may include follow-up discussions and site visits, the Committee will consider accepting the applicant.

Following acceptance by the Committee, the applicant will submit a signed attestation document complying with all aspects of the Initiative. In the case of unincorporated laboratory organizations, all owners must sign the document. For incorporated laboratory organizations, the Chief Executive Officer or senior Divisional Officer must sign on behalf of the ownership.

It is anticipated that the Environmental Laboratory Data Integrity Initiative will evolve over time. On an annual basis and at the beginning of all subsequent years, the signatories will reaffirm in writing their continuing conformance to all existing and new requirements of the Initiative approved by ACIL. Original and continuing annual application fees will be paid by the signatory organization. The fees will be used solely to cover the direct Committee costs associated with administration of the Environmental Laboratory Data Integrity Initiative.

The Committee will issue an annual report regarding the operations of the Environmental Laboratory Data Integrity Initiative. This report will be provided to all current signatories and other interested parties.

V. COMPONENTS OF THE SELF-GOVERNANCE PROGRAM

The framework for responding to data integrity issues is an effective self-governance program. The self-governance programs that Signatories commit to instituting are designed to manage risks by preventing, detecting, and responding to violations or potential violations of applicable laws, regulations, and policies, and by promoting compliance with such laws, regulations, and policies. These programs must respond to change by monitoring developments in the laws, regulations, and policies that affect organization activities and by incorporating any appropriate modifications in the program. The self-governance program and all related policies that contribute to the program should be readily available to all employees.

Management at the highest levels in the organization must endorse and be committed to the self-governance program, with a senior manager responsible for the implementation and effectiveness of the program. However, accountability for compliance must be established throughout the organization, from the highest levels to all employees. Managers should make discussion of compliance related issues a part of their routine meetings. Incentive, performance appraisal, and recognition systems within the organization should be consistent with achieving compliance goals. Sufficient resources should be identified and allocated so that the program can operate effectively.

The essential elements of a 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.

A. Business Ethics and Data Integrity Policy

The cornerstone of any effective self-governance program is a meaningful and comprehensive written policy that clearly communicates the laboratory's commitment to the highest standards of business ethics and honesty. The policy should also communicate the laboratory's commitment to compliance with all applicable laws, regulations, other requirements that are imposed upon the laboratory in the conduct of its business, and in practice of the highest professional standards applicable to the laboratory. Signatories commit to establishing and publicizing a Business Ethics and Data Integrity Policy (the "Policy") and communicating this Policy to its employees. The Policy should be displayed prominently within facilities and in employee handbooks or other such publications. Instruction in the contents, meaning, and interpretation of this Policy will be provided to each individual at the laboratory within 30 days of being hired and annually thereafter. This will include requiring management and all employees to state in writing that each individual has read, understands, and agrees to adhere to the Policy. This acknowledgement of the Business Ethics and Data Integrity Policy will also be executed annually by each individual in the laboratory

At its core, the Policy is a simple statement of the laboratory's commitment to comply with all applicable laws, regulations, and policies, and to adhere to the highest professional and ethical standards. However, the Signatories agree to a more comprehensive policy that

encompasses, as a minimum, the other elements of an effective self-governance program as discussed in the subsections below. Depending upon individual business considerations, other areas that may be included in the Business Ethics and Data Integrity Policy are, for example, government procurement and contracting, environmental protection and handling of hazardous materials and wastes, employment discrimination, workplace safety, and any other area deemed appropriate by the laboratory.

B. Ethics and Compliance Officer

To ensure that compliance is properly considered in the operation of the laboratory, each Signatory will agree to appoint an individual as an Ethics and Compliance Officer who will be responsible for or assume the additional responsibility for compliance within the laboratory and for adherence to the Business Ethics and Data Integrity Policy. This will be a senior individual within the laboratory with the ability to communicate directly with the laboratory director or the highest levels of management within the laboratory regarding compliance issues. This individual may hold other positions within the laboratory.

C. Effective Training Program

An essential component of any effective self-governance program is properly trained personnel. Signatories will agree to institute a formal and documented training program to cover all facets of an employee's work efforts. In the environmental laboratory, this must encompass all elements of method training, reporting of data, and all of the ancillary training needed for employees to conduct their work in a safe, compliant, and complete fashion in conformance with organizational policies and procedures, as well as all applicable laws, regulations, and governmental policies. This training will include training in business ethics and data integrity,

and specifically the laboratory's Business Ethics and Data Integrity Policy. This training will also include training in acceptable scientific practices, including training in proper manual integration, calibration, and documentation procedures.

This training program will include both initial and refresher training. Initial training will be conducted within the first 30 days after a laboratory hires an individual and before the employee is permitted to produce any analytical data or conduct any system practice without direct supervision. It will include initial instruction in the laboratory's Business Ethics and Data Integrity Policy and either proficiency testing or training in the methods for the particular area where the individual will be working. If an organization hires staff without proven competence in fundamental skills, then general training must begin at the lowest necessary level to ensure that such skills are present in the employees. This initial proficiency testing or training will be documented and kept in the individual's training file. Training should be tailored to the analyst and the method and be understandable and practical.

Annual refresher training will be conducted in the laboratory's Business Ethics and Data Integrity Policy. This annual business ethics and data integrity training should be provided by appropriately trained individuals from either internal or external sources. Annual business ethics and data integrity training should also be used to address any organization or facility specific issues discovered as the result of internal or external audits of laboratory practices. After both the initial and the annual business ethics and data integrity training, management and all employees should execute a certificate that they understand and will comply with the laboratory's Business Ethics and Data Integrity Policy.

Additionally, annual refresher training in specific methods or laboratory practices, either provided by laboratory personnel or through outside sources, will be conducted on an as needed basis. The training program will also include periodic testing of analysts in the methods that they are performing. The results of this testing, as well as all initial or refresher training, will be documented and maintained in a permanent training file to be kept by the laboratory.

Standard Operating Procedures (“SOPs”) or other guidance documents that fully describe the step-by-step practices that must be completed by an analyst to obtain a valid test result or other procedures required for the efficient operation of the laboratory must be kept current and made readily accessible to those in the laboratory. The training program should specifically include instructions in these SOPs. Each SOP must be sufficiently detailed to ensure that if analysts complete the work assignment consistent with the requirements of the SOP, the data generated will be of known and documented quality.

D. Effective Enforcement of Self-Governance Program

Effective enforcement of a Signatory’s self-governance program requires a commitment by management at all levels to adhere to the program and to subject any employee who intentionally violates the program and the laboratory’s Business Ethics and Data Integrity Policy to disciplinary action, including possible termination. Employees who violate the laboratory’s Business Ethics and Data Integrity Policy or knowingly bypass required quality control or quality assurance procedures will be disciplined consistent with the severity and circumstances surrounding the violation. Signatories will not tolerate individuals who knowingly and intentionally falsify data or otherwise commit criminal acts.

E. Internal Investigations and Reporting of Alleged Misconduct

It is important to any effective self-governance program that the laboratory provide for the reporting and investigation of alleged incidents of misconduct or violations of the laboratory's Business Ethics and Data Integrity Policy. The laboratory's Business Ethics and Data Integrity Policy and self-governance program should be fair and equitable to employees, including violators, and should assure that there will be no retaliation against employees for simply raising compliance issues.

While Signatories hope and expect that individual analysts or other employees will bring alleged misconduct to the attention of their supervisors, other senior management, or the designated Ethics and Compliance Officer, they will also provide for other methods of reporting alleged misconduct. Key to this will be some form of a confidential "hotline" or some other mechanism for anonymously or confidentially reporting alleged incidents of misconduct. This may take many forms, such as a confidential telephone hotline or drop box. A primary element of the mechanism is to assure confidentiality and a receptive environment in which all employees may privately raise ethical or data integrity issues or report items of concern.

Signatories also commit to promptly investigate any alleged incidents of misconduct, whether raised through the hotline or otherwise, document the results of that investigation, and report those results back to the person who raised them, if known. The laboratory shall establish a procedure for performing internal investigations of suspected misconduct that is reported by employees or identified through other detection mechanisms. This investigation must be performed by individual(s) free from the influence of those being investigated. This is especially important when a person higher in the organization structure is being investigated. In this

instance, to ensure independence, an outside or third party should be considered or brought in to handle the investigation. Special considerations are required when the issue is raised by an individual who is entitled to certain legal protections under the law.

The procedure for handling the internal reporting of suspected misconduct shall also include a process for investigating the reported incident, reporting conclusions, and if necessary, establishing a corrective action plan and a follow-up monitoring process to ensure effective resolution and prevention of repeated misconduct. The confidential reporting procedures must ensure that the reporting of an incident, investigation findings, and ultimate resolutions are reported to the senior management of the organization.

In addition, Signatories agree to take timely remedial action to correct any data that may have been affected by any misconduct and to inform a customer if data that has been released to the customer is adversely affected by the misconduct. Signatory laboratories agree to voluntarily disclose to appropriate individuals or organizations any significant data integrity violations that are discovered, investigated, and substantiated. The Initiative recognizes that it is within the discretion of the Signatory as to when to make a voluntary disclosure, but requires that all Signatories have a procedure in place to review serious allegations and to determine if a disclosure should be made.

F. Data Recall

In the normal course of business, environmental laboratories periodically find that some reports they have submitted to their customers contain erroneous data. There may be many possible causes for the erroneous data, including calculation errors, data entry errors, analytical problems that were not caught during data review, and deviations from standard operating

procedures. In some cases, the erroneous reports are due to misconduct, such as deceptive data recording practices by one or more individuals within a laboratory. Signatories to the Environmental Laboratory Data Integrity Initiative must have procedures and guidance in place for recalling erroneous data when discovered, determining appropriate remedial actions, and informing clients and appropriate authorities. This should complement the procedures for investigating allegations of alleged misconduct.

G. Effective Internal and External Monitoring System

Critical to an effective self-governance program is a mechanism for monitoring compliance with the specifications of the program. This is commonly called “surveillance” and is performed as a combination of internal laboratory mechanisms and external or independent mechanisms. It is different than, but should be integrated with, the laboratory’s quality control/quality assurance program. The combination of different monitoring techniques provides an effective early warning system to prevent problems, helps to identify failures and weaknesses in the quality system, and acts as a deterrent to improper or inappropriate behavior. Signatories agree to establish and maintain an internal and external monitoring or audit system to review compliance with applicable laws, regulation, and policies and help eliminate data integrity issues.

Management must establish detailed and documented systems, practices, and procedures to effectively monitor the performance of the laboratory’s operation. A combination of secondary data review, internal and external audits, source data audits, performance test samples, review of electronic data, automated data surveillance techniques, interviews, and surveys should

be included. The laboratory should augment its monitoring practices using automated techniques and tools whenever practical.

This assumes that the laboratory has already established a quality system and documentation to assess and monitor the quality of the operation and the data generated. The quality system requires its own monitoring systems. The purpose of this part of the self-governance program is to augment the quality system requirements specifically to focus on ensuring the integrity of the data generated.

The laboratory shall establish a record retention policy. This policy shall include records relating to any internal or external audit, including reported incidents or related investigations. The laboratory shall identify the records to be retained resulting from the reported incident and any associated investigation, and such records will be maintained in a confidential manner and as prescribed by law.

H. Best Practices

ACIL is committed to providing its members, and Signatories to this Initiative, with information on best practices in the business ethics and data integrity area. This will provide members and Signatories with practices and procedures that have proven effective in various situations and information on how to tailor these practices to an individual laboratory's circumstances. This will be provided through various methods, including seminars, programs, and publications.

ACIL is also committed to working with federal, state, and local regulatory authorities and to maintaining an ongoing dialogue with such authorities to find ways to better address mutual problems related to data integrity and to better define industry best practices.

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