UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CRIMINAL ENFORCEMENT, FORENSICS, AND TRAINING

REPORT
OF THE
LABORATORY FRAUD WORK GROUP

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I. PURPOSE OF THIS REPORT

The Office of Criminal Enforcement, Forensics and Training established the Work Group on laboratory fraud due to increasing trend in laboratory fraud cases over the last few years. Laboratory fraud could potentially undermine the foundation of EPA's regulatory programs. Since the Agency and its state partners do not have the resources to perform regular monitoring of every regulated facility, environmental programs rely heavily on a system of self-reporting. The past decade has also seen a shift toward more self-monitoring and less regulatory oversight. Third-party audits are now prevalent in many EPA and state environmental programs. Because a system of direct government oversight and inspections now shares the landscape with one which allows greater self-policing and flexibility by the regulated community, it is imperative that these new systems possess the highest degree of integrity and trustworthiness possible.

Although there are several causes for laboratory fraud, they can be divided into two obvious categories; one is money and the other is the lack of regulatory oversight. Like most crimes of fraud, money is the incentive. In laboratory fraud, the monetary goal could be either making money or saving money. There could be a collusive arrangement between the laboratory and the client facility, whereby the facility knows, either directly or implicitly, that the laboratory will produce desired results for a fee. The reality of the marketplace is that the laboratory business is very competitive and, as one defendant in a laboratory fraud case once admitted, "We had to be *commercial.*" The monetary savings are realized when laboratories fail to buy expensive analytical equipment but still claim to have the capability to perform analyses for which the specific equipment is needed. The laboratory also saves money by cutting corners on required analyses, for instance failing to perform quality assurance/quality control, or retaining unanalyzed samples long beyond specified holding times, or simply not performing the analyses at all. The other factor driving the proliferation of lab fraud is the lack of regulatory oversight. Independent environmental laboratories fall outside of the regulatory reach of most EPA and state programs. Some states have audit and certification programs for laboratories analyzing samples for regulated facilities. EPA's oversight is limited to its Contract Laboratory Program, where laboratories are submitting data directly to the Agency in support of its functions; *e.g.*, remediation at a site on Superfund's National Priority List. For the majority of environmental programs, the statutory focus is on the regulated facility, and jurisdiction is lacking to perform routine administrative inspections of independent laboratories. This is the classic recipe for a fraud crime: money to be made or saved and little risk of detection.

There have been several instances of high profile cases of laboratory fraud which have had major impacts on the regulatory programs involved. Craven Laboratories and its president, Don Craven, were prosecuted for falsifying data used to support pesticide registrations. The company was fined $15.4 million and Don Craven was sentenced to five years in prison and a $50,000 fine. Saybolt Labs was convicted of falsifying oxygen levels in reformulated gasoline and was sentenced to pay a fine of $3.4 million. The Clean Air Act requires reformulated gasoline in certain areas to limit air pollution from vehicles. In a related case, Caleb Brett USA, Inc., and six of its supervisors were prosecuted for falsifying oxygen levels in 200 to 300 million gallons of reformulated gasoline and/or misleading EPA about their knowledge of the scheme. Furthermore, the ramifications stemming from a laboratory's falsifications spread far beyond the specific tampered results; once the laboratory's integrity is compromised, all the data generated by that laboratory is questionable.

The Laboratory Fraud Work Group is comprised of forensic scientists, criminal and civil investigators, and attorneys from both EPA and the Department of Justice. We have also received valuable assistance from a financial analyst. We interviewed key people in state and federal laboratory oversight programs, other scientists, investigators, and laboratory managers in the private sector. We also reviewed EPA's criminal docket to determine trends and common themes. We limited the scope of our docket review to third-party independent laboratories only. Otherwise, the universe would be too large and unwieldy.

This report is the culmination of our research. It evaluates the extent of laboratory fraud in environmental regulatory programs. It also cites the work of EPA's Office of Inspector General and makes recommendations to improve internal EPA controls to detect instances of fraud involving laboratories performing analyses for the Agency. Most importantly, this report should be used as a practical resource for investigators and prosecutors. It describes indicators that investigators and inspectors should look for to spot suspicious laboratory practices. It also gives investigative strategies for developing laboratory fraud cases. Lastly, it highlights common legal issues for which prosecutors should be mindful when involved in one of these cases. Laboratory fraud is a very serious problem in federal and state environmental regulatory programs. We strongly support efforts to increase enforcement emphasis to deter laboratory fraud.

II. EXTENT OF THE PROBLEM

The exact extent of the problem of falsification and alteration of lab data is impossible to determine at this time. The indications and the factors supporting widespread laboratory fraud in environmental programs are both present. In those states that perform routine inspections of laboratories pursuant to a laboratory certification program, the state agency with jurisdiction will regulate and conduct inspections of a wide variety of laboratories, not just those performing analyses to determine compliance with environmental standards. Environmental testing labs may only be a small component of the inspectors work. As stated above, EPA lacks the statutory authority to perform routine inspections of environmental laboratories, other than those participating in EPA's Contract Laboratory Program. This lack of oversight creates an environment that allows labs to falsify data with minimal threat of detection.

In 1999, the Center for Strategic Environmental Enforcement (CSEE), Criminal Investigation Division, Office of Criminal Enforcement, Forensics, and Training performed a review of EPA Criminal Investigation Division (CID) lab fraud cases. The review team concluded that there were many contributing factors that lead to lab fraud: management's policy to keep the customer happy by passing tests; overworked, improperly trained, or lazy employees; understaffed labs; inadequate lab equipment, and the need for a higher volume to produce more cash flow.

The extent of lab fraud cases has grown over the last few years. In the majority of the cases investigated and reviewed, either the state regulating authority or an ex-employee referred the case to EPA CID and further assisted with information. Therefore, in order to identify lab fraud cases effectively, the assistance of an informant is crucial to obtaining information that would not be obtainable otherwise.

III. RECOGNIZING LABORATORY FRAUD

This section focuses on the following questions: How can laboratory fraud be characterized? How do laboratories and their workers commit fraud? What are some of the common practices and terms?

A. What is Laboratory Fraud?

From a regulatory standpoint, laboratory fraud is any false material statement, representation, or certification involving the generation or reporting of laboratory data and includes knowing alteration or omission of any material element. EPA's Office of Inspector General has defined laboratory fraud as "The deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable." There is often an associated motive or benefit. At the core, the motive is money, but more specifically it can be giving the false appearance that the regulated entity is "in compliance" or ensuring the continued prosperity or survival of the laboratory. Other motives are discussed below.

B. Purpose and Function of an Environmental Analytical Laboratory

The Agency has promulgated environmental regulations which specify limits of contaminants or other properties for which testing is to be performed. For example, the drinking water regulations require testing for a list of potential contaminants to protect the public from harmful exposures. The hazardous waste regulations require testing or generator knowledge to determine if listed constituents are present, or the wastes present some type of characteristic hazard. Testing under CERCLA[1] may determine harm and responsible parties. States and municipalities have their own regulations which are sometimes more stringent than federal requirements.

Given the range and volume of testing, various governmental agencies have passed the analytical testing responsibilities on to the regulated community. If the responsible entity does not have the requisite analytical capability, that entity may contract an outside laboratory.

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[1] *Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. Sections 9601-9675.*

An environmental analytical laboratory (subsequently referred to as the "laboratory") is expected to report data that accurately characterizes or quantifies the analytes (the species or property sought) in the sample. The depiction may be in the form of analyte concentrations, accompanied by assessable accuracy and precision. Or, as in the case of some RCRA characteristics, the data may be a statement as to whether or not a certain property of regulatory significance is exhibited (e.g., reactivity).

To accomplish this task, a chain of events normally takes place. A sample is taken. Having been given a unique identity to prevent a mix up, the sample is transported to the laboratory. The sample is protected from alteration. A test method is used to determine the amount or character of the constituent or property. If a numerical value is sought, a calibration of that method is performed to establish the sample value on some scale. The method must meet certain scientific and regulatory requirements. Often, the required method for a parameter (analyte or property) will be prescribed in applicable regulations. In many cases, methods have quality control[2] requirements, which are additional testing steps to help verify the reliability of the reported data.

In many cases, the testing requires employees with education and experience in the disciplines involved. Many of the test methods rely on analytical instrumentation, which can be complex and expensive. In order to isolate the analyte, additional preparatory steps for samples are often required. After initial data is generated, the data is processed (rendered into a useful and meaningful form). This often requires a computer and the knowledge to use it correctly. Lastly, the data is summarized and reported to the requestor. Each critical function is vulnerable to fraudulent manipulation.

C. Types of Environmental Analytical Laboratories

There are three types of environmental laboratories commonly encountered in the regulated community.

- Laboratories that are owned or controlled by a regulated business or entity
- Government laboratories, including state and municipal laboratories

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2 *Quality control steps are those additional measures employed to help characterize such aspects as the precision and accuracy of the data reported.*

$ Third-party contract laboratories that analyze samples for regulated businesses or entities

D. Common Types of Laboratory Fraud

There are a number of ways laboratory fraud can occur. Some of the common techniques and associated terms are as follows:

- *Drylabbing* - A common practice of deliberately fabricating analytical results
- *Pencil Whipping* - The practice of changing data or records (now more often through computer manipulations) without a legitimate reason.
- *Peak shaving* - The practice of reducing peak heights or areas, without a legitimate reason, to affect results. The opposite, *peak enhancement*, is the practice of adding peak area or peak height.
- *Juicing* - the practice of adding or diluting analyte in the sample, calibration standard, or QC samples to change results or make reported results appear acceptable.
- *Peak Dialing* - Adjusting the instrument dials, resistors, attenuators, other controls or computer outputs to achieve the desired output for the sample or calibration.
- *Sample swapping* - Intentionally analyzing or causing the analysis of the wrong sample, including substituting plain or distilled water for the sample.
- *Time travel* or *time warping* - The fraudulent practice of changing times and dates to make the documentation requirements appear acceptable. For example, some types of samples such as volatile organic samples, may degrade rapidly with time or lack of refrigeration. Therefore, there is an incentive to analyze samples within prescribed holding times or make it appear as though they had.

There are a number of other laboratory fraud techniques. A more extensive classification appears as Attachment 1.

E. Motives For Laboratory Fraud

Commonly these are:

- Economic benefit
- Time constraints
- Client motivations
- Overly burdensome contract requirements

Economic benefit is a common thread in many lab fraud cases. The laboratory owner needs to make a profit, and in most cases, the contract laboratory business is very competitive. A laboratory must avoid critically large capital expenditures without compensating revenues. Chemicals, scientifically trained personnel, laboratory equipment, and instrumentation costs can be substantial. A major laboratory may easily invest several million dollars in scientific instruments. Laboratory space costs about three times that of office space. Quality control requirements add an economic cost. Additional tests to show calibration accuracy, reproducibility, and validate methodology typically add an extra 10 to 20% to the cost of analysis. Testing can be time consuming, complex, and tedious. Also, poor human resource practices can contribute to fraud.

Although time may be related to money, time (or the lack thereof) as a commodity is also a motivation. Each work process has a time requirement and problems occur if the process cannot be performed in the allowed time using available resources. Also, samples that change in time typically have a holding time requirement. When time resources or time sequencing jeopardizes the lab's credibility, a motive for laboratory fraud emerges.

Fraud may be rationalized by the perpetrator where contract conformance is difficult for it to achieve. For example, contracts requiring extremely low detection limits, that require special calibration procedures, or difficult quality assurance requirements provide a temptation to take "shortcuts" to be on time and within budget. Also, contracts that require time consuming, difficult, or what may be perceived by the laboratory as excessive quality control measures, may provide similar temptations.

Varying standards may also provide a temptation to commit fraud by creating the illusion of "discretionary behavior." For example EPA has compiled volumes of test methods in

SW 846,[3] many of which were intended only as guidance. Yet many EPA and especially state programs have adopted such procedures as rigid requirements. Also, widely debated are the use of performance based methodologies (PBMS). The adoption of this approach would eliminate certain required methodologies where other methods can be shown to produce equal or superior accuracy and precision. Such an adoption or philosophy would give the laboratory wide latitude and discretion (in addition to confounding many investigators). Requirements perceived to be unnecessary may tempt those persons to take shortcuts.

A laboratory's clients have different motivations. They face the threat of fines for regulatory violations. Often, the laboratory that is selected by a client may also be the one that can keep it out of trouble with the environmental authorities, though this does not necessarily mean real compliance with the regulations. There may be some direction given to the laboratory by the customer to sample selectively, calculate erroneously, or alter results in another manner.

IV. IDENTIFICATION OF SUSPECT LABORATORIES AND PRACTICES

This section discusses the means of identifying suspect labs and key witnesses.

A. How Fraud is Reported

Sources of information concerning lab fraud cases are most often:

- *Laboratory employees* or *former employees* (often *informants)* with specific knowledge
- *Data reviewers and data users*
- *Auditors and inspectors*
- *Regulators*

All these individuals have direct or indirect contact with laboratories and laboratory personnel.

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3 *SW 846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Third Edition (November, 1986).*

For each of the sources just mentioned, the following provide illustrative scenarios:

A *laboratory employee* discovers other employees falsifying data and tells the laboratory QA manager. The QA manager talks to the laboratory owner, who decides to self report the fraud.

An *ex-laboratory employee* who was recently fired from a laboratory, reports that mercury data is reported; however, the laboratory did not have the required equipment to analyze samples for mercury. He talks to his former college professor. Recognizing the significance, the professor talks to the state. The state subsequently contacts the US EPA.

An EPA *data reviewer* observes that the identical calibration measurement results are used for all the data packages submitted during a whole year. A subsequent laboratory inspection confirms that an employee, contrary to required procedure, merely patches the same computer standardization file into each run.

Pursuant to an Air Force contract, an *auditor* is sent to inspect a laboratory. He examines the calculations necessary to validate the laboratory's reported detection limit and also the levels of chemical standards that the laboratory uses. He determines that there is no way that the laboratory can achieve the detection limits required and reported.

A company has contracted with a laboratory to analyze samples pursuant to discharging waste under NPDES. The company begins to notice that the reported data seems too consistent and that it seems low in relation to the company's production process. It sends several split samples to another laboratory and obtains completely different results. This company is a *data user.*

A *regulator* receives a fish kill report that is traced back to a particular factory discharge upstream of the kill, using a pH instrument, which shows low pHs. Upon investigation, the regulator finds out that the company's discharge pH measurement for that day and for the past year is near neutral. Upon further investigation, the regulator determines that the company inserts its continuous pH probe into a glass of tap water rather than the moving effluent stream.

Individuals involved with laboratories, data reviewers, auditors, inspectors, etc., upon observing suspect practices, should be looking for signs that a laboratory is involved in fraud. These signs generally fall within two classes.

- *Missing elements*: Those elements that are key to laboratory operations, described above, in Section III. B. of this report, or are otherwise necessary for the production of laboratory data required.

- *Manipulation:* Alterations and substitutions. Changes in sample data, QC data, calibration data. Substitution of such things as the same calibration data from one run to another, avoiding necessary recalibration.

For a more comprehensive list of observances that indicate laboratory or data problems, call for further investigation, and, as a result, may lead to findings of fraud, see Attachment 2 to this report. One should not interpret much of what appears in Attachment 2 as a direct indicator of fraud, only a place to start if suspicious problems or deceptive patterns are found.

B. Contacts

1. Laboratory Employees

The employees of laboratories are often in the best position to identify suspect laboratory practices resulting in findings of fraud because of their first hand knowledge of events. Informant employees (or past employees) often provide essential information as well as probable cause necessary for certain subsequent investigative activities.

2. Data Users

Data users are those individuals or entities, usually outside the immediate laboratory environment, relying on (or in some other way requiring) data produced by a laboratory. Companies and municipalities report data to government agencies under programs such as the National Pollution Discharge

Elimination System (NPDES), equivalent state programs, pretreatment regulations, drinking water programs, and various Resource Conservation and Recovery Act (RCRA) programs. The data is used to determine compliance with the environmental statutes. Typically, levels of compounds reported in the data are compared with some regulatory threshold.

The ultimate data user is the governmental agency, federal, state, or local. Given the large and diverse requirement for monitoring pollution and establishing guidelines, government entities rely on private laboratories other than their own to accomplish these tasks. The mandate for useable data is that it accurately depicts the levels of constituents present for a condition sampled. For this reason, the data user should be, and often is, involved in some type of assessment(s) to ensure that the data it receives meets its requirements. This form of assessment may be broadly categorized as *review and assessment* of reported data or data packages, and on-site laboratory *inspection.*

3. Inspectors

These can be individuals involved in precontract, certification audits, or inspections[4] pursuant to some type of regulatory program or enforcement action.

Companies or other entities employing contract (third-party) laboratories may require a preliminary laboratory inspection and assessment prior to initiating the contract in order to determine the laboratory's suitability. Thereafter, there may be subsequent inspections and assessments to ensure contract compliance.

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[4] *Audits usually refer to some type of routine or regular checking of laboratory activities and records against the auditors' requirements. The term "inspection" may be used synonymously, although some regulators reserve this term for determining more formal or specific allegations. The term "inspection" also may be used to differentiate visual, on-site viewing of the subject matter and physical circumstances as opposed to an audit, which can include off-site review of data, including electronic data whether stored on magnetic tape, discs, or other media. Discussion of the practices and techniques involved in on-site laboratory inspections of this type is beyond the scope of this document and are geared predominantly to identify scientific, civil regulatory, or contract requirement problems. Agents should be aware, however, that cooperating current or former laboratory employees may be familiar with inspectors or auditors. Agents investigating lab fraud cases should contact such parties.*

Likewise, some states have certification programs that require preliminary and recurrent inspection and assessment of laboratories. Certification programs typically are specific for a particular type or group of analytes ; *e.g.,* certifications under state drinking water programs. Some states certify laboratories located in other states producing data for their own state's use. The analysis of performance samples[5] is a frequently used mechanism to see if laboratories can analyze samples in the most simplistic manner and obtain valid results. Observable discrepancies in reported results could trigger further inquiry. For example, if a laboratory repeatedly failed such evaluations, the regulator might find it difficult to believe that other reported results were satisfactory. On the other hand, the lack of observed problems with such performance evaluation samples in no way proves that problems do not exist with a laboratory. Put differently, absence of evidence is not evidence of absence.

On-site laboratory inspections offer a unique opportunity to request information and identify problems. Regulatory personnel are in a position to meet laboratory workers and make site observations. Also, there is an opportunity to review records. Some findings can immediately identify fraud (e.g., a key piece of missing instrumentation). Other anomalous findings may lead an agent to ask other questions, which then leads to findings of fraud. Once the regulatory contact is made, informants may come forward more readily.

4. Data Validators

Data validators are individuals who look at reported data or data packages and [6] assess usefulness of data submitted in response to their needs. These

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5 *Performance samples are known concentrations of specific analytes often made up in pure solvent (sometimes lacking the ability to evaluate matrix effects found in real samples), that are sent to laboratories in order to determine if laboratories can obtain results falling within expected statistical tolerances. Some labs give these samples special attention or may cheat in various ways in order to obtain acceptable results.*

6 *Data packages include not only the reported data itself, but also the supporting quality control/quality assurance information and other supporting information that the regulator requires. The regulator may request all the analytical "run information" on some type of magnetic or electronic storage media for careful examination of calibration, quality control, and other requirements.*

individuals can assist in identifying potential laboratory fraud. Besides on-site audits, when only the reported data are available for immediate examination, there are other data validation techniques[7] which may be used to identify laboratory problems. When problems are identified, follow-up measures could or should be employed to explore the anomalies. The data validator could request more verbal or written information. Additional primary or quality assurance data for example could be requested. The anomaly could spawn an on-site inspection and more detailed assessment.

EPA's Contract Laboratory Program (CLP) has reviewers and auditors that can spot laboratory problems. The CLP was created in the 1980s in response to the Agency's need for contract laboratories to perform the large amount of analyses required predominately under RCRA and CERCLA. Because EPA was to rely heavily on the quality of this data, laboratories participating in this program had to meet a regimen of requirements including detailed, specific quality control. Data validation and audits were prescribed.

5. Accreditation

More recently, there have been initiatives to have laboratories become accredited. The National Environmental Laboratory Accreditation Conference (NELAC) is a voluntary association of state and federal agencies, the purpose of which is to establish and promote performance standards for the operation of environmental laboratories. EPA's National Environmental Laboratory Accreditation Program (NELAP) provides support to NELAC and, once standards are finalized, will oversee the accrediting authority programs. The investigator could check to see if the laboratory claims to be accredited, if so, when and under what circumstances.

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7 *Data validation is a term used by regulators to describe the quality assurance function of ensuring that sought- after laboratory data is reliable and, of known quality. It involves looking at the underlying and associated quality control data. Quality control refers to the individual measures such as precision and accuracy used to assess the worth of the data. Data validation may also include more complex measures such as anion/cation balance, mass balance, analyte agreements, etc. Data validation and evaluation can be technically complex, requiring an experienced technical person to perform it correctly.*

6. Regulators

Regulators are federal, state, and local employees who administer regulations and check for compliance. Regulators can be auditors, inspectors, or data users. Regulators that are responsible for receiving compliance data are also in a position to identify anomalies and suspect patterns, that upon investigation may show fraud. EPA and state chemists/technical personnel are invaluable in distinguishing between legitimate or potentially fraudulent discrepancies : for example, explaining how the computer software works and what are the fraud-vulnerable functions of the software .

C. Encouraging Individuals to Report Laboratory Fraud and Enhancing Disclosure

Individuals who are in the position to spot fraud should know why it is important to report the potential fraud, where, and to whom to report fraud, and that their reporting will be taken seriously. Further improvement in these areas should bring about more cases.

How can these objectives be accomplished?

1. Presentations

Criminal investigators and prosecutors can present talks and informal discussions to regulators involved with environmental laboratories. These presentations enhance rapport between federal and state investigators, prosecutors and technical personnel, improve knowledge and provide encouragement to state personnel to report suspicious activities.

2. Publications

Newspaper and magazine articles have been used to publicize cases. Agency reports have been helpful in providing and disseminating findings.

3. Training Courses

Inspector or auditor training often includes material on identification and handling of fraud.

4. Other Communications

Record of successful prosecutions are routinely circulated within EPA. This has helped create awareness among regulators.

V. INVESTIGATION OBJECTIVES AND TECHNIQUES

Once leads have been identified, it is important to outline the objectives and the most efficient means of investigation and evidence collection to result in effective prosecution. This section discusses investigative investigative objectives and techniques.

A. Preliminary Investigation

1. Pre-search or Pre-subpoena Activities

One of the best ways to gain preliminary evidence is the examination of existing records and witnesses. Not only should the preliminary information be researched as thoroughly as possible, but its significance should be established by talking to appropriate technical, program, and legal personnel. It is critically important to understand how the programs are administered by the regulatory authority to discern what is required, as opposed to what may be a fraudulent practice. It is important to recognize that the various regulatory agencies may have different perspectives on and interpretations of similar requirements.

Proactive operations in lab fraud investigations, while possibly requiring a significant amount of initial work, may be one of the most cost effective means of determining if a violation is occurring and, if so, proving it. One approach involves the introduction of a "blind" sample into the suspect laboratory for analyses. It may be necessary to obtain the cooperation of a laboratory client, or to set up an artificial client in order to implement this technique. The crucial consideration is ensuring that a proper analysis of the submitted sample will provide sound evidence of any wrongdoing.

Physical surveillance of the lab may also help prove wrongdoing. For example, noting the arrival and departure of lab personnel and comparing that information with lab records may show that particular personnel were not physically present at the lab at the time their presence would have been required to perform a necessary or identified function. Surveillance can be particularly effective where labs also conduct their own sampling or sample retrieval. Times of arrival, use of equipment, whereabouts of personnel, hours of operation are examples of potentially useful information that can be gathered through surveillance.

2. Developing Inside Inside Contacts

The challenge of investigating lab fraud is discovering what is happening within an environment that may be initially obscured to the investigator. Reviewing submitted data, including quality assurance/quality control (QA/QC) data, can provide some information, but this is a time-consuming process. The most expeditious way to penetrate any scheme or conspiracy is to have the cooperation of an inside witness. In lab fraud, this can be very important, because of the often complex aspects of the crime. When we have suspicion of wrongdoing, the cooperating person can potentially tell us about the character of the participants, company policies that may be responsible for the wrongdoing, the actual resources and capabilities of the laboratory, the competence of the employees, and how the fraud was committed. All this can help clarify the important question whether the problem is due to intentional wrongdoing, ignorance, and incompetence or some other factor that is not fraudulent in character.

Developing informants can be the specialty of the trained investigator. This investigative technique involves identification of individuals, establishing rapport, confidence, and motivation, as in any investigation. Useful informants include present employees, former employees, and clients or personnel with knowledge from other laboratories.

Informant information is critical when preparing a search warrant. An informant can tell the case team what to look for and where to find it. This information can be the basis for the probable cause to show that certain documents exist at a particular location. The insider's information will also be an important part of the basis for the *Items To Be Seized* section of the warrant. Additionally, he or she can provide detailed information regarding the layout of the offices, the filing system used, the number and types of computers, and the file names of records of interest. The informant can also tell the case team the work hours of particular employees that may affect how and when to serve the warrant. Informants with inside knowledge will be of further value as additional evidence is gathered and the case enters the prosecution stage.

Another important aspect is limitation of scope. Large laboratories are often divided into sections (organic, inorganic, prep, etc.), limiting the scope of

wrongdoing to a particular section, team, or even workgroup, and often there is little overlap. It is important to consider this before targeting an entire lab, which could make the investigation too unwieldy. It is important to be "surgical" and focused.

VI. PROSECUTORIAL ISSUES

This section of the manual addresses certain prosecutorial and legal issues that commonly occur in lab fraud cases. As a threshold matter, it is important to distinguish between the two basic types of laboratory fraud cases.

Basic Types of Laboratory Fraud

The first basic type involves fraud committed by the laboratory in conjunction with, or at the behest of, the laboratory's client(s). A case exemplifying this type of fraud is *United States v. Caleb Brett U.S.A., Inc.* (Crim. No. 00-622 (HAA)), *a prosecution in New Jersey involving reformulated* gasoline (RFG) in which Caleb Brett pleaded guilty in September 2000 to a charge of conspiracy. In that case, a petroleum blending company wanted to sell hundreds of millions of gallons of RFG that did not meet federal, state, or commercial specifications. Rather than re-blend the RFG, the blender put pressure on Caleb Brett, the laboratory that analyzed the RFG, to falsify test results to make the RFG appear to meet the specifications. In order to keep the blender's business, the laboratory agreed to participate in an elaborate scheme to falsify analytical results. Related prosecutions have resulted in ten additional guilty pleas, including pleas by the petroleum blender and two of its executives in October 2001, and a guilty plea by the former president of Caleb Brett in November 2001.

The second basic type of fraud is where the laboratory's clients are the victims of the fraud. The usual fact pattern for this type of fraud involves a laboratory that wants to maximize its profits and consequently underbids projects, promises unrealistic turnaround times, and accepts work for which it has neither adequate personnel nor necessary equipment. Often the client-victim is a governmental entity, such as a department or agency of the United States Government. In order to meet its contractual obligations, a laboratory will cut corners by not calibrating its equipment, by ignoring established laboratory procedures and protocols, and generally by focusing its resources on the quantity - but not quality - of its analyses. An example

of this type of fraud is the case of *United States v. Intertek Testing Services Environmental Laboratories, Inc., et al.* (Crim No. 300-CR-375-D), in which the corporation and five individuals entered guilty pleas to conspiracy and related crimes in September-October 2001 in the Northern District of Texas. A $9 million corporate fine was imposed in the case. In November 2001, however, following a six-week jury trial, eight of the laboratory's employees were acquitted. In Intertek, it was alleged that over an eight-year time period, a laboratory in Richardson, Texas, failed to calibrate or improperly calibrated equipment utilized in thousands of analyses. Some of the alleged victims included the United States Army Corps of Engineers and the United States Air Force. While it was established at trial that the laboratory cut corners on quality control measures, the eight acquittals may have been based, in part, on the fact that Intertek's clients received test results that were basically accurate. (See discussion of "materiality" in section on mail and wire fraud.)

A. Laws Violated

While there are no criminal statutes specifically addressing laboratory fraud, certain traditional Title 18 provisions often apply.

1. Conspiracy (18 U.S.C. § 371)

The essential elements of this offense consist of (1) two or more persons who (2) conspire (3) to commit an offense against or to defraud the United States or one of its agencies in any manner for any purpose, and (4) one or more of these persons does an act to further the conspiracy. Conspiracy only requires proof of an agreement between or among the defendants to commit an offense and overt acts taken in furtherance of that agreement. It does not require that the defendants succeed in fulfilling the object of their conspiracy. The conspiracy charge is particularly appropriate for the first type of laboratory fraud, where by its very nature the laboratory is agreeing with its client(s) to falsify analytical results. It may also apply in the second type of fraud, however, especially since that type of fraud usually requires agreement among and between supervisors and laboratory technicians on the manner in which shortcuts will be taken. Three benefits of a conspiracy charge include: (a) venue exists in each district in which an overt act was committed; (b) in the case of an ongoing conspiracy, conduct that would otherwise be barred by the statute of limitations may be charged; and (c) liberal hearsay rules may enable co-conspirators' statements (that would otherwise be inadmissible) to

be admissible against the defendants. Finally, because a conspiracy charge is designed to criminalize the agreement, that the substantive offenses may not have been completed is irrelevant.

2. False Statements (18 U.S.C. § 1001, 1505)

A defendant violates this statute if he knowingly and willfully does one of the following three acts in a matter within the jurisdiction of a department or agency of the United States: (1) falsifies, conceals, or covers up a material fact by any trick, scheme, or device; or (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing that it contains any materially false, fictitious, or fraudulent statement or entry. In the lab fraud context, a false statement would be committed by a laboratory which falsely reports the results of a test to a federal department or agency, or under certain circumstances, to a state agency. Furthermore, under 18 U.S.C. § 2, in the case of the first type of laboratory fraud, the client(s) that requested the laboratory falsify results would also be criminally responsible. A defendant could also violate Section 1001 if he or she lies about a material fact to an agent investigating the matter.

3. Mail and Wire Fraud (18 U.S.C. §§ 1341, 1343)

These statutes are violated by anyone who knowingly: (1) devises, intends to devise, or participates in a scheme or plan to defraud or obtain money or property by means of false pretenses, representations, or promises; (2) with intent to defraud; and (3) uses the mails, a private or commercial interstate carrier, a transmitted writing, signal or sound by wire, radio, or television communication in interstate or foreign commerce in order to advance or further that scheme. In the laboratory fraud context, mail fraud may be committed where the United States mail or a commercial interstate carrier (such as Federal Express) is used to send documents that are essential to the scheme, even if the documents themselves are not fraudulent. For wire fraud, the same concept would apply where documents essential to the scheme are sent by fax across state lines, or where interstate telephone conversations occur concerning the fraudulent scheme. As with 18 U.S.C. §

1001, the client can be criminally liable for conduct committed by laboratory personnel under 18 U.S.C. § 2 (and vice versa).

The United States Supreme Court has held that "materiality of falsehood is an element of the federal mail fraud [and] wire fraud . . . statutes." United States v. Neder, 527 U.S. 1, 25 (1999). Thus, where the laboratory's scheme is designed to deceive its clients, the Government must be prepared to prove that the laboratory misrepresented or concealed not just any facts, but facts that were material. This could be difficult in circumstances where the laboratory cut corners on quality control measures, but where its clients ended up receiving test results that were essentially accurate.

4. False Claims (18 U.S.C. §§ 286, 287)

A person makes a false claim if he: (1) makes or presents to a government agency a claim against the United States (2) knowing that the claim is false, fictitious, or fraudulent. The statute also prohibits people from entering into agreements or conspiracies to make false claims against the government. For the purposes of laboratory fraud cases, false claims may be made by laboratories that request payment from government agencies for testing services which are fraudulently completed or not completed in accordance with procedures prescribed by applicable law or regulations. 18 U.S.C. § 2 would also apply here.

5. Reporting Requirements Under Environmental Statutes

Some of the environmental statutes contain independent reporting requirements and criminal enforcement provisions that are analogous to those contained in Title 18. For example, the Clean Air Act prohibits such acts as knowingly making false statements, knowingly failing to file required notifications, and knowingly tampering with or falsifying monitoring devices that are required to be maintained under the Act. See 42 U.S.C. § 7413(c)(2). If, for example, a laboratory were to submit falsified test data on behalf of a client that was required to submit such data under the Act, the laboratory would be in violation of this reporting requirement. Other environmental statutes contain similar provisions. See, e.g., Clean Water Act, 33 U.S.C. § 1319(c)(4); Resource Conservation and Recovery Act, 42 U.S.C. § 6928(d)(3) and (4); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9603(c).

B. Prosecutorial Issues

The following issues commonly arise in laboratory fraud cases:

1. Entrapment Defense

Most laboratory fraud cases are reactive in nature: The government receives a tip from a disgruntled employee or a competitor, and then investigates the allegations by interviewing witnesses and reviewing documents. A powerful tool available to the government involves the use of proactive investigative techniques, including the use of an undercover officer in a sting operation. For example, if the government learns that ABC Lab, in the first laboratory fraud scenario, is willing to falsify wastewater test results to obtain customers, an agent may pose as a customer needing analytical tests performed on its wastewater. After this "client" obtained the confidence of the laboratory, it could then ask the laboratory manager to "help out" on some wastewater samples it fears are high in fecal coliform. Of course, the samples would have been previously tested, and if the lab manager agrees to falsify the test results so that the samples falsely appear to meet the coliform limits, the government's case is materially stronger.

In this kind of undercover operation, however, where government agents participate in the charged offense, the defendant may claim that he was entrapped – that he would not have committed the crime if the government agents had not induced him to do so. There are two tests that courts employ when assessing the applicability of an entrapment defense.

a. Predisposition or Subjective Test

This test focuses on whether the offense was induced by a government agent. If so, the government must prove beyond a reasonable doubt that the defendant was predisposed to commit the crime before she was approached by government agents. If the government shows that the defendant was ready and willing to commit the crime whenever the opportunity arose, the defendant may not avail herself of an entrapment defense. If,

however, the government cannot establish the defendant's predisposition beyond a reasonable doubt, then the defendant may avail herself of the defense.

a. *"Shock the Conscience" or Due Process Test*

Alternatively, some courts may disregard the subjective test and focus exclusively on the government's conduct in a case, without regard to any criminal predisposition that a defendant might otherwise possess. If the conduct of the government agents is so outrageous that it shocks the conscience, some courts have ruled that principles of constitutional due process require that the charges be dismissed. Under this test, the defendant bears the burden of proving that the government's conduct was outrageous. The defense may claim that any government conduct in a case may be subject to examination under this approach, regardless of whether the particular conduct induced the defendant to commit the criminal activity.

2. Drafting the Search Warrant

In addition to the normal considerations that go into drafting a search warrant, prosecutors in laboratory fraud cases should be mindful of some particular concerns in these cases. Most importantly, where chromatographic analyses have been performed (such as by GC or GC/MS instruments), the search warrant must include provisions for seizing backup media containing electronic information. Specifically, when these types of instruments are calibrated or used for analyses, an "audit trail" is electronically recorded within the instrument. If results have been manually adjusted during calibration or actual tests, these adjustments are recorded. Because the instruments have limited memory capacity, however, this backup information must be downloaded every few weeks to storage media, such as CDS or magnetic tape. This media can provide a treasure trove of incriminating information, particularly if the laboratory has routinely engaged in peak shaving or peak enhancement during calibration of its instruments.

3. Parallel Proceedings and Interfacing with Regulators

When investigating and prosecuting criminal charges in laboratory fraud cases, prosecutors need to be aware of the possibility of simultaneous civil or administrative proceedings that relate to the same conduct. In other words, in addition to the criminal investigation, a defendant's conduct may give rise to a civil action by the government or

an administrative action by the regulatory agency. While the criminal prosecutor should monitor the progress of any such parallel civil proceeding or regulatory action, the prosecutor should be extremely careful not to influence the conduct in those parallel proceedings. The prosecutor and investigative personnel should also recognize the requirement under Fed. R. Crim. P. 6(e) to protect the confidentiality of evidence obtained through the grand jury process. This kind of evidence cannot be used to assist in a civil proceeding or regulatory action without a court order.

The prosecutor should always consult applicable DOJ policies and seek guidance in appropriate cases from designated personnel.

C. Sentencing Issues

Laboratory fraud cases raise some particular sentencing considerations.

1. Evaluating Harm

Determining the harm which results from laboratory fraud cases is not always a simple matter. In the second laboratory fraud scenario outlined above, part of the harm is easily identified as the financial loss incurred by the defrauded client. Beyond that element, however, there arguably exists additional harm that occurred as a result of the falsified laboratory data. Suppose, for example, a client submits a sample of waste to a lab in order to determine how to dispose of the waste properly. The laboratory falsely reports that the waste is nonhazardous when, in fact, the waste is hazardous. As a result, the client is misled into believing that disposal of the waste at a nonhazardous landfill is appropriate. After such disposal, the client's waste leaks from the landfill which is not properly equipped to handle this type of hazardous waste. The harm caused by this leak – whether to the environment, surrounding population, or to the landfill which incurs cleanup costs – should also be taken into consideration in determining the harm caused by the laboratory's fraud.

Similar difficulties are present in determining the harm caused by the first type of laboratory fraud. In that scenario, the client is no longer a harmed victim because it has conspired with the laboratory. Rather, the harm is incurred by entities which receive and rely upon the fraudulent test data. As with the foregoing example, the resultant harm

may be to the environment, a specific community or the government, depending on what happens to the tested material after the fraudulent test data is procured. Whatever the outcome, all potential avenues for harm need to be assessed to determine a sentence which is proportionate to the harm caused by the offense.

It should be noted that both §§ 2Q1.2 and 2Q1.3 contain a provision (b)(3) that provides for an enhancement of two to six levels, if the offense involved a "disruption of public utilitiessor evacuation of a community, or if cleanup required a substantial expenditure." Determining the level of enhancement depends "upon the nature of the contamination involved." See § 2Q1.2 Application Note 7; § 2Q1.3 Application Note 6.

2. Fine/Restitution

In laboratory fraud cases, Chapter 8 of the Federal Sentencing Guidelines Manual governs any payment of restitution, community service, and probation for corporations. In determining an appropriate fine for a corporation, however, pursuant to the Commentary to U.S.S.G. § 8C2.1, "the provisions of §§ 8C2.2 through 8C2.9 do not apply to counts for which the applicable guideline offense level is determined under Chapter Two, Part Q (Offenses Involving the Environment). For such cases, § 8C2.10 (Determining the Fine for Other counts) is applicable." U.S.S.G. § 8C2.10, in turn, directs the court to apply the provisions of Title 18, United States Code, Sections 3553 and 3572 to determine the appropriate fine. Accordingly, calculation of the fine in any particular case will hinge on whether the Guidelines calculations proceed under the environmental provisions (§§ 2Q1.2 and 2Q1.3) or another provision, often fraud (§ 2F1.1). Under the latter scenario, U.S.S.G. § 5E1.2 outlines the provisions relating to fines.

U.S.S.G. § 8B1.1 effectively requires that corporate offenders provide restitution. The guidelines state: "As a general principle, the court should <u>require</u> that the organization take all appropriate steps to provide compensation to victims and otherwise remedy the harm caused or threatened by the offense." U.S.S.G. § 8B1.1 Intro Cmt. (emphasis added). <u>See also</u> 18 U.S.C. § 3553(a)(7) (stating that the court "shall consider" "the need to provide restitution to any victims of the offense" "in determining the particular

sentence to be imposed"). The substantive provisions of § 8B1.1 bear out this legislative intent and should be applied accordingly.

3. § 2Q1.2 Hazardous/Toxic Substances versus § 2Q1.3 Pollutants

Whether the Guidelines calculation will proceed with a base offense level of eight or six depends on the type of substance being analyzed by the laboratory. Where the laboratory is committing fraud in its analyses of hazardous or toxic substances, such as halogenated organic compounds or benzene, or pesticides, the base offense level is eight, pursuant to § 2Q1.2. In circumstances where the fraud occurs in the context of nonhazardous pollutants, such as wastewater laden with fecal coliform, the base offense level is six under § 2Q1.3. Where the fraudulent conduct consists of a false statement in violation of 18 U.S.C. § 1001, however, the appropriate sentencing provision is § 2F1.1. See U.S.S.G. § 1B1.2 Application Note 1 ("The court is to use the Chapter Two guideline section referenced in the Statutory Index (Appendix A) for the offense of conviction [that provides that 18 U.S.C. § 1001 offenses should be sentenced under § 2F1.1]."). See also id. (noting that court should determine appropriate guideline where a statute proscribes a variety of conduct which could be subject to different guidelines).

4. Ongoing, Continuous, or Repetitive Discharge, Release, or Emission

In most cases of laboratory fraud, the scheme to defraud will span months or years. If the scheme is successful -- whether for calibrations or for quantitative/qualitative analyses -- and analytical results are actually falsified, the government can successfully argue that the scheme resulted in ongoing, continuous, or repetitive discharges, releases, or emissions, and the six-level increase should apply. For example, in the case of the first type of fraud described above, the government may be able to show that the fraud enabled the client to sell its sub-standard gasoline into commerce, resulting in the release of higher levels of benzene and carbon monoxide into the atmosphere. In an example using the second scenario, the government should be able to prove that, because a laboratory's instruments were improperly calibrated, test results obtained from the instruments were unreliable which led to the improper discharge of chemicals (e.g., hazardous wastes were placed in a landfill because the instrument failed to identify the hazardous chemical in the sample).

5. Environmental Recordkeeping Issues (U.S.S.G. §§ 2Q1.2, 2Q1.3)

The Sentencing Guidelines contain two provisions which are regularly used for environmental offenses. Both provisions in turn contain additional sub-provisions relating to recordkeeping offenses.

a. *Simple Recordkeeping or Reporting Violations Involving Hazardous or Toxic Substances*

Under U.S.S.G. §§ 2Q1.2(b)(6), a case which involves a "simple recordkeeping or reporting violation" relating to hazardous or toxic substances deserves a two-level decrease, if no other substantive environmental offense is involved or concealed. According to the commentary, the term "simple recordkeeping offense" means "a recordkeeping or reporting offense in a situation where the defendant neither knew nor had reason to believe that the recordkeeping offense would significantly increase the likelihood of any substantive environmental harm." This provision applies only to cases involving hazardous or toxic substances and not to cases involving other pollutants. This sentencing provision might apply to a situation in which fraudulent laboratory data was submitted by technicians who did not and could not reasonably expect their fraud to result in a greater chance of harm to the environment.

b. *Recordkeeping Offenses Which Reflect an Effort to Conceal a Substantive Environmental Offense*

In cases where the recordkeeping offense demonstrates an effort to conceal a substantive environmental offense – whether involving hazardous, toxic, or any other regulated pollutant – the guidelines dictate that the offense level for the substantive offense apply. See U.S.S.G. §§ 2Q1.2(b)(5), 2Q1.3(b)(5). According to the commentary, the term "recordkeeping offense" includes "both recordkeeping and reporting offenses." Thus, if a laboratory falsifies test data required to be reported by its client to the U.S. Environmental Protection Agency under the Clean Air Act in order to conceal a criminal violation by the client of the Act, the applicable offense level is to be determined in accordance with the appropriate guidelines under U.S.S.G. § 2Q1.2 if the offense involved a hazardous or toxic pollutant or under § 2Q1.3 if the offense involved another type of pollutant. See, e.g., United States v. Liebman, 40 F.3d 544 (2d Cir. 1994) [noting that applicability of § 2Q1.2(b)(5) "is dependent upon a determination of whether that offense 'reflected an effort to conceal a substantive environmental offense'") (quoting §

2Q1.2(b)(5)]; appeal after remand, 1995 WL 760395 (2d Cir. Dec. 26, 1995) (noting that district court found that defendant's "failure to report the environmental offenses reflected an effort to conceal the offenses" and affirming sentence imposed by district court).

6. Adjustments

a. *Use of Special Skill* (U.S.S.G. § 3B1.3)

The guidelines provide for an increase of two levels to a defendant's offense level if he "used a special skill" to commit the offense. The term "special skill" means "a skill not possessed by members of the general public and usually requiring substantial education, training or licensing." "Chemists" are specifically included as a representative example of persons with special skills. A similar argument should be made for comparably trained laboratory personnel. This adjustment may not be applied in addition to an adjustment for an aggravating role under U.S.S.G. § 3B1.1. Where both §§ 3B1.1 and 3B1.3 apply, prosecutors should decide which adjustment is most appropriate in a given case.

VII. IMPROVING INTERNAL PROCEDURES

Since many environmental regulatory programs rely heavily on analytical results performed by independent laboratories and regulated facilities, it is essential that EPA have adequate internal procedures in place to safeguard its programs from laboratory fraud. In 1999, then Deputy Administrator Fred Hansen requested that the Inspector General determine what the Agency could do to detect and prevent fraudulent activities. The IG prepared a report, dated June 25, 1999, which discussed its findings and also proposed several recommendations.

The IG report identified three major factors that have fostered lab fraud.

1. Ineffective oversight of laboratory data
2. Shrinking market resulting in a focus on production over quality
3. "One size fits all" approach to analytical requirements

The first of these factors is a result of the fact, according to the IG, that the Agency "does not appear to give fraud prevention and detection adequate attention in conducting oversight." There is limited guidance and training for those EPA employees who receive and assess outside laboratory results. The second factor concerns the economic realities of the marketplace. Over the last decade, the number of third-party environmental testing laboratories has declined from approximately 1200 to fewer than 900. This has caused the surviving laboratories to compete aggressively for business, including a willingness to provide fraudulent data for clients. The last factor refers to a laboratory cutting corners on proper protocols, like quality assurance/quality control (QA/QC) in order to save money.

A. Recommendations

The IG's Report made several recommendations to curtail the proliferation of lab fraud. They are divided according to the three factors discussed above.

1. Ineffective Oversight of Laboratory Data

$ The State of California, with assistance from EPA, developed the *Best Practices for Detection and Deterrence of Laboratory Fraud* (Best Practices). The IG report recommends that this manual should be used by all EPA program offices that receive, evaluate, and rely upon outside laboratory analysis.

$ Provide training for on-site auditors/inspectors, as well as individuals responsible for reviewing laboratory data that would incorporate fraud detection techniques and provide modified on-site audit checklists to prompt auditors/inspectors to look for potential fraud.

$ Promote ethics in laboratories performing environmental testing and provide ethics training, such as the training offered at the 1998 Waste Testing and Quality Assurance symposium.

$ Pursue and publicize all means of providing individuals performing environmental testing with appropriate contacts to report possible misconduct *(e.g.,* a fraud hotline).

$ Promote the use of automated data screening tools which look for patterns in a data set that may not be predictable or observable by conventional data review techniques. This capability is generally called "data mining" and is applicable to

electronic data deliverables (EDD). Additionally, EPA should seek standardization in the use of EDD.

2. Shrinking Market for Analytical Services

$ The IG report suggests that EPA assess whether it should incorporate a quality certification system, like the National Environmental Laboratory Accreditation Conference (NELAC), among its mandatory requirements for all program areas.

3. Applying Appropriate Quality Assurance/Quality Control

$ Use a systematic planning process, like EPA's Data Quality Objectives (DQO) when planning data collection activities. This will assist in determining what extent QA/QC is necessary and appropriate for the intended use of the data.

These recommended internal procedures, in conjunction with effective enforcement against laboratories generating fraudulent data, would greatly improve the integrity of the outside laboratory data relied upon by EPA and other environmental agencies.

VIII. VICTIM AND WITNESS ASSISTANCE

This section focuses on the requirement of Federal law enforcement agencies to render assistance to victim/witness of crimes and includes a discussion of the obligations of the Agency in addressing this matter.

1. Background

Individuals and private entities who are victims of federal crimes are guaranteed certain rights and are eligible for specific services from Federal law enforcement agencies. As explained below, these rights and eligibilities do not extend to Federal departments and State and local agencies.

Pursuant to the Victim and Witness Protection Act (VWPA) of 1982 and subsequent legislation, Congress codified a selected list of rights for victims of crimes. In these statutes, Congress also directed the Department of Justice and other Federal agencies engaged in crime detection, investigation, and prosecution to provide specific services to crime victims. In addition, Congress instructed the Attorney General to assure that the Department of Justice and all Federal law enforcement agencies outside the Department of Justice adopt guidelines consistent with the purposes of the VWPA. The guidelines developed by the Attorney General (AG Guidelines) serve as the basis for other Federal law enforcement agency guidelines.

The list of victim rights, commonly referred to as "victims bill of rights," is found at 42 U.S.C. § 1066. Congress codified the list of responsibilities that Federal agencies are directed to provide to crime victims at 42 U.S.C. § 1067. The rights of crime victims (42 U.S.C. § 1066(b)) include:

> (1) the right to be treated with fairness and with respect for the victim's dignity and privacy.
> (2) the right to be reasonably protected from the accused offender.
> (3) the right to be notified of court proceedings.
> (4) the right to be present at all public court proceedings related to the offense, unless the court determines that testimony by the victim would be materially affected if the victim heard other testimony at trial.
> (5) the right to confer with attorney for the Government in the case.
> (6) the right to information about the conviction, sentencing, imprisonment, and release of the offender.

Victim is defined at 42 U.S.C. § 1067(e)(2). That definition states in part that victim "means a person that has suffered direct physical, emotional, or pecuniary harm as a result of the commission of a crime...." With respect to lab fraud, the victim rights statutes and implementing guidelines provide for assistance to private individuals and entities. The AG Guidelines commentary specifically notes that "[F]ederal departments and State and local agencies, as entities, should not be considered 'victims'...." As such, the victims of lab fraud eligible for assistance will typically include private individuals and businesses that have been harmed or defrauded by the lab's actions.

2. EPA's Role

Consistent with Congress's directive, the Environmental Protection Agency (EPA) Office of Criminal Enforcement, Forensics, and Training (OCEFT) has developed written guidelines for implementing the provisions of the VWPA, the Crime Control Act of 1990, and the Antiterrorism and Effective Death Penalty (AEDP) Act of 1996. These guidelines are found in EPA's Criminal Investigative Division (CID) Special Agent Investigative Manual (Manual) - Chapter 14. Among other things, the Manual describes the responsibilities of the Director of CID, the Special-Agent-in-Charge (SAC) for Investigations, the SAC Area Office, and the primary contact person (PCP) who is designated by the SAC Area Office. The PCP is tasked with discharging the responsibilities of the guidelines as required by the statutes.

9. LABORATORY FRAUD DUE DILIGENCE

A. Summary of Laboratory Fraud Due Diligence Process

1. Definition of "Lab Fraud Due Diligence"

Lab fraud due diligence is the process of addressing the consequences or impacts of fraud as distinct from its investigation and prosecution. Due diligence can be divided into three primary tasks, each of which can be further subdivided into a series of procedures. The three basic lab fraud due diligence tasks are to: (1) collect information and identify the scope/magnitude of wrongdoing, (2) implement core due diligence effort based on information provided by the first task, and (3) direct, coordinate and document the overall effort. This section discusses the due diligence objectives and process.

2. Summary of Responsibilities for EPA Offices

Briefly, the responsibility for each of these tasks should be as follows:

a. Collect Information

The collection of information (the investigative phase) should be carried out by the investigative team elements. Depending upon the circumstances, this would ordinarily include the Criminal Investigation Division (CID), the Regional Criminal Enforcement Counsels

(RCECs), the Department of Justice, and, in appropriate cases, the EPA Office of Inspector General (OIG).

Once an investigation has determined that lab fraud has occurred, an EPA Headquarters directed due diligence effort should be initiated by OCEFT. This will occur under the following circumstances: (1) the lab fraud may have adversely and significantly affected the environmental programs in more than one EPA Region or (2) the fraud involves a program or programs in a single Region, but the fraud has national implications (*e.g.*, a laboratory has falsified reformulated gasoline results and the gas may be distributed in many states and EPA Regions). Due diligence addressing laboratory fraud that is geographically limited in its impact to a single EPA Region should be managed solely within the Region and does not require EPA Headquarters oversight. The procedures outlined below are limited to multi-regional lab fraud cases or those impacting national programs.

b. Due Diligence Direction and Coordination

Core due diligence direction and coordination should be carried out by an EPA Headquarter's coordinating committee (*coordinating committee*) comprised of the media-specific program offices (air, water, solid waste, etc.), the Office of General Counsel (OGC), EPA's Office of Environmental Information (OEI), the Office of Inspector General (OIG), if appropriate, and OCEFT. Each of these offices will have a distinct role to play. Because the majority of the coordination activities will likely involve program offices, program offices must assume primary responsibility for the due diligence effort and lead the *coordinating committee* effort. The coordinating committee should be chaired by the organization that is most impacted by the lab fraud; for example, if the primary impact of the lab fraud is in the Water Office, that office should chair the committee for that case.

2. Due Diligence Implementation

Core due diligence implementation should be conducted by the program offices within the affected Regions and in coordination with States within the Region that have been affected by the fraudulent data. For example, if a lab has falsified Superfund clean-up sampling in Region III, Region III's Superfund program should be responsible for reviewing and evaluating all information necessary to determine what data and programs may have been compromised. If

any State programs within the Region also are affected, the States should undertake the necessary file reviews as well to determine if there has been any reliance on compromised data.

B. Lab Fraud Due Diligence Process

1. Collection and Identification of Information from the Labs

The first phase of the lab fraud due diligence effort is the responsibility of the criminal investigation team. The team's membership will vary depending on the target of the investigation and the resources available. Regardless of what Agency offices are involved, OCEFT, through CID, will have the role of identifying the specific wrongdoing alleged and communicating this information to the *coordinating committee*. The *coordinating committee*, in turn, will be responsible for managing the due diligence effort and the release of information to the Regions and other offices as the information becomes available.

As part of the investigation, there must be an assessment of the magnitude of the wrongdoing, including how extensive the potential fraud may be and whether it is limited to specific EPA Regions. For example, during one investigation, it was eventually determined that the fraud potentially compromised thousands of samples nationwide, and included almost all media. As a result, a comprehensive search of all media files in all EPA Regional offices was undertaken. By contrast, in another case, the fraud was determined to be limited to gasoline analyses and thus resulted in a much more focused examination.

In addition to the information needs identified above, it is necessary to have a complete customer list and the lab's marketing brochures. The customer list is a particularly important piece of information because it allows for an immediate assessment of the geographic dimensions of the fraud and may otherwise help focus the Agency's efforts relevant to a proper due diligence review.

In summary, the investigative team should:

ii Identify the class of lab: Captive, government, or contract

$ Determine if the lab is nationwide in scope or regional/local

$ Identify States in which the lab is/was certified and any state/national certifications

$ Fully identify media capabilities (air, water, hazardous wastes, pesticides, biological (e.g., fecal coliform), WET testing, asbestos, medical) by determining whether the lab can do those tests that it holds itself out as being able to perform, and by preparing an inventory of the significant analytical equipment possessed by the lab .

$ Obtain a full customer list or equivalent information (including addresses and telephone numbers)

$ Obtain all marketing brochures for the lab

$ Prepare a standardized written report on all such information, and

$ Forward all results to the *coordination committee* for further action.

2. Direction, Coordination, and Documentation of the Overall Effort

EPA Headquarters must establish a *coordinating committee* with responsibility and authority to manage and direct the due diligence effort. The committee is to be comprised of the affected media-specific program offices (air, water, solid waste, etc.), the OGC, the OEI, the OIG if appropriate, and OCEFT. Centralized coordination of this effort is essential because lab fraud can be nationwide and affect a wide spectrum of entities and activities. A centralized coordination source also is necessary in order to:

$ Ensure the momentum of the due diligence effort

$ Communicate information gathered from regional due diligence efforts to appropriate parties including investigators and prosecutors, Headquarters Program Offices, and OGC's Debarment Office

$ Coordinate with State and Federal agencies that may have relied upon data from that lab

$ Develop a communication strategy to control external release of information, especially any release that may compromise the criminal investigation (particularly Rule 6(e) materials) and/or any information that could expose the Agency to civil and constitutional tort liability

$ Establish ground rules for internal communication including any e-mail and memos that may compromise the case (including statements speculating on the impact of the fraud)

$ Assure Agency-wide consistency during the due diligence effort, and avoid duplication of effort, and

$ Coordinate any debarment initiatives.

Once the investigative team has forwarded its initial findings to the *coordinating committee,* the committee must: (1) ensure that OGC has resolved constitutional tort and CBI issues concerning the release of the customer list, and, if OGC approves such release (2) determine who is responsible for notifying customers and victims. Once these issues are resolved, the committee will provide the following to each affected Regional office:

$ A list of the lab's analytical capabilities including all the media the lab was capable of analyzing and what is suspected was falsified

$ A customer list

$ Direction as to who is responsible for contacting customers/victims, and

$ Pertinent information about States where the lab was certified.

$ Implementing the Core Due Diligence Effort

Implementation of the core due diligence effort typically should be carried out in the EPA Regional offices where the lab fraud impacts occur. The due diligence effort should be conducted by each Regional office because in many cases this is where the programs will likely be affected by the falsifications. Likewise, to the extent that the Regions will have to coordinate

efforts with States within their jurisdiction, the Regions have the relationships with State offices to assure a thorough implementation of the due diligence effort.

The due diligence implementation should proceed as follows:

a. Prioritization of the File Review by the Regional Program Offices

Once the information developed by the *Coordinating Committee* has been provided to the Regions, the Regions must undertake a thorough file review in order to determine which program areas and activities may be relying upon compromised data. The Regions should prioritize their review as follows:

$ Human health and safety issues consistent with the types of media the lab analyzes and the type of equipment reported to be present

$ Current litigation and administrative enforcement actions

$ Closed litigation and administrative enforcement actions

$ Regulatory reporting requirements

$ Guidance, and

$ Permitting actions.

b. Additional Specific Responsibilities of the Regional Program Offices

Contemporaneously with prioritizing its file review, the Regions should additionally:

$ Contact appropriate State program offices to inform them of the situation and recommend they review their files for compromised data

$ Identify EPA contractors and sub-contractors who may have relied upon the lab's data and, if appropriate and the action does not raise constitutional tort issues, inform these parties of the situation

- Contact DOJ regarding any ongoing litigation that is using data from that lab
- Contact DOJ regarding any closed litigation that may have relied upon data from that lab
- Review files to ascertain existence of back-up data for any of the data from the lab under investigation
- Appoint an individual and alternate who will coordinate the findings of the file review and be responsible for compiling reports that will be forwarded to EPA Headquarters
- Identify instances in which federal agencies, other than EPA, might be relying upon potentially falsified data
- Prepare periodic written reports, using a standardized form, that includes the findings of the due diligence effort to date, and includes, at a minimum, the following:
- Any instances where human health and safety or environmental quality were demonstrably impaired as a consequence of reliance on compromised data
- Any instances of ongoing or closed enforcement actions potentially impaired as a consequence of reliance on compromised data
- Any information that the Region believes could be relevant to furthering the criminal investigation
- Summary of impacts of falsifications on Regional programs and activities, and
- Identity of any federal agencies that might have relied upon falsified data (and the sites to which the data pertains).

Care should be taken to ensure that sensitive materials are not included in the reports. Such materials include 6(e) matters, information that could expose the Agency to civil liability, and any other information that could impair a criminal prosecution. It is suggested that all reports be submitted to the *coordinating committee* in draft format and the committee will have legal counsel review the reports prior to their finalization and dissemination.

c. Conclusion

Laboratory fraud affects many aspects of EPA's mission. Detecting and prosecuting lab fraud, and implementing the due diligence effort with respect to it, are distinct activities, each of which requires the participation of different organizations within the Agency. Because lab fraud cuts across so many of the Agency's functions and responsibilities, broad coordination is essential in addressing it. Moreover, because a due diligence effort is primarily one of damage assessment and response, it is crucial to have the active participation of those organizations that best understand the impact of compromised data on their programs. Finally, to ensure the success of the due diligence effort, the *coordinating committee* must have the appropriate authority to assure that its directives are followed and that sufficient resources are employed.

ATTACHMENT 1

COMMON TYPES OF LABORATORY FRAUD PRACTICES

A. Outright Fabrication: data manufactured, changed, or substituted using simple or sophisticated (e.g., computer algorithms) schemes, without utilizing laboratory analysis.

B. Constructive Fabrication

1. Knowingly misrepresenting sample collection time or place
2. Alteration of the sample [e.g., sample switching (i.e. distilled water)], destruction of analyte, removal of analyte (e.g., filtration of zinc sulfide or preacidification of sulfide in sulfide determination; addition of hypochlorite to fecal coliform sample). Also, failing to add proper preservatives or allowing significant sample degradation.
3. Reporting one method, but using another
4. Alteration of the procedure to defeat the test
5. Inappropriate calculations, and manipulations in calculations
6. Deliberately and inappropriately changing instrument outputs to change reported results.
   a. Peak dialing: electronically creating artificial sample or standards peaks to *synthesize data,* change calibrations, calibration records, quality control records, etc.
   b. Peak shaving: inappropriately reducing peak areas to change sample results, calibrations, quality control results, etc.
   c. Peak enhancement: inappropriately increasing peak areas of sample or standards
   d. Juicing: adding to or subtracting the amount of analyte from standards, samples and QC samples to impart false results
7. Falsifying calibration or QC standard values to change reported results
8. Frauds of omission and inclusion: selectively choosing or ignoring samples, sample data to produce fraudulent results, e.g.
   a. Analyzing a sample multiple times until a statistical outlier is chosen as the "correct result"
   b. Knowingly selecting *statistical outlier* replicates or inappropriately ignoring replicates in reported averages to enhance results
   c. Knowingly failing to report valid results which show noncompliance
9. Knowingly misidentifying analyte peaks

C. Manipulation of quality control (QC) results or documentation to comply with the method or applicable contract.

1. Fabrication, substitution, or alteration of QC data
2. "Juicing" QC samples, spiked samples, or replicates to fit criteria
3. Manipulating QC calculations
4. Manipulating QC results in other ways
5. Time travel: altering analysis times to misrepresent proper sample holding times

D. Associated Fraud

1. Mail Fraud
   a. False representation to clients
   b. False representation to government

2. Business Fraud

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ATTACHMENT 2

PRESCREENING FOR LABORATORY PROBLEMS
EXAMPLES

Fraud cases sometimes arise from observable discrepancies: a noted inconsistency, a pattern of problems, etc. As regulators review submittals and inspect laboratories under civil procedures, inconsistencies and problematical patterns may emerge. Observable problems that perhaps may prompt further inquiry are listed below. Items here are indexed by significance, most significant first; sampling problems indicating fraud are listed thereafter.

Examples of Findings Indicating Fraud

- Substitution of previous acceptable QC or calibration computer files for bad to make run appear acceptable
- Full sample containers after data reported[a][8]
- Materially misrepresenting actual laboratory methods and practices to clients

Suspicious Condition or Practices

- Reported results without supporting records of analyses
- Lack of required equipment to perform required analysis[a]
- Lack of required chemicals, reagents, other raw ingredients to perform the analyses
- Instruments or other equipment in poor or nonoperational condition
- No log books (paperless lab?)[a]
- Entries in log books missing[a]
- Missing data
- More samples analyzed than reported (indicating that results are illegitimately altered by selection)
- Discrepancies in times between various stages of sample handling and analyses[a]
- Discrepancies between values reported in raw, intermediate, and final results
- Illegitimately selecting calibration points or data to meet method criteria

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[8] *Items appearing with the superscript [a] are items that might not require detailed technical knowledge for discernment.*

- Illegitimately adjusting, altering, or improperly selecting peak heights or counts and ratios during tuning or calibration
- Illegitimately selectively picking scan data to achieve tune criteria in GC/MS methods
- Different print styles in reports[a]
- Other suspicious anomalies in appearance of report or data outputs[a]
- No QC failures over a significant period of time
- Tough or "ridiculous" QC requirements (e.g., inviting alteration to pass)
- Deliberately omitting QC steps such as method blanks and control samples to avoid unfavorable QC results
- Use of affiliate labs to analyze performance samples for tests normally done in-house [a]
- Altering QC performance summaries
- Removing statistical outliers to improve reported detection limits
- Illegitimate use of manual integration in chromatographic techniques
- Inappropriate "averaging" to achieve calibration or performance criteria or to stay in compliance
- Suspicious computer calculation subroutines or macros
- Unexplained editing of electronic files
- Unexplained erasures, white-outs[a]
- Altered or forged signatures on report[a]
- Report signature not of the author (e.g., supervisor or manager signing analyst's lab report)[a]
- Extraordinary lab results (ultra low detection limits, impossible productivity, etc.)
- Special phone logs on positive or other results[a]
- Other suspect "special" files[a]
- Failing to tell the "whole" truth
- Abnormal directives to employees, oral or written; directives to change results [a]
- Intimidated employees[a]
- Abnormal pressure to produce results[a]
- Employee(s) out of town when analyses performed (travel and charge card records)[a]

Questionable Condition or Practice

- No maintenance records on instruments
- Log books missing from series[a]

- No original or primary records kept[a]
- Data on scraps of paper[a]
- Missing reports from files[a]
- Missing computer files
- Incomplete data packages
- Unexpected or abrupt change in lab practices,[a] procedures, conditions
- Problem found in raw data
- High, arbitrary or unjustified detection limits; detection limits that exceed regulatory limits
- Results differing using two different methods
- Deviations from required methodology
- Numerous "stupid" errors indicative of sloppy work
- Differing SOPs without explanation
- Unexpected high or low analyte recoveries
- Not following required or stated procedures
- Lax QA/QC or no QA/QC[9]
- Not following laboratory QA requirements
- Large number of QC failures
- Adding surrogates after sample extraction rather than prior to sample extraction; reporting pre-digested spikes or duplicates as post-digested spikes or duplicates
- Closer than expected agreement on PE samples between affiliate labs, sister labs, industry organization laboratories
- Data too consistent
- Owner or supervisor acting suspiciously (e.g., wants to do all the work himself)[a]
- Discrepancies between sample identifications in log-in and chain-of-custody sheets versus samples tallied in final reports[a]
- Faulty data parameter correlations (anion/cation balance, mass balance, COD vs BOD, etc.)
- No receipts for instruments, chemicals, equipment in their absence[a]; no billings for maintenance[a]
- Other[a]

Sampling Related

- Samples not taken[a]
- Samples purposely biased through selection, sampling the "good batch" or the "good portion"; avoiding the "hot spots" or avoiding sampling during certain batch dumps; sampling at certain times versus others, etc.
- Fraudulent location[a]
- Fraudulent time[a]
- Samples purposely switched or corrupted (e.g., cyanide samples left in the sun; volatile samples left open or caused to aerate)
- Samples purposefully subsampled incorrectly
- Continuous monitor probe placed in static sample

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9 *May directly evidence fraud if a government contract requirement*

ATTACHMENT 3

GLOSSARY

Analyte: The sample constituent that is sought or intended to be measured

Bench data: Usually primary sample or QC data that is recorded at the laboratory "bench" directly by an analyst, now often substituted by electronic records.

Blind sample: A sample with known values introduced to a laboratory as though it were a routine sample, but without the recipient's knowledge of its nature.

Calibration: Often used synonymously, but incorrectly, with standardization. Calibration refers to the process of establishing a scale of instrumental response versus the concentration of substance to be measured.

Chain-of-custody: The documentation that identifies unique sample control.

Continuous monitor: One that continues to measure over time typically in a flowing sample stream versus a discreet monitor that typically makes individual measurements as new samples are manually exchanged.

Data package: The series of calibration, raw, intermediate, final, QC data and various other approvals and documentation that are used to evidence the authenticity of a discrete set of analytical data.

Detection Limit: A term variously defined. A simple definition is the amount of an analyte that can be observed reliably in an instrumental output over the amount attributable to spurious electronic, mechanical, and other types of interferences.

GC/MS: Gas chromatography/mass spectrometry (or spectrometer). An instrumental procedure used to identify and quantitate various organic compounds.

ICP/OES: Inductively coupled plasma/optical emission spectrometry. An instrumental procedure used simultaneously or sequentially to analyze samples for a host of elemental constituents.

Integration: The raw output of many instruments appears as a peak. The size of the peak may be quantitated through the measurement of peak height or area. Integration is the process of calculating peak area by summing very small "slices" of peak area obtained by multiplying the width of each slice by its height.

Intra-laboratory: A comparison made between two laboratories, often as to results on the split samples.

Logbooks (or "logs"): Typically bound notebooks that are used to record bench data or QC data where it is not recorded electronically or otherwise.

Macro: A small program for calculating data similar to a subroutine

Manual integration: Most electronic integrators have "canned" integration programs. In some instances, as determined by trained operators and according to procedures, it is necessary to modify manually the integration procedure to obtain more accurate results.

Method: The procedure used as guidance to perform a measurement or process.

Parameter: A measurement, property, description, etc., identifying an attribute or quality.

PE: Performance evaluation. Typically a sample submitted to a laboratory which attempts to assess that laboratory's capability to produce a valid result.

Peak: A voltage (or current) signal over time, recording the electronic response of an analyte.

Peak height: The maximum signal over time with respect to the baseline in an instrumental response. Often used to assess the concentration of an analyte.

pH: The measurement of the negative logarithm, base 10, of the hydrogen ion concentration.

Procedure: The exact method employed by a laboratory to perform a measurement or process.

Probe: A peripheral device extending to the sample from the main instrument that allows measurement ;for example, the glass probe used to make pH measurements.

Quality Control: Procedures that substantiate and validate reported analytical values

Quality Assurance: The overall management system in place that establishes, directs, and assesses quality control procedures.

Raw data: Data first produced, written, or electronically recorded which may then enter into or be transformed mathematically into final data.

SOP: Standard operating procedure.

Split sample: Portions of a sample thought to be divided such that each has identical properties and often used to assess the performance of one laboratory against another or others.

Subroutine: A computer program within a program used to perform a calculation.

TCLP: Toxic characteristic leaching procedure. A method defined chemical analysis designed to simulate the leaching effect of water percolating though a waste to determine the amount of toxic substances that the water would concentrate and transmit to ground water used as a drinking water source.

Tape Audit: In the past, GC/MS data was backed up on magnetic tapes. This type of audit looks at stored data, including QC data, on electronic media in a detailed examination for the basis of reporting data.

Tune: Synonymous in GC/MS with that portion of its "calibration."

Volatile organic: Any of a series of compounds analyzed under several EPA procedures which volatilize at set temperatures, are separated by gas chromatographic columns, and then measured by several types of detectors.

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