Best Practices for the Detection and Deterrence of Laboratory Fraud

California Military Environmental Coordination Committee

Chemical Data Quality/Cost Reduction Process Action Team

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Foreword

On December 5, 1991, Governor Pete Wilson signed Executive Order W-21-91 to establish the California Base Closure Environmental Committee (CBCEC). The CBCEC's mission was to expedite environmental restoration and reuse of closing military bases in California. In January 1995, the Governor redesignated the CBCEC as the California Military Environmental Coordination Committee (CMECC) by Executive Order W-116-95 and expanded its role to include former and active bases and to also address compliance issues. Member organizations include the U.S. Department of Defense, Military Services (Army, Navy and Air Force), U.S. Environmental Protection Agency (US EPA) Region 9, and the California Environmental Protection Agency's (CAL/EPA) Department of Toxic Substances Control and State Water Resources Control Board. The CMECC assists both the Governor's Office of Planning and Research and the Office of the Deputy Under Secretary of Defense for Environmental Security via improved interagency communications and cooperative efforts (such as process action teams) that promote cost effective compliance with Federal and State environmental laws and regulations.

As part of this effort the CMECC established the Chemical Data Quality/Cost Reduction Process Action Team (CDQ/CR PAT). In addition to the mission previous stated, the PAT's efforts include fostering the generation of environmental laboratory data of known and documented quality through the development of performance standards for environmental laboratories for implementation by state and federal agencies in a consistent manner.

Due to the heightened awareness of CMECC on problems concerning laboratory performance from the investigations performed by the member organizations, the CDQ/CR PAT was charged to develop a guidance on laboratory fraud prevention that can be used by the DOD and regulatory agencies. As directed, the PAT developed this document, ***"Best Practices for the Detection and Deterrence of Laboratory Fraud"***. The objective of the guidance is to deter fraud and save the member agencies monies and time by ensuring that decisions made using laboratory generated data are based on quality and not fraudulent data. The guidance is further intended to assist military and regulatory remedial project managers and military base consultants in applying and instituting the data quality objectives process, improving laboratory oversight measures, improving the quality of data generated, reducing costs (for re-analysis and potential loss of data due to fraud), and reducing occurrences of fraud. The measures identified in the guidance must be used in concert to optimize each measure, as each measure is not as effective when used alone.

Acknowledgements

This document was prepared through collaborative efforts by all members of the Chemical Data Quality/Cost Reduction Process Action Team (CDQ/CR PAT), under the direction of the CMECC. The CDQ/CR PAT Chair and point of contact for this document is Alan Hurt (619) 532-3964.

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1.0 Introduction

Laboratory fraud is defined as the deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable during reporting. It has historically been detected either by reports from disgruntled employees or electronic data audits. In both of these circumstances the laboratory is already performing fraudulent work and the damage is done. Up to now, there has been little systematic effort to understand laboratory fraud and develop strategies to detect and deter laboratory fraud. This "Best Practices for Detection and Deterrence of Laboratory Fraud" is a first step toward filling that vacuum and is intended to contribute to the elimination of laboratory fraud. It identifies a number of measures that can be used not only to detect laboratory fraud but to deter it. Some of these tools should be used in any laboratory contracting situation, while a carefully selected combination can be used in other cases that is cost effective and based on laboratory performance or project specific information.

Five major fraud cases in California have come to light since 1993. Large efforts for data assessment and replacement data have become necessary for sites affected by fraud. Twenty-eight military installations were exposed to extensive fraudulent activities from one laboratory alone, resulting in about $5,000,000 of lost data, resampling costs, and associated expenses. Sites impacted by laboratory fraud have experienced delays of up to 2 1/2 years. The U.S. Environmental Protection Agency (US EPA) Office of Inspector General (OIG) reported in its draft audit report of nine Superfund sites in three US EPA regions dated October 28, 1996, that 11 million plus dollars were spent on rejected analyses, resampling, and associated costs that could have been avoided through the use of effective quality assurance oversight systems. The magnitude of fraudulent laboratory activity is potentially much higher and the losses to DOD and regulatory agencies immeasurable. The compounded losses in time, resources and monies spent to pursue damages and reassess decisions made with fraudulent data is an enormous vulnerability that regulators, decision makers, and laboratory users cannot afford.

The mission of the CMECC/CDQ CR PAT is to expedite environmental investigation and restoration at active and formerly used defense sites in order to return bases back to beneficial uses. Laboratory fraud constitutes a serious drawback to this effort. Whether generating fictitious data or performing electronic manipulations to make data appear to pass quality control requirements, laboratory fraud can result in serious decision errors. In some cases clean up may fail to take place when it is needed and in other cases, resources may be wasted to cleanup areas that are no longer contaminated. The severe impacts from fraud on costs and decisions may warrant cleanup schedules to be halted when fraud is suspected, to avoid compounding the problem at the site and to avoid them becoming more pervasive at several sites.

The preventive measures identified in this document should occur before any samples are sent to a laboratory. These measures include development of data quality objectives, identification of Quality Assurance/Quality Control (QA/QC) requirements in the laboratory contract, use of pre-award performance evaluation samples, sharing of laboratory performance histories, verification of a laboratory ethics program, and performing pre-award audits of the laboratory that include an inspection of the laboratory's electronic data handling procedures.

2.0 Objectives

In response to the concerns arising from laboratory fraud cases and resulting losses of data, time, and monies associated with fraudulently generated data, it was determined by the CMECC CDQ/CR PAT that guidance was necessary to deter and detect laboratory fraud. While strategies to deter and detect fraudulent activity exist at the regulatory and DOD level, these strategies have not been documented in a practical guide.

The purpose of this guidance is to:

1. Enhance current laboratory oversight activities practiced by regulatory and DOD agencies to deter and detect fraudulent activities;

2. Contribute to the elimination of fraud by identifying "best practices" that can be implemented by regulatory and DOD agencies;

3. Reduce costs associated with re-analysis and losses of data by deterring and detecting fraudulent activities;

4. Assist CMECC/CDQ CR PAT to achieve its goal in expediting investigation and restoration at federal facility sites by generating data of known quality, defensible and usable for its intended purpose, the first time.

The strategies which follow are provided as measures to aid in the prevention of laboratory fraud and to lead to more efficient, cost-effective site investigations and cleanups. In addition, the strategies address some of the US EPA OIG audit report recommendations (Appendix A).

3.0 Best Practices for Determining Laboratory Data Quality

3.1 Data Quality Objectives (DQO) Planning and Development Process

Data Quality Objectives (DQOs) should have a fundamental role in any environmental data collection activity. Data collection should not take place without first defining the DQOs for the project and should involve parties collecting data and any other stakeholders that will use the data for decision making. The DQO process allows decision makers, during the planning stages of the data collection activity, to define their data requirements and acceptable levels of data error based on how the data will be used. Relevant data quality requirements which impact data use limitations should be specified in the DQO process. The goal of the DQO process is to minimize expenditures while producing data of sufficient quality and quantity needed for decision making. Details on the DQO process are addressed in the *U.S. EPA's Guidance for the Data Quality Objectives Process, Final, EPA QA/G-4, September 1994* and will not be elaborated on here.

Method selection and QA/QC requirements for a contract laboratory are derived from the DQO process. QA requirements are qualitative statements regarding quality management and practices a laboratory must follow when analyzing samples, and handling and reporting analytical results. QC requirements are often numerical criteria (i.e., quantitation limits, precision and accuracy acceptance limits for laboratory control samples, matrix spikes, surrogate spikes, and initial and continuing calibration, contract required holding time). Appropriate QA/QC criteria should be developed to meet the individual project requirements. Too narrow or overly stringent QA/QC acceptance limits may lead to unnecessary cost. However, where public health is at immediate risk or major litigation is expected, more stringent QA/QC performance measures may be required to ensure that the data are defensible and support the decision to be made.

The analytical and sampling activity requirements necessary to achieve the DQOs should be documented in the Quality Assurance Project Plan (QAPP) and Field Sampling Plan (FSP).

3.2 Identification of QA/QC Requirements in the Laboratory Contract

Evaluating QA/QC requirements established for a contract laboratory are an effective means to determine whether a laboratory is having difficulty complying with contract and method specific requirements.

In order to obtain data of the expected quality from a contract laboratory, it is recommended that a project manager clearly specify the QA/QC requirements needed for the project. To enable enforcement of the QA/QC requirements, it is also recommended that they be included in a contract with the laboratory. Example contract language can be found in Appendix B. A laboratory that enters in an enforceable government contract with rigorous QA/QC requirements is clearly aware of the risk of reporting fraudulent data. The project manager contracting with the laboratory is also responsible for understanding these requirements in order to provide laboratory oversight.

In addition to reviewing the QA/QC laboratory performance criteria discussed above, further measures to deter and detect fraudulent activities by a laboratory are described in the following sections.

3.3 Laboratory Selection and Use of Phased Audits

3.3.1 Selecting a Laboratory

Lead agencies or their primary contractors are responsible for selecting laboratories capable of meeting project DQO requirements. Pre-award on-site audits and follow-up audits are useful tools to determine the ability of a laboratory to perform analytical work and to deter laboratory fraud. Projects awarded to laboratories based solely on price or a written proposal are much more likely to experience serious problems than those for which criteria for laboratory selection includes a thorough audit and reference check.

3.3.2 Use of Phased Audits for Monitoring

Laboratory Performance

The implementation of a two-phase audit and check system is a method for oversight of contract laboratory operations. A two-phase check involves a system of pre-award on-site audit and follow-up inspections with attendant documentation for control over data quality and processes relevant to contract requirements.

3.3.2.1 Pre-Award On-Site Audit.

These audits include review of project initiation systems, laboratory sample handling and tracking procedures, sample analysis procedures, routine quality control checks, data handling and reduction, data and report review systems, data storage, electronic data handling, reporting, and storage, personnel qualifications and training, corrective action systems, standards control, document control, waste handling and disposal, and the laboratory ethics training. If there are highly specific project requirements, the audit should include an assessment of whether the systems either are in place or can be put in place to meet the requirements.

In situations where a recent, thorough systems audit has been performed covering project specific analyses, additional in-depth review of the laboratory may be unnecessary. In a thorough audit there will normally be some areas identified that need improvement. If pervasive problems are found during a pre-award audit, the laboratory should not be awarded a project until their systems have been brought up to the standards required by the lead agency or primary contractor. Professional judgement should be used when determining whether a laboratory will be contracted using historical information. Laboratory performance history, age, source of information, and analyses performed all need to be considered when using existing reports. The existing reports and pre-screening information reviewed should be documented and provided in the QAPP and FSP.

Scope and Limitations: Pre-award on-site laboratory audits are useful in identifying laboratories that do not meet the technical or managerial capabilities required by the project, e.g., insufficient laboratory instrumentation or staff, staff lacking recommended education and experience, or inadequate internal quality assurance programs. Pre-award on-site audits are particularly useful in identifying high risk laboratories that may be more prone to commit fraud, but are usually less effective at identifying fraud.

3.3.2.2 Audit Reports.

A report summarizing audit findings must be generated by the lead agency or its primary contractor following each audit. Laboratories should be expected to respond promptly to all audit findings.

Ideally, any critical deficiencies that would adversely affect a laboratory's ability to produce quality data consistent with project specific DQOs must be resolved to the satisfaction of the lead agency or primary contractor prior to initiation of projects involving environmental measurements. Copies of audit reports should be provided to all interested regulatory agencies.

3.3.2.3 Monitoring Laboratory Performance Over Time Using Follow-Up Audits.

Once a laboratory passes the pre-award on-site audit and is contracted to perform analytical work, the effective management of that laboratory must be considered. Laboratory oversight is the responsibility of the lead agency contracting the laboratory. If laboratory work is subcontracted by a primary contractor for these agencies, the lead agency is indirectly responsible for providing laboratory oversight through its primary contractor. If the latter case applies, laboratory subcontract specifications should be developed that explicitly include the execution of primary contractor quality control oversight activities (Appendix B contains example language).

If the pre-award on-site audit revealed significant laboratory deficiencies, follow-up audits should be performed at the discretion of the lead agency or primary contractor to ensure that corrective measures have taken place to sufficiently address the deficiencies and to ensure data quality requirements are being met. Follow-up audits also should be conducted periodically to ensure the continued adequacy of laboratory performance. These audits should focus heavily on project specific data. They should incorporate the review and tracking of raw data from the original measurements through the generation of a final report. Audits normally should require some regeneration of raw data from electronic files to verify the integrity of this process. If significant problems are found through periodic audits, a stop work order or contract cancellation could result.

Scope and Limitations. Continuing audits are useful for verifying the adequacy and maintenance of instrumentation, the continuity of personnel meeting experience requirements or education requirements, and the acceptable performance of analytical and QC procedures. Failure in these areas may mean the laboratory is more susceptible to committing fraud. However, historically, on-site laboratory audits have not been effective in identifying fraud; which may go undetected even when frequent on-site audits are performed.

3.4 Performance Evaluation Samples

Performance Evaluation Samples (PES) are used to assess routine performance levels of laboratories. It is recommended that PES be used in routine QA oversight as well as in the investigation of laboratory fraud. The type of fraudulent activity that can be determined using PES is identified in Table 1. The use of PES in uncovering fraudulent practices is illustrated in the case studies (Appendix F).

The use of PES sends a message to a laboratory that the client wants to assess the performance of the laboratory. The laboratory should be aware that there are many PE options available to the lead agency or primary contractor, depending upon the size and the length of the project. The lead agency or primary contractor may send double blinds, single blinds, duplicates, splits, or co-located samples to different laboratories, or a any combination thereof. It would also be cost-effective for the military services to share individual laboratory PES results. The sharing of PES results would have a positive

impact on individual laboratory performance as their current performance, may impact its ability to obtain future contracts.

In single-blind PES, the concentrations are unknown to the laboratory. Frequent use of this type of PE can be quite effective. If a laboratory has to put experienced personnel on the project and has to ensure proper instrument calibration to handle the single blinds, then laboratory fraud is deterred.

A double blind PES is a sample submitted to evaluate the performance of a laboratory to perform analyses on a sample of known concentration and identity (i.e., known only to the parties submitting the PES to the laboratory). The concentration and identity of the double blind PES should not be known by the laboratory. Double blind PES labeling, packaging and chemical composition should mimic those of the routine samples to mask the identity of the sample to the laboratory, however, it may not always be possible to disguise the sample as a "real world" routine sample. Double blind PES submitted concurrently with site samples are useful in increasing the overall level of confidence in the defensibility of data when the results submitted by laboratories fall within acceptance ranges.

The compounds, analytes, and concentrations should match those expected from the site as much as possible. The use of double blind PES should be included in the QAPP or FSP. The PES supplier should have a documented quality system, such as that required by *ISO 9001* or equivalent. If appropriate PES are not commercially available, prepared PES should be validated with a reliable reference laboratory.

Successful completion of a PES can build confidence in the use of a particular laboratory. Continuing success assures the data users of the reliability of the laboratory. Conversely, a laboratory's repeated failure with more than one contaminant and with more than one type of PES, brings into question the reliability of the laboratory. It is the experience of US EPA Region 9 that in some cases, fraud occurs after repeated poor performance by a laboratory. Repeated poor PES results may be a good reason for awarding the analytical contact to another laboratory when the existing contract ends.

Scope and Limitations: PES are particularly useful in building confidence in the quality of data when the laboratory does well on the PES. They are also useful in deterring non-compliant data and fraudulent data by increasing the level of laboratory oversight. Laboratory analysts will tend to do a better job of maintaining and calibrating testing equipment and may be deterred from attempting to commit fraud when PES are routinely used to monitor laboratory performance. PES, by themselves, cannot confirm laboratory fraud; which may go undetected even when they are used. It is recommended that PES be used as a routine QA oversight tool as well as in investigation of laboratory fraud.

3.5 Split-Sample Analyses

Split-sample analysis can be a useful tool in detecting and deterring data quality problems. A well designed split-sample program is a unique tool for measuring interlaboratory performance on samples matrices relevant to the project. Split-samples are essentially duplicate field samples. One of the duplicate samples is sent to a second laboratory while the corresponding sample is submitted to the primary laboratory contracted to perform the analyses. The samples submitted to the primary laboratory are labeled to mimic those of routine samples. The existence of this second laboratory can be made known to the primary laboratory, however, the specific sample batch in which the split-sample will be submitted shall not be disclosed. This fact may serve as a fraud deterrent.

Results from both laboratories are compared to check on laboratory performance. The methodology used by the laboratories should be comparable in terms of specific techniques, QA/QC procedures and deliverables to allow direct comparison of results. Historic inter-laboratory comparison data should be used to establish statistically acceptable criteria relative to specific test parameters in aqueous and solid matrices.

Review of results from the different laboratories should be a dynamic process to ensure that problems are detected and solved as sampling and analysis occurs. When discrepancies are found between the laboratories, the reasons for the discrepancies should be investigated. In addition to detecting analytical problems, split-sample analysis may bolster credibility and usability of the data generated by having different laboratories producing similar results.

It should be noted that split-samples do not take the place of PES, as the matrix variation and contaminant concentrations are unknown. PES should be included in the sample shipment to the primary laboratory at the same time the split-samples are submitted.

Scope and Limitations: Split-sampling is particularly useful in increasing the level of confidence in data when the results from both laboratories are in agreement. They can be useful in identifying gross laboratory problems. However, it can be difficult to ascertain which laboratory is having problems when the results do not agree or to be certain that discrepancies or imprecision are not due to sample matrix effects.

3.6 Laboratory Performance Histories

Laboratory performance histories (e.g. audit and performance on PES) will be shared among services, regulatory agencies, and government project managers using existing methods for exchange of information. The contact points for information are:

Air Force Center for Environmental Excellence
Major Eric Banks, Chief of Chemistry, (210) 536-5677

Army Corps of Engineers, USACE HTRWCX,
Chemical Data Quality Management Branch
Kevin Coats, Chief, (402) 697-2563

Army Corps of Engineers in California
Russell Davis, Senior District Chemist, (916) 557-5348

Naval Facility Engineering Services Command
Pati Moreno, Laboratory QA Manager, (805) 982-1659

Navy South West Division
Narciso Ancog, QA Officer, (619) 532-2540

California Department of Toxic Substances Control
Barton Simmons, Acting Chief of Hazardous Materials Laboratory, (510) 540-3112

State Water Resources Control Board
Bill Ray, QA Program Manager, (916) 657-1123

California Environmental Laboratory Accreditation Program
George Kulasingam, Manager, (510) 540-3596

Lawrence Livermore National Laboratories
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Facility 518, Consulting Environmental Chemist, (510) 422-3593

US EPA, Region 9
Steve Remaley, Regional Technical Project Officer, (415) 744-1496

3.7 Data Validation

The data validation strategy should be established at the beginning of the project, and be consistent with project DQOs. All data should receive some level of review by an independent third party, i.e., someone unassociated and without any interest with the laboratory and project. Data validation is a systematic process for reviewing a body of data against a pre-established set of quality control "acceptance" criteria to determine whether it is within the criteria windows to determine the quality of the data. Where data do not meet the "acceptance" criteria, they are flagged with a qualifier identifying the associated problem. Data validation should occur at the earliest opportunity for optimizing cost effectiveness. This allows for corrective actions to take place early in the analytical process. After validation, the data is assessed to determine if it is adequate for its intended purpose and the data user should have data of known quality.

Data validation can provide useful information on overall laboratory performance by identifying non-compliant data, and is also a useful deterrent to both non-compliant and fraudulently reported data. In some instances, follow-up investigations of deficiencies identified through data validation can lead to identification of fraud. Table 2 and the case studies (Appendix F) identify the types of fraudulent laboratory activities which can be detected through data validation.

An appropriate percentage of data should be fully validated according to procedures consistent with those specified in the *US EPA National Functional Guidelines (NFG) for Inorganic and Organic Data Review (EPA 540/R94-013 and EPA 540/R94-012, respectively)*. As a general guideline, 10-20% of the data for a project is validated. However, it is recognized that in some situations validation of a greater or lesser percentage of data will be indicated. Since full data validation will generally not be performed on all of the data for a project, critical decision points should be given priority in the selection of data to be fully validated. The percentage of data to be validated may increase when problems are found. Professional judgement should be employed to determine the frequency of data that will be fully validated when this level of effort is required. While complete adherence to the NFG will not be possible for non-CLP methods, the data validation logic should include the functional elements described in the US EPA guidance.

Scope and Limitations: Data validation is an important part of an ongoing program of laboratory oversight. It is very useful in identifying problems and contract non-compliances that can be brought to the attention of laboratory management during on-site visits for discussion and corrective action. Such ongoing oversight and feedback is not only useful in correcting problems that have been

identified, but is also useful in deterring non-compliant data by placing a value on good quality work and putting the laboratories on notice that they are being monitored.

Data validation has been used to detect fraud, but it should be noted that the nature of fraudulent reporting is to make hard copy data packages appear compliant and, therefore, data manipulation in most cases will not be detected by this tool. Some of the best QA/QC results and data packages have turned out to be the most fraudulent. It is important to realize that data validation can recognize potential fraud, but by itself is not sufficient to proving fraud. Additional tools are recommended for further investigation. These include the use of double blind PES and electronic data audits for independent regeneration of data.

3.8 Electronic Data/Tape Audits

Electronic data audits are useful both to deter and detect laboratory fraud. The type of fraud that can be determined using this type of audit can be found on Table 3. Electronic data audits can occur in three different contexts; (a) internal audits performed by the laboratory or contracted by the laboratory, (b) independent on-site audits performed as part of pre-award audits or ongoing compliance audits, and (c) independent off site audits. These will be discussed in turn.

3.8.1 Laboratory Internal Electronic Data Audits

Laboratories should have well documented procedures for handling electronic data, and conduct periodic audits to ensure compliance with the procedures. Elements that should be part of the procedure are:

- a defined convention for naming files that will result in traceable data files for every sample including quality control samples and calibration data;
- a backup system that can be used to retrieve old data files;
- a policy for making changes to electronic data.
- a documentation procedure that will flag every data file that has been manually manipulated, show the changes that have been made, explain the rationale for the changes, and identify the individual making the changes and the date and time the changes were made.

Laboratories should periodically audit their electronic data to verify that the procedures are being followed. There should be a program to perform a random audit of electronic data. In cases where problems are indicated from other quality assurance measures, such as systems audits or PES, electronic data audits should be targeted at the areas of concern. The audit should result in a report that includes description of the tapes inspected, the date of the audit, the person performing the audit, any findings or problems observed, recommended corrective actions, and recommended frequency of future audits (*2185-Good Automated Laboratory Practices*). Any findings that may affect data quality or data integrity should be reported to the laboratory management. Any findings that are verified to affect data quality or data integrity should be reported to the affected clients.

While many laboratories have similar internal audit programs, some laboratory managers or owners may feel that they do not have the resources or required expertise to audit their program effectively. There are a variety of companies that have the required expertise to perform these audits and are available for contracting.

A laboratory that has (1) clearly written procedures for data handling and documentation and (2) an active and effective program to audit electronic data internally is less likely to have an employee handling data inappropriately, and is also less likely to have a pervasive data integrity problem. These programs protect the owners of the laboratory, the employees of the laboratory, and the clients.

3.8.2 Independent On-Site Audits

During any pre-award or follow-up audit, an independent on-site audit should be performed. While it cannot be as detailed as either an internal audit program or an off-site external audit program, it is important as a QA tool to verify that the laboratory's internal program is effective.

As a first step, laboratory auditors should review the information from the internal electronic data audit program. Once this is complete, the auditor should choose some data packages and enlist the laboratory's assistance in finding the associated logbooks. The logbooks should be reviewed to see if any files were documented to require manual changes to the original results. If so, these files should be reviewed to verify that the manual changes were based on technically sound judgement, and that the results in the electronic file are the same as the results on the hard copy report or the hard copy files. A number of files that are not documented as requiring manual changes should also be inspected. The laboratory personnel should be asked to regenerate the original data. It should be inspected for manual changes, and be compared to the hard copy report or files.

This kind of on-site audit cannot verify fraud, nor would it detect certain types of inappropriate data manipulation, but it can only help to assess the effectiveness of the laboratory's internal electronic data audit program. Significant discrepancies found during this process would indicate that either the laboratory's program is weak or that there may be a more pervasive data integrity problem. In a pre-award audit, either conclusion should be sufficient to eliminate the laboratory from further consideration, and in a follow-up audit, it could result in a stop work order or contract cancellation.

This type of on-site audit will also encourage the development of strong internal audit programs throughout the laboratory industry. If the ability to acquire work is dependent upon an effective internal electronic audit program, then these programs will become a priority for laboratory managers.

3.8.3. Independent Off-Site Electronic Data Audits

Independent off-site electronic data audits are by far the most rigorous form of electronic data audits. They can be a definitive tool in identifying gas chromatography (GC) and gas chromatography/mass spectrometry computer fraud. These have been the most frequently detected categories of laboratory data fraud. Off-site electronic data audits have been the tool of choice to definitively identify computer data fraud, and have been crucial as evidence in convicting laboratories of computer fraud. They have been used to detect fraudulent reporting of DFTPP and BFB tuning compound results, calibrations, surrogate recoveries, internal standard areas, and under reporting of target compound concentrations where the laboratory was required to dilute and re-analyze highly contaminated samples. While these audits require considerable expertise on the part of the auditor, they can detect a wide variety of inappropriate data manipulations.

When data fraud has occurred, electronic data audits are required to determine the extent to which the data fraud affected data quality. In doing this, the electronic data audits can salvage critical environmental data.

An independent off-site electronic data audit program can help to deter computer fraud. Laboratory managers who are aware that their data is likely to undergo this level of scrutiny will be more likely to institute effective internal data handling procedures and an internal audit program. However, any questionable practices revealed through this type of audit have already affected some quantity of environmental data. The laboratory internal audits and the on-site pre-award audits can detect the potential for data fraud before a contract has been signed and before any samples have been collected. It is important, therefore, to use all three of these tools in conjunction with each other. A laboratory should not be put under contract unless it has an internal program that is verified to be effective through an on-site audit. The independent off-site audits should be used as a periodic oversight tool and in cases where inappropriate data handling is suspected.

Additional information about the uses of electronic data audits can be found in Appendix C.

Scope and Limitations: Electronic data audits are useful in identifying and deterring computer fraud and non-compliant work. They are needed to confirm or deny potential fraud that is brought to the attention of the government by whistleblowers, PES, on-site audits, and data validation, and to assess the magnitude of fraud and its effect on data. Electronic data audits can be used in some circumstances to salvage data that has been fraudulently reported. Electronic data audits are not effective in identifying all types of fraud, e.g, "juicing" and "time traveling".

3.9 Quality Assurance Officer

A government employee acting as a QA Officer (QAO) on behalf of the DOD and regulatory agency should direct the project investigation during the initial planning stages of investigation and throughout its lifetime to help ensure the DQO requirements established in the QAPP and FSP are met.

Part of the QAO's responsibility is to review QAPPs, FSPs, revisions and addendums; other responsibilities addressed by the QAO can be found in Appendix D. The QAO and government project managers should be identified clearly in the organization chart and their responsibilities described in the QAPP. The QAO's signature block should be clearly indicated on the approval page of the document. Comments provided by the DOD and regulatory agency QAO for QAPPs and FSP should be provided to the DOD and regulatory project managers. All responses to comments should likewise be exchanged to ensure all comments are satisfactorily addressed.

Once a QAPP, FSP, revision or addendum is approved by the DOD and regulatory QAO, government project managers may assist the DOD and regulatory QAO in the implementation of the approved documents by transferring custodial oversight responsibility to them (some suggested training for project managers providing investigation oversight is identified in Appendix D). Under the direction and oversight of the QAO, project managers are fully responsible for understanding and ensuring that the work performed in the field and laboratory meet the DQOs set forth in the QAPPs, FSP, and any revisions or addendums thereof. Regulatory and DOD QAOs retain all and full QA authority over the program within their respective agencies. The extent to which the custodial oversight responsibilities are transferred to the project manager should be documented in the corresponding QAPP.

Once a plan, revision, or addendum is approved and custodial oversight transferred, the project managers are responsible for providing oversight to ensure the success, or failure, of the project. Project managers are at the forefront of the activities occurring in the field and laboratories and are the parties most knowledgeable about the day to day activities and out of control events. They are the immediate

and active deterrent to prevent deviation from QAPPs and FSPs. Because limited authority is provided to project managers, they must seek approval from the QAO on issues arising in the field and laboratory which potentially impact data quality.

Where selection of a laboratory is a primary contractor's responsibility, the primary contractor is responsible for ensuring that the laboratory can perform the data quality technical requirements identified in the QAPP or FSP. The primary contractor will also provide a copy of the QAPP or FSP to the laboratory to ensure that it has the necessary documentation to follow and reference. Both the primary contractor and laboratory will be responsible for ensuring that all data quality requirements are met as stipulated in the contract. This does not relieve project managers from the regulatory and DOD agencies from performing their custodial oversight responsibilities to ensure that data is collected and analyzed as specified in the QAPP or FSP and that the overall work performed meets the DQO requirements of the project. It is suggested that project mangers work closely with a chemist from their respective agencies to assist in the oversight of the laboratory, if necessary.

3.10 Electronic Data Deliverables

Use of electronic data deliverables and electronic data validation, wherever possible, will promote objectivity, substantially reduce costs, and facilitate data exchange. This will also allow data validators to focus and spend more time on inspection of raw data.

3.11 Statement of Work and Ethical Conduct

The Statement of Work for laboratories should include the following:

A) All laboratories should have a company ethics policy read and signed by employees. An example ethics agreement is provided in Appendix E. The laboratory shall have arrangements to ensure that its personnel are free from any commercial, financial, and other pressures which might adversely affect the quality of their work (*ISO Guide 25, and NELAC Quality System Standard*).

B) Training should be provided to laboratory staff on the ethics of generating analytical data and for meeting the technical requirements established in the method.

Training files on the analyst will be maintained by the laboratory. These files will contain signatures of the analyst certifying that they have received the trainings. The ethics trainings received or to be received by the staff will be documented in an approved QAPP or FSP. Certificates of completion will be signed annually.

C) Specific SOPs should be drafted for each method to be performed by the laboratory. These SOPs should identify the specific corrective measures to be performed should problems occur with the analyses. These measures will be strictly adhered to; no deviations will be allowed without documentation.

To ensure consistency in performing a method, which may permit different options, the SOP must document the specific activities the analyst will perform.

D) The laboratory's quality system must include "arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work" (*ISO Guide 25, 5.2.I*).

E) The laboratory management must provide adequate resources and assign sufficient authority and independence to line management and to staff to enable them to plan, implement, assess, and improve the laboratory's quality system effectively (*ANSI/ASQC E-4, 2.1.1*).

3.12 Use of More than One Laboratory

For large facilities with multiple operations, it is sometimes necessary to contract with more than one laboratory in order to meet all analytical needs. For data quality reasons, it is also advisable not to submit all samples to the same laboratory. Decisions should be supported by data from different laboratories to minimize losses if fraud problems should surface. Although submitting samples to more than one laboratory does not prevent fraud from occurring, this practice can detect problems which otherwise may not be apparent. If different laboratories repeatedly provide divergent results in the absence of mitigating factors, further investigation is recommended. A well designed split-sample strategy can be used to ensure decisions are supported by more than one laboratory, and is recommended especially in cases where critical decisions are being made. Different laboratories that provide similar results build confidence for the data users that the data are reliable.

The acceptable time frame in which to submit samples to different laboratories will be decided on a case-by-case basis by the project manager. For large projects, the project manager should use several laboratories over the life of the project. This will help to ensure that key decisions are not based on a single and potentially fraudulent data source.

4.0 Applying the Measures Identified in this Document

The evaluation tools presented in this guidance should be used in concert to optimize the information that can be obtained from each one separately. Some of the tools identified in this document should be used in any laboratory contracting situation, while in other cases, all of the tools may need to be applied concurrently.

To avoid providing prescriptive guidance on the approach that should be taken by the parties applying these tools, four Case Studies are provided in Appendix F which illustrate how differently these tools can be used to respond to the immediate situation. Taking a more step-by-step, SOP approach, might be more easily understood, but would also be too restrictive. A more dynamic approach that encourages the use of professional judgement and allows the individual the freedom to choose the approach and the tools that will be used, some or all, serves the best interests of the regulatory and DOD agencies.

If there are other laboratory evaluation tools users of this guidance are aware of, that were not identified in this document, the CMECC/CDQ CR PAT welcomes your contribution; contact Alan Hurt, U.S. Navy SWDIV, CMECC/CDQ CR PAT Chair, (619) 532-3964; Vance Fong, US EPA Region 9 Quality Assurance Manager, (415) 744-1492; Barton Simmons, Acting Chief of Hazardous Materials Laboratory, California Department of Toxic Substances Control, (510) 540-3112.

Appendix A

U.S. EPA's OIG Recommendations

Appendix B

Example Model Contract Language

B1.0 Several issues presented in these guidelines involve recommendations for language that should be incorporated in Government contract specifications and scopes of work for environmental investigations and remedial actions. Presented below are several issues considered to be of importance in conjunction with model language that ***may*** be incorporated into contract documents, where appropriate. The majority of this language would be appropriate for firm fixed price contracting mechanisms. Minor modifications, such as, eliminating references to "repeat of work at no additional expense to the Government" would be necessary in order to use these examples for cost plus contracting mechanisms.

All text referring to Program Manager, Project Manager, QC System Manager, Project Chemist, and Technical Professionals presented in this Appendix are contractors, and not Government representatives.

B2.1 It is recommended that all Government contracts involving laboratory work should include provisions for archiving of the raw unprocessed instrument output data files on some form of electronic, magnetic or optical media (floppy disc, removable storage media, magnetic tape, cd-rom, etc.).

B2.2 Contract language must be clear and explicit in indicating that all data necessary to reconstruct the entire analytical process must be maintained at the laboratory. In addition to raw instrument output, this would include all other records produced by the laboratory, such as sample receipt records, internal chain of custody, extraction bench sheets, laboratory notebooks, etc.

B2.3 Contract language should specify that instrument output (where applicable) and other records must be maintained in a retrievable condition for a specified period following the completion of project related analytical tasks. (Suggested period - 10 years.)

B2.4 Model Contract Language for B2.1 - B2.3:

Data Archive: The Contract Laboratory shall preserve all information regarding sample analyses (standards records, calibration records, extraction logs, laboratory notebooks, etc.) such that the analytical process can be reconstructed at some future time. The QAPP shall describe the specific procedures to be employed to archive data, including a description of any hardware involved (computers, data warehouse, etc.).

Handling and storage procedures for all raw instrument data shall also be described in the QAPP. All raw unprocessed instrument output data files and processed quantitation output files must be stored at the laboratory on some form of electronic, magnetic or optical media. Optical media are preferred due to the greater stability and longer shelf life relative to magnetic media.

The Contract Laboratory shall maintain all data associated with this project for a period of ten years following submission of the certificate of analysis including all relevant electronic media used for data storage.

B3.1 When sampling and analysis activities are coordinated by a primary contractor with the laboratory employed as a subcontractor, it is recommended that Government contracts should include clear specifications indicating that the quality of all data produced by the sub-contract laboratory is the responsibility of the primary contractor. In this context it would be expected that the primary contractor would take reasonable measures to ensure that the subcontract laboratory implements program and project analytical specifications described in the contract. However, it would be recommended that the Government contract should include clear specifications for a formal system of laboratory oversight to be executed by the primary contractor.

B3.2 Model Contract Language for B3.1:

QC System Manager: As part of the project organization, the Consultant shall appoint a QC System Manager who is responsible to a senior company officer. The QC System Manager must have knowledge of chemical quality control and experience in the sampling and analysis of toxic/hazardous chemicals. This role may be shared by two persons with lines of authority and responsibility clearly defined. The QC System Manager will be appointed by senior corporate or project management to be principally responsible for execution of all quality control operations for field and laboratory activities.

Project Chemist: As part of the project organization, the Consultant shall appoint a Project Chemist. The Project Chemist must have knowledge of environmental analytical chemistry methodologies as described in US EPA SW-846 and general knowledge of remedial process chemistry, fate and transport of organics and inorganics, experience in the sampling and analysis of toxic/hazardous chemicals and radiological contamination in environmental matrices.

The Project Chemist will be required to have advanced expertise in chemical data quality management of environmental analytical data. The Project Chemist must have a minimum of four years of combined experience at the level of the analytical laboratory or working as a part of a Consultant project management team.

The Project Chemist will be expected to have a “hands on” role in management of project tasks associated with sampling and analysis including preparation of the FSP, instruction of field personnel in sampling and preservation requirements, general oversight of field personnel involved in sampling activities, coordination with the analytical laboratory to insure readiness to implement project specific requirements, review of analytical data as it becomes available to insure conformance with quality standards, implementation of corrective actions in accordance with these specifications when review of data uncovers deficiencies, and serve as a point of contact for the Government for issues related to environmental chemistry. The Project Chemist shall conduct or oversee all on-site analytical testing including field screening tests. The Project Chemist shall review and verify all chemical data for hazardous waste manifests. The Chemist shall also prepare all data validation reports or review for accuracy all data validation reports prepared by subcontractors.

The Project Chemist will perform an inspection of the Contract Laboratory at or near the beginning of sample analyses to insure laboratory capability to implement methods specified in the contract. Method specific checklists in conjunction with the SOW and the (draft) Final FSP shall be used as the basis for

this inspection. Findings of this inspection shall be delivered by memorandum to the Government within 15 days of completion. Inspection checklists shall be included as an attachment to the memorandum of findings. This review of the Contract Laboratory may be conducted concurrently with a project kickoff meeting, preparatory, or initial inspection. The Project Chemist shall be employed or subcontracted by the Consultant and shall not be employed by the laboratory performing analyses for this project.

Consultant Quality Control: The text of the FSP shall address the responsibilities of all project personnel as they relate to the quality management function and describe the integration of the corporate quality assurance program into the execution of quality control operations for project related tasks. Key personnel must be identified along with their function and qualifications. The text shall address specific Consultant procedures for control of the quality of work of subcontractors utilized for drilling, well installation, geophysics, etc. In particular, the text should address Consultant control mechanisms in relation to the quality of work performed by the Contract Laboratory. The text shall acknowledge and describe implementation of the three phase control system for all aspects of the work specified. The discussion of Consultant Quality Control (CC) in the FSP should focus on field procedures, while the discussion presented in the QAPP should focus on both field, laboratory, and general CC. The sections describing CC procedures shall address the following topics:

A. A description of the quality control organization including acknowledgment that the CC staff shall implement the three phase control system for all aspects of the work specified. The staff shall include a CC system manager who shall report to the program manager or corporate quality assurance director. Program manager in this context shall mean the individual with responsibility for the overall management of the project, including quality and production. In general, the chain of command should provide for separate reporting to executive management for the quality function relative to the project management function.

   Note: In aspects of work related to sampling, the Project Chemist shall have equal responsibilities for the quality assurance function relative to the Project QC Systems Manager. In aspects of work related to sample analyses, the Project Chemist shall have lead responsibility for the quality assurance function.

B. The name, qualifications, duties, responsibilities, and authorities of each person assigned a CC function. The text shall include resumes for all non-laboratory Consultant personnel to include the Program Manager, Project Manager, QC System Manager, Project Chemist, and Technical Professionals directly involved in execution of work for this project. If staff changes are necessary during the execution of this work, resumes shall be submitted for new personnel, as well as a description of their responsibilities in a technical memorandum to the Government. Changes in the responsibilities of existing staff (if any) will also be described in technical memoranda prepared for this purpose.

C. A copy of the letter to the QC System Manager signed by an authorized official of the firm, which describes the responsibilities and delegates sufficient authorities to adequately perform the functions of the QC System Manager, including authority to stop work which is not in compliance with the contract, will be included in the text of the QAPP. The QC System Manager shall issue letters of direction to all other various quality control representatives outlining duties, authorities, and responsibilities. Copies of these letters will also be included in the QAPP.

D. Procedures for scheduling, reviewing, certifying, and managing submittals. Submittals in this context refer to all final investigation reports, data submittals, quality control summary reports, etc. The text of the QAPP shall describe the organization and documentation required by the Consultant internal quality control review process. At any time the Government may request copies of documentation (internal review comments as well as the review ladder) of the Consultant internal quality control review process for project specific submittals.

E. Procedures for tracking preparatory, initial, and follow-up control phases and control verification.

F. Procedures for tracking field and laboratory deficiencies from identification through acceptable corrective action. These procedures will establish verification that identified deficiencies have been corrected.

G. A list of the definable features of work. A definable feature of work is a task which is separate and distinct from other tasks and has separate control requirements. It could be identified by different trades or disciplines, or it could be work by the same trade in a different environment. The three phase quality control system shall be implemented for each definable feature of work.

Three Phase Quality Control: The three phase control system, and all attendant reports, will be implemented by the Consultant and by major sub-contractors including the Contract Laboratory. Minutes of preparatory, initial, and follow- up inspections and meetings held at the Contract Laboratory will be delivered to the Government, as well as minutes of meetings held at field sites. Minutes of initial, preparatory, and follow-up inspections will be signed by all participating personnel. The Project Chemist and other Consultant personnel may participate in meetings held at the Contract Laboratory by teleconferencing. The Project Chemist is required to participate in preparatory and initial meetings at the Contract Laboratory. Follow-up inspections may be conducted by Contract Laboratory personnel with involvement of Consultant personnel as required.

Preparatory Phase: This phase shall be performed prior to beginning work on each definable feature of work and shall include:

a. A review of each paragraph of applicable specifications from the SOW, FSP, and QAPP.

b. A review of the site diagrams detailing locations where samples are expected to be obtained.

c. A check to assure that all materials and/or equipment are acceptable for use.

d. A check to assure that provisions have been made to provide required control inspection and testing.

e. Examination of the work area to assure that any required preliminary work has been completed and is in compliance with the SOW.

f. A review of the appropriate activity hazard analysis or Site Specific Health and Safety Plan to assure safety requirements are met.

g. Discussion of procedures for execution of work including repetitive deficiencies. Document performance standards for that phase of work.

h. The Government shall be notified at least 72 hours in advance of beginning any of the required action of the preparatory phase. This phase shall include a meeting conducted by the CC System Manager and attended by the Project Chemist, Project Manager, and other CC personnel (as applicable). The results of the preparatory phase actions shall be documented by separate minutes prepared by the QC System Manager and attached to the Daily Quality Control Report. The Consultant shall instruct applicable workers as to the acceptable level of performance required in order to meet the requirements of the contract specifications.

Initial Phase: This phase shall be accomplished at the beginning of a definable feature of work. The following shall be accomplished:

a. A check of preliminary work to ensure that it is in compliance with SOW, FSP, and QAPP requirements. Review minutes of the preparatory meeting.

b. Verification of full contract compliance. Verify required control inspection and testing.

c. Establish levels of performance and verify compliance with minimum acceptable performance standards.

d. Resolve all differences.

e. Check safety to include compliance with and upgrading of the safety plan and activity hazard analysis. Review the activity analysis with each worker.

f. The Government shall be notified at least 72 hours in advance of beginning any of the required action of the initial phase. This phase shall include a meeting conducted by the CC System Manager and attended by the Project Chemist, Project Manager, and other CC personnel (as applicable). The results of the initial phase actions shall be documented by separate minutes prepared by the QC System Manager and attached to the Daily Quality Control Report. The Consultant shall instruct applicable workers as to the acceptable level of performance required in order to meet the requirements of the contract specifications.

g. The initial phase should be repeated for each new crew to work on-site, any time acceptable specified quality standards are not being met, or when modifications to the SOW impact existing Consultant procedures.

Follow-up Phase: Daily checks shall be performed to assure continuing compliance with contract requirements until completion of the particular feature of work. The checks shall be made a matter of record in the CC documentation. Final follow-up checks shall be conducted, and all deficiencies corrected, prior to the start of additional features of work which may be affected by the deficient work.

Additional Preparatory and Initial Phases: As determined by the Government, additional preparatory and initial phases may be conducted on the same definable features of work if the quality of on-going work is unacceptable, if there are changes in the applicable CC staff, on-site supervision or work crew, if work on a definable feature is resumed after a substantial period of inactivity, or if other problems develop.

B4.1 When a Non-conformance Investigation (NCI) is initiated as a result of adverse findings, it is recommended that the Government contract should specify that the NCI shall be conducted at no additional expense to the Government.

B4.2 Contract language should specify that when a electronic data audit is required as a function of objective indicators of fraud or gross error, the cost of the data audit should be performed at no additional expense to the Government.

B4.3 Model contract language for B4.1 and B4.2:

Non-Conformance Investigation: When any out of control event relative to contract requirements is identified by the Government or by the Contractor, a non-conformance investigation must be initiated by the Contractor. Out of control in this context signifies any failure to execute the specific requirements of the contract for field or laboratory work. In the event of such an occurrence, the Contractor or Contract Laboratory must initiate an investigation into possible reasons for the discrepancy, and submit a plan to resolve the problem. All such activities shall be considered as non-conformance events, and be supported by the appropriate documentation. In the event of laboratory non-conformances, the Government may require that additional raw data packages be submitted and delivered to the Government offices for review. Such investigation and correction activities, including submittal of additional raw data packages as required, shall be performed at no additional cost to the Government. In the case where a comprehensive off-site or on-site “data/tape audit” is required as a function of objective indicators of fraud or gross error, this activity shall be performed at no additional expense to the Government. These requirements shall be acknowledged in the QAPP.

B5.1 When sample analyses are performed as a sub-contracted activity, it is necessary to include provisions in the contract for “access to data” to insure unimpeded access to the laboratory by Government representatives with or without the prior consent of the primary contractor. It is recommended that all contracts should contain provisions allowing for access to all project data maintained on the laboratory premises by designated representatives of the Contracting Officer. This may include representatives of the implementing agency or representatives of interested regulatory agencies.

B5.2 Model contract language for B5.1:

Access to Data: The Government shall have direct access to all data produced by the Contract Laboratory at all times. At any time, Government representatives shall be granted access to data that is currently available at the laboratory for sample analyses for this project with or without the prior consent of the Consultant. If the Contract Laboratory has an electronic system for delivery or early review of data, the Government shall be allowed electronic access to data with or without the consent of the Consultant. The Consultant shall instruct the Contract Laboratory in writing prior to initiation of sampling and analysis that Government representatives shall have unrestricted access to data and the Government shall be provided with a copy of this communication.

Appendix C

Additional Information on the Use of Electronic Data/Tape Reports

Electronic data audits are needed to identify or confirm computer fraud such as peak shaving, where laboratory analysts deliberately override and change processed data files for filed results for quality assurance compounds such as calibrations, surrogates, or internal standard areas to make them falsely appear to pass. An electronic data audit consists of reintegrating chromatographic peaks and reprocessing results for instrument performance check compound results from raw data obtained by the analytical laboratory during the analysis of a batch(es) of samples and archived on electronic media. The results obtained by the auditor are compared to the results reported by the laboratory during routine submission of the hard copy data package. Discrepancies between the auditor obtained results and the laboratory reports are identified. In some cases the files submitted by the laboratory will provide a pictorial display of the peak integrations performed by the laboratory.

The majority of laboratory fraud is brought to the government's attention by whistle blowers. Independent off-site electronic data audits are needed to follow-up on allegations of fraud brought by whistle blowers. Whenever laboratory employees make allegations that fraud is occurring, it is necessary to investigate the allegations. Independent off-site electronic data audits are an important tool in these investigations. In the cases where the allegations are confirmed, the audits can assess the extent and magnitude of any manipulations and the effects on data.

These audits can be used to resolve questions on data quality and fraud raised by other oversight tools. They provide a deeper level of review when data deficiencies are identified through data validation, poor PES results, on-site audits, or split-sample results. They can be used to determine whether a laboratory is conforming to the requirements of analytical methods and contracts. Aside from their utility in detecting data fraud, they can also be useful in detecting numerous data quality problems due to incorrect scanning ranges in GC/MS systems, incorrect quantitation procedures, or poor chromatographic performance.

Appendix D

Quality Assurance Officer Role and Responsibility
Recommended Training for QAOs and Project Managers

Quality Assurance Officer Role and Responsibility

A DOD QUALITY ASSURANCE OFFICER, WHO MUST BE A FEDERAL EMPLOYEE, GENERALLY HAS THE FOLLOWING RESPONSIBILITIES IN ENVIRONMENTAL DATA COLLECTION AND CLEANUP ACTIVITIES. THE EXECUTION OF THESE RESPONSIBILITIES MAY BE PERFORMED BY HIS OR HER DESIGNED (I.E, STAFF WORKING IN THE QA PROGRAM OFFICE).

(1) Prepares applicable Quality Assurance Program Plan and conducts management system reviews of environmental data collection activities conducted by the applicable base(s) to ensure that sound quality assurance is being practiced. Refer to *EPA Requirements for Quality Management Plans, EPA QA/R-2* and *Guidance for Preparing, Conducting, and Reporting the Results of Management System Reviews, EPA QA/G-3* for further information.

(2) Oversees and supports base project manager(s) and DOD consultants in the development of site-specific data quality objectives, preparation and review of Quality Assurance Project Plans and Field Sampling Plans, project scoping and planning for environmental data collection activities, and review/validation of the resulting data. Ensures that QA documents prepared by bases are consistent with the Service's mandated Quality Assurance Program, technically sound, and scientifically accurate by conducting internal QA and peer review.

(3) Provides QA input to contracting officers in the acquisition laboratory and consultant services. Performs review of QA/QC requirements in laboratory contract documents. Oversees contract laboratories to ensure data integrity and all QA/QC criteria required by the contract are met.

(4) Maintains a network of QA contacts within DOD and in the regulatory agencies to communicate standard quality assurance practices and to share government knowledge regarding laboratory performance.

(5) Develops a QA training program and provides training to the base project manager(s) and DOD consultant(s).

(6) Serves as a technical authority to review new analytical methods, innovative site characterization methods/technologies, and QA/QC requirements in remedial design, construction and remedial actions.

(7) Conducts QA system, laboratory and field audits to determine compliance with the Service's QA Program, approved QA Project Plans and Field Sampling Plans, conformity with QA requirements and guidances issued by US EPA and the Service, and adherence to good QA/QC standards and practices. Takes appropriate corrective actions to rectify QA/QC deficiencies.

Appendix D continued

Recommended Training for QAOs and Project Managers

RECOMMENDED TRAINING FOR QUALITY ASSURANCE MANAGERS AND PROJECT MANAGERS PROVIDING OVERSIGHT OF ENVIRONMENTAL DATA COLLECTION ACTIVITIES

Provided below is a list of courses developed by the Quality Assurance Division (QAD), Office of Research and Development, US EPA. These courses are useful for regulatory and DOD QAO and project managers to attend in order to acquire necessary skills to fulfill their QA responsibilities (identified in this appendix and in Section 3.9). A list of Region 9 courses that supplement the courses provided by QAD is also provided. All available courses are denoted with a Ù. A key to assist QAOs and project managers in deciding the courses to attend is provided in the text following the list of courses. DOD and regulatory QAOs and project managers should use their discretion in deciding which courses would be of immediate benefit to them.

Other government agency training programs equivalent and consistent with those of US EPA can be substituted for the courses identified below:

1. Orientation to Quality Assurance

    111: Orientation to Quality Assurance

    115: The Three Phases of Effective QA

    117: Quality Management Systems

    211: The EPA Quality System

    311: DQOs in a Projects Lifecycle

2. Quality Management Plans

    221: Quality Management Plans

    222: Quality Management Plans: Example

3. Management Systems Reviews

    131: Introduction to Management Systems Reviews

    132: Planning the MSR

    133: Conducting the MSR

    134: Evaluating the MSR

    135: Reporting the MSR

136: Interviewing Skills

232: Management Systems Reviews

140: The DQO Process Overview

141: Planning for Decision Making: The DQO Process

142: A Simple Example of Data Quality Objectives

241: The Data Quality Objectives Process

242: Data Quality Objectives Fly Ash Example

243: Data Quality Objectives Ground Water Example

244: DQO Skills Exercise

245: DQO Case Study Exercise

246: Data Quality Objectives Process for Superfund

247: Superfund Data Quality Objectives Example

248: Improving Superfund DQO Skills

249: Superfund DQO Case Study Exercise

341: Implementing the Data Quality Objectives Process

342: Managing the Data Quality Objectives Process

347: Overview of the DQO DEFT Software

348: DQO Decision Error Feasibility Trials (DEFT) Software (II)

445: Sampling Issues

447: Determination of Sample Size

5. Quality Assurance Project Plans

151: The Purpose of the Quality Assurance Project Plan

251: Quality Assurance Project Plans

252: QA Project Plan Example: Chesapeake Bay

253: QA Project Plan Example: Sassafras Creek

255: Statistics, PARCC, and Key Descriptors

351: Relating DQOs to the Quality Assurance Project Plan

352: Quality Assurance Project Plan Example

451: Sampling Hazardous Waste Sites

454: The Design of Experiments

457: Teguchi Methods

6. Standard Operating Procedures

460: Calibration and MDLs

461: Setting Minimum Detection Limits

7. Quality Training

8. Technical Assessments

9. Data Quality Assessments

191: Introduction to Data Quality Assessment

192: Looking at the Data, Making the Numbers Talk

193: Summarizing Data

194: Data Quality Assessment

291: An Overview of Data Quality Assessment

292: Data Distributions and Inference

391: Data Quality Assessment

398: The Data QUEST Software

492: Dealing with Data Below Detection Limits

493: Making Multiple Statistical Tests

The following training courses are available from Region 9

R9-Meth	Analytical Method Selection
R9-Lab	Analytical Laboratory Selection
R9-FSP	Field Sample Plan Preparation

Key:

Courses from QAD's set 1 and 4 are intended for those who are involved with any aspect of the Quality Assurance Program, either at US EPA, State, DOD, or other organization. Courses from set 2, 5, 6, 8, 9 and the Region 9 training courses are intended for US EPA QAOs Project Managers, and individuals from State, DOD, or other organizations that write, review or approve QMPs, QAPPs and FSPs, or provide oversight over field and laboratory activities. Courses from set 3 are intended for those who have need of knowledge regarding the planning or conduct of an Management System Review (MSR), either as an MSR team member or member of an organization that will undergo an MSR.

The Region 9 QA Program is currently working on a comprehensive curriculum inclusive of QAD's training courses. Courses ranging from general to increasingly specific and detailed concepts are planned. When they are complete, it is strongly recommended that US EPA, State, and DOD QAOs and Project Managers register to attend these courses.

Appendix E

Example Ethics Agreement

_____

(Laboratory Name)

ETHICS AND DATA INTEGRITY AGREEMENT

I. I, _____ *(Name)*, state that I understand the high standards of integrity required of me with regard to the duties I perform and the data I report in connection with my employment at _____ *(Laboratory)*.

II. I agree that in the performance of my duties at *(Laboratory)*:

a. I shall not intentionally report data values that are not the actual values obtained;

b. I shall not intentionally report the dates and times of data analyses that are not the actual dates and times of data analyses; and

c. I shall not intentionally represent another individual's work as my own.

III. I agree to inform _____*(Laboratory)* of any accidental reporting of non-authentic data by myself in a timely manner.

IV. I agree to inform _____*(Laboratory)* of any accidental or intentional reporting of non-authentic data by other employees.

_____

(Signature)

_____

(Date)

Appendix F

Case Studies

Case Study 1

Time Traveling

A major contractor for the State of California used an in-house laboratory to support the Remedial Investigation/Feasibility Study (RI/FS) at a major Superfund site. The laboratory was unable to meet the 14 day holding time for GC/MS analysis of ground water samples, and some chemists resorted to "time traveling" by changing the date and time on the GC/MS computer clock to indicate that samples had been analyzed within the 14 days, when in reality they had not. The contractor disclosed a holding time problem to the state and US EPA. The disclosure triggered investigations including paper audits and electronic data/tape audits of laboratory records.

Because the fraud involved falsification of original electronic data, it was not possible to accurately assess the extent of fraud. The impacts of the fraud included:

1) invalidation of a portion of data used in the RI/FS;

2) resampling and reanalysis of some ground water wells;

3) investigation costs for the state, including contractors, and

4) delays in litigation involving the RI/FS data.

The investigation and litigation involving the fraud was compromised by the lack of a current Quality Assurance Project Plan. A QAPP had been written for the project, but had not been revised when the scope of work changed.

Techniques which may have deterred the fraud:

A signed ethics statement from each employee may have discouraged chemist from engaging in time traveling;

A government QA officer may have detected problems in turnaround times;

Split-samples may have indicated a turnaround time problem;

Submission of electronic deliverables may have deterred the practice if chemists were aware that the time traveling would be discovered.

Appendix F continued

Case Study 2

Introduction

The following case example illustrates the paramount importance of follow-up, the potential value of pre-award on-site audits, and the definitive value of electronic data audits in identifying fraud at a laboratory that was subjected to considerable QA oversight but escaped detection by other routine oversight tools.

History of Routine Oversight of the Laboratory

Routine oversight of a contract laboratory consisted of **National Functional Guidelines data validation** of complete data packages including all raw data on 100% of the data packages, **quarterly single blind PES** (the laboratory was aware that it was analyzing a test sample), **quarterly data package audits** conducted to assess contract compliance, **annual laboratory on-site audits** following an **initial pre-award laboratory on-site audit**, and audits of raw data backed up to **electronic tape** on a semi-annual basis.

Laboratory Not Prepared for Contract According to Pre-Award On-Site Audit

The laboratory had successfully completed a three year contract and according to laboratory performance tracking reports, which track the results of on-site audits, performance evaluation sample results, and contract compliance screening, the laboratory was performing acceptably. The laboratory bid on a second contract following completion of its first contract and was scheduled for a pre-award on-site laboratory audit because it successfully passed pre-award PES and was among the three lowest bidders. The auditor who conducted the pre-award evaluation identified numerous deficiencies while on-site and recommended to the contracting officer that the laboratory would benefit from taking more time to prepare for a contract under the newly revised Statement of Work and that if an award was made, that quality assurance oversight during the initial start up stage of the contract would be critical. A contract award was made against the recommendation of the auditor.

Routine Semi-annual Electronic Data Audit Definitive in Catching Fraud that Escaped Detection by Other Oversight Tools

Results of a routine, semi-annual electronic data audit performed during the first several months of the laboratory's performance under the newly awarded contract documented blatant fraud in the form of peak shaving of failed calibration and other QC results to make them appear to be acceptable. According to contract requirements, the laboratory was not allowed to analyze samples until any problems with the testing equipment were corrected and the calibration results met criteria.

The case was referred for criminal investigation. The criminal investigation supported by laboratory analyst testimony confirmed that peak shaving and false reporting of QC results had been a practice in the laboratory, particularly during periods of key testing equipment downtime, when the company was faced with meeting deadlines for data deliverables. The investigation also revealed that the company engaged in other types of fraudulent reporting, such as falsely reporting instrument sensitivity by fortifying calibrations and samples with additional analyte ("juicing') and time traveling (back dating

the analysis time to meet holding times). The investigation also revealed that the illegal practices had been prevalent during the first three year contract with the government and that routine electronic data audits had documented the fraud, but that there had been no follow-up on the audit results by previous oversight staff and, there was no referral for investigation.

Lessons Learned:

1) The pre-award on-site audit alerted the auditor of laboratory deficiencies that warranted close monitoring.

2) Major impacts to the environmental program would have been avoided if the auditor's advice had been followed and contract award had been avoided or delayed.

3) Follow-up was of paramount importance because electronic data audit reports on an earlier contract documented similar fraudulent findings. An agency-wide Standard Operating Procedure that ensures that quality assurance staff will review electronic data audit results and take appropriate corrective action has since been implemented.

4) The criminal investigation uncovered "juicing" and "time travel" that escaped detection by all the oversight tools used. This is not uncommon or unexpected. However, data validators should be aware that time traveling and juicing do occur and should pay special attention to reported dates and inconsistencies in data packages. For example, data validators should ensure that extraction dates precede analysis dates. In addition, high response factors for characteristically low response factor compounds could be an indicator of "juicing". These measures are not fool proof, but may help to deter or detect fraud.

5) If the data validators had been looking for anomalies, they may have been able to identify repeated manual edits of criteria compound QC results that normally do not require manual edits. In this instance, they had not been removed from quantitation reports.

Case Study 3

Introduction

This case history highlights the importance of follow-up and the usefulness of data validation, PES, and electronic data audits in identifying fraud.

Laboratory's Work Was Deficient for First Federal Agency

The laboratory was a major government contractor and had numerous contracts with various agencies of the federal and state government. Data validation of the first hard copy data deliverables conducted by one of the agencies doing a very small amount of business with the laboratory through a small order sub-contracting mechanism identified a major (non-fraudulent) non-compliance with the calibration of testing equipment. HPLC testing equipment sensitivity was so low for many compounds during testing equipment calibration that it was doubtful that the laboratory could detect contaminants in site samples. The agency refused to pay for the deficient work and requested that the laboratory not receive future awards under the sub-contract program because of the poor quality work and its poor response to the problem.

Follow-up Consisted of PES Followed by Electronic Audits Which Caught Fraud

Several months later during the review of a Quality Assurance Project Plan, it was learned from a conversation with a remedial project manager that another federal agency was planning to contract the laboratory to analyze samples for a major Superfund site clean up. Arrangements were made with this agency to submit double blind PES to the laboratory concurrently with the first set of field samples from the site as part of quality assurance oversight for the site. Ideally, the laboratory would be unaware that it was analyzing a test sample of known composition and concentrations. It should be noted that PES were not routinely used as part of the quality assurance oversight system by this agency at that time. Therefore, follow-up on the part of the first agency was crucial to identifying problems in this case. The laboratory reported contaminants that were known not to be present in the test samples and failed to identify contaminants that were spiked into the test samples. In addition, the laboratory data package deliverable did not summarize internal standard areas, an important quality assurance indicator. Because the laboratory performed unacceptably for no apparent reason on the PES, a deeper level of review of the laboratory's work was pursued. Raw data produced during the analysis of the PES and site samples and archived on electronic tape was obtained from the laboratory for the purpose of conducting an electronic data audit. It should be noted that electronic data audits were not part of the routine quality assurance system used by the contracting agency. Audits of these data tapes and additional data tapes revealed pervasive fraud throughout a large number of sample data audited. The audits determined that it was a practice for laboratory analysts to override and change failed computer results for GC/MS calibrations, surrogates, internal standards and tuning compounds to make them appear acceptable. It was common practice for laboratory analysts to manipulate more than half of the results for the target analytes during instrument calibration, in this way. The data tape audits also disclosed that analysts covered their manipulation of data by removing manual edit flags from the data trail (M flags) that would have alerted data validators.

In addition, prior to the criminal investigation, complete data packages were obtained from the laboratory in order to fully evaluate and understand the deficient scores on the PES. These packages included summaries of internal standard areas, which were not part of the required data deliverables for the site. Excessively fluctuating responses for this method QC indicator (12%-100% in the same analytical run) was indicative of a major problem with the analytical system. A follow-up investigation of the problem by the primary contractor for the site demonstrated that out of control testing equipment responses for internal standard areas had been prevalent throughout the entire project at the site.

Lessons Learned

1) Follow-up and sharing of information between agencies was critical in documenting fraud at this laboratory. The government was first alerted to potential problems through validation of data from a different method and instrument. Follow-up consisted of recommending PES and electronic data/tape audits, which were not part of the routine oversight for the site.

2) Because PES and electronic data/tape audits were not used, the laboratory's fraudulent activities went undetected and affected more than 28 sites over five years duration. Electronic data audits would have caught the fraudulent work of the laboratory years earlier had they been part of the routine quality assurance oversight of the laboratory. Follow-up on deficient PES results may have also caught the problem had they been part of the routine quality assurance oversight of the laboratory.

3) The fraud was not readily detectable through data validation of the hard copy data deliverables because the purpose of the fraud was to make the data packages appear to be of excellent quality. Electronic data audits and PES were needed to identify the fraud. The laboratory covered up evidence of its fraudulent manipulation using excessive manual edits and by removing "M flags" from the data trail to avoid being caught by data validators.

4) In retrospect, a data validator looking for fraud may have detected that the laboratory removed "M" flags from compounds that are normally expected to be "M" flagged (manually integrated), i.e., the laboratory covered their trail too well. The lesson learned is that in the future data validators should look for such anomalies as these and follow-up on them.

5) Important summaries of internal standard areas showing that the analyses were out of control were not reviewed by data validators because they were not part of the required documentation from the laboratory.

Case Study 4

Introduction

This case history highlights the importance of substantiating allegations of fraud with electronic data audits and investigations, and the importance of pre-award on-site audits and data validation that includes a review of raw data.

History of Routine Laboratory Oversight

Laboratory oversight consisted of pre-award and ongoing on-site audits, routine data validation of quality control summaries for a about 20% of the total data packages submitted by the laboratory (validation did not include review of raw data nor was raw data required documentation), submission of single blind PES on a regular basis (the laboratory was aware that it was analyzing PES) and split sampling on about 10% of the total data.

Allegations of Fraud Brought to the Attention of the Government

About two years into the government contract a former laboratory employee alleged to the regulatory agency that employees routinely engaged in the fraudulent practices of peak shaving and peak enhancement in the GC laboratory. He stated that erratically functioning equipment in the GC laboratory caused surrogate recoveries to fall outside method acceptance limits. According to the employee, in order to make the surrogate recoveries appear to pass criteria without correcting the underlying cause of the problems, the analysts falsified surrogate recovery results by using the computer to add area to surrogate peaks from adjacent peaks. According to the employee, the laboratory also manipulated instrument calibration results using the computer to make failed results appear to pass. He stated that he personally engaged in excess of 500 instances of peak shaving and that the practice had been propagated through several generations of employees working in the laboratory.

Electronic Data Audits were Necessary to Investigate the Allegations

In order to determine if there was any substance to the allegations, the regulatory agency conducted both on-site and off-site electronic data audits of the laboratory's raw data that had been produced during the

analysis of site samples and archived on magnetic tape. The data/tape audits substantiated the former employee's allegations of peak enhancement in the GC laboratory. In addition to confirming manipulations in the GC laboratory, electronic data audits identified problems with the way the laboratory processed tuning compound results in the GC/MS laboratory. DFTPP and BFB tuning compound results that must meet method criteria prior to sample analysis were processed inappropriately by laboratory analysts, which made them appear to

pass. It should be noted that the manipulation of tuning results in this case (but not all cases) could have been detected by validation of raw data which was not required.

On-Site Systems Audit Revealed Numerous Deficiencies

In addition to electronic data audits, thorough on-site audits were conducted of all laboratory departments. The laboratory on-site audit determined that the practices in the laboratory did not reflect the quality assurance manual and that standard operating procedures were not written for many methods. In addition, numerous deficiencies were identified, such as use of expired instrument calibration standards and use of analytical balances that had not been validated for accuracy.

As a result of the problems with this laboratory, replacement data was necessary for the risk assessment at a major Superfund site and the cleanup was delayed by two years. This was made necessary by the general lack of data defensibility considering the combination of laboratory manipulations and deficiencies documented during the investigative on-site systems audit and the fact that data of unknown quality cannot be used for risk assessment.

Lessons Learned

1) On-site and off-site electronic data audits and a thorough investigation were necessary to determine if the former employee's allegations could be substantiated. Findings on the electronic data audits were confirmed by the testimony of employees obtained during an investigation. This case history highlights the importance of acting on information that is received from former employees or outside sources to gather additional information. The majority of laboratory fraud cases have historically been brought to the government's attention by disgruntled employees.

2) A thorough pre-award on-site audit could have been used to avoid making a contract award to the laboratory. The laboratory on-site audit that was conducted after problems with the laboratory came to light identified numerous deficiencies.

3) Blatant inappropriate background subtractions of DFTPP and BFB tuning results to make them appear to pass was potentially identifiable from the raw hard copy data packages submitted by the laboratory. Raw data should be required for a percentage of the data deliverables submitted for data validation and data validators should pay special attention to the possibility of gross illegal background subtraction procedures, such a using the apex of an adjacent peak to perform what is supposed to be background subtraction.

4) There is always the possibility that laboratories will take special care when analyzing PES. Increasing the frequency of single blind PES submission may force the laboratory to properly

calibrate and maintain testing equipment, or the use of double blind PES (PES disguised as site samples), are recommended quality assurance oversight measures to deal with this.

5) Split sampling results will not necessarily catch data manipulation. In this case, the majority of split sampling results were non-detect and therefore the laboratory's manipulations did not affect the concentrations of contaminants.

6) The lead agency put all of its "eggs in one basket" by relying on only one laboratory to produce all the data for the site. This lead to a two year delay at the site after fraud was identified, since a replacement sampling effort was necessary. In other cases where more than one laboratory analyzed data, it was possible to delete the data from the unreliable laboratory without delaying the clean up or requiring resampling.

Appendix G

Glossary

4-BROMO-FLUORO-BENZENE (BFB): The compound chosen to establish mass spectral instrument performance for volatile organic analysis (VOA). It is also used in the VOA fraction as a system monitoring compound (SMC).

CRITICAL DECISION POINT(S): The end use of data determines the degree of quality assurance/quality control (QA/QC) that is required for an environmental data collection activity. The level of detail and stringency of the QA/QC necessary for a particular project is a function of a) the project category and b) decisions that need to be made within these categories. The different project categories that US EPA recognizes and the types of decisions that may be made in a data collection process are discussed below:

Category I Projects require the most rigorous and detailed QA, since the resulting data must be both legally and scientifically defensible. Category I projects include critical decisions on enforcement actions and projects of significant national or congressional visibility. Such projects are typically monitored by the Administrator. Category I projects must produce results that are autonomous; that is, results that can prove or disprove a hypothesis without reference to complementary projects.

Category II Projects are those producing results that complement other inputs. These projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to serve as a reliable foundation for making rules, regulations or policies. Projects that do not fit this pattern, but have high visibility, would also be included in this category.

Category III Projects are those producing results used in decision making regarding evaluation and selection of options, or feasibility studies or preliminary assessments of unexplored areas which might lead to further work.

Category IV Projects are those producing data for decision making in assessing suppositions.

Within these categories, there may be decision points considered critical. Some examples are:

- determining whether there are problems associated with a laboratory or sample matrices — done at the beginning of the investigation;
- confirming high “hits” or concentration results when using the information for risk assessment;
- data used in informing the public about a risk posed by a hazardous situation;
- determining the boundaries of ground water contamination;
- using the data for enforcement or litigation;
- data used in a record of decision;
- determining whether treatment continues or ceases;
- confirming whether a site is clean;
- data used in final delisting of a site;
- establishing rules, regulations, or policies.

This list is not exhaustive; each environmental investigation may face a set of different decision points unique to itself.

DATA QUALITY OBJECTIVES (DQOs): Qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. For more details, refer to (1) *US EPA's "Guidance for the Data Quality Objective Process," EPA QA/G-4, September 1994*; and (2) *US EPA's "Data Quality Objectives Process for Superfund, Interim Final," EPA/540/G-93/071, September 1993*.

DATA QUALITY OBJECTIVES PROCESS: A Quality Management tool based on the Scientific Method, developed by the US EPA to facilitate the planning of environmental data collection activities. The DQO Process enables planners to focus their planning efforts by specifying the intended use of the data (the decision), the decision criteria (action level), and the decision maker's tolerable decision error rates. The products of the DQO Process are the DQOs.

DATA VALIDATION: Data validation is a systematic process for reviewing a body of data against a pre-established set of criteria to determine the quality of the data. The process involves reviewing data against a set of quality control "acceptance" criteria to determine whether it is within the criteria windows. Where data do not meet the "acceptance" criteria, they are flagged with a qualifier identifying the associated problem. US EPA has data validation guidelines, known as national functional guidelines, for its own contract laboratory program. These US EPA guidelines require that data validation include a review of documentation such as raw data, instrument printouts, chain of custody records, and instrument calibration logs. A data validation report is generated that documents the major findings from this review. In that report Data Validation Qualifiers are assigned based on how well the data met the acceptance criteria.

DECA-FLOURO-TRI-PHENYL-PHOSPHINE (DFTPP): The compound chosen to establish mass spectral instrument performance for semivolatile analysis (SVOA).

DOUBLE BLIND PE SAMPLE: A full volume test sample submitted to a laboratory along with site samples such that the laboratory is unaware of the composition of analyte(s) spiked into the test sample and concentration(s) in the test sample. Ideally, the test sample is indistinguishable from the site samples in that it is identical to site samples in terms of bottle labeling, sample matrix characteristics, and contains analytes and interferences at concentrations similar to those detected in the site samples. The test sample is disguised as a site sample to minimize the possibility that the laboratory become aware it is analyzing a test sample and potentially pay special attention to the test sample during its handling and analysis.

ELECTRONIC/MAGNETIC DATA/TAPE AUDIT: An auditor regeneration and processing of raw, unprocessed analytical data produced by an analytical laboratory during the analysis of volatile and semivolatile samples by GC, GC/MS, or other methods which have archival systems, and a review of laboratory processed files for the purpose of identifying deviations from methods and contracts. A comparison of results obtained by the auditor for calibrations and other criteria compounds against the results reported by the laboratory in the hard copy deliverables is made to identify possible discrepancies between what was reported by the laboratory and actual quality control results.

ELECTRONIC DATA DELIVERABLES: A summary of analytical and quality control results for sample analyses organized in a contract specified format and submitted in diskette form, in addition to routine hard copy data package deliverables, that is amenable to semi-automated data validation (i.e., the process involves reviewing data against a set of quality control "acceptance" criteria to determine

whether it is within the criteria windows. Where data do not meet the "acceptance" criteria, they are flagged with a qualifier identifying the associated problem).

ELECTRONIC DATA VALIDATION: Automated data review through the use of computer programs. An example of an automated data validation program is US EPA's Computer-Aided Data Review and Evaluation (CADRE).

FIELD DUPLICATE SAMPLES: Samples that are collected as successive replicates, spatially co-located, or homogenized duplicates which are more representative of a single location at a particular time.

FIELD SAMPLING PLAN: A written plan that documents the objectives, rationale, and procedures for collecting and analyzing environmental samples.

FIELD SPLIT SAMPLES: Samples collected in the field that are divided into two samples. One sample is sent to the contract laboratory and the other sample is sent to an independent laboratory. The results from the two laboratories are compared and the differences analyzed.

GAS CHROMATOGRAPHY (GC) AND GAS CHROMATOGRAPH/MASS SPECTROMETRY (GC/MS): Refers to instrumental methods of analysis of volatile and semivolatile organic contaminants by gas chromatography and gas chromatography/mass spectrometry (e.g., US EPA methods 8010 and 8260).

INDEPENDENT: A party that has no financial or other interest in the project and able to provide an objective review of activities or reports.

LABORATORY AUDITS: On-site laboratory evaluation to determine the managerial and technical capability of the laboratory to perform analysis in conformance with specification in contracts and approved analytical methods. Audits normally evaluate a laboratory's technical expertise, operating procedures, facility and equipment sufficiency, and possible sources of sample contamination.

LABORATORY FRAUD: The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.

LEAD AGENCY: DOD or regulatory agency which has the primary investigatory responsibility at a site.

PERCENT RECOVERY: The measured concentration of a standard reference material (e.g., PES) divided by the known concentration, multiplied by 100, expressed as a percentage.

PERFORMANCE EVALUATION SAMPLE (PES): A test sample prepared with known concentrations of specific analytes, within specified limits of uncertainty, and submitted to a laboratory for chemical analysis, which yields quantitative data that can be used to evaluate the ability of the laboratory to successfully handle, analyze and identify the contaminants and accurately report their concentrations. PES results are typically presented as percent recovery.

PRE-AWARD ON-SITE TECHNICAL SYSTEMS AUDIT:

An on-site evaluation to assess a laboratory's capability to meet technical and managerial requirements specified in the contract prior to contract award. An inspection to verify the adequacy of the facility; adequacy and maintenance of instrumentation; ability of personnel to meet experience or education requirements; and the acceptable performance of analytical and QC procedures.

QUALITY ASSURANCE (QA): An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client. QA is concerned with those activities performed on an occasional basis to gain an independent assessment of monitoring operations. For example, blind samples and laboratory audits are used to check whether or not the QC measures are working.

QUALITY ASSURANCE OFFICER: See Appendix D.

QUALITY ASSURANCE PROJECT PLAN (QAPP): A formal document describing, in comprehensive detail, the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

QUALITY CONTROL (QC): The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer, operational techniques and activities that are used to fulfill requirements for quality. QC deals with those internal operations performed during the measurement process to document the quality of data. QC activities include performing calibrations, duplicate analyses, and preparing spiked samples and blanks.

SINGLE BLIND PE SAMPLE: A test sample sent to a laboratory where the laboratory is unaware of the analyte spiked into the sample or the concentrations, but is aware that it is analyzing a test sample. Single blind PES are usually ampulated and submitted to the laboratory with directions for preparing a full volume sample for analysis.

STANDARD REFERENCE MATERIAL: Quality control standards which are traceable to the National Institute of Standards and Testing (NIST) materials. NIST traceable materials are used for calibration and quality control of all US EPA approved testing protocols.

STANDARD OPERATING PROCEDURES: A written document that gives precise descriptions of routine procedures for operations, analyses, or actions. An SOP is a written document which provides directions for the step-by-step execution of an operation, analysis, or action which is commonly accepted as the method for performing certain routine or repetitive tasks. The SOP is functional, clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts.

STATEMENT OF WORK FOR LABORATORIES:

A Statement of Work (SOW) is part of the documentation for a contract between the Federal government and a laboratory performing analyses in support of site investigations. The SOW details the specific analytical procedures to be adhered to, QA/QC requirements, a description of deliverables requirements, target compound lists, reporting of data, chain of custody and sample documentation which the contractor must follow.

Appendix H

Acronyms

BFB	4-Bromo-Fluoro-Benzene
CBCEC	California Base Closure Environmental Committee
CMECC	California Military Environmental Coordination Committee
CMECC CDQ/CR PAT	California Military Environmental Coordination Committee Chemical Data Quality/Cost Reduction Process Action Team
CAL/EPA	California Environmental Protection Agency
CLP	US EPA's Contract Laboratory Program
CRDL	Contract Required Detection Limit
CRQL	Contract Required Quantitation Limit
DFTPP	Deca-Fluoro-Tri-Phenyl-Phosphine
DOD	Department of Defense
DQOs	Data Quality Objectives
FSP	Field Sampling Plan
GALP	Good Automated Laboratory Practices
GC/MS	Gas Chromatography/Mass Spectrometry
ISO	International Organization for Standardization [the abbreviation of the name in French is ISO]
MCLs	Maximum Concentration Levels (Regulatory Levels from the Safe Drinking Water Act)
NFG	National Functional Guidelines for data review/validation
NPL	National Priorities List for ranking Superfund Sites
OIG	Office of the Inspector General
PAT	Process Action Team
PES	Performance Evaluation Sample

QA	Quality Assurance
QAD	Quality Assurance Division
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
RI/FS	Remedial Investigation/Feasibility Study
SOPs	Standard Operating Procedures
US EPA	United States Environmental Protection Agency

Appendix I

Reference List

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Appendix J

References Available from US EPA, Region 9

Table 1

Double blind Performance Evaluation Samples (PES)

Type of Fraud	What to Look for	Further Investigation Suggested	Real World Example	Potential Impact
gross peak shaving of some contaminants in PE sample	concentrations of analytes grossly outside acceptance ranges; or trend of repeated failures on PES without adequate explanation	off-site or on-site electronic data audits	Case # 3	unreliable data
drylabbing	false positives or negatives	electronic data audits		fictitious data

Table 2

Data Validation

Type of Fraud	What to Look For	Further Investigation	Real World Example, Appendix	Potential Impact
peak shaving	unexpected manual integration, e.g., of internal standards, or excessive manual edits	electronic data audit	Case # 2, 3, 4	concentrations of sample data inaccurate
peak shaving	absence of manual edits where expected may imply M (i.e., manual edit) flag removal to cover fraud or poor work	electronic data audit	Case # 3	concentrations of sample data inaccurate
backdating analysis (time traveling)	inconsistencies, e.g., analysis date precedes extraction date	electronic data audit to check for other fraud; refer to regulatory agency	Case # 1, 2	concentrations may be low due to excessive holding times
manipulation of tuning results	numerous computer operations such as ADD, SUB, CLP of tuning results; or improper background subtraction	conduct electronic data/tape audit	Case # 3, 4	possible false identification of analytes
drylabbing	overlapping analysis times on same instrument; too many samples analyzed within timeframe	refer to regulatory agency; conduct electronic data audit to check for evidence of file copying and other fraud	Case # 3	data fictitious
juicing	high response factors (i.e., sensitivity) for compounds where relatively lower response factors are expected	scrutinize laboratory for other problems including electronic data audit to check for other fraud	Case # 2	sample concentrations low, possible false negatives

Table 3

Electronic Data Audit

Type of Fraud	What to Look For	Further Investigation Suggested	Real World Example	Potential Impact
peak shaving or enhancement to make failed calibrations, surrogates, internal standards appear to pass	discrepancies between auditor and laboratory QC results; record (pictorial) of shaved peak in processed (quantitation output) file	referral to regulatory agency	Case # 1, 2, 3	data quantitatively inaccurate
re-naming old data and submitting a second time (drylabbing)	evidence of file copying procedures	set up database and check for duplicate tunes, calibrations etc. refer to regulatory agency	Case # 2	fictitious data
manipulating failed DFTPP or BFB tunes to make them appear to pass acceptance criteria	inability to duplicate tune and meet criteria by legal means	refer to regulatory agency	Case # 3	possible false negatives and positives