

ENVIRONMENTAL DATA QUALITY REPORT

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By

Environmental Data Quality Team

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1. EXECUTIVE SUMMARY

An Environmental Data Quality Team was formed to review the data quality management programs in the California Environmental Protection Agency (Cal/EPA) with respect to collection and analysis of soil, water, wastewater, solid or hazardous waste and related media (excluding air). The membership consists of parties that have a stake in the subject matter.

1.1 Mission

The Team mission is to improve the quality of data used by Cal/EPA for specific actions. A charter which describes this environmental data quality project in detail is given in Appendix A.

1.2 Background

Cal/EPA is mandated to administer the environmental laws in California to protect the public health and the environment. It needs to use environmental data of adequate quality for decision making.

In the last few years, there have been numerous cases of laboratory fraud in the generation of environmental data. The most notorious case occurred in 1995 when a laboratory was indicted and convicted of committing fraud in performing its contractual obligations in environmental testing with the Federal government. The fraudulent practices cost the government about \$5.5 million worth of data. Cleanups were delayed for up to 2.5 years. This laboratory also performed work for Cal/EPA under several contracts.

Therefore, the Team was formed to review the current environmental data generation and evaluation practices and to make recommendations to improve the processes to obtain reliable and legally defensible environmental data in a cost effective manner. The Team consists of representatives from the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), the Department of Health Services, the Department of Food and Agriculture (CDFA), the United States Environmental Protection Agency (US EPA), the Office of Environmental Health Hazard Assessment (OEHHA), and the Association of California Testing Laboratories (ActLABs), a private organization representing the major environmental testing laboratories in California.

1.3 Analysis

Based on the analysis conducted by the Team, accurate and meaningful environmental data are key to good decision making in environmental projects. Inadequate or inaccurate data can lead to poor decision making, costly rework, delays and possible health and environmental hazards, as well as community concerns and loss of credibility for Cal/EPA and its programs.

Inaccurate data can result from:

- ∇ field samplers not following appropriate procedures
- ∇ problems in sample preservation and transport which affect sample integrity
- ∇ laboratories not following appropriate procedures
- ∇ fraudulent results

Incomplete data can result from:

- ∇ highly competitive market which induces laboratories to modify procedures without valid justification
- ∇ lack of understanding of sample matrix effects, lack of documentation, and lack of knowledge on quality assurance and quality control principles
- ∇ inadequate planning of projects
- ∇ inadequate identification of data needs and requirements of all data users
- ∇ desire of responsible party or permittee to minimize sampling to reduce costs

Based on this analysis, the Team identified the findings and recommendations below. There are a number of recommendations to prevent, identify or address the different causes of poor quality environmental data and documentation. A collective effort by the participating parties to address this important issue will enable all of the organizations to benefit from the improvements. It will allow us to maximize improvements with the resources we devote to improving the quality of environmental data.

1.4 Principal Findings

Principal findings are:

Laboratory Fraud - Cost to State/Federal Governments

Laboratory fraud has resulted in a waste of federal and state resources in terms of time and money.

Some findings and recommendations of the Office of Inspector General (OIG) report on Federal Facility Superfund sites where commercial laboratories were used for sample analysis should be adopted. Cal/EPA and responsible parties and permittees also have used some of the same laboratories, and experienced some of the same problems as US EPA

Some examples of the principal findings from the OIG report include the following: (1) Site-specific data quality objectives, a prerequisite to Quality Assurance Project Plans (QAPPs), were generally not prepared. The lack of specific data quality objectives was one reason serious problems were found with environmental data quality. (2) QAPPs, the primary tool for controlling laboratory quality, were not well designed to prevent and detect inappropriate data. (3) Oversight of laboratory data quality needed to be increased. (4) US EPA had not assessed the adequacy of other Federal agencies' quality systems for environmental data. (5) There was no Federal system to share laboratory evaluations between agencies.

Personnel qualification requirements

There are no specific requirements in terms of education, training, and experience for Quality Assurance Officer or Samplers.

Continuing field audits lead to fewer violations

Facility field audits, including sampling protocols, of the facilities, and constructive feedback to the facilities tended to reduce the number of violations observed.

Inconsistency among Cal/EPA Quality Management Programs

The quality management programs within Cal/EPA do not have consistent requirements for data quality.

No overall Quality Management Plan for data collection

Only one of eighteen Cal/EPA programs reviewed has active plans to prepare a Quality Management Plan (QMP).

Relevant quality documents not fully utilized

Cal/EPA documents provide little or no information on the value or need of quality assurance/quality control (QA/QC); US EPA Technical and QA/QC documents appear substantially better; and based on the voluminous number of Cal/EPA technical documents, there is a wide variation in how QA/QC procedures are established and followed.

The Environmental Laboratory Accreditation Program cannot guarantee performance on a daily basis

ELAP requires various standards for certification or accreditation regarding environmental testing, but cannot verify day-to-day performance. A laboratory certified by ELAP means that the laboratory meets the ELAP certification requirements at a point in time. It does not follow that the laboratory performance and its work products will always meet the ELAP requirements.

Performance evaluation samples can detect unacceptable laboratory practices

Though announced single blind performance evaluation samples are often treated differently than routine samples, double blind and single blind performance evaluation samples are valuable tools to assess laboratory performance.

The National Environmental Laboratory Accreditation Conference (NELAC) has adopted uniform national accreditation standards for environmental testing laboratories, which can benefit Cal/EPA programs.

Where applicable, Cal/EPA's adoption and implementation of NELAC standards would benefit the environmental data quality statewide.

Current procurement process inadequate and inefficient

The lowest bids rather than the most reliable and best professional services are used to award contracts for environmental sample analyses.

1.5 Recommendations and Implementation

The Team has made various recommendations and has estimated the cost of implementing the recommendations. An entity (such as a program or unit within a large organization) may need to implement only those recommendations it deems beneficial. The recommendations can be selectively implemented over time. The recommendations are listed below. The benefits and estimated cost of implementation are provided in Table A (page 43). The predicted positive impact is provided in Table B (page 46). The recommendations for small projects are provided in Table C (page 48). Technical terms used here are defined in the glossary (Appendix B, page 56.)

In Table A, the benefits of the recommendations are provided. The relative cost and relative effectiveness of the recommendations were estimated by a scale of from 1 (low) to 5 (high). The ratios of effectiveness to cost for the recommendations are also provided. A recommendation with a high ratio means it would be more cost effective compared to a recommendation with a lower ratio. Table B summarizes the possible impacts of the various recommendations on different items or issues. Table C has specific recommendations for small projects because it will not be cost-effective for small projects to implement all recommendations enumerated in Table A. A small project can be defined as a project that costs less than \$25,000 and can be completed within one year. Each Board, Office, or Department within Cal/EPA should establish a data quality policy which recognizes the needs of small projects and the limits of the quality control/quality assurance requirements for them.

The recommendations include the use of Quality Assurance Project Plans and Sampling and Analysis Plans. These documents specify the appropriate quality control protocols for the various projects depending on the data quality objectives and the intended use of the environmental data at issue. Documentation will enable efficient verification and audit of the project performance.

To ensure that adequate quality systems are in place, programs which use environmental data in all Boards, Offices, and Departments (BODs) within Cal/EPA should

establish Quality Management Plans (QMPs).

To ensure that adequate quality management is established, including implementation and enforcement, all BODs within Cal/EPA should

ensure that Quality Assurance Project Plans (QAPPs) and Sampling and Analysis Plans (SAPs), including appropriate quality control procedures, are prepared and implemented in accordance with current US EPA guidance and requirements;

provide the appropriate and necessary training for Cal/EPA staff for the preparation and implementation of QAPPs and SAPs, including the use of the Data Quality Objectives

(DQOs) process;

develop guidance and training for Responsible Parties on appropriate QAPPs and SAPs;

require that QAPPs and SAPs be reviewed at least annually and the review and any consequential changes be documented;

revise the QAPPs to require that magnetic data is maintained and made available to Cal/EPA Boards, Offices, and Departments;

specify in QAPPs the reporting requirements for non-target analytes, if any;

require a timely approved QAPP and SAP for every Cal/EPA project;

ensure that QAPPs and SAPs are implemented, verified, and made available to all affected parties;

ensure reasonable data quality objectives are developed before the QAPP and SAP are completed for each site investigation and suitable test methods are used, including non-EPA methods, when appropriate; and

specify in QAPPs required magnetic tape audits if major deficiencies are found by other quality assurance methods, such as data validation or performance evaluation samples.

For sample collection and analysis, BODs should

establish policy requiring permittees, responsible parties, and other applicants to identify the samplers and laboratories they or their subcontractors use throughout the project;

establish consistent laboratory and field audit protocols;

use double blind samples in Cal/EPA programs, use double blind sample results to monitor data quality and laboratory performance, and establish a mechanism for sharing performance evaluation sample results among BODs; and

establish a frequency of laboratory and field audits and perform laboratory and field audits, use NELAC standards for laboratory audits, and share written audit information among agencies without necessarily increasing the number of audits.

For Environmental Data Management, BODs should

use the US EPA National Functional Guidelines for data validation as outlined under the Contract Laboratory Program (CLP) as default;

adopt standardized content for hard copy deliverables;

specify the requirements for electronic data deliverables and electronic data validation;

require a minimum of 10% of data be validated by qualified personnel; and

require that data validation be completed by a party independent of the laboratory, its parent company, the permittee, and the prime contractor.

To maintain and update the standards of quality of the environmental data used for decision making, BODs should

adopt NELAC standards where feasible for Cal/EPA programs;

require Cal/EPA staff to use US EPA QA/QC documents (see Appendix D): a survey on the frequency of use of the documents listed in Appendix D should be conducted and some documents should be selected for use in environmental data collection and evaluation, and models for simple and complicated sites with examples of documentation requirements would be useful to State staff;

establish specifications for Quality Assurance Officer;

develop an alternative procurement system to the low bidder system for laboratory services;

encourage ELAP to continue to implement ISO and NELAC standards/guidelines wherever possible; and

require that State laboratories which support Cal/EPA programs, both within and outside Cal/EPA, be accredited by the National Environmental Laboratory Accreditation Program (NELAP), when accreditation is available.

1.6 Performance Measures

The performance measures for this project are a means of measuring the effectiveness of the recommendations implemented to improve the quality of environmental data which is used for decision making.

The performance measures selected by the Team include:

- ∇ Monitor whether Cal/EPA and Department of Health Services (DHS) programs increase their use of data quality programmatic elements according to the Programmatic Elements of Data Quality (Table 1, page 65).
- ∇ Monitor results of Comprehensive (groundwater) Monitoring Evaluation (CME) or equivalent audits over time to assess the trends in numbers and types of violations.
- ∇ Compare Water Pollution (WP)/Water Supply (WS) overall performance of contract laboratories and sub-contracted laboratories performing studies for prime contractors on Cal/EPA sites to the overall performance of California laboratories. If performance of contract laboratories does not exceed the average for California laboratories, the Team should investigate the cause(s).
- ∇ Assess whether there is a significant change in the number of suspect or fraudulent data.
- ∇ Assess laboratory performance by using double or single blind performance evaluation samples.

Performance can be measured by looking at data quality in the future to see if improvement occurs.

1.7 Future Team Activities

Future Team activities are:

One year after the final report is completed, the Team will determine which recommendations have been implemented.

Two years after the final report is completed, the Team will evaluate the effectiveness of recommendations using performance measures.

1.8 Conclusion

The Environmental Data Quality Team has examined, studied, or investigated the various aspects and activities associated with the collection and analyses and reporting of environmental samples. The main aspects and activities examined include the perpetration of laboratory fraud, US EPA Office of Inspector General audit reports, environmental testing laboratory accreditation programs, the quality assurance/quality control practices of the boards, offices and departments within Cal/EPA, and performance evaluation testing programs.

The Team has compiled numerous findings that are summarized in this Executive Summary as well as in other sections of this report. The Team has also made various recommendations and implementation cost estimates to improve the quality of the environmental data that governmental entities use for decision making which affects the public health and the environment. The recommendations are summarized in this Executive Summary and in section 5. The possible positive impact of the recommendations is provided in Table B (page 46). Implementation of the recommendations may prevent laboratory fraud that caused waste of time and money, improve efficiency, and lead to better decision making that protects the public health and the environment.

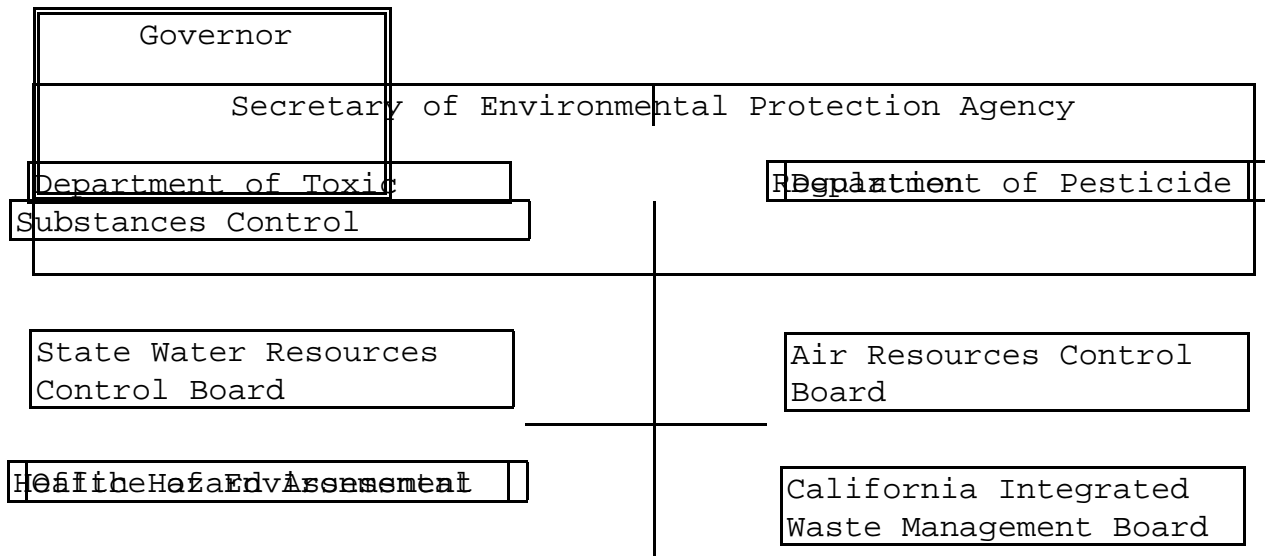
2. MISSION

The mission is to review the quality of existing environmental data which is used for decision making. Based on the review of available information, recommendations are to be made to improve the quality of environmental data. The goals are to improve the quality of field sampling and field measurements; to improve laboratory services; and to improve the ability to prevent, detect, investigate, and prosecute laboratory fraud. Improvement means changes or modifications of existing methods, requirements, or operations so that the same or better end results can be obtained at a lower cost or shorter time-frame compared to existing methods, requirements or operations.

3. INTRODUCTION AND STATEMENT OF THE PROBLEM

The governor of California is empowered with broad authority to protect the public health and the environment. This authority is derived through the state constitution, federal and state laws. The governor carries out this mission through agencies formed by executive order and legislation. The California Environmental Protection Agency (Cal/EPA) is primarily responsible for the protection of public health and the environment from hazardous substances.

Cal/EPA carries out this mission through six separate boards, offices, and departments, identified in the chart below.



The Air Resources Control Board and the State Water Resources Control Board each oversee regional boards located throughout the state. They are semi-autonomous, although all are responsible for the same overall mission: protection of the public health and the environment.

A common factor that is crucial for each of these organizations to carry out their mission expeditiously and in a cost effective manner is the use of environmental data collected by various means. The manner in which these data are collected, and in turn analyzed, is crucial to determining public health and environmental risks. A sample collected from an inappropriate location or media will not provide information relevant to the location of concern. A sample collected properly, but analyzed inappropriately, may provide false results. Mindful of the latter,

the California Legislature in 1988 created the Environmental Laboratory Accreditation Program (ELAP) within the Department of Health Services. Subsequently, all data used for regulatory purposes must be generated by laboratories accredited by ELAP. This accreditation, however, only ensures that the laboratory is capable of following designated test and analysis methods; it does not ensure that such laboratories will consistently generate the quality of data expected without oversight. Accredited laboratories vary considerably in the performance of chemical analyses. These laboratories, though accredited, may not follow the required quality control/quality assurance protocols on a daily basis to ensure accurate analytical results. Further, it is believed that, in many cases, the lowest bidding laboratory that provides analysis of samples falls short of expectations, with regard to consistent data quality. Because users of laboratories are paying for, and selecting these laboratories, limited only by the latter's accreditation status, it is not surprising that the lowest bidder criterion controls selection. This is further compounded by some laboratory practices that are dubious, and in some cases fraudulent; for example, in 1995 \$5.5 million worth of environmental data was rejected, resulting in a 2.5 year delay in mitigation of a public health and environmental threat. Although criminal convictions resulted for the individuals involved, and a \$1.8 million fine was levied against the corporate defendant, the question is apparent: could there have been something done to detect and prevent this problem earlier?

Field personnel carry out a wide variety of environmental sampling that includes collection, handling, preservation, and transportation. Some samplers undertake little training whereas others have extensive training. Proper sample collection and handling techniques are essential to generate useable data specific to the intended application. The Department of Toxic Substances Control (DTSC) has observed private facility samplers improve their skills following DTSC field oversight and coaching. The sampling community, however, requires additional assistance (e.g., training, detailed sampling and analysis plans, etc.) to meet useability criteria for scientific data.

The useability of data should depend on the site-specific data quality objectives and intended applications needed for site characterization, risk assessment, evaluation of remedial alternatives, monitoring, and remedial design. The specific use of the data needed for each of these applications defines the level of data quality needed. The level of data quality is measured by the parameters of precision, accuracy, representativeness, completeness, and comparability which determine the sample collection and chemical identification/detection methods. Some applications, such as a rapid and preliminary site evaluation, may require analytical methods with different performance parameters (such as precision, accuracy, speed of determination, field portability, etc.) than required of other more rigorous applications, such as health risk assessments. The useability of data for each application depends on evaluation and satisfaction of the appropriate data quality objectives. Significant cost savings can be achieved by ensuring that data collected meets the objectives applicable to the intended use.

Therefore, because the administrative decision process is so interlinked with the quality of data, it is essential that a review of current data quality practices be determined, and findings be made with the goal of recommending areas of improvement, and to establish performance criteria to

maintain the high level of data quality reporting that is expected.

Consequently, the Environmental Data Quality Team was formed to review current information regarding data quality as it affects the governmental decision making process. The Team examined the Federal Office of Inspector General audit reports; the quality systems or quality management used by the various boards, offices and departments within Cal/EPA; the field audits and observation performed by the Department of Toxic Substances Control staff; and the performance evaluation samples programs designed to measure the performance of individual environmental testing laboratories. The Team also looked into the functions, goals, activities of two environmental laboratory accreditation organizations - the California Environmental Laboratory Accreditation Program (ELAP) and the National Environmental Laboratory Accreditation Program (NELAP). After extensive discussions and deliberations, the Team has prepared this Environmental Data Quality Report that includes recommendations to develop techniques which could be implemented to improve the quality of environmental data.

The Environmental Data Quality Report has eight sections and four appendices. The sections include: the Executive Summary, the State of Environmental Data Quality regarding the generation and use of environmental data, and Recommendations and Implementation. Appendix A is the Team Charter that describes the nature and composition of the Team. Appendix B is a collection of abbreviations and a glossary of terms that are used in the report. Appendix C is a detailed description and discussion of subsection 4.4 (Quality systems in Cal/EPA and Relevant Documents). Appendix D is an extensive list of US EPA and Cal/EPA Guidance Documents.

4. THE STATE OF ENVIRONMENTAL DATA QUALITY

Environmental data generation invariably involves several essential steps. They are sample collection, sample preservation and transportation, sample analysis, data validation, and final report preparation. The quality of the data is affected by any deviation from the standards in the performances of the steps. Of the steps mentioned, the most complicated and expensive one is sample analysis. It usually requires sample and instrument preparation and skilled personnel to operate sophisticated equipment. To cut costs, some environmental testing laboratories resort to practices that amount to fraud.

4.1 Laboratory Fraud

In 1993, the US EPA suspended an environmental testing laboratory located in Sacramento, California, for failure to comply with the contractual quality assurance/quality control requirements. The compliance failure was detected by using double blind performance evaluation samples to monitor the performance of the laboratory. Subsequently, the laboratory was indicted by the Federal Government for committing fraud. Two senior employees were convicted, and the corporate laboratory was fined \$1.8 million. Because of the laboratory's fraudulent practices, the Federal Government suffered a \$5.5 million loss and the State Government suffered a \$2 million loss for a total of about \$7.5 million losses in compromised environmental data and related costs.

The Sacramento laboratory was not the first such laboratory to be indicted, only it had the most pervasive effect. In 1990, US EPA had 22 laboratories across the country under investigation for potential fraud (Chemical & Engineering News, Feb 25, 1991, page 14). Several investigations have been completed, leading to indictments of laboratory personnel for criminal fraud. Recently, US EPA Region 9 has investigated and acted on two cases, as well as making several new allegations that are still in the preliminary stages. It is apparent that the successful prosecution of the Sacramento laboratory has not deterred fraudulent actions by others, as evidenced by over 20 investigations (including the convicted Sacramento laboratory) for fraud since the first highly published case involving an environmental testing laboratory in San Diego in 1990.

Although not well documented, there are some common grounds leading to the commission of laboratory fraud. The known cases seemed to be the result of pressure to produce analytical data in a most profitable way. Additionally, the laboratory operating systems did not seem to detect fraudulent practices. Typical practices involved time traveling and peak-shaving. Time traveling means altering the time period between sample collection and analysis in order to meet the holding time requirements. Peak-shaving means altering the area counts (arbitrarily drawing the baselines of peaks in order to increase or decrease the total area counts of the peaks) of certain analytical standards in order to meet the quality assurance/quality control criteria. For example, when the Hazardous Materials Laboratory (HML) of the Department of Toxic Substances

Control audited a San Diego laboratory in 1990, HML found 5.6% of a total of 4,685 data files had time discrepancies (time traveling).

Findings

Some environmental laboratories resorted to fraudulent practices in their performance of contractual obligations.

4.2 US EPA Office of Inspector General Audits

In 1995 and 1996 the US EPA Office of Inspector General (OIG) performed two audits on US EPA's data quality oversight at Federal Facility Superfund sites. The purpose of the first audit was to determine if US EPA Region 9 had sufficient procedures in place to ensure that laboratory data was of known and acceptable quality under Federal facility agreements. The second audit was expanded to address the adequacy of oversight of Federal facilities cleanups in Regions 8, 9, and 10. The audits were performed in response to the identification by US EPA Region 9 of extensive fraudulent reporting of data produced for the cleanup at March Air Force Base and Region 9's suspension of other laboratories for improper analyses. Region 9 oversees California, Arizona, Nevada, and Hawaii. Region 8 oversees Colorado, North and South Dakota, Wyoming, and Montana. Region 10 oversees Washington, Oregon, and Idaho.

The OIG audits cover the review of 9 Federal facility sites in three US EPA Regions and 19 Quality Assurance Project Plans (QAPP). The OIG audits found that US EPA oversight of laboratory data quality at Federal facility Superfund cleanups was not fully effective and that the Department of Defense (DOD) quality assurance systems for laboratory data quality had serious weaknesses. The audits determined that QAPPs, which should contain provisions for laboratory oversight, did not contain some key quality assurance oversight tools that are considered to be the most effective in deterring and identifying data quality problems. These include performance evaluation samples, laboratory on-site audits, data validation of complete data packages, and electronic audits of raw data. The US EPA OIG audit identified \$11 million spent on rejected analyses, resampling, and associated costs and cleanup delays of 2.5 years at the 9 sites included in the audit. The OIG believes that it is unlikely that all inferior laboratory analyses have been identified because laboratory data quality was not being adequately monitored. The OIG concluded from their findings that an effective quality assurance oversight system could have helped avoid this loss. Some specific OIG findings include the following:

- ∇ Department of Defense quality assurance plans for sites impacted by fraudulent reporting of data by a Sacramento laboratory did not contain provisions for key quality assurance activities that the US EPA region ultimately used to detect fraudulent data submitted by the laboratory at March Air Force Base (performance evaluation samples and magnetic tape audits). US EPA Region 9 found extensive laboratory fraud at the Sacramento laboratory which was used by 28 Department of Defense installations in three US EPA regions, resulting in about \$5.5 million dollars of lost data, resampling, and associated expenses. One million dollars of data was rejected at March Air Force Base alone and the

cleanup was delayed 1.25 years.

- ∇ The Federal government did not have an effective plan for sharing laboratory evaluations such as laboratory on-site audits. The Army, Navy, and Air Force paid for five audits of a Sacramento laboratory between January 1991 and October 1992. The first Air Force audit, done in January 1991, found major problems with this laboratory. An Army manager at Rocky Mountain Arsenal told the OIG that the Sacramento laboratory would not have been used if he had been aware of the Air Force audit findings. Rocky Mountain Arsenal ultimately rejected samples analyzed by the Sacramento laboratory at a cost of \$3.8 million. This rejection set back the Arsenal's water monitoring program by about 1 year.
- ∇ The environmental data for Sacramento Army Depot was of unknown quality because data packages did not contain sufficient documentation to verify the quality of the sample analyses. Additionally, the analyses were not validated using standardized review procedures in accordance with the US EPA National Functional Guidelines. As a result, the OIG recommended that Region 9 withdraw its certification that one of the operable units was cleaned up until an evaluation of data quality at the site was made. (Subsequent data validation by the US EPA Region 9 identified serious data quality problems and a replacement data effort was necessary).
- ∇ The OIG found that the quality assurance plan for Travis Air Force Base did not incorporate the quality assurance oversight measures designed to detect or deter laboratory problems. Three rounds of sampling for Travis Air Force Base were completed to determine the extent of contamination at the base. The samples were sent to the contractor's own laboratories for analysis. An Air Force on-site audit of the laboratories subsequently found major problems. Because of the problems, the region was not able to determine the quality of the analyses. This delayed the cleanup by more than 2.5 years.
- ∇ Because data review of laboratory deliverables was cursory and thorough data validation was not completed until 1.25 years into the site investigation, problems with data quality at Hunter's Point Naval Shipyard went undetected. When thorough data validation was performed 1.25 years into the project, the Navy determined that it was necessary to reject \$2.5 million dollars worth of data, then spent another \$1 million dollars to replace the rejected data. The cleanup was set back about 2 years. The US EPA ultimately suspended the laboratory for using improper data reduction practices (processing raw data to generate reportable results) at another site. The laboratory did work at five DOD sites in two US EPA regions. The OIG also determined that the region's data quality oversight plan was never implemented. The OIG further determined that data quality objectives for the site were unclear, data packages were incomplete, requirements for laboratory audits, performance evaluation samples, and electronic (tape) data audits were lacking.

- ∇ The laboratory that performed most of the analyses for the investigation at Luke Air Force Base was suspended by US EPA and the data was determined to be of unknown quality. The cleanup was delayed by nearly 1 year and replacement sampling was necessary. The OIG believed the delay could have been avoided if the quality assurance plan had been better designed to include key quality assurance oversight measures and the quality assurance plan properly implemented.
- ∇ The Department of Energy (DOE) had laboratory reports with alleged fraudulent laboratory analyses at Hanford, one of the nation's largest environmental cleanup sites. The value of these analyses was not available. Further, approximately \$240,000 dollars of laboratory analyses were rejected at its Fernald site.
- ∇ The Region 9 did not monitor compliance with the laboratory audit specified in the QAPP for Fort Wainwright Operable Unit 2. The QAPP required laboratories to be validated by the Army prior to their use and every 18 months thereafter. The OIG found that the Army had not complied with this requirement. Serious data problems were found with the laboratory that was used to analyze samples for this operable unit. The Army extended its certification of the laboratory for one year after it expired without conducting an on-site audit. When the Army finally conducted its audit, it found significant performance deficiencies and concluded that the laboratory was not qualified to perform analyses for the Army. The Region 9 was not aware of the untimely audit because copies of the relevant laboratory audits had not been obtained and reviewed.

The complete findings and recommendations of these two audits are discussed in "Environmental Data Quality at DOD Superfund Sites in Region 9", E1SK5-09-0031-5100505 released on September 26, 1995 and "Laboratory Data Quality at Federal Facility Superfund Sites, Draft Report", E1SKB6-09-0041, October 28, 1996. The key quality assurance oversight measures that were recommended by the US EPA OIG are discussed in the California Quality Action Team recommendations individually.

Findings

The OIG report described findings from Federal Facility Superfund sites where commercial laboratories were used for sample analysis. Cal/EPA and responsible parties and permittees also use commercial laboratories. In fact, Cal/EPA programs have used some of the same laboratories, and experienced some of the same problems as US EPA. Therefore, the Team concluded that some of the findings and recommendations from the OIG report were applicable to our situation.

Examples of the principal findings of the OIG report included the following: (1) Site-specific data quality objectives, a prerequisite to Quality Assurance Project Plans (QAPPs), were generally not prepared. The lack of specific data quality objectives was one reason serious problems were found with environmental data quality. (2) QAPPs, the

primary tool for controlling laboratory quality, were not well designed to prevent and detect inappropriate data. (3) Oversight of laboratory data quality needed to be increased. (4) US EPA had not assessed the adequacy of other Federal agencies' quality systems for environmental data. (5) There was no Federal system to share laboratory evaluations between agencies.

4.3 Field Audits and Observations

Since 1986, the Department of Toxic Substances Control (DTSC) has been conducting field audits at Resource Conservation and Recovery Act (RCRA) land disposal facilities. These audits are part of the RCRA grant commitment to US EPA. Early audits (1985-87) were actually done by the Regional Water Quality Control Boards (RWQCBs), with assistance by DTSC. Since 1986, DTSC has had the lead for these audits. Today, DTSC and RWQCBs coordinate the inspections, with DTSC conducting the inspections. Follow-up is coordinated with the RWQCBs.

There are primarily two types of groundwater audits done for the RCRA grant: Comprehensive (groundwater) Monitoring Evaluations (CMEs) and Operation and Maintenance Inspections (O&Ms). The CMEs include an evaluation of the monitoring well placement and design. They also include a field audit of the groundwater sampling and handling procedures. The CME inspection is broader in scope and thus tends to find more violations and deficiencies than the O&M inspection. The O&M inspection focuses only on the groundwater sampling and handling procedures. O&M inspections are typically done at facilities that are thought to have an adequate monitoring network based on a previous CME. Occasionally, an O&M may recommend a site have a future CME because the monitoring system has changed or been modified, or for some other reasons.

Annually, DTSC conducts between 4 and 10 RCRA inspections. In the last 10 years, DTSC inspected several sites more than once. Comments in this report will only focus on the groundwater sampling and handling procedures, and not focus on the groundwater monitoring design. Historically, DTSC has found that most sites were out of compliance with their groundwater sampling and handling procedures. Sites with repeated inspections show improvement in their procedures. Figure 1 graphically depicts the number of inspections per year for the period from 1988 to 1996. Figure 2 shows the numbers of violations per inspection for the same period. The seven routine types of violations depicted in Figure 2 are described as follows:

- | | |
|-----------------------|--|
| A = SAP Inadequate: | The Sampling and Analysis Plan is missing or grossly deficient in key procedures such as sample handling, analytical methods, or chain-of-custody procedure. |
| B = SAP Not Followed: | The sampling team is deviating significantly from the specified procedures. At one site, the plan specified that the wells will be purged to dryness prior to sampling. In the actual implementation, some wells were purged only 50% of their volume. This resulted in a \$25,000 fine as a result of this 1990 inspection. |

- C = Poor Equipment Calibration: The sampling team is unfamiliar with or fails to follow the calibration methods for the field equipment, or the standards have expired.
- D = Blanks Not Sent Blind: Trip, field, and equipment blanks must be sent blind to the analytical lab. Frequently, the samplers label the blanks as "field blank" or "trip blank."
- E = No Annual Reports: The regulations require that the facility submit an "Annual Report" by March 1 following each calendar year. Some facilities fail to submit the report.
- F = Chain-of-Custody Errors: Samples are to be kept in a secure area, with limited access. Some facilities fail to keep the samples secure. At one site, the samples were kept in the lunch room refrigerator with a number of brown paper bags (lunches) readily accessible to all the employees.
- G = Facilities Not Sampling: The regulations require either quarterly or semi-annual sampling. In a few cases, the site reported they were not sampling after we had notified them that we were going to audit their sampling. A somewhat more common violation is that the facility has identified they have a release but are not sampling at the frequency specified in the regulations.

During the first few years (1988-1991), 27 inspections were conducted. Nearly all the sites investigated had "Major Violations" (a "class 1" violation that requires penalty assessments). Of the 27 inspections, only 1 had no violation. During 1992-1996, 28 sites were inspected. Of the 28 inspections, 13 had no violations; a dramatic decrease in the number of violations.

This reduction in the number of violations is due to a variety of reasons: (1) The same facility was audited more than once. During the initial inspections (1988-1991), violations were noted, primarily because sampling plans were inadequate or not being followed. In subsequent inspections (1992-1996), the facility corrected these earlier violations. (2) The DTSC inspector provided guidance on how to prepare and implement sampling plans. DTSC emphasized the collection of usable scientifically valid groundwater data. Operators were shown how to minimize cross contamination between sample points and limit constituent loss in water handling procedures.

Improperly designed groundwater monitoring systems forced DTSC, in its regulatory capacity, to delay permits and cleanups. Secondly, inadequate sampling procedures led DTSC to discard invalid data. Enforcement of current requirements is key to obtaining good data. DTSC field presence, including technical guidance documents, (see Appendix D for a complete listing) helped facilities meet minimum RCRA requirements.

Findings

The RCRA program administered by DTSC has shown a significant decrease in the number of violations during 1992-1996 compared to 1988-1991 probably as a result of the continuing inspections, trained inspectors, and guidance documents. The sampling community, however, requires additional assistance (e.g., training, detailed sampling and

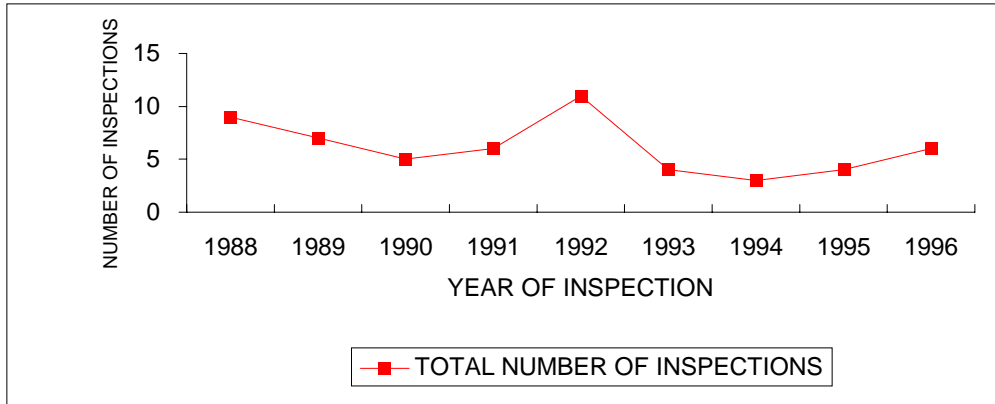


Figure 1

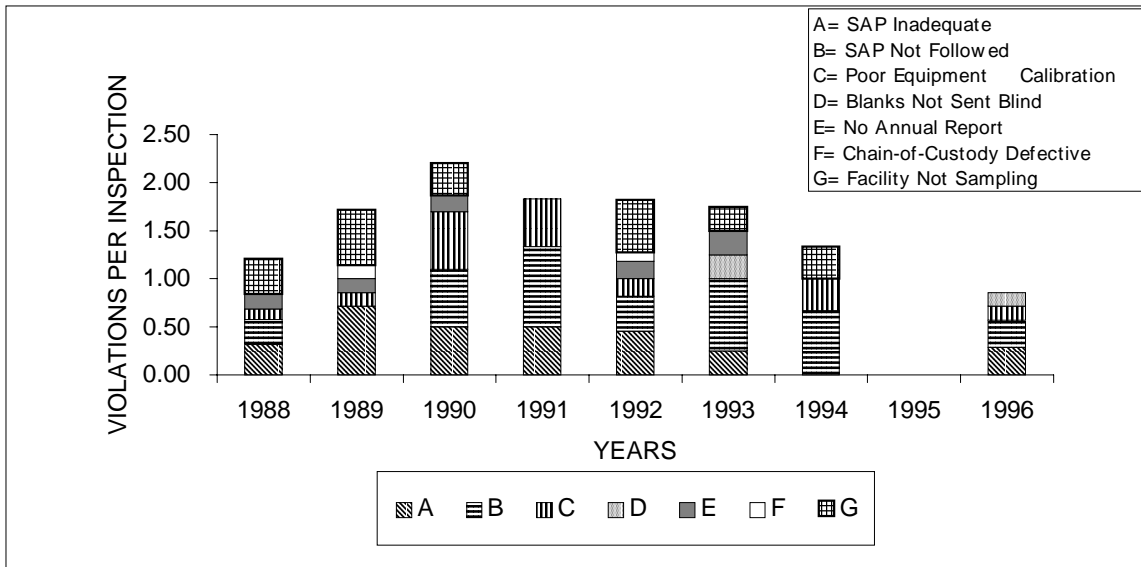


Figure 2

analysis plans, etc.) to meet scientific data useability criteria.

4.4 Quality Systems in Cal/EPA and Relevant Documents

Due to the details involved, the description of documents and discussion for this subsection are provided in Appendix C.

Findings

There is little consistency in quality elements used by Cal/EPA programs.

As shown in Table 1 (page 65), there is great variability among programs. There is no obvious rationale for the variety of quality elements used in the listed programs. Only one of the listed programs has a Quality Management Plan (in preparation) although many include Quality Assurance Project Plans.

The reviewed programs generally do not meet current US EPA quality requirements.

Although California is generally regarded as a leader in environmental issues, the California environmental quality standards have been established in reaction to US EPA requirements. Since California environmental programs implement many federal statutes, the California quality systems have been established in response to US EPA requirements as conditions of grants and contracts. In the last 10 years, the US EPA has revised its quality system requirements to conform to relevant national and international standards. Selected Cal/EPA programs were compared with the current US EPA quality requirements. As shown in Table 1 (page 65), Cal/EPA programs generally do not meet the current US EPA quality standards. In particular, there is little conformance to the Quality Management Plan (QMP) approach, as reflected in the E-4 standard established by the American National Standards Institute and the American Society for Quality Control, in spite of the fact that US EPA has adopted the E-4 standard for all environmental programs and plans to require its use for grants and contracts to states.

There is no agency-wide Cal/EPA quality management system which meets relevant national or international standards.

As shown in Table 1 (page 65), the existing quality elements vary greatly among the programs, and there is no agency-wide quality system. Although Cal/EPA has quality improvement projects, including this project, there is no system which conforms to ANSI/ASQC E-4, ISO 9000, or ISO 14000 standards.

Although US EPA provides guidance for the development of Data Quality Objectives (DQOs), there is little use of DQOs in Cal/EPA programs.

The listed references include current US EPA guidance for the use of the DQO process, but DQOs have limited use in the listed programs. The US EPA Office of Inspector General cited the lack of DQOs as a major deficiency in the California military facilities.

Data Management Plans are also seldom used in Cal/EPA. Neither US EPA nor Cal/EPA provides guidance for Data Management Plans, and there is great variability in data management for the reviewed programs. Data Management Plans include a description of how data will be used, including the use of data qualifiers. US EPA has established a system for data qualifiers, but it is little used in Cal/EPA programs.

Although there are 123 available guidance documents related to environmental data, there is variable and often deficient guidance for staff on quality assurance and quality control.

No Cal/EPA or DTSC documents assign responsibility for development of QA/QC procedures and data quality assessment to individual professionals.

The recently released US EPA guidance documents on quality systems are superior to most Cal/EPA guidance documents.

4.5 Environmental Laboratory Accreditation Program (ELAP) - General Description

Background

Under the provisions of the California Environmental Laboratory Improvement Act (Department-sponsored Assembly Bill 3739, Chapter 894 of California Statutes of 1988), ELAP was established in the California Department of Health Services on January 1, 1989. Under the Act, accreditation is required for an environmental laboratory if it produces data for California regulatory agencies: Department of Health Services- Division of Drinking Water and Environmental Management (DDWEM), Department of Toxic Substances Control (DTSC), State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCB), and California Department of Food and Agriculture (CDFA). The data may be used to demonstrate compliance with applicable requirements of drinking water, wastewater, food for pesticide residues, shellfish testing, and hazardous waste sections of the California Health and Safety and Water Codes. ELAP assures accredited laboratories have demonstrated capability to accurately analyze environmental samples.

Scope

The scope of the program covers testing of drinking water, hazardous waste, wastewater, pesticide residues in food, shellfish sanitation, and aquatic toxicity spread over 23 fields of testing. Laboratories may apply for certification for *1 or more* of the 23 fields of testing. At present, more than 800 laboratories are certified by ELAP, nearly 700 of which are in the state of California, and more than 100 laboratories are out of state. The laboratories include commercial, municipal, State, or Federal laboratories. Nearly 500 laboratories are accredited for drinking water analysis, nearly 400 laboratories for hazardous waste analysis, more than 500 laboratories for wastewater analysis, and nearly 20 laboratories for pesticide residue testing in food.

Quality Assurance Program

A laboratory seeking accreditation is required to submit a Quality Assurance Manual along with a completed application form and appropriate fees. Each laboratory must develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory must develop and maintain a Quality Assurance Program Manual. The Manual must address all quality assurance and quality control practices to be employed by the laboratory and must, at the least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual must include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures, custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance;

assessment of precision and accuracy; corrective action; and quality assurance reports. The laboratory director or designee must review, and amend if necessary, the quality assurance program and Quality Assurance Program Manual at least annually.

Site Visit

Site visits are conducted by ELAP technical staff prior to certification and every other year thereafter. Follow-up visits may occur at any time. Site visits are conducted also when a laboratory requests an addition of one or more subgroups, or when there is an ownership change. During the site visit, ELAP will verify the following: the laboratory uses only the analytical test methods approved for each subgroup for which the laboratory is seeking certification; personnel qualifications and facilities adequate; the instrumentation and equipment meet the requirements specified in the California Code of Regulations, Title 22, Section 64813; the quality assurance and quality control procedures meet the requirements specified in the Code of Regulations, Section 64815; and the information contained in the application meets requirements. The laboratory has to correct all deficiencies noted at the site visit, and submit a written response documenting all corrective actions taken.

Performance Evaluation Testing

Performance evaluation samples must be successfully analyzed prior to certification and at least annually thereafter for all applicable parameters for which samples are available. If a laboratory fails to submit acceptable results for the analysis of performance evaluation sample study sets, the laboratory may request that it be given a second attempt to submit acceptable results. Failure of a laboratory to submit acceptable results will result in the denial or restriction of the certification.

Certification

Certificates are issued for a period of two years based upon completion of the application process, verification of the quality assurance program, successful completion of the site visit, and acceptable performance evaluation sample analyses. Laboratories may request amendment of their certificate by filing an amendment application. ELAP conducts investigations and enforcement actions as needed.

Regulations

The adoption of the ELAP regulations (Title 22, Division 4, Chapter 19, Sections 64801 to 64827) established the rules and the requirements for the certification of environmental testing laboratories. Additional regulations are now being developed to comply with the mandates of AB3475 (1996) for recognizing and approving third party accrediting organizations and to include accreditation standards as adopted by the National Environmental Laboratory Accreditation Conference (NELAC). The proposed requirements will be included, where

necessary, to meet national standards of recognition. These changes made to comply with the requirements of NELAC include primarily quality systems, proficiency testing, and on-site assessment, among others. Other proposals in regulations revision are mainly administrative in nature and are necessary to remove confusing and unworkable portions in the current ELAP regulations. Also, ELAP program is funded by user fees on a cost recovery basis which is set by state law. It is costly and logistically very difficult to change practices such as single blind samples to double blind on a routine basis. In some cases, double blind samples would not be available.

4.6 Summary of ELAP Performance Evaluation Studies

4.6.1 Summary of Environmental Laboratory Accreditation Program (ELAP) Performance Evaluation Studies

ELAP manages the following performance evaluation (PE) studies as part of the certification process:

<u>PE Study</u>	<u>Frequency</u>	<u>Source</u>
WP (Water Pollution)	2 / year	US EPA
WS (Water Supply)	2 / year	US EPA
Hazardous Waste	2 / year	ELAP with RTC (contractor)
Microbiology	4 / year + 1 follow up	ELAP with Microbial Disease Lab
Bioassay	1 to 2 / year	ELAP
Radiochemistry	6 or more / year	US EPA, Las Vegas
Shellfish Sanitation	1 / year	US FDA
Pesticide Residues	2 to 4 / year	ELAP with CDFFA

4.6.2 Performance Evaluation Results

WP (Water Pollution)/WS (Water Supply)

The following table represents PE results from WP34, WP35, WS35, and WS36 studies. It shows the number of laboratories that participated, the number of data points reported, and the percent of acceptable results for State laboratories (State primary laboratories which fall under the scrutiny of the US EPA), California certified laboratories (laboratories certified by the State of California, Department of Health Services), and other laboratories throughout the country (laboratories other than the State laboratories).

Summary of WP & WS Results (1995-1996)

Round No.	State Labs in USA			CA Certified Labs			Other Labs in USA		
	# labs	# data points	% Accept	# labs	# data points	% Accept	# labs	# data points	% Accept
WP34	127	8383	90.4	505	36,701	86.7	3156	158,800	84.2
WP35	128	7684	89.3	483	28,253	87.7	2862	142,393	84.8
WS35	105	3994	91.4	288	12,745	87.2	2163	70,024	84.9
WS36	107	6382	92.4	294	13,858	87.6	2266	80,609	86.0

California laboratories generally tested more analytes per laboratory than other certified laboratories. Since the PE samples in these studies are not double blind samples, it is a known practice for some laboratories to put their best effort in the analyses of the PE samples. The PE results may not reflect a laboratory's normal performance, nor would they screen out any fraudulent activities. However, the results are used to identify laboratories that are not able to produce acceptable data with PE samples. Such performance is, therefore, an indicator of potential poor data quality which may be generated by the laboratory with real samples.

Hazardous Waste PEs

ELAP has conducted two hazardous waste PE studies. For the study HW01, which was done in 1995, a total of 209 laboratories participated in inorganic analyses, and 89% of the results reported for certification were acceptable. A total of 156 laboratories participated in organic analyses, and 88% of the results reported for certification were acceptable. For the study HW02, which was done in 1997, a total of 326 laboratories received the PE samples for inorganic analyses, and 89% of the results received were within the acceptance limit. A total of 374 laboratories received the PE samples for organic analyses, and 80% of the results received were within the acceptance limit. The acceptance limits were set as the mean \pm 1.96 standard deviation (95% prediction interval). The mean and standard deviation were determined either from the results of the reference laboratories or from the results of the participant laboratories.

Pesticide Residue PEs

The results of pesticide residue in food products performance evaluation samples are summarized in four tables. They are attached and labeled "DHS Proficiency" covering from January 1994 through 1996.

The samples are comprised of fresh or frozen fruits and vegetables which contain incurred pesticide residues or have added pesticide residues. Typically 3 samples are included in a set and are spiked with 0 to 6 chemicals each (typically 3 or 4 chemicals). The samples are verified in the preparation laboratory by running replicates of the prepared materials. The samples are submitted on "single blind" basis to three or four "expert" reference laboratories and the applicant laboratories under the same time and shipping conditions. The laboratories are given 30 days to determine the identity of pesticides contained and to quantify the levels. As soon as all of the laboratory reports are received, the target values are faxed to the participants for their review.

The results of the analyses are reviewed for general statistics and outliers. The results are tabulated and scored on a system that incorporates the target values and the results from the reference laboratories. Individual laboratory data sheets are prepared for each participant with details of their score and participants also get the summary sheet. (In the summary sheet the data is typically randomized on the ascending value of the first column of data so the laboratories cannot keep track of each other [i.e. the laboratory code number is only good for one specific summary sheet]).

DHS Proficiency Set # 2 -- January 1994



= Outlier at 5% confidence level.

Incurred Target PPM	Orange (1994-1A)			Lettuce (1994-1B)			Grapes (1994-1C)		
	Methoxychlor 0.26	Ethion 1.1	Imazalil Yes	Acephate 0.21	Methoxychlor 0.26	Methiocarb 0.38	Carbaryl 0.26	Parathion 0.090	Dicloran 0.14
Lab Code #									
1	0.23	1.0	**	0.15	0.30	0.47	0.20	0.14	0.16
2	0.18	1.2	**	0.26	0.40	0.64	0.32	0.09	0.15
3	0.22	1.1	**	0.14	0.25	0.40	0.19	0.074	0.12
4	0.086	*	**	0.32	0.11	0.40	0.29	0.13	0.036
5	*	1.0	**	0.13	*	0.46	0.13	*	*
6	0.25	1.1	1.2	0.22	0.26	0.33	0.22	0.082	0.15
7	0.56	1.2	**	0.27	0.15	0.39	0.13	0.12	0.16
8	*	0.83	**	0.24	*	0.34	0.19	0.092	0.35
9	0.28	1.1	1.2	0.19	0.27	0.42	0.24	0.080	0.14
10	0.15	0.23	**	*	0.15	*	*	0.080	0.080
11	0.24	1.6	**	0.22	0.31	0.38	0.24	0.11	0.11
12	0.22	0.86	**	*	0.25	0.33	0.28	0.075	0.12
13	0.20	0.38	**	0.18	0.34	0.18	0.20	0.15	0.059
14	0.020	1.7	**	0.36	*	0.33	0.11	0.13	0.38
15	0.17	1.1	**	0.16	0.14	0.35	0.30	0.10	0.10
16	0.39	1.3	1.3	1.2	0.38	0.36	0.28	0.11	0.19
17	0.16	1.0	**	0.20	0.36	0.34	0.26	0.081	0.15
18	0.30	0.58	**	0.18	0.23	0.29	0.26	0.08	0.14
19	0.25	4.4	**	0.60	0.32	0.40	0.30	0.30	0.13
20	0.21	0.86	**	0.16	0.25	0.35	0.23	0.090	0.090
21	0.23	0.84	1.1	0.25	0.23	0.32	0.30	0.070	0.13
22	0.42	0.93	**	*	0.15	*	0.24	0.12	*
23	0.49	1.6	**	*	0.39	*	*	0.068	*

* = Not Detected


** = Not in CDFA screen

Mean ppm (1)	0.25	1.0	1.2	0.21	0.26	0.37	0.23	0.10	0.12
Std. Dev. (1)	0.13	0.37	0.082	0.065	0.091	0.048	0.060	0.025	0.039
%CV (1)	51	37	7	31	35	13	26	25	31

Data Summary for DHS PE Set 95-1

	p,p'-DDE Spinach	Permethrin Spinach	Dicloran Carrots	p,p'-DDT Carrots	Trifluralin Carrots	Trifluralin Corn	Dimethoate Spinach	Chlorpyrifos Spinach	Acephate Spinach	Methiocarb Corn	Methomyl Corn
Target	0.059	0.164	0.059	0.059	0.091	0.091	0.202	0.304	0.452	0.543	0.416
Lab	(All Values are in ppm)										
1	0.040	0.200	0.060	0.060	*	*	0.160	0.210	0.350	0.750	0.350
2	0.042	0.208	0.038	*	*	*	0.263	0.590	0.590	0.521	0.385
3	0.049	*	0.058	0.057	0.069	0.064	0.191	0.268	0.392	0.518	0.352
4	0.050	0.130	0.050	0.040	*	*	0.170	0.290	0.420	*	0.430
5	0.050	0.150	0.050	0.040	0.100	0.090	0.220	0.270	0.350	0.470	0.370
6	0.052	0.120	0.054	*	0.120	0.110	*	0.360	*	0.540	0.350
7	0.057	*	0.050	*	0.084	0.078	*	0.360	*	*	0.268
8	0.058	0.280	0.056	*	0.110	0.110	0.200	0.200	*	0.051	*
9	0.060	0.120	0.050	0.070	0.060	0.100	0.190	0.230	0.350	0.510	0.400
10	0.060	0.034	*	*	0.079	0.073	0.640	0.220	0.370	0.480	0.350
11	0.069	0.145	0.065	0.060	0.092	0.088	0.250	0.290	0.520	0.520	0.430
12	0.070	*	0.080	*	0.110	0.100	0.280	0.280	0.580	*	0.430
13	0.070	0.500	*	0.070	0.030	0.020	0.220	0.220	0.260	0.520	0.400
14	0.071	0.060	0.063	0.057	0.085	0.081	0.170	0.310	0.550	0.590	*
15	0.072	0.290	*	*	0.075	0.040	0.225	0.155	0.287	0.536	0.263
16	0.080	0.080	0.150	0.080	*	*	0.230	0.280	0.480	0.310	0.380
17	0.094	0.210	0.073	0.070	0.074	0.084	0.190	0.290	0.450	0.480	0.370
18	0.260	0.430	*	0.100	0.066	0.048	0.330	0.260	0.310	*	0.290
19	*	*	*	*	0.120	0.100	0.230	0.290	0.430	0.580	0.500
20	*	*	0.064	*	*	0.066	0.210	0.260	0.160	0.310	*
Mean	0.072	0.197	0.064	0.064	0.085	0.078	0.243	0.282	0.403	0.480	0.372
Min	0.040	0.034	0.038	0.040	0.030	0.020	0.160	0.155	0.160	0.051	0.263
Max	0.260	0.500	0.150	0.100	0.120	0.110	0.640	0.590	0.590	0.750	0.500
Range	0.220	0.466	0.112	0.060	0.090	0.090	0.480	0.435	0.430	0.699	0.237
StdDev	0.049	0.132	0.026	0.017	0.025	0.026	0.108	0.088	0.118	0.153	0.061
% CV	67.3	66.7	40.5	26.8	29.0	32.8	44.4	31.3	29.2	31.8	16.4

DHS Proficiency Set #95-2

 = Outlier at 5% confidence level.

Incurred Target PPM	Cantaloupe					Tomato					Brussels Sprouts			
	Dicofol	Oxamyl	Methamidophos	Captan	Chlorothalonil	Mevinphos	Dicloran	Permethrin	Carbaryl	Oxamyl	Acephate	Endosulfan II	Methoxychlor	Methomyl
	0.650	0.750	Yes	Yes	Yes	0.150	0.450	0.850	0.950	0.750	0.890	0.750	0.900	0.650
1	*	*	0.410	0.740	0.040	0.240	0.680	0.780	1.530	*	0.420	*	0.640	1.150
2	*	0.310	0.260	0.190	0.136	0.124	0.140	*	0.650	0.270	0.395	*	0.346	0.486
3	2.980	0.650	0.430	0.660	*	0.190	0.360	0.690	0.880	0.650	0.620	1.470	0.810	0.950
4	1.610	0.590	0.241	2.240	0.114	0.189	0.410	0.785	0.837	0.639	0.419	0.612	*	0.810
5	1.200	0.130	0.225	0.430	0.075	0.136	0.460	0.890	0.820	0.630	1.000	0.720	0.930	0.570
6	0.930	0.810	0.240	1.650	0.130	0.160	0.500	1.140	1.200	0.900	0.890	0.650	1.130	0.700
7	0.880	0.760	0.200	0.360	0.079	0.130	0.490	0.990	1.030	0.750	1.000	0.710	1.070	0.450
8	0.870	0.630	0.160	0.750	0.120	0.210	0.510	1.000	1.230	0.750	0.520	0.720	0.780	0.580
9	0.820	*	0.180	1.291	0.086	0.101	0.534	0.989	1.147	*	0.750	0.943	1.052	0.608
10	0.724	*	0.333	0.367	0.097	0.137	0.445	1.020	1.100	*	2.330	1.000	1.790	*
11	0.690	0.740	0.360	0.280	0.150	0.210	0.400	0.750	1.100	0.760	1.580	0.700	0.710	0.670
12	0.616	0.537	0.170	*	0.173	0.107	0.376	0.830	0.786	0.477	0.391	0.651	1.163	0.508
13	0.480	0.580	0.070	0.740	0.120	0.160	0.460	0.720	1.300	0.670	0.430	0.600	0.520	0.360
14	0.426	0.505	0.215	0.137	0.088	0.229	0.189	0.707	0.812	0.546	0.456	0.550	0.684	0.395
15	0.260	0.640	0.040	0.330	0.060	0.140	0.290	0.540	1.030	0.670	0.840	0.500	0.390	0.510
16	0.171	0.547	*	1.250	*	0.227	0.377	1.240	0.921	0.518	*	0.713	0.826	0.476
17	0.150	0.640	0.270	0.900	0.090	*	0.400	1.010	1.030	0.740	0.630	0.610	0.730	0.570
18	0.150	0.690	0.230	2.000	0.170	0.130	0.480	1.010	1.860	0.710	0.690	0.570	0.610	0.490
19	0.139	0.723	0.281	0.294	0.208	0.210	0.396	1.138	*	0.345	0.940	0.964	*	0.909

* = Not Detected

Mean ppm (1)	0.770	0.593	0.240	0.812	0.114	0.168	0.416	0.902	1.070	0.627	0.795	0.746	0.834	0.622
Std. Dev. (1)	0.700	0.171	0.102	0.632	0.044	0.045	0.121	0.187	0.291	0.162	0.490	0.235	0.344	0.210
% CV (1)	91	29	43	78	39	27	29	21	27	26	62	32	41	34

(1) : Does not include "Not Detected" values.

Grand mean % C.V. including outliers = 41

Mean PPM (1)	0.809	0.578	0.240	0.812	0.114	0.168	0.416	0.902	1.024	0.627	0.704	0.755	0.774	0.622
Std. Dev. (1)	0.704	0.167	0.102	0.632	0.044	0.045	0.121	0.187	0.221	0.162	0.315	0.240	0.248	0.210
% CV (1)	87	29	43	78	39	27	29	21	22	26	45	32	32	34

(1) : Does not include "Not Detected" values.

Grand mean % C.V. excluding outliers = 39

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○ = Outlier at 5% confidence level.

Incurred Target PPM	Pear						Nectarine					Collard Green				
	Azinphos methyl	Parathion methyl	Ethion	Endosulfan	Lindane	Carbofuran	Diazinon	Chlorpyrifos ethyl	Iprodione	Aldicarb sulfone	Carbaryl	Dimethoate	Endosulfan sulfate	Lindane	Carbaryl	Dacthal Yes
1	2.574	0.143	*	0.249	*	0.108	0.134	○0.039	*	0.161	0.235	0.429	*	*	0.193	0.127
2	1.547	0.271	0.385	0.344	0.173	○0.125	0.396	0.106	*	0.159	0.254	0.297	0.307	0.304	0.175	0.135
3	1.490	0.320	0.272	0.310	0.070	○0.300	0.238	0.107	0.398	○0.390	0.410	0.230	0.270	0.060	○0.388	*
4	1.340	0.258	0.246	0.292	*	0.113	0.287	0.097	*	0.118	0.182	0.598	*	*	0.175	○0.965
5	1.100	0.130	0.170	0.242	0.119	0.088	0.200	0.075	0.503	0.109	0.214	○1.700	0.260	0.216	0.197	0.159
6	0.688	0.153	0.262	0.330	0.150	0.100	0.270	0.107	0.520	0.070	0.270	0.398	0.330	0.380	0.210	0.160
7	0.670	0.210	0.360	○0.620	0.250	0.150	0.520	○0.200	○1.260	*	0.460	0.410	0.420	0.480	0.260	0.240
8	0.590	0.140	0.200	0.270	0.140	*	0.290	0.090	0.520	*	0.270	0.380	0.480	0.360	0.240	0.180
9	0.530	0.140	0.250	0.440	0.100	0.090	0.470	0.090	*	0.200	0.420	0.340	0.300	0.190	0.350	0.130
10	0.515	0.156	0.246	0.267	0.160	0.172	0.316	0.078	0.330	*	0.253	0.301	0.340	0.382	0.217	0.145
11	0.476	0.136	0.198	0.377	0.147	0.112	0.244	0.074	0.457	0.104	0.240	0.327	0.240	0.196	0.225	0.154
12	0.461	0.131	0.199	0.290	0.142	0.150	0.247	0.076	0.420	0.170	0.220	0.264	0.250	0.280	0.210	0.130
13	0.450	0.140	0.200	0.300	0.120	0.160	0.150	0.090	0.440	0.180	0.290	0.660	0.400	0.290	0.250	0.200
14	0.410	0.170	0.230	0.330	0.140	0.120	0.260	0.100	0.640	0.110	0.240	0.420	0.340	0.320	0.250	0.160
15	0.390	0.170	0.240	0.300	0.130	0.110	0.240	0.100	0.350	0.150	0.270	0.340	0.250	0.300	0.240	0.110
16	0.370	0.210	0.270	0.200	0.070	*	0.290	0.100	0.410	*	0.200	0.540	*	0.180	0.170	*
17	0.233	0.085	0.131	0.190	0.050	0.127	0.207	0.099	0.126	*	0.210	0.272	0.136	0.110	0.172	0.138
18	0.192	0.126	0.160	0.241	0.124	0.073	0.245	0.070	0.137	0.212	0.194	0.302	0.189	0.313	0.139	0.134

* = Not Detected

Mean ppm (1)	0.779	0.172	0.236	0.311	0.130	0.131	0.278	0.094	0.465	0.164	0.268	0.456	0.301	0.273	0.226	0.204
Std. Dev. (1)	0.610	0.060	0.065	0.098	0.047	0.053	0.099	0.031	0.268	0.079	0.080	0.331	0.089	0.108	0.062	0.205
%CV (1)	78	35	28	32	36	40	36	33	58	48	30	73	30	40	28	101

(1) : Does not include "Not Detected" values.

Grand mean % C.V. including outliers = 45

Data recalculated for outliers

Mean PPM (1)	0.779	0.172	0.236	0.292	0.130	0.120	0.278	0.091	0.404	0.145	0.268	0.383	0.301	0.273	0.216	0.153
Std. Dev. (1)	0.610	0.060	0.065	0.062	0.047	0.028	0.099	0.013	0.145	0.043	0.080	0.120	0.089	0.108	0.049	0.033
% CV (1)	78	35	28	21	36	23	36	14	36	30	30	31	30	40	22	21

(1) : Does not include "Not Detected" values.

Grand mean % C.V. excluding outliers = 32

4.6.3 ELAP Enforcement Actions

ELAP will take enforcement actions for the following reasons pertaining to performance of laboratories.

- 1) A laboratory's single non-participation in a PE study for certified categories is evaluated as unacceptable performance and warrants a compliance order directing the laboratory to participate in the next PE study or to lose their certification.
- 2) With the exception of radiochemistry and pesticide residues, each laboratory must provide evidence of acceptable performance once per year in the category for which the laboratory is certified. Two successive unacceptable performances result in denial or removal of affected categories from the laboratory's certificate.
- 3) Enforcement actions are also taken when a laboratory cannot correct deficiencies found during the site visit. The categories affected by deficiencies are denied or removed from the certificate.

During 1996, ELAP issued 27 compliance orders, 59 denials or removals of categories, and 1 suspension of certification out of more than 800 laboratories certified. The results from PE studies, ELAP enforcement actions, and the reports from site visits could be used for assessing laboratory performance. This information is available through ELAP, and could be considered by government agencies for the purpose of evaluating and contracting laboratory services.

Findings

State and Federal laboratories tend to perform better on PE studies than commercial/industrial laboratories.

ELAP Performance Evaluation (PE) studies tend to measure the best performance of a laboratory at one point in time, as they typically are single blind studies.

ELAP certification cannot guarantee the quality of data that a laboratory generates on a daily basis.

4.7 Summary of ActLABs Performance on WP and WS Studies

4.7.1 Performance Evaluation Samples

Performance evaluation (PE) samples received by laboratories are typically one of three types. They may be *double blind* samples, in which case they arrive at the laboratory as unknowns in the same kinds of bottles as a laboratory's regular samples. They may be *single blinds already made up to volume* prior to receipt by the lab. They may be *single blind ampules*. The potential

exists for laboratories to treat each of these types of samples differently. When a laboratory receives a true double blind sample there is little likelihood that they will process it in a manner different from their regular samples because they do not know in advance that it is not a regular sample. For certain PE samples such as organics, it is sometimes difficult to effectively make a sample truly double blind because it will typically have compounds present which the laboratory does not normally see. This still allows room for false positives, false negatives, and inaccurate quantitation. The same thing may be true for PE samples for metals. However the laboratory will have run the sample before they have identified the possibility that a sample is a double blind so it may not be physically possible to treat it differently than other samples, other than a more careful review of the data.

In contrast, single blind samples are already identified by the laboratory upon receipt as a quality control (QC) sample. This automatically raises a flag with the laboratory, which they cannot help but notice. When a sample is already diluted, the laboratory can typically only process the sample once and even though they are already aware of the fact that it is a QC sample; the amount of rework possible on the sample is thus limited. Although consciousness is typically raised, it is not likely to make a big difference in processing.

When samples are received in ampules and identified as QC samples, they are often associated with certification for the laboratory, and everyone's awareness is raised. Similarly, the concentrations are often much higher than routine samples. In the case of the water supply/water pollution (WS/WP) PE samples, a laboratory's continued approval in many states rests on their performance on these samples. Given this importance and the fact that samples also arrive in concentrated ampules requiring dilution before analysis, there is ample opportunity for laboratories to not only pay closer attention to these samples in a variety of ways, but even pre-analyze them in concentrated form in order to get the best possible numbers. Although there are stories about this practice, there is no clear evidence that it is actually done with any frequency. Typically auditors ask to review PE data, including raw supporting data, and will question this type of action.

The Team is not aware of any cases, even in laboratories which have been investigated for fraud, where analysis of PE concentrates has been done to generate final results. There are always stories about laboratories putting their best analyst on the PE samples or dropping all other work while processing PE samples. Given the importance of PE samples, this is again feasible and believable. While this may be true of some laboratories, perhaps more typically these laboratories with limited work loads, the reality is that a commercial laboratory which is busy can't afford to ignore other clients for a PE sample and few have a best analyst for a given test. Certain states, such as New York, require an affidavit with each set of PEs stating that they were not treated any differently than routine samples. What is much more typical is that results from a single blind PE sample are reviewed much more carefully than results from regular samples, again because a lab's certification to do business is riding on this and because measured concentrations are not typical of most samples. In spite of this potential for treating single blind PE samples differently from routine samples, scores on US EPA PE samples are

seldom 100% and the average score within California is 89%. This indicates that for California laboratories overall, over 10% of the individual results on PE studies are in error, even when samples are known to be PEs. The results reported may represent the best a laboratory can do. Hence, a failure on a PE sample is quite serious and indicates that the laboratory may do poor quality work.

4.7.2 ActLABs and WP-WS Results

ActLABs (Association of California Testing Laboratories) consists of approximately 25 commercial laboratories located in California, which together account for over 50% of the environmental testing conducted in California by commercial laboratories. For the past several years, the association has evaluated the performance of all members on the ELAP required performance evaluation studies. This performance can be compared to California laboratories as a whole. Several things are notable about ActLABs members in these studies.

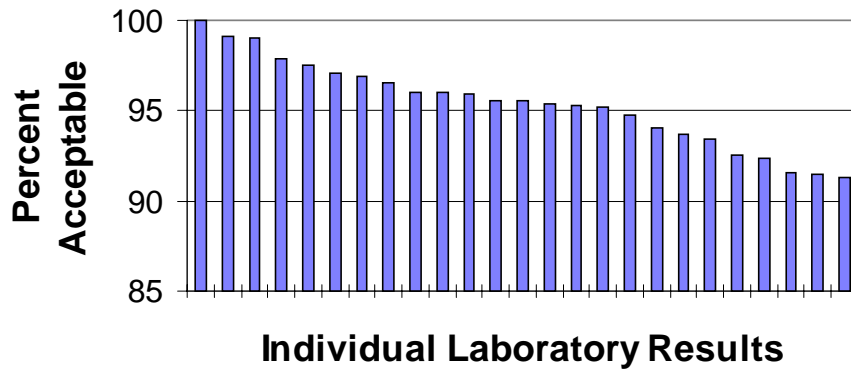
- ∇ For Water Pollution studies (WP), ActLABs= median performance is substantially higher than overall California certified laboratories. For WP 34 and 35, the median score was 97% and the range for all members was 93% to 99%. The median for all California laboratories for these same studies was 92%. Additionally ActLABs members attempted an extraordinarily large number of analytes (median of over 270 analytes between the two studies out of approximately 295 possible analytes compared to an average of 131 for all California laboratories).
- ∇ For Water Supply studies (WS), ActLABs= median performance is again substantially better than overall California performance. For WS036 and WS037, the median score was 93%, and the range for all members was 84% to 100%. The median for all California laboratories for these same studies was 89%. Although fewer analytes were attempted for drinking water than for wastewater (reflecting the predominance of hazardous waste oriented commercial labs), the median was over 150 analytes tested between the 2 studies out of approximately 235 possible analytes.
- ∇ When WS and WP studies are combined, the median score was over 95% (the combined study median score for all California laboratories was 91%) and the lowest ActLABs member score was 91%. The attached Figure 3 summarizes the performance of all ActLABs members without identifying individual laboratories. This should be compared to overall California certified laboratory performance and overall national performance.

Findings

ActLABs consists of a number of California certified laboratories which are committed to quality. These laboratories also do consistently well on PE samples. That over half of the ActLABs member laboratories were able to score above 95% on PE studies on an ongoing basis suggests that PE performance criteria can be used as a screen for contracting to

encourage continued high performance.

Figure 3: ActLABs Members' Overall Percent Acceptable Combined 1995 WS/WP Studies



4.8 Double Blind Performance Evaluation Studies

Introduction

Controversy regarding the performance of laboratories under routine conditions have been documented in various studies. Several commercial companies have developed double blind testing programs to help laboratory users evaluate the performance of contract laboratories. One of the earliest and most comprehensive studies of this sort was conducted by Shell Development Company (Stanko, 1991).

Description of Study

In this study, Shell arranged for contracts with 25 separate laboratories, that were asked to analyze unknown samples for volatiles by Gas Chromatography/Mass Spectrometry (GC/MS) (method 8240), including tentatively identified compounds (TICs), eleven metals by Inductively Coupled Plasma (ICP) (method 6010), and several conventional pollutants such as pH, Biochemical Oxygen Demand (BOD), Oil and Grease, Total Organic Carbon (TOC), and Chemical Oxygen Demand (COD). The study was designed to monitor performance of laboratories rather than to evaluate the quality of the selected methods. The laboratories were led to believe that the contracts were with an engineering company and each laboratory provided all appropriate sample bottles and shipping containers.

The samples were all prepared by a contractor to represent a range of readily detectable concentrations (9 volatiles at concentrations of 5-70 ppb and 11 metals at concentrations of 0.03 to 50 ppm) and several analytes were prepared as Youden pairs (samples with similar but measurably different concentrations to evaluate the ability of an analyst to distinguish them). The prepared samples were added to the bottles submitted by the laboratories.

Results

Performance of the laboratories was evaluated based on both accuracy and service issues. The results of this study indicate that analytical results should be reviewed carefully and not automatically assumed to be correct.

Turnaround times ranged from 15 to 58 days. However, many reports were not complete, even after this time. There was also no correlation between turnaround time for the laboratories and quality of data. Neither the fastest nor the slowest laboratories had the best data. Similarly the quality of sample bottles and coolers prepared by the laboratories varied considerably, adding significant uncertainties to data quality. Pricing varied by over a factor of two and because each laboratory priced items differently it was not possible to estimate average costs or to correlate cost with performance.

US EPA method criteria (which are relatively broad) were met for most laboratories for metals

and volatile organics, although there were some significant outliers for each analyte. For the general parameters, results were more varied than expected.

For volatile organics, average percent recoveries from all laboratories for 9 target analytes ranged from 59% (carbon tetrachloride below the acceptable range for this compound by GC/MS) to 105% (methylene chloride). Average recoveries for all target analytes for a single laboratory were more variable, ranging from 55% to 117%. Overall performance on volatiles was within expected method ranges for target analytes.

For metals mean recoveries from all laboratories (after removing outliers) ranged from 89% to 107% for the 11 spiked metals and average recoveries for a single laboratory ranged from 80% to 108% (again after excluding outliers).

For the general parameters, mean recoveries ranged from 59% to 104% for all laboratories whereas individual laboratory average recoveries ranged from 55% to 115%. pH measurements were most precise and accurate, with a range from 95% to 113% among all laboratories. In contrast, BOD recoveries ranged from 16% to 128% (excluding 5 outliers out of 25 laboratories).

Generally, precision within a single laboratory was good to excellent for all target analytes, but clearly accuracy was much more variable.

Of great interest to environmental studies was the ability of laboratories to identify tentatively identified compounds (TICs), which were non-target analytes spiked into the samples. Here the performance of laboratories (all experienced with GC/MS) was much more spotty. No single laboratory qualitatively identified all nine TICs. Most of the TICs were identified by less than 50% of the laboratories. The range of acceptable identification of TICs was from 0% to 84%.

Findings

This study was one of the first double blind evaluations of environmental laboratory performance and clearly demonstrates the limitations of unscrutinized environmental data.

The range of recoveries reported by laboratories for readily detectable levels of target analytes (especially for conventional parameters) points out the needs for better internal laboratory controls on accuracy and the utility of double blind studies (or samples) to discover (and fix) problems before they lead to bad decisions. Additionally, the poor results on TIC analysis called into question the use of TICs to evaluate site conditions because detection of TICs was inconsistent and apparently unreliable.

The state of the art has improved significantly since 1991, when this study was reported. However, this does not eliminate the value of such studies. Several subsequent double blind studies conducted by others have identified similar problems with data accuracy for metals in particular (Moore and Grimes, 1992). Such studies will disclose not only potential analytical problems, but also more serious ones such as laboratory fraud.

4.9 The National Environmental Laboratory Accreditation Conference

The National Environmental Laboratory Accreditation Conference (NELAC) is sponsored by US EPA to provide a forum to establish national uniform standards for accreditation of environmental laboratories and for accrediting authorities. Participation in NELAC is voluntary. The main participants have been Federal officials, State representatives, laboratory community, and other organizations concerned with environmental testing and related matters.

The NELAC has adopted various standards to achieve its goals. The standards include Constitution and Bylaws, Program Policy and Structure, Proficiency Testing Program, On-Site Assessment, Accreditation Process, Quality Systems, and Accrediting Authority. Standards are revised or supplemented at the NELAC annual meeting.

For an environmental testing laboratory to be accredited under the NELAC standards, the laboratory will need, at a minimum, to pass proficiency testing, pass an on-site assessment, and have an adequate quality system.

Under the NELAC standards, an accrediting authority such as the Environmental Laboratory Accreditation Program (ELAP) of the California Department of Health Services needs to document information such as; authority to grant laboratory accreditation; requirements for an environmental laboratory to become accredited; requirements for granting, maintaining, withdrawing, suspending or revoking laboratory accreditation; the laboratory accreditation process; fees charged to applicants and accredited laboratories; and listing of accredited laboratories describing accreditation granted.

Findings

The NELAC standards are designed to have environmental testing laboratories nationwide meet minimum requirements before they are accredited. The NELAC standards also sets minimum qualification for an accrediting authority in order for the accrediting authority to accredit testing laboratories.

4.10 Procurement Process - Low Bids

The current procurement process for most state contracts for laboratory services is predominantly a low bid process. Contracts are advertized, and although there are typically some pre-qualification criteria (such as availability of required equipment and proof of certifications) and sometimes ongoing performance specifications (such as criteria for duplicate analyses or recovery on unknowns), there is in general no attempt to require rigorous pre-qualification criteria such as minimum scores on state or US EPA performance evaluation samples or the delivery of a QAPP for evaluation prior to selection. Additionally, most contracts are not evaluated on a professional services basis with an evaluation of qualifications first followed by evaluation of cost (or selection without regard for cost followed by negotiation). By not treating

laboratory services as a professional service, the State encourages the view of laboratory services as a commodity. Thus by definition the procurement process becomes a low bid specification. This is demonstrated graphically by the example of a Sacramento laboratory, which held millions of dollars of state and federal contracts, all garnered by low bid.

Findings

The current procurement process for environmental laboratory services aims to secure low bids without adequate consideration of the professional quality of services.

5. RECOMMENDATIONS AND IMPLEMENTATION

The Team has made various recommendations and has estimated the cost of implementing the recommendations. An entity (such as a program or unit within a large organization) may need to implement only those recommendations it deems beneficial. The recommendations can be selectively implemented over time. The recommendations are listed below. The possible benefits and estimated cost of implementation are provided in Table A (page 43). The predicted positive impact is provided in Table B (page 46). The recommendations for small projects are provided in Table C (page 48). Technical terms used here are defined in the glossary (Appendix B, page 56.)

In Table A, the benefits of the recommendations are provided. The relative cost and relative effectiveness of the recommendations were estimated by a scale of from 1 (low) to 5 (high). The ratios of effectiveness to cost for the recommendations are also provided. A recommendation with a high ratio means it would be more cost effective compared to a recommendation with a lower ratio. Table B summarizes the possible impacts of the various recommendations on different items or issues. Table C has specific recommendations for small projects because it will not be cost-effective for small projects to implement all recommendations enumerated in Table A. A small project can be defined as a project that costs less than \$25,000 and can be completed within one year. Each Board, Office, or Department within Cal/EPA should establish a data quality policy which recognizes the needs of small projects and the limits of the quality control/quality assurance requirements for them.

The recommendations include the use of Quality Assurance Project Plans and Sampling and Analysis Plans. These documents specify the appropriate quality control protocols for the various projects depending on the data quality objectives and the intended use of the environmental data at issue. Documentation will enable efficient verification and audit of the project performance.

To ensure that adequate quality systems are in place, programs which use environmental data in all Boards, Offices, and Departments (BODs) within Cal/EPA should

establish Quality Management Plans (QMPs).

To ensure that adequate quality management is established, including implementation and enforcement, all BODs within Cal/EPA should

ensure that Quality Assurance Project Plans (QAPPs) and Sampling and Analysis Plans (SAPs), including appropriate quality control procedures, are prepared and implemented in accordance with current US EPA guidance and requirements;

provide the appropriate and necessary training for Cal/EPA staff for the preparation and

implementation of QAPPs and SAPs, including the use of the Data Quality Objectives (DQOs) process;
develop guidance and training for Responsible Parties on appropriate QAPPs and SAPs;

require that QAPPs and SAPs be reviewed at least annually and the review and any consequential changes be documented;

revise the QAPPs to require that magnetic data is maintained and made available to Cal/EPA Boards, Offices, and Departments;

specify in QAPPs the reporting requirements for non-target analytes, if any;

require a timely approved QAPP and SAP for every Cal/EPA project;

ensure that QAPPs and SAPs are implemented, verified, and made available to all affected parties;

ensure reasonable data quality objectives are developed before the QAPP and SAP are completed for each site investigation and suitable test methods are used, including non-EPA methods, when appropriate; and

specify in QAPPs required magnetic tape audits if major deficiencies are found by other quality assurance methods such as data validation or performance evaluation samples.

For sample collection and analysis, BODs should

establish policy requiring permittees, responsible parties, and other applicants to identify the samplers and laboratories they or their subcontractors use throughout the project;

establish consistent laboratory and field audit protocols;

use double blind samples in Cal/EPA programs, use double blind sample results to monitor data quality and laboratory performance, and establish a mechanism for sharing performance evaluation sample results among BODs; and

establish a frequency of laboratory and field audits and perform laboratory and field audits, use NELAC standards when approved for laboratory audits, and share written audit information among agencies without necessarily increasing the number of audits.

For Environmental Data Management, BODs should

use the US EPA National Functional Guidelines for data validation as outlined under the Contract Laboratory Program (CLP) as default;

adopt standardized content for hard copy deliverables;

specify the requirements for electronic data deliverables and electronic data validation;

require a minimum of 10% of data be validated by qualified personnel; and

require that data validation be completed by a party independent of the laboratory, its parent company, the permittee, and the prime contractor.

To maintain and update the standards of quality of the environmental data used for decision making, BODs should

adopt NELAC standards where feasible for Cal/EPA programs;

require Cal/EPA staff to use US EPA QA/QC documents (see Appendix D): a survey on the frequency of use of the documents listed in Appendix D should be conducted and some documents should be selected for use in environmental data collection and evaluation, and models for simple and complicated sites with examples of documentation requirements would be useful to State staff;

establish specifications for Quality Assurance Officer;

develop an alternative procurement system to the low bidder system for laboratory services;

encourage ELAP to continue to implement ISO and NELAC standards/guidelines wherever possible; and

require that State laboratories which support Cal/EPA programs, both within and outside Cal/EPA, be accredited by the National Environmental Laboratory Accreditation Program (NELAP), when accreditation is available.

Table A: Recommendations, Estimated Costs, and Benefits of Implementation
Scale 1 (low) to 5 (high)

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
1. Establish Quality Management Plan (QMP) for all BODs (Boards, Offices and Departments) within CAL/EPA which use environmental data.	0.25 py/program	Primarily Quality Manager time	2	Consistency in Quality Systems	5	2.5
2. Ensure QAPP and SAP, including appropriate quality control procedures, are prepared and implemented in accordance with the current US EPA guidance and requirements.	0.5 py/program	No change for some programs	1	Consistency in Quality Management	4	4
3. Provide appropriate and necessary training for CAL/EPA staff for the preparation and implementation of QAPPs and SAPs.	0.1 py/program	Staff Time	1	Informed in QAPP, DQO	4	4

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
4. Develop guidance and training for Responsible Parties on appropriate QAPPs and SAPs.	0.1 py/program	Primarily a one-time activity plus annual revision of guidance	1	Savings from more optimized plans	4	4
5. Require review of QAPPs and SAPs at least annually.	10-20 hrs/project	Project manager and Quality Assurance staff time	1	Improvement through changes based on updated information. Documentation of project requirements	4	4
6. Revise the QAPPs to require that magnetic data is maintained and made available to Cal/EPA Boards, Offices and Departments.	Negligible cost to require magnetic data	Requires access to lab data systems which can do magnetic audits and skilled technical personnel	1	Provide auditable records	3	3
7. Specify in QAPPs the reporting requirements for non-target analytes,	0.1 py	Staff Time	1	Deters the practice	3	3

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
if any.				of not reporting non-targets		
8. Require a timely-approved QAPP and SAP for every CAL/EPA project.	0 to 0.1 py/project	No Cost to programs which already require QAPPs and SAPs	2	Up-front protocols to achieve objectives. Savings from more optimized plans	5	2.5
9. Ensure QAPPs and SAPs are implemented and made available to all affected parties.	0 to 0.1 py/project	No cost for programs which already monitor QAPP implementation	2	Verify specified tasks are carried out. Savings by reducing invalid data	5	2.5
10. Ensure reasonable data quality objectives are	20 hrs/project	No cost for programs already requiring	2	Specify objective	5	2.5

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
included for each site investigation and ensure that suitable methods are used, including non-EPA methods, when appropriate.		reasonable DQOs		s. Optimized planning		
11. Specify in QAPPs to require magnetic tape audits if major deficiencies are found by other quality assurance methods, such as data validation or performance evaluation samples.	Cost for data audit:60 hrs/audit plus equipment costs	Staff time plus audit contracts	3	Deterrence of lab fraud; detection of fraud	5	1.7
12. Establish policy requiring permittees, responsible parties and other applicants to identify the samplers and laboratories they or their subcontractors use throughout the project.	Negligible	Identification of subcontractor(s) in agreements	1	More efficient fraud investigation	4	4
13. Establish consistent laboratory and field audit protocols.	0.1 py	Staff time	1	More efficient field audits	3	3

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
14. Use double blind samples in Cal/EPA programs.	\$1300 - \$2600 /project	Commercially available PT samples for semi-volatiles, volatiles, and metals; quality staff management	2	Detection of fraudulent and suspect data	5	2.5
15. Establish frequency of lab and field audits and perform lab and field audits. NELAC standards should be used when approved for laboratory audits. Written audit information should be shared among agencies without necessarily increasing the number of audits.	0.1 py/program	Staff time for lab audits and preparing audit reports. Quality manager time.	2	Detection and correction of poor lab practices. Earlier detection of fraud and suspect practices	4	2
16. Use the US EPA National Functional Guidelines for data validation as outlined under the Contract Laboratory Program (CLP) as default.	0 to 0.1 py	No cost for programs already using Functional Guidelines	1	More efficient data validation	4	4
17. Adopt standardized content	0.1 to	Conformance of	2	More	4	2

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
for hard copy deliverables.	0.2 py/program	standard deliverables by labs		efficient data validation		
18. Specify requirements for electronic data deliverables and electronic data validation.	0.2 py/program	Development net cost if formats and validation softwares developed by US EPA or DoE	3	Savings in data validation cost	5	1.7
19. Require a minimum of 10% of data be validated.	40 hrs/data package	Quality assurance staff time	3	Detection of fraud and poor data	4	1.3
20. Require data validation be completed by a party independent of the laboratory, its parent company, the permittee and the prime contractor.	Minimal	Cost borne by PRP or permittee; no cost to PRPs which already use independent validators.	2	Impartial evaluation of lab data	2	1
21. Adopt NELAC standards where feasible for Cal/EPA programs.	0.1 py	verification of data suppliers meeting NELAC standards	1	known quality standards recognized nationwide	4	4

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
22. Require Cal/EPA staff to use US EPA QA/QC documents (see Appendix D). A survey on the frequency of use of the documents listed in Appendix D should be conducted and some documents should be selected for use in environmental data collection and evaluation. Models for simple and complicated sites with examples of documentation requirements would be useful to State staff.	0.1 py/program	Staff time	1	Consistency in quality standard	3	3
23. Establish specifications for Quality Assurance Officer.	0.1-0.2 py	Some training may be required to meet specifications	2	Documented competence of quality assurance officer	4	2
24. Develop an alternative procurement system for	0.2 py	Cal/EPA staff time plus Dept. Of General	2	Eliminate marginal	4	2

Recommendations	Estimated Annual Cost (py = person-year)	Description of Costs	Estimated Relative Cost (over 5 years)	Description of Benefits	Estimated Relative Effectiveness	Estimated Effectiveness/Cost
laboratory services.		Services staff time		contract laboratories		
25. Recommend ELAP to conform to ISO and NELAC standards/guidelines whenever possible.	2 py (DHS)	Required anyway if DHS seeks National Laboratory Accreditation Program (NELAP) accreditation.	3	Calif. envir. labs recognized by other states through reciprocity	5	1.7
26. Require that state laboratories which support Cal/EPA programs, both within and outside Cal/EPA, be accredited by NELAP, when accreditation is available.	3 py/Lab	Staff time, PE program, addition in QA/QC, annual MDL	3	Meet national standard	4	1.3

Table B: Predicted Positive Impact of Recommendations

Recommendations	Fraud Prevention	Fraud Detection	Improvement in sampling	Improvement in lab analyses	Improvement in Data Assessment	Estimated Effectiveness/Cost (See Table A)
1. Establish Quality Management Plan (QMP) for all BODs (Boards, Offices and Departments) within CAL/EPA which use environmental data.	X	X	X	X	X	2.5
2. Ensure QAPP and SAP, including appropriate quality control procedures, are prepared and implemented in accordance with the current US EPA guidance and requirements.			X	X	X	4
3. Provide appropriate and necessary training for CAL/EPA staff for the preparation and implementation of QAPPs and SAPs.			X	X	X	4
4. Develop guidance and training for Responsible Parties on appropriate QAPPs and SAPs.			X	X	X	4
5. Require review of QAPPs and SAPs at least		X	X	X	X	4

Recommendations	Fraud Prevention	Fraud Detection	Improvement in sampling	Improvement in lab analysis	Improvement in Data Assessment	Estimated Effectiveness/Cost (See Table A)
annually.						
6. Revise the QAPPs to require that magnetic data is maintained and made available to Cal/EPA Boards, Offices and Departments.	X	X				3
7. Specify in QAPPs the reporting requirements for non-target analytes, if any.				X		3
8. Require a timely-approved QAPP and SAP for every CAL/EPA project.			X	X		2.5
9. Ensure QAPPs and SAPs are implemented and made available to all affected parties.		X	X	X		2.5
10. Ensure reasonable data quality objectives are included for each site investigation and ensure that suitable methods are used, including non-EPA methods, when appropriate.	X		X	X		2.5
11. Specify in QAPPs to require magnetic tape audits if major deficiencies are found by other quality assurance methods, such as	X	X				1.7

Recommendations	Fraud Prevention	Fraud Detection	Improvement in sampling	Improvement in lab analysis	Improvement in Data Assessment	Estimated Effectiveness/Cost (See Table A)
data validation or performance evaluation samples.						
12. Establish policy for requiring permittees, responsible parties and other applicants to identify the samplers and laboratories they or their subcontractors use through out the project.		X				4
13. Establish consistent laboratory and field audit protocols.	X	X			X	3
14. Use double blind samples in Cal/EPA programs.	X	X				2.5
15. Establish frequency of lab and field audits and perform lab and field audits. NELAC standards should be used when approved for laboratory audits. Written audit information should be shared among agencies without necessarily increasing the number of audits.	X	X	X	X	X	2

Recommendations	Fraud Prevention	Fraud Detection	Improvement in sampling	Improvement in lab analysis	Improvement in Data Assessment	Estimated Effectiveness/Cost (See Table A)
16. Use the US EPA National Functional Guidelines for data validation as outlined under the Contract Laboratory Program (CLP) as default.					X	4
17. Adopt standardized content for hard copy deliverables.					X	2
18. Specify requirements for electronic data deliverables and electronic data validation.					X	1.7
19. Require a minimum of 10% of data be validated.					X	1.3
20. Require data validation to be completed by a party independent of the laboratory, its parent company, the permittee and the prime contractor.					X	1
21. Adopt NELAC standards where feasible for Cal/EPA programs.				X	X	4
22. Require Cal/EPA staff to use US EPA QA/QC documents (see Appendix D). A survey on			X	X	X	3

Recommendations	Fraud Prevention	Fraud Detection	Improvement in sampling	Improvement in lab analysis	Improvement in Data Assessment	Estimated Effectiveness/Cost (See Table A)
the frequency of use of the documents listed in Appendix D should be conducted and some documents should be selected for use in environmental data collection. Models for simple and complicated sites with examples of documentation requirements would be useful to State staff.						
23. Establish specifications for Quality Assurance Officer.	X	X	X	X	X	2
24. Develop an alternative procurement system for laboratory services.	X			X		2
25. Recommend ELAP to conform to ISO and NELAC standards/guidelines whenever possible.				X		1.7
26. Require that state laboratories which support Cal/EPA programs, both within and outside Cal/EPA, be accredited by NELAP, when accreditation is available.				X		1.3

Table C: Recommendations for Small Projects

Recommendations	Recommendations for Small Projects (< \$25,000 and < 1 year)
1. Establish Quality Management Plan (QMP) for all BODs (Boards, Offices and Departments) within CAL/EPA which use environmental data.	None
2. Ensure QAPP and SAP, including appropriate quality control procedures, are prepared and implemented in accordance with the current US EPA guidance and requirements.	SAP only, when feasible
3. Provide appropriate and necessary training for CAL/EPA staff for the preparation and implementation for QAPPs and SAPs.	Training for SAP preparation only
4. Develop guidance and training for Responsible Parties on appropriate QAPPs and SAPs.	Training for writing SAPs, where appropriate
5. Require review of QAPPs and SAPs at least annually.	None
6. Revise the QAPPs to require that magnetic data is maintained and made available to CAL/EPA Boards, Offices and Departments.	None
7. Specify in QAPPs the reporting requirements for non-target analytes, if any	None
8. Require a timely-approved QAPP and SAP for every CAL/EPA project.	SAP, when feasible
9. Ensure QAPPs and SAPs are implemented and made available to all affected parties.	SAPs only
10. Ensure reasonable data quality objectives are included for each site investigation and suitable methods are used, including non-EPA methods, when appropriate.	DQOs should be established when non-standard procedures will be used.
11. Specify in QAPPs to require magnetic tape audits if major deficiencies are found by other quality assurance methods, such as data validation or performance evaluation samples.	None
12. Establish policy requiring permittees, responsible parties and other applicants to identify the samplers and laboratories they or their subcontractors are use throughout the project.	When appropriate
13. Establish consistent laboratory and field audit protocols.	None
14. Use double blind samples in CAL/EPA programs.	Single blind, at a minimum
15. Establish frequency of lab and field audits and	None

Recommendations	Recommendations for Small Projects ($< \$25,000$ and < 1 year)
perform lab and field audits. NELAC standards should be used when approved for laboratory audits. Written audit information should be shared among agencies without necessarily increasing the number of audits.	
16. Use the US EPA National Functional Guidelines for data validation as outlined under the Contract Laboratory Program (CLP) as default.	None
17. Adopt standardized content for hard copy deliverables.	Not applicable
18. Specify requirements for electronic data deliverables and electronic data validation.	Not applicable
19. Require a minimum of 10% of data be validated.	None
20. Require data validation be completed by a party independent of the laboratory, its parent company, the permittee and the prime contractor.	None
21. Adopt NELAC standards where feasible for CAL/EPA programs.	Same as large project
22. Require CAL/EPA staff to use US EPA QA/QC documents (see Appendix D). A survey on the frequency of use of the documents listed in Appendix D should be conducted and some documents should be selected for use in environmental data collection and evaluation. Models for simple and complicated sites with example of documentation requirements would be useful to State staff.	Same as large project
23. Establish specifications for Quality Assurance Officer.	Same as large project
24. Develop an alternative procurement system for laboratory services.	Same as large project
25. Recommend ELAP to conform to ISO and NELAC standards/guidelines whenever possible.	Same as large project
26. Require that state laboratories which support CAL/EPA programs, both within and outside CAL/EPA, be accredited by NELAP, when accreditation is available.	Same as large project

6. PERFORMANCE MEASURES

The performance measures for this project are a means of measuring the effectiveness of the recommendations implemented to improve the quality of environmental data which is used for decision making. By collecting data before and after the recommendations are implemented, the Team will be able to identify if there has been improvement, and if further refinement of the process is necessary to achieve the desired results.

The performance measures selected by the Team include:

- ∇ Monitor whether Cal/EPA and Department of Health Services (DHS) programs increase their use of data quality programmatic elements according to the Programmatic Elements of Data Quality (Table 1, page 65).
- ∇ Monitor results of Comprehensive (groundwater) Monitoring Evaluation (CME) or equivalent audits over time to assess the trends in numbers and types of violations.
- ∇ Compare Water Pollution (WP)/Water Supply (WS) overall performance of contract laboratories and sub-contracted laboratories performing studies for prime contractors to Cal/EPA to the overall performance of California laboratories and past laboratory performance for Cal/EPA. If performance of contract laboratories does not exceed the average for California laboratories, the Team should investigate the cause(s).
- ∇ Assess whether there is a significant change in the proportion of suspect or fraudulent data.
- ∇ Assess laboratory performance by using double or single blind performance evaluation samples.

Performance can be measured by looking at data quality in the future to see if improvement occurs.

7. FUTURE TEAM ACTIVITIES

Future Team activities are:

One year after the final report is completed, the Team will determine which recommendations have been implemented.

Two years after the final report is completed, the Team will evaluate the effectiveness of recommendations using performance measures.

8. REFERENCES

Contract labs charged with fraud in analyses of superfund samples, Chemical and Engineering News (C & EN), Feb 25, 1991, page 14.

Environmental Data Quality at DOD Superfund Sites in Region 9, E1SK5-09-0031-5100505 released on September 26, 1995.

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Moore, T. and Grimes. (1992). *A study to determine the performance of US EPA Approved Methods at Concentrations between the MDL and the PQL*. Presented at WEF Conference, New Orleans, LA.

National Environmental Laboratory Accreditation Conference (NELAC), Second Interim Meeting, February 3-6, 1997.

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Appendix A

TEAM CHARTER

TEAM NAME: Environmental Data Quality

MISSION: To improve the quality of environmental data which is used for decision-making.

GOALS: The goals are to improve the quality of field sampling and field measurements; to improve laboratory services; and to improve the ability to detect, investigate, and prosecute laboratory fraud.

BACKGROUND: The California Environmental Protection Agency (Cal/EPA) has the statutory duties to administer environmental laws in California. In performing the duties, Cal/EPA reviews environmental data in order to make informed decisions affecting the protection of the public health and the environment.

Where the environmental data play a critical role such as the determination of the cleanup level in a hazardous waste site, the decision can only be as sound as the quality of the available environmental data. If the quality of the environmental data is inadequate, the decision could be faulty. A faulty decision may result in wasting the scarce public funds and delaying the necessary environmental cleanups and could jeopardize the public health and the environment.

Field personnel carry out a wide variety of environmental sampling, that includes collection, handling, preservation, and transportation. Some samplers have little training, whereas others have extensive training. Proper sample collection and handling techniques should generate useable data specific to the intended application. The Department of Toxic Substances Control (DTSC) has observed samplers improve their skills following DTSC field oversight and coaching. The sampling community however, requires additional assistance (e.g., training, detailed sampling and analysis plans, etc.) to meet scientific data useability criteria.

The useability of data depends on the site-specific data quality objectives and intended applications needed for site characterization, risk assessment, evaluation of remedial alternative, monitoring, and remedial design. The specific use of the data needed for each of these application defines the level of data quality needed. The level of data quality is measured by the parameters of precision, accuracy, representativeness, completeness, and comprehensiveness which determine the sample collection and chemical identification/detection methods. Some applications, such as site screening, require less precision and accuracy, and may use lower quality data than required of other more rigorous applications, such as health risk assessments. The useability of data for each application depends on evaluation and satisfaction of the appropriate data quality indicators. Significant cost savings can be achieved by ensuring that data collected meets the objectives applicable to the intended use.

Environmental laboratories performing certain testing for regulatory purposes must be certified by the Environmental Laboratory Accreditation Program (ELAP) of the California Department of Health Services. The ELAP certification process should ensure that a laboratory is capable of following methods, but does not guarantee that the laboratory will continually produce quality data. There is still a great deal of variability in laboratory performance among certified laboratories. The problem is exacerbated by the general manner in which laboratories are selected by users. In many cases low bid rather than professional service or quality of service is used as the selection criteria. When coupled with the need for many cleanup or site investigation activities to be conducted over short time frames with many samples, these may lead to missed holding times and/or questionable QA/QC practices.

In addition, some certified environmental laboratories engaged in dubious and fraudulent practices in the analyses and reporting of sample testing results. In 1995, the most notorious case involved criminal indictment and conviction of laboratory personnel and a \$1.8 million fine on the corporate laboratory. About \$5.5 million worth of environmental data were rejected and site cleanups were delayed for 2.5 years.

Therefore, an urgent need exists to improve the quality of environmental data.

DURATION OF PROJECT: One year for the formation of the team and the presentation of recommendations. A follow up period of one to two years in order to assess implementation of the recommendations.

TEAM SPONSOR COMMITMENTS: The team sponsor will receive oral or written reports from the team leader monthly. The sponsor will regularly review the reports. The sponsor will periodically meet with team to discuss progress, and specific recommendations or proposals. The sponsor will provide responses to recommendations or proposals from the team within reasonable periods of times depending on the nature and complexity of the recommendations or proposals.

TEAM SPONSOR: Robert Stephens
Deputy Director

AUTHORITY OF THE TEAM: The team has the authority to: review the current environmental data and documentation requirements; identify possible areas for improvements; meet with other department staff or appropriate parties, including external "customers" or "stakeholders" to identify their needs in regard to the data generation process; make recommendations or proposals for improvement to the team sponsor for consideration and implementation; and conduct research and collect data as needed to complete the project.

DUTIES: The duties of the team members and the team leader include, but are not limited to, participation in team training; attendance and participation in team meetings at a frequency and durations, as appropriate; completion of assignments for the team; and observation of the ground

rules. The team leader and/or the whole team may present oral or written recommendations or proposals to the team sponsor or the management council.

TEAM MEMBERS: The team leader is Bart Simmons of the Hazardous Materials Laboratory (HML), Department of Toxic Substances Control (DTSC). Team members include Don Cox, Chein Kao, Fred Seto, and Judy Zarate of DTSC, William Ray of the State Water Resources Control Board (SWRCB), George Kulasingam and Shinae Park of the Environmental Laboratory Accreditation Program (ELAP) in the Department of Health Services, Terry Jackson of the Department of Food and Agriculture (CDFA), Steve Remaley of the United States Environmental Protection Agency (US EPA), Susan Knadle of the Office of Environmental Health Hazard Assessment (OEHHA), and Andrew Eaton of the Association of California Testing Laboratories (ActLABs), a private organization representing the major environmental testing laboratories in California. These members represent known parties who should be interested or should have a stake at the project. Where appropriate, the team will seek supporting members and technical experts available for assistance.

Appendix B

ABBREVIATIONS AND GLOSSARY

ActLABs	Association of California Testing Laboratories
ANSI/ASQC	American National Standards Institute/American Society for Quality Control
ASTM	American Society for Testing and Materials
BOD	Biochemical Oxygen Demand
BODS	Boards, Offices and Departments
Cal/EPA	California Environmental Protection Agency
CDFA	California Department of Food and Agriculture
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CLP	US EPA's Contract Laboratory Program
CME	Comprehensive (groundwater) Monitoring Evaluation
COD	Chemical Oxygen Demand
DDWEM	Division of Drinking Water and Environmental Management
DHS	Department of Health Services
DMP	Data Management Plan
DMRQA	Discharge Monitoring Requirement Quality Assurance
DOD	Department of Defense
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
DTSC	Department of Toxic Substances Control
ELAP	Environmental Laboratory Accreditation Program
FSP	Field Sampling Plan
GC/MS	Gas Chromatography/Mass Spectrometry
HML	Hazardous Materials Laboratory
ICP	Inductively Coupled Plasma
ISO	International Organization for Standardization
NCP	National Contingency Plan
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
O&M	Operation and Maintenance Inspection
OEHHA	Office of Environmental Health Hazard Assessment
OIG	Office of Inspector General
PEs	Performance Evaluation Sample
PRPs	Potentially Responsible Parties
QA/QC	Quality Assurance/Quality Control
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
RCRA	Resource Conservation and Recovery Act
RP	Responsible Party

RTC	Resource Technology Corporation
RWQCB	Regional Water Quality Control Board
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
SWRCB	State Water Resources Control Board
TIC	Tentatively Identified Compound
TOC	Total Organic Carbon
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration
WP	Water Pollution
WS	Water Supply

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 \cong criteria to determine whether it is within the criteria window. Where data do not meet the Acceptance \cong 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 validation include a review of documentation such as raw data, instrument printouts, chain of custody records, and instrument calibration logs. A 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.

Data Quality Assessment (DQA)

Data Quality Assessment (DQA) is the scientific and statistical evaluation of data to determine if the data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. DQA is built on a fundamental premise: data *quality*, as a concept is meaningful only when it relates to the *intended use* of the data. DQA involves five steps: 1) review the DQOs and sampling design, 2) conduct a preliminary data review, 3) select the statistical test, 4) verify the assumptions of the statistical test, and 5) draw conclusions from the data.

Data Management Plan

The Data Management Plan is a plan for how data will be stored and used, including the use of data qualifiers.

Double Blind Performance Evaluation (PE) Sample

Double Blind PE Sample is a full volume test sample submitted to a laboratory along with routine site samples such as that the laboratory is unaware of the composition of the 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 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.

Data Quality Objectives

Data Quality Objectives (DQOs) are qualitative and quantitative statements derived by establishing criteria for defensible decision-making before an environmental investigation begins that 1) clarify the study objective, 2) define the most appropriate type of data to collect, determine the most appropriate conditions from which to collect the data, and specify tolerable limits on decision errors which will be used as the basis for establishing the quantity and quality of data needed to support the decision. The Data Quality Objective process is a strategic planning approach based on the Scientific Method that is used to prepare for a data collection activity. It provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when to collect samples, where to collect samples, the tolerable level of decision errors for the study, and how many samples to collect. The objective of using the DQO process is to minimize expenditures related to data collection by eliminating unnecessary, duplicative, or overly precise data, and at the same time, collect data of sufficient quality and quantity to support defensible decision making.

A process comparable to providing DQOs would require that the project history and specific goals of this effort be described and suggest that all data users be involved in planning of sampling and analysis activities to insure that data gathering activities were subdivided according to the data quality that is required for different professional uses, and assert the need for QA/QC activities to insure that data accurately reflected environmental concentrations.

Electronic Data Deliverables

Electronic Data Deliverables is a summary of analytical and quality control results from sample analysis organized in a contract specified format and submitted in a electronic 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/Magnetic Data/Tape Audit

Electronic/Magnetic Data/Tape Audit is an auditor regeneration and processing of raw, unprocessed analytical data produced by an analytical laboratory during analysis of volatile and semi-volatile samples by GC, GC/MS, or other methods which have archival systems, and a review of a laboratory processed files for the purpose of identifying deviation from methods and contracts. A comparison of results obtained by the auditor for calibration 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 Validation

Electronic Data Validation is an 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 Sampling Plan

Field Sampling Plan is a written plan that documents the objectives, rationale, and procedures for collecting and analyzing environmental samples.

Gas Chromatography (GC) and Gas Chromatograph/Mass Spectrometry (GC/MS)

Gas Chromatography and Gas Chromatography/Mass Spectrometry refers to instrumental methods of analysis of volatile and semi-volatile organic contaminants by gas chromatography and gas chromatograph/mass spectrometry (e.g., US EPA methods 8010 and 8260).

Laboratory Audit

Laboratory Audit is a on site laboratory evaluation to determine the managerial and technical capability of the laboratory to perform analysis in conformance with the specification in contracts and approved analytical methods. Audits normally evaluate a laboratory=s technical expertise, operating procedures, facilities and equipment sufficiency, possible sources of sample contamination.

Laboratory Fraud

Laboratory fraud is a deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.

Peak-shaving

Peak-shaving means altering the area counts (arbitrarily drawing the baselines of peaks in order to increase or decrease the total area counts of the peaks) of certain analytical standards in order to meet the quality assurance/quality control criteria.

Percent Recovery

Percent Recovery is a 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)

Performance Evaluation Sample is 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.

Quality Assurance (QA)

Quality Assurance is an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Management Plan (QMP)

The quality Management Plan is a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted. (EPA QA/R-2, EPA QA/G-2)

Quality Assurance Project Plan (QAPP)

The Quality Assurance Project Plan (QAPP) is a critical product of the planning process of any environmental data operation in as much as it integrates all technical and quality aspects of the project, including *planning*, *implementation*, and *assessment*. The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QAPP and its effective implementation. Since the QAPP is the principal product of the planning process, it must include all the stakeholders (i.e. data users, data producers, decision makers, etc) to ensure that all needs are defined adequately and that the planning for quality addresses the specific needs defined. The QAPP documents how Quality Assurance (QA) and Quality Control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected. Quality Assurance is 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. Quality Control is 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. The content and level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data as described in the DQOs.

A document similar to a QAPP would contain the project history and specific goals of this effort, describe the intended data users and the quality of the data planned for each professional activity by the intended sampling and analysis activities, provide detailed instructions on sampling and analysis methods, calibration and operation of measurement equipment, and detail the activities and responsible individuals to insure and verify that data meet the quality level agreed to in DQOs.

Quality Control (QC)

Quality Control is the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

Sampling and Analysis Plan (SAP)

The Sampling and Analysis Plan is a detailed document describing procedures used to collect, handle and analyze samples for detection or assessment or monitoring parameters. The plan should detail all quality control measures which will be implemented to ensure sample collection, analysis and data presentation activities met the prescribed requirements.

Single Blind PE Sample

Single Blind PE Sample is 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 contained in ampules and submitted to the laboratory with directions for preparing a full volume sample for analysis.

Standard Operating Procedure (SOP)

A Standard Operating Procedure (SOP) documents routine or repetitive administrative and technical activities to facilitate consistency in the quality and integrity of the product. The development and use of SOPs for both technical and administrative functions is an integral part of a successful quality system. SOPs facilitate activities that would be managed under work plan or a Quality Assurance Project Plan. The development and use of an SOP promotes quality through consistency within the organization, even if there are personnel changes. SOPs are valuable for reconstructing project activities, reducing work effort, and improving data comparability, credibility, and defensibility. An SOP is

intended to be specific to the organization or site.

As an example, an SOP written for a standard analytical method would specify analytical procedures in greater detail than appear in the published method to ensure that the procedure is conducted in a standard, reliable, and reproducible fashion within the organization. As noted in ASTM D5172-91, AA significant part of the variability of results generated by different laboratories analyzing the same general reference is due to differences in the way the analytical test methods and procedures are actually performed in each laboratory. These differences are often caused by the slight changes or adjustments allowed by the general reference, but that can affect the final results.≡

Standard Reference Material

Standard Reference Material is a quality control Standard which are traceable to the National Institute of Standards and Technology (NIST) testing materials. NIST traceable materials are used for calibration and quality control of all US EPA approved testing protocols.

Statement of Work for Laboratories

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

Time Traveling

Time traveling means altering the time period between sample collection and analysis in order to meet the holding time requirements.

Appendix C

QUALITY SYSTEMS IN Cal/EPA AND RELEVANT DOCUMENTS

Quality Systems

To measure the baseline quality systems in Cal/EPA, the quality management in selected programs were compared with the benchmarks established by the U.S. Environmental Protection Agency (US EPA). As described later, US EPA has recently published a new set of requirements and guidance for quality systems in environmental programs. US EPA generally requires conformance with the relevant requirements as a condition of a grant or contract. Therefore, US EPA will be requiring the use of many of the elements when grants or contracts are renewed. In addition to the US EPA elements, the Team added AData Management Plans≅ and ATimed Routine Reports≅ because they are used in some Cal/EPA programs. The list of primary elements are listed below with the US EPA document numbers are in parentheses.

Quality Management Plan (R-2, G-2)

Quality Assurance Project Plan (R-5, G-5)

Data Quality Objectives (G-4)

Sampling and Analysis Plan

Data Management Plan (Not universally required by US EPA, but required by some programs)

Timed Routine Reports (Not required by US EPA, but used by some Cal/EPA programs)

Standard Operating Procedures (G-6)

The selected Cal/EPA programs were compared with the quality elements; the results are shown in Table 1.

Table 1: Programmatic Elements of Data Quality

Program	Quality Management Plan ^a	Quality Assurance Project Plan ^b	Data Quality Objectives ^c	Sampling and Analysis Plan ^d	Data Management Plan ^e	Timed Routine Reports ^f	Standard Operating Procedure ^g
SWRCB/RWQCB							
Federal 205(J)	0	0	2	2	1	2	1
NPDES Permits	0	0	0	0	0	4	0
Waste Discharge Permits	0	0	0	0	0	4	0
Discharge Monitoring Enforcement	0	1	0	1	0	1	2
Mussel Watch & Toxicity Studies	0	3	3	3	3	3	2
Dept. of Defense (DOD)	0	4	2	4	0	2	2
UST - Local Oversight Program (LOP) ^h	0	3 (Master QAPP)	0	0	0	0	0
Chapter 15 SWAT/TPCA/RCRA	0	1	0	0	1	0	0
CDFAⁱ-Laboratory Component							
Environmental Monitoring	0	0	0	1	0	3	2
Worker Health & Safety	0	0	0	2	0	3	3
Formulation Product Quality	0	0	0	0	0	3	0
Pesticide Residue	0	0	0	0	0	3	2
DPRⁱ-Project Management & Sampling							
Environmental Monitoring	0	1	0	3	0	1	2
Worker Health & Safety	0	1	0	3	0	2	3
DTSC							

Statewide Cleanup Program	0	3	2	1	3	3	1
Office of Military Facilities	0	3	2	3	1	3	1
Hazardous Waste Management Program	0	3	2	3	1	3	1
Technology Verification/Certification	4	2	2	2	0	1	2

(Table 1 continued)
Table 1: Programmatic Elements of Data Quality

Rate each data quality element with the following code:

0 - Not done 2 - Often done 4 - Legally (statute or regulation) required
1 - Seldom being done 3 - Always done

- a Quality Management Plan is a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted. (EPA QA/R-2, EPA QA/G-2)
- b Quality Assurance Project Plan is an orderly assemblage of detailed procedures designed to produce data of sufficient quality to meet the data quality objectives for a specific data collection activity. (EPA QA/R-5, EPA QA/G-5)
- c Data Quality Objectives is defined as qualitative & quantitative statements derived from the DQO process (7 steps) that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality & quantity of data needed to support decisions. (EPA QA/G-4)
- d Sampling and Analysis Plan is a detailed document describing procedures used to collect, handle and analyze samples for detection or assessment of monitoring parameters. The plan should detail all quality control measures which will be implemented to ensure sample collection, analysis and data presentation activities met the prescribed requirements.
- e Data Management Plan is a plan for how data will be stored and used, including the use of data qualifiers.
- f Timed routine reports - regular normal reports submitted as per contract requirement or regulation requirement.
- g Standard Operating Procedure is a detailed written description of how an organization executes a particular procedure or method intended to standardize its performance.
- h UST clean ups are over seen by Local agencies, and to a lesser extent, RWQCBs. Local Oversight Program (LOP) local agencies have QAPPs per

contracts with SWQCB. US EPA approved an "overall" QAPP for California's UST program in 1990. RWQCBs have their own QA officers and QAPPs. We do not review their QA programs. Similarly, non-LOP agencies are on their own, i.e., they don't report to SWRCB on these or other regulatory matters: Ch.6.7 of the Health & Safety Code(the main UST law) has made this largely a locally controlled program. For local contacts, please see attachments.

I Strict Adherence to US EPA R&G. Both CDFA laboratory sections and DPR project, sampling and data evaluation units do equivalents to most US EPA R&G documents. Many of the equivalents were instituted prior to US EPA documents.

Relevant US EPA and Cal/EPA Documents

US EPA and State documents provide guidance to State professional staff involved in overseeing or carrying out programs in which environmental media are sampled and analyzed to determine concentrations of hazardous substances. The breadth and number of topics addressed in individual guidance documents varies greatly. Some guidance documents broadly cover all aspects of topics such as site remediation (e.g., *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA*, US EPA, 1988) while others address very specific technical procedures (e.g., *Drilling, Coring, Sampling and Logging at Hazardous Substance Release Sites*, Cal/EPA, 1994).

The ultimate success of the entire environmental program depends on the quality of the environmental data collected and used in decision-making. Although some guidance documents provide overview and direction for the overall process and others provide guidance for specific technical operations, guidance on the establishment of a quality assurance (QA)/quality control (QC) program is necessary to not only establish procedures to produce environmental data of the quality desired, but to provide assurance that these procedures have been implemented. QA/QC measures may be broad in their application, such as the preparation of a Quality Assurance Project Plan (QAPP) which documents how environmental data operations are planned, implemented, and assessed during the whole life cycle of a project or task. In contrast, QA/QC measures may be technical and specific, such the specifications for the type of material and diameter from which well casings should be constructed. It should be noted that a broad QA/QC document, such as a QAPP, will contain, reference, or have attached any specific technical QA/QC measures that are used in the project.

Guidance documents that broadly cover all aspects of topics such as site remediation may be expected to describe the broadly applicable QA/QC measures that apply, whereas technical guidance may be intended to address only those measures specific to satisfactory performance of a technical procedure or a site-specific activity. State professional staff require information from both broad and specific guidance documents, but it is the broadly applicable guidance documents which describe the QA/QC procedures to set up for the specific technical activities.

US EPA has recently updated and expanded the number of documents which describe requirements and implementation of QA/QC measures. The recent documents in the US EPA Quality System Series are:

EPA QA/R-1, US EPA Quality Systems Requirements for Environmental Programs;

EPA QA/R-2, US EPA Requirements for Quality Management Plans;

EPA QA/G-4, Guidance for Data Quality Objectives Process;

EPA QA/R-5, US EPA Requirements for Quality Assurance Project Plans for

Environmental Data Operations;
EPA QA/G-6, Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents;

EPA QA/G-9, Guidance for the Data Quality Assessment Process.

These documents are part of a mandatory Agency-wide Quality system that requires all organizations performing work for US EPA to assure that

- ∇ environmental data collected are of the appropriate type and quality for their intended use, and
- ∇ environmental technology used for pollution control or waste remediation are designed, constructed, and operated according to defined specifications and protocols.

These documents generally replace existing US EPA requirements or guidance on QA/QC procedures which had been required or recommended for use by US EPA staff, its contractors, and cooperative agreement states or locales as shown in Table 2. For example, EPA QA/R-5 replaced QAMS-005/80. Appendix A, a Crosswalk Between EPA QA/R-5 and QAMS-005/80, indicates that only six of 25 topics to be discussed in a QAPP were added to EPA QA/R-5. These items were project narrative, special training requirements or certification, documentation and records, inspection/acceptance requirements for supplies and consumables, data acquisition requirements and data quality management.

Table 2: Comparison of Current and Previous Guidance Documents

Current Documents	Previous Documents
<p>EPA QA/R-1, US EPA Quality Systems Requirements for Environmental Programs</p> <p>US EPA Order 5360.1 Policy and Program Requirements to Implement the Quality Assurance Program</p>	<p>ANSI/ASQC E4-1994 American National Standard: Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.</p>
<p>EPA QA/R-2, US EPA Requirements for Quality Managements Plans, Draft Interim Final</p>	<p>US EPA Quality Manual for Environmental Programs, Chap. 4</p>
<p>EPA QA/G4, Guidance for the Data Quality Objectives Process</p>	<p>EPA 540/G87/003, Data Quality Objectives for Remedial Response Activities: Development Process; EPA 540/G87/004, Data Quality Objectives for Remedial Response Activities: Example Scenario</p>
<p>EPA QA/R-5, Requirements for Quality Assurance Project Plans for Environmental Data Operations; EPA QA/G-5, Guidance on Quality Assurance Project Plans</p>	<p>QAMS-005/80</p>
<p>EPA QA/G-6, Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents</p>	<p>ASTM D 5172-91 Standard Guide for Documenting the Standard Operating Procedures Used for Analysis of Water</p>
<p>EPA QA/G-9, Guidance for the Data Quality Assessment Process: Practical Methods for Data Analysis</p>	<p>EPA/540/G-90/008, Guidance for Data Useability in Risk Assessment, Interim Final, October, 1990; Guidance for Data Useability in Risk Assessment (Part A and B) Final, Publication 9285.7-09A and B; PB92-963356</p>

Documents which provide broad direction on site investigation, remediation, and health risk assessment also generally describe the importance of QA/QC elements. No specific guidance documents have been required to be used by State staff who are not working on a site under US EPA authority.

In order to gather some data on the extent and quality of QA/QC information available to State staff involved in sites where soil and ground water may be contaminated, an attempt was made to prepare a list of the guidance documents most frequently used. Gathering a list from even a small number of professional staff proved to be a formidable task, as it appears that each type of data user (project managers, geologists, toxicologists, etc.), in each division and/or region uses a number of different guidance documents. A list of 123 guidance documents and fact sheets was assembled and is included as Appendix D. A survey of these documents indicates that their scope varies from broad overviews to very specific technical topics.

In order to obtain a snapshot survey of the specificity and quality of information on the implementation of QA/QC items that were used by State staff directing environmental sampling and analysis, a subset of technical guidance documents that appeared relatively broad in scope were chosen for a more detailed review. The recently released US EPA guidance documents on QA/QC were not included. The QA/QC items which were evaluated for frequency of use by boards and departments in Cal/EPA (see Table 1, page 65) were used to evaluate the quality of QA/QC information provided by Cal/EPA documents for staff investigating and remediating hazardous substance release sites. These items include:

Quality Management Plan (QMP),

Data Quality Objectives (DQOs),

Quality Assurance Project Plan (QAPP),

Sampling and Analysis Plan (SAP) or Field Sampling Plan (FSP)

Data Management Plan (DMP),

Standard Operating Procedures (SOPs), and

Timed Reports.

Criteria were developed to compare descriptions of these QA/QC parameters in technical documents to determine how specific and instructive the information would be for State staff. The primary criterion selected to evaluate was the use of language and references which would increase the ability of professional staff with no previous training in QA/QC to distinguish a high quality QA/QC procedure from an inadequate one. A grading system of A, B, C, D, and F was used to score the quality of guidance on these specific QA/QC items in technical documents.

Please note that this scoring system does not refer to the overall quality of technical information provided, only the specific guidance on QA/QC procedures offered. The description of grade scores used in Table 3 is as follows:

A: Detailed description allows reader to distinguish procedures that will produce AA quality environmental data from AB, AC, AD or AF quality.

B: A general description with some detail for distinguishing Asatisfactory from Aunsatisfactory environmental data quality, and a reference to a more detailed guidance document.

C: A brief description or an outline which may or may not refer to a QA/QC procedure by name but which generally provides the reader with a small amount of ability to distinguish satisfactory QA/QC procedures and work products from unsatisfactory ones.

D: Sentences which can be interpreted as describing a QA/QC element, but which do not refer to it by name or provide criteria for determining satisfactory fulfillment of the need to have it.

F: No description or reference to the need for a QA/QC element.

The scoring was subjective, despite the criteria established, an attempt was made to apply the criteria consistently from document to document. The following examples will illustrate descriptions which provide insufficient information to identify satisfactory QA/QC procedures and work products.

AField procedures should be described in detail in the work plan or in an accompanying field sampling plan. This description does not convince the reader that an SOP should be developed to insure consistency from day to day, sampler to sampler, and location to location in sampling technique, that measurement equipment should be calibrated, that standards for field instruments are critical because instrument readings are indirect and concentration is compared to that in standards, etc. Other examples are, AThe suite of chemical analyses must be adequate to identify the full range of contaminants that may occur at the site. and AThe number of samples and suite of chemical analyses will depend on site characteristics, but must be sufficient to identify the nature of contaminant sources, to define the distribution of contaminants in the subsurface, and to provide data for risk assessment, remedy selection and remedial design.

Instructions on the use of DQOs at the start of the project in order for all data users to discuss their definitions of adequate and sufficient would earn a higher score than the quoted statements.

Table 3: Specificity of Description of QA/QC Items in Technical Guidance Documents

Document Name	Q M P	Q A P P	D Q O	FSP or SAP	D M P	Timed Routine Reports	S O P s	Comments
Code of Federal Regulations 40, Parts 300-399, July 1, 1990 (National Contingency Plan)	F	C	C	C	F	C	C	The NCP requires QA/QC measures such as a QAPP, SAP and FSP, but it uses ambiguous phrases such as, " the lead agency shall develop sampling and analysis plans that shall provide a process for obtaining data of <i>sufficient</i> quality and quantity to satisfy data needs, and "the QAPP describes policy, organization, and functional activities and the data quality objectives and measures necessary to achieved <i>adequate</i> data for use in planning and documenting the removal action."
"Guidance for Conducting RI/FS Studies Under CERCLA", October 1988, EPA/540/G-89/004	C+	A-	B+	C+	B	B+	A-	Appendix B discusses the QAPP in detail, the SAP, which contains the QAPP and FSP, more generally. Appendix B discusses the FSP in less detail, except for the portions on SOPs.
"Preliminary Endangerment Assessment," Cal/EPA, DTSC, January 1994	F	F	F	C	F	D	C	The PEA does not discuss a need for QA/QC, or QA/QC measures, except for a limited description of data quality assessment (p.2-14 - 2-16).
"Guidelines for Hydrogeologic Characterization of Hazardous Substance Release Sites, Vol. 1: Field Investigation Manual," Cal/EPA, Interim Final, September 1994	F	C+	C-	B-	F	D	B-	Section 1.3 Scope Guidance, states,"This document is a brief description of the Department's recommended approach to hydrogeologic site characterization and a summary of data requirements. References are provided to eight DTSC documents... this document should be used with Guidance for Conducting Remedial Investigations and Feasibility Under CERCLA (US EPA, 1988)
"Guidelines for Hydrogeologic Characterization of Hazardous Substances Release sites, Vol. 2: Project Management Manual, Cal/EPA, Interim Final, August 1994	F	B+	B+	A-	F	B	B+	References to US EPA documents with more detailed descriptions are provided through out the text. Distinctions between qualitative and quantitative procedures allow the reader to see distinctions in quality, methods are contrasted according to precision and accuracy, and Appendix A provides an example of a simple

Document Name	Q M P	Q A P P	D Q O	FSP or SAP	D M P	Timed Routine Reports	S O P s	Comments
Code of Federal Regulations 40, Parts 300-399, July 1, 1990 (National Contingency Plan)	F	C	C	C	F	C	C	The NCP requires QA/QC measures such as a QAPP, SAP and FSP, but it uses ambiguous phrases such as, " the lead agency shall develop sampling and analysis plans that shall provide a process for obtaining data of <i>sufficient</i> quality and quantity to satisfy data needs, and "the QAPP describes policy, organization, and functional activities and the data quality objectives and measures necessary to achieved <i>adequate</i> data for use in planning and documenting the removal action."
"Guidance for Conducting RI/FS Studies Under CERCLA", October 1988, EPA/540/G-89/004	C+	A-	B+	C+	B	B+	A-	Appendix B discusses the QAPP in detail, the SAP, which contains the QAPP and FSP, more generally. Appendix B discusses the FSP in less detail, except for the portions on SOPs.
"Preliminary Endangerment Assessment," Cal/EPA, DTSC, January 1994	F	F	F	C	F	D	C	The PEA does not discuss a need for QA/QC, or QA/QC measures, except for a limited description of data quality assessment (p.2-14 - 2-16). and complex site investigation.

Abbreviations: QMP = Quality Management Plan
Objectives

FSP = Field Sampling Plan

SAP = Sampling and Analysis Plan DMP = Data Management Plan

SOP = Standard Operating Procedure NCP = National Contingence Plan

QAPP = Quality Assurance Project Plan

DQO = Data Quality

Appendix D

US EPA AND Cal/EPA GUIDANCE DOCUMENTS

Regulations

Code of Federal Regulations, 40, Parts 300 to 399, Revised as of July 1, 1990. National Contingency Plan.

California Health and Safety Code, Division 20, Chapter 6.8, section 25300 et seq. (Hazardous Substance Account Act.)

California Health and Safety Code, Division 20, Chapter 6.85, section 25396 et seq. (California Expedited Remedial Action Reform Act of 1994).

California Public Resources Code, Division 13, Chapters 1 through 6, section 21000 et seq. (California Environmental Quality Act [CEQA]).

Title 22, California Code of Regulations, Chapter 40, Selection and Ranking Criteria for Hazardous Waste Sites Requiring Remedial Action, section 67400 et seq. (Emergency Regulations for the California Expedited Remedial Action Reform act of 1994).

US EPA Documents

A Rationale for the Assessment of Errors in the Sampling of Soils, May, 1990, EPA/600/4-90/013.

Batch-Type Procedures for Estimating Soil Adsorption of Chemicals, US EPA, 1992, 530/SW-87/006.

CERCLA Site Discharges to POTWS; CERCLA Site Sampling Program, 1990, 540/2-90/008.

Community Relations in Superfund: A Handbook, 1992, #PB92-963341.

Compendium of Superfund Field Operations Methods, US EPA, 1987, 540/P-87/001.

Ground Water Issue - Evaluation of Soil Venting Application, US EPA, 1992, 540/S-92/004.

Guidance for Conducting Remedial Investigations and Feasibility Studies--(RI/FS) Under CERCLA, #PB89-184626/CCE A09.

Guidance for Data Usability in Risk Assessment, Part A, Final, April, 1992, #PB92-963356.

Guidance for Data Usability in Risk Assessment, Part B, Final, May, 1992, #P92-963362.

Guidance on Expediting Remedial Design and Remedial Action, August 1990, #PB90-273871CDH, PC A04/MF A01.

Guidance on Oversight of Potentially Responsible Party Remedial Investigations and Feasibility Studies, Volume 1, June 1991, #PB91-28361CDH.

Guidance on Oversight of Potentially Responsible Party Remedial Investigations and Feasibility Studies, Volume 2, Appendices, June 1991, #PB91-228379CDH.

Guidance on Oversight of Potentially Responsible Party Performed RD/RA, February 1990, #PB90-249707CDH, PC A04/MF A01.

Guide for Conducting Treatability Studies Under CERCLA, US EPA, 1991, 540/2-91/019A.

Guide for Conducting Treatability Studies Under CERCLA, Interim Final, US EPA, 1989, 540/2-89/058.

Guidance on Remedial Actions for Contaminated Ground Water at Superfund Sites, #PB89-184618/CCE A06.

Guidance for Evaluating the Technical Impracticability of Ground Water Restoration, #PB93-963507.

Methods for Evaluating the Attainment of Cleanup Standards, Volume 1: Soils and Solid Media, #PB89-234959.

Methods for Evaluating the Attainment of Cleanup Standards, Volume 2: Ground Water, #PB94-138815.

Innovative Treatment Technologies, US EPA, 1991, 540/9-91/002.

Performance of Risk Assessments in Remedial Investigation/Feasibility studies (RI/FSs) Conducted by Potentially Responsible Parties (PRPs), August 1990, #PB91-139493CDH.

RCRA Ground-Water Monitoring Technical Enforcement Guidance Document, 1986, OSWER-9950.1.

Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Interim Final, #PB90-155581/CCE A13.

Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual, Part A. Interim Final, #P90-155599/CCE A04.

Soil Sampling Quality Assurance Users Guide (2nd Edition). Environmental Monitoring Systems Laboratory, 1989 EPA 600/9/89/046.

Soil Screening Guidance: Technical Background, May 1996, #PB96-963502, EPA 540/R-95-1128.

Soil Screening Guidance: User's Guide, July 1996, Publication 9355.4-23.

Statistical Methods for Evaluating the Attainment of Cleanup Standards, Volume 3: Reference-Based Standards for Soils and Solid Media, EPA 230/R/94/004.

Test Methods for Evaluating Solid Waste Volumes 1A, 1B, 1C (Laboratory Manuals), and II (Field Manual), US EPA 1986, SW-846.

US EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review, February, 1994, EPA-540/R-94-012(PB94-963501).

US EPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review, February, 1994, EPA-540/R-94-013 (PB94-963502).

US EPA QA/QC Guidance Documents

Data Quality Objectives for Remedial Response Activities, Development Process, March 1987, EPA 540/G-87/003.

Data Quality Objectives for Remedial Response Activities, Exposure Scenario, March 1987, EPA 540/G-87/004.

Data Quality, Objectives Process for Superfund, Interim Final, September 1993.

Decision Error Feasibility Trials (DEFT) Version 4.0 (Software for the Data Quality Objectives Process for Superfund), EPA QA/G4D.

Guidance for DATAQUEST - The Data Quality Assessment - Process Software. EPA 0QA/G-9D.

Guidance for Data Quality Assessment: Practical Methods for Data Analysis, EPA QA/G-9, EPA/600/R-96/084.

Guidance for Data Quality Assurance Project Plans (draft), EPA QA/G-5.

Guidance for the Data Quality Objective Process, EPA QA/G-4, Final, September 1994.

Guidance for Preparing Quality Management Plans for Environmental Programs, EPA QA/G-2.

Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents, EPA QA/G-6.

Guidance for Reviewing Quality Assurance Project Plans, US EPA, 1992.

Quality Manual for Environmental Programs, August, 1994, QAMS-004/80, or US EPA Requirements for Quality Management Plans, Interim Final, Spring, 1997, EPA QA/R-2.

Quality Assurance/Quality Control Guidance for Removal Activities: Sampling QA/QC Plan and Data Validation Procedures, US EPA 1990, #PB90-274481/CCE A04, 540/G-90/004.

Quality Assurance Program Plan for Region 9, Quality Assurance Policies, Procedures, and Management Systems, US EPA Region 9, 1988, DCN 9QA-01-89.

QA/QC Requirements for Reviewing the Data Generated by RPs, US EPA, 1986.

Requirements for Quality Management Plans, EPA QA/R-2.

Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5.

Department of Toxic Substances (DTSC) Guidance

CalTOX: A Multimedia Total Exposure Model for Hazardous Waste sites (Technical Reports) Final Draft, 1993, Office of Scientific Affairs, DTSC.

CEQA, California Environmental Quality Act, Statutes and Guidelines, 1992, Stock #7540-931-1022-0, Governor's Office of Planning and Research.

Hazardous Materials Laboratory (HML) Users Manual, October 31, 1991.

Preliminary Endangerment Assessment Guidance Manual, January, 1994, Stock 7540-958-1022-1, DTSC.

Managing Voluntary Site Mitigation Projects Policy (The Voluntary Cleanup Program), September, 1995, EO-95-006-PP, DTSC .

Public Participation Policy Manual, July 1994, #EO-94-002-PP, DTSC.

Oversight and Supervision of Investigations and Removal and Remedial Actions at Hazardous Substance Sites Policy, August 1992, #SM 92-1, DTSC.

Treatment Technologies Applications Matrix for Base Closure Activities, November 1994, California Base Closure Environmental Committee.

Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities, July 1992, Office of Scientific Affairs, DTSC.

Guidance for Ecological Risk Assessment at Hazardous Waste Sites, and Permitted Facilities, Part A Overview, Draft July 1996, Office of Scientific Affairs, DTSC.

Guidance for Ecological Risk Assessment at Hazardous Waste Sites, and Permitted Facilities, Part A: Scoping, Draft July 1996, Office of Scientific Affairs, DTSC.

Remedial Action Plan (RAP) Policy, December 1995, #EO-95-007-PP, DTSC.

Removal Action Workplans - Senate Bill 1706 Memorandum. March 1995, Statewide Cleanup Operations, DTSC.

Technical Standards for Selecting Soil Sampling Designs for Hazardous Waste Sites (Unpublished Draft Standards, Chapter 15), 1990, DTSC.

Waste Classification Regulation Guidance Manual, 1994, DTSC.

Workbook for Conducting Initial Studies Under the California Environmental Quality Act (CEQA), May 1994, DTSC.

Appendices to Workbook for Conducting Initial Studies Under the California Environmental Quality Act (CEQA), May 1994, DTSC.

Cal/EPA Documents

Application of Surface Geophysics at Hazardous Substance Release Sites: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August 1994.

Application of Borehole Geophysics at Hazardous Substance Release Sites: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Aquifer Testing for Hydrogeologic Characterization: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Drilling, Coring, Sampling and Logging at Hazardous Substance Release Sites: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Ground Water Modeling for Hydrogeologic Characterization: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Guidelines for Hydrogeologic Characterization of Hazardous Substance Release Sites. Volume 1: Field Investigation Manual, Interim Final, Cal/EPA, September, 1994.

Guidelines for Hydrogeologic Characterization of Hazardous Substance Release Sites. Volume 2: Project Management Manual, Interim Final, Cal/EPA, August, 1994.

Guidance for Preparation of Transportation Plans for Hazardous Substance Release Sites, July 1995, Cal/EPA, Stock #7540-958-1030-0.

Monitoring Well Design and Construction for Hydrogeologic Characterization: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Representative Sampling of Ground Water for Hazardous Substances: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

Reporting Hydrogeologic Characterization Data at Hazardous Substance Release Sites: Guidance Manual for Ground Water Investigations, Interim Final, Cal/EPA, August, 1994.

US EPA Fact Sheets

A Guide to Selecting Superfund Remedial Actions, #9355.027FS PB90-273863/CCE A02.

A Guide: Methods for Evaluating the Attainment of Cleanup Standards for Soils and Solid Media, #9355.4-04FS PB91-921365/CCE A02.

Compendium of ERT Soil Sampling and Surface Geophysics Procedures, #PB91-921273/CCE A03.

Compendium of ERT Surface Water and Sediment Sampling Procedures, #PB91-921274/CCE A03.

Compendium of ERT Waste Sampling Procedures, #PB91-921276/CCE A04.

Data Review Report Format, US EPA Region 9, 1989, DCN 9QA-09-89.

Expedited Response Actions, #PB93-963410CDH A02.

Getting Ready: Scoping the RI/FS, #9353.3-O1FS1 PB890274390/CCE A02.

Guidance on Conducting Non-Time-Critical Removal Actions Under CERCLA, #PB93-963402.

Guide on Remedial Actions for Contaminated Ground Water, #9283.1-2FS PB90-272576/CCE A02.

Guide to Discharging CERCLA Aqueous Wastes to POTWS, US EPA 1991, 9330.2-13FS.

Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States Compliance; Final Rule: Federal Register, December 22, 1992, Part 2. 40 CFR Part 131.

Laboratory Documentation Requirements for Data Validation, US EPA Region 9, 1990, DCN 9QA-07-90.

Memorandum: Analysis of Treatability Data for Soil and Debris. US EPA, 1989, 9380.3-04.

The Remedial Investigation: Site Characterization and Treatability Studies, #9355.3-O1FS2 PB90-274408/CCE A02.

The Feasibility Study: Development and Screening of Remedial Action Alternatives, #9355.3-O1FS3 PB90-274416/CCE A02.

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