



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

September 5, 2001

THE INSPECTOR GENERAL

Open letter to the environmental analytical laboratory community:

This letter is intended to draw your attention to issues of misconduct or unethical practices in analytical laboratories, related to inappropriate manipulation of laboratory data, that may also constitute laboratory fraud.

The EPA Office of Inspector General (EPA-OIG) has seen an increase in the number of allegations that environmental laboratories inappropriately manipulate laboratory data. This has been defined by my Office as: "The intentional falsification of analytical and quality assurance results." The falsification of environmental data undermines the ability of federal, state, tribal, and local governments, and the regulated community, to make environmental decisions necessary to protect the health and safety of the general public.

In a continuing effort to deter these practices, the EPA-OIG is working closely with EPA's Criminal Investigations Division, other federal investigative organizations, and the Department of Justice to investigate and, as appropriate, prosecute all allegations of laboratory fraud. These efforts to date have resulted in substantial fines, penalties, incarcerations, federal suspension and debarment actions, and laboratory closures.

Of particular concern is the fraudulent practice of using improper manual integrations by chromatographic analysts to falsify test results in initial calibrations, continuing calibrations, and surrogate recoveries, to make the control samples appear to meet quality control requirements. The routine practice of laboratory management spot checking a percentage of manual integrations performed in your laboratories would send a strong message to your laboratory staff that you are committed to ensuring that they follow proper laboratory procedures, identify improprieties, and correct them immediately. All too often, EPA-OIG's laboratory fraud investigations involve significant data manipulations conducted by multiple analysts using many analytical methods over several years. These investigations can raise questions about the reliability of all the data from a laboratory.

A laboratory's best protection against fraudulent activity is the effective implementation of strong, proactive, and independent ethical practices and Quality Systems. The Quality System should clearly establish and identify acceptable and unacceptable analytical practices. In addition,

data authenticity checks should be incorporated into laboratory peer reviews, data verification, and/or Quality Assurance Officer's reviews to assure product integrity and to limit liability and exposure to "rogue analysts."

There are many factors that can contribute to misconduct: poor training, ineffective ethics programs, shrinking markets for analytical services, and greater economic incentives for laboratories to implement cost-cutting measures. Nevertheless, laboratory management is responsible for maintaining effective operations. To better ensure proper conduct, management can:

- Create a corporate environment conducive to quality operations, ethical standards, personal integrity, and accountability. This environment contributes to effective fraud prevention beyond anything industry standards and government oversight can accomplish.
- Plan for routine "down-time" to perform instrument maintenance and repairs to meet method quality control requirements. These efforts can be marketed as a hallmark of quality assurance and technical ability.
- Acknowledge that improving quality promotes profits and an *increase* in business because a reputable laboratory *attracts* business.

I encourage you to evaluate your Quality System, with particular attention to the detection and prevention of improper laboratory activities. OIG staff are available to work with the environmental laboratory community and other stakeholders to encourage ethical laboratory operations and to prevent fraud. Any inquiries or comments regarding laboratory fraud should be directed to Emmett Dashiell, Acting Assistant Inspector General for Investigations, at (202) 260-3404.

Sincerely,

/s/

Nikki L. Tinsley