Office of Inspector General

Report of Audit

Laboratory Data Quality at Federal Facility Superfund Sites

E1SKB6-09-0041-7100132
March 20, 1997

Tooele Army Depot

Inspector General Division Conducting the Audit:	Western Audit Division Sacramento Branch Office
Regions Covered:	Regions 8, 9, and 10
Program Offices Involved:	Office of Solid Waste and Emergency Response Office of Research and Development Office of Enforcement and Compliance Assurance
Cover Photograph:	Tooele Army Depot, Tooele, Utah Photograph by Dan Cox, EPA OIG

MAR 20 1997

MEMORANDUM

SUBJECT: Laboratory Data Quality at Federal Facility Superfund Sites
Audit Report No. E1SKB6-09-0041-7100132

FROM: Michael Simmons
Deputy Assistant Inspector General
for Internal Audits

TO: Timothy Fields, Jr.
Acting Assistant Administrator
for Solid Waste and Emergency Response

Robert J. Huggett
Assistant Administrator
for Research and Development

Steven A. Herman
Assistant Administrator
for Enforcement and Compliance Assurance

Attached is our audit report titled Laboratory Data Quality Oversight at Federal Facility Superfund Sites. The purpose of this audit was to determine whether EPA had sufficient procedures in place to ensure laboratory data was of known and acceptable quality under Federal facility agreements. We performed this audit due to the serious problems with laboratory data quality found in our previous audit of Department of Defense (DOD) Superfund sites in Region 9.

The report identifies corrective actions the Office of Inspector General (OIG) recommends involving data quality at federal facility Superfund sites. As such, it represents the opinion of the OIG. Final determinations on the matters in the report will be made by EPA managers in accordance with established EPA audit resolution procedures. Accordingly, the findings described in this report do not necessarily represent the final EPA position and are not binding upon EPA in any enforcement proceeding brought by EPA or the Department of Justice.

Since the recommendations are addressed to three assistant administrators, we are designating the Acting Assistant Administrator for Solid Waste and Emergency Response as the

primary action official. As such, the primary action official should take the lead in coordinating the Agency's official response to this report so that the 90-day time frame for response is met. Thus the Assistant Administrator for Research and Development and the Assistant Administrator for Enforcement and Compliance Assurance are secondary action officials and should coordinate with the primary action official.

EPA Order 2750 requires the primary action official to provide our office with a written response to the audit report within 90 days of the report date. The response should address all recommendations. For corrective actions planned but not completed by the response date, reference to the specific milestone dates will assist us in deciding whether to close this report. We have no objection to the release of this report to the public.

We appreciate the cooperation from your staff during this review. Should you or your staff have any questions about this report, please contact Truman Beeler, Western Divisional Inspector General for Audit, at (415) 744-2445, or Katherine Thompson of our Sacramento office at (916) 498-6535.

Attachment

Distribution: Appendix I

EXECUTIVE SUMMARY

PURPOSE

The purpose of the audit was to determine if EPA had sufficient procedures in place to ensure that laboratory data was of known and acceptable quality under Federal facility agreements.

FINDING

Our audit of nine Federal facility Superfund sites in EPA Regions 8, 9, and 10 showed that EPA and Federal facilities did not have sufficient procedures in place to ensure that data was of known and acceptable quality. Specifically, we found that:

- Quality assurance project plans, the primary means for controlling laboratory quality, were not well designed to prevent and detect inappropriate data;
- Oversight of laboratory data quality needed to be increased;
- EPA had not assessed the adequacy of other Federal agencies' quality systems for environmental data; and,
- There was no Federal system to share laboratory evaluations between agencies.

We believe one primary reason for these weaknesses was that EPA's oversight role at Federal facility Superfund sites was unclear. In our opinion, effective quality assurance systems could have helped avoid $11 million spent on rejected analyses, resampling, and associated costs and cleanup delays of up to 2½ years at the nine sites we audited.

Because of the problems with EPA oversight and Federal quality assurance systems, it is our opinion that laboratory analyses conducted to date at the Department of Defense (DOD) and the Department of Energy (DOE) sites cannot be presumed to be of appropriate quality for cleanup decision making. This should be a national concern since DOD and DOE have over 90 percent of the 160 Federal facility Superfund sites on or pending inclusion on the National Priorities List.

Prior EPA Actions

We noted that EPA, the Department of Defense, and the Department of Energy had developed model Federal facility agreements in 1988. These agreements required Federal facilities to prepare quality assurance project plans. Also, these plans were required to be primary documents subject to EPA review.

RECOMMENDATIONS

Our recommendations to improve laboratory data quality at Federal facilities include:

- Revising the guidance for quality assurance project plans to require the inclusion of the more effective quality assurance activities;
- Issuing guidance specifying regional oversight responsibilities;
- Assessing other Federal agencies' environmental data quality systems; and,
- Requesting that Executive Order 12580 be modified to expressly identify EPA's oversight role for environmental data quality.

The Agency program offices generally agreed with the findings and recommendations, and advised that the Office of Enforcement and Compliance Assurance and the Office of Solid Waste and Emergency Response, *" ...working with the regions and other federal departments and agencies, will undertake a program to improve the quality of the RI/FS work the federal departments and agencies conduct...At this time, OECA and OSWER view the best approach to improving the data quality supporting federal facility response actions is the cooperative, yet aggressive, approach..."*

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Laboratory Data Quality at Federal Facility Superfund Sites

PURPOSE

The purpose of the audit was to determine if EPA had sufficient procedures in place to ensure that laboratory data was of known and acceptable quality under Federal facility agreements. The national audit was triggered as a result of serious problems found in our 1995 audit of environmental data quality at DOD Superfund sites in Region 9.

RESULTS IN BRIEF

Our audit of nine Federal facility Superfund sites in three EPA regions showed that EPA and Federal facilities did not have sufficient procedures in place to ensure that data was of known and acceptable quality. Specifically, we found that:

> *"It shall be the policy of all EPA organizational units to ensure that...environmentally related measurements are of known quality."*
>
> ***-EPA Order 5360.1***

- Quality assurance project plans, the primary means for controlling laboratory quality, were not well designed to prevent and detect inappropriate quality data;
- EPA did not have controls to ensure these plans were in place and operating;
- EPA had not assessed the adequacy of other Federal agencies' quality systems for environmental data; and,
- There was no Federal system to share laboratory evaluations between agencies.

We believe one primary reason for these weaknesses was that EPA's oversight role at Federal facility Superfund cleanups was unclear. In our opinion, effective quality assurance systems could have helped avoid $11 million spent on rejected analyses, resampling, and associated costs and cleanup delays of up to 2½ years at the nine sites included in our audit.

Because of the problems with EPA oversight and Federal quality assurance systems, it is our opinion that laboratory analyses conducted to date at the Department of Defense (DOD) and the

Department of Energy (DOE) sites cannot be presumed to be of appropriate quality for cleanup decision making. This should be a national concern since DOD and DOE have over 90 percent of the 160 Federal facility Superfund sites on or pending inclusion on the National Priorities List.

We recommend that EPA strengthen oversight of data quality at Federal facility Superfund sites. Our specific recommendations to correct data quality problems start on page 26. The Agency generally agreed with these recommendations, as discussed starting on page 28. The Agency's complete response is presented in Appendix A.

Prior EPA Actions

We noted that EPA, DOD, and DOE had developed model Federal facility agreements in 1988. These agreements required Federal facilities to prepare quality assurance project plans; also, these plans were required to be primary documents subject to EPA review.

BACKGROUND

Federal facilities are a significant part of EPA's Superfund workload. In 1995, Federal facilities had 160 sites on or pending inclusion on EPA's Superfund National Priorities List, a register of the nation's worst contaminated hazardous waste sites. DOD and DOE had over 90 percent of these sites, including military bases, manufacturing plants, and laboratory facilities. (Acronyms are explained in Appendix B.)

Federal facilities comprise nearly 60 percent of EPA's Superfund workload under remedial investigation or feasibility study phases. These are the cleanup phases when most environmental data is collected. Environmental data is collected by sampling contaminated water, soil, air, and other materials, and having the samples analyzed by a laboratory.

EPA Regions 8, 9, and 10 oversee about 40 percent of the Federal facility Superfund sites including:

- Hanford Nuclear Reservation, one of DOE's (and the nation's) two largest Superfund cleanups; and
- Rocky Mountain Arsenal, one of DOD's two largest cleanups.

Cleanup Rules

CERCLA, Executive Order 12580, and Federal facility agreements set rules for Superfund cleanups at Federal facilities. Under

CERCLA (the Comprehensive Environmental Response, Compensation, and Liability Act), Federal agencies are required to carry out their hazardous waste cleanups according to the same guidelines as other facilities. Executive Order 12580 further delegates certain Superfund cleanup authorities to DOD and DOE.

Federal facility agreements are site-specific agreements that govern cleanups. These agreements set requirements and enforceable schedules for completing studies, reports, and cleanup decisions. Once a site is placed on the Superfund National Priorities List, EPA, the Federal facility, and the state typically negotiate a Federal facility agreement. EPA is responsible for overseeing these agreements and has final decision-making authority for selecting the cleanup remedy. (The Federal facility Superfund cleanup process is described in Appendix C of this report.)

Data of Known Quality

In order to oversee Federal facility cleanups, EPA should ensure that environmental data supporting decisions is of appropriate quality. EPA Order 5360.1 requires environmental data to be of known quality and defensible. The quality of this data may be adversely impacted by weaknesses in sampling, laboratory analysis, and the validation of results. Poor quality data can negatively impact or delay the decision making process. Further, incorrect decisions can lead to inadequate health protection or expenditures for unneeded cleanup remedies.

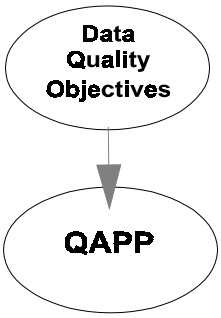
> *"The primary goal of the QA program is to ensure that all environmentally related measurements...[laboratory analysis] produce data of known quality. The quality of data is known when all components...are thoroughly documented, such documentation being verifiable and defensible."*
>
> ***-EPA Order 5360.1***

Steps for Laboratory Analysis Quality

There are two major steps to plan for appropriate quality laboratory analyses at a site.

First, data quality objectives (DQOs) must be determined. Such objectives define how data will be used, and establish corresponding quality objectives before data is collected, thereby resulting in a defensible decision-making process.

Second, a quality assurance project plan (QAPP) must be developed according to 40 CFR 300.430. The quality assurance activities necessary to achieve the DQOs are incorporated into a QAPP. This plan is a blueprint for ensuring the laboratory analyses produce data of appropriate quality and quantity for decision-making.



EPA Oversight

EPA regions oversee Federal facility Superfund cleanups. Three EPA headquarters offices provide guidance that impact this oversight role: the Federal Facilities Restoration and Reuse Office; the Federal Facilities Enforcement Office; and the Quality Assurance Division.

Federal Facilities Restoration and Reuse Office

This office, under the Office of Solid Waste and Emergency Response (OSWER), develops guidance and policy for Superfund cleanups at Federal sites; it also supports the development of related policies by other agencies.

EPA's Federal Facilities Restoration and Reuse Office

The mission of the Federal Facilities Restoration and Reuse Office is to assist the Federal government to promote effective and timely clean up and reuse of Federal facilities.

Federal Facilities Enforcement Office

This office is part of the Office of Enforcement and Compliance Assurance, and is responsible for developing national Federal facility enforcement and compliance policy and managing the resolution of enforcement disputes.

Quality Assurance Division

This division, part of the Office of Research and Development, is responsible for directing and overseeing implementation of Agency-wide policy for quality assurance applicable to all environmental data collection activities.

SERIOUS PROBLEMS WITH LABORATORY DATA QUALITY

Federal facilities have experienced serious problems with the quality of laboratory analyses used to make cleanup decisions. There is evidence these problems are widespread. To illustrate:

- Extensive laboratory fraud was found at one laboratory, which was used by 28 DOD installations in three EPA regions, resulting in about $5 million dollars of lost data, resampling costs, and associated expenses.

- EPA suspended another laboratory for improper analyses. This laboratory did work at five DOD sites in two EPA regions. One of these sites was Hunters Point Naval Shipyard, where $2.5 million of data from this laboratory and another laboratory was deemed unusable and the cleanup was delayed 2 years.

> *"As we protect public health and the environment, we need to be confident that the laboratory results we rely on are accurate."*
>
> ***-Director, Superfund Programs***
> ***EPA Region 9***

- DOE had problems with laboratory analyses at its Hanford and Fernald Superfund sites. Fraudulent laboratory analyses were alleged at Hanford, one of the nation's largest environmental cleanup sites. Further, approximately $240,000 of laboratory analyses were rejected at its Fernald site.

H Reactor
Hanford Nuclear Reservation, Washington

- Additional laboratory analyses, costing about $3.2 million could not be used for their intended purpose at Rocky Mountain Arsenal, Luke Air Force Base, Travis Air Force Base, and Sacramento Army Depot because of laboratory

quality issues. Moreover, the cleanup of one operable unit at Travis Air Force Base was delayed more than 2½ years.

(Additional discussion on some of these data quality problems is provided in Appendix D.)

A total of nine Federal facility Superfund sites, covering EPA Regions 8, 9, and 10, were reviewed in our audit. As discussed above, $11 million was spent on rejected analyses, and resampling, and associated costs. Further, the cleanups at these sites were delayed up to 2½ years.

We believe that the full extent of the data quality problems had not been identified because:

- QAPPs, the primary means for controlling laboratory quality, were not adequately designed to prevent and detect inappropriate quality data;
- Oversight of laboratory data quality needed to be increased to ensure QAPPs were followed;
- EPA had not assessed the adequacy of other Federal agencies' quality systems for environmental data; and,
- There was no Federal system to share laboratory evaluations between Federal agencies.

We believe one of the primary reasons these problems existed was because EPA's oversight role at Federal facility Superfund cleanups was unclear.

We also observed that EPA needed to improve its management control system over laboratory data quality by documenting its data quality system and establishing performance measures for environmental data quality.

QUALITY ASSURANCE PROJECT PLANS NOT WELL DESIGNED

One of the major reasons for data quality problems was that QAPPs were not designed to prevent and detect inappropriate quality data.

> *"The QAPP is an important part of the EPA Quality System, and is required for all data collection activities that generate data for use by EPA."*
>
> ***-EPA QA/G-4***

We reviewed 19 QAPPs at nine Federal facilities in

Regions 8, 9, and 10. These nine sites included two or more operable units. QAPPs are usually prepared for each operable unit of a Superfund site. Additionally, sometimes there are site-wide QAPPs. Superfund sites are frequently divided into operable units to make sites more manageable.

Our evaluation of 19 QAPPs found that:

- Data quality objectives were either not defined or adequately defined in 14 of the 19 QAPPs used at the nine sites;
- A QAPP was not used for the collection of critical risk assessment data at one site; and
- QAPPs did not make appropriate use of three quality assurance activities which have been found to be effective in detecting unacceptable quality data.

Consequently, the QAPPs we reviewed were not adequately designed for collecting data of appropriate quantity and quality to support the decision-making process. We believe these QAPPs were representative of the typical Federal facility QAPP in these regions.

Data Quality Objectives Were Deficient

Our review of data quality objectives (DQOs) for nine Federal facilities showed that objectives were either not established or adequately defined for 14 of 19 QAPPs. As a result, it was difficult to determine whether data of appropriate quality and quantity was collected to support decision making at the sites.

The DQO process is a series of planning steps based on the scientific method that is designed to ensure that the type, quantity, and quality of environmental data used in decision making is appropriate for the intended application. The process allows decision makers to define their data requirements and acceptable levels of decision errors before they collect data. The outcome of the process, data quality objectives, should be the driving component of the QAPP. EPA's document, QA/G-4, provides guidance for the DQO process.

We found that satisfactory DQOs had been established for 5 of the 19 QAPPs reviewed. For the other 14 QAPPs, DQOs were either not defined or not adequately defined as shown below:

Weaknesses Found With DQOs

Weakness	QAPPs With Weakness
DQOs not defined	7
Objectives not defined for each data collection activity	3
Objectives not defined for each collection activity and analytical levels* not defined for each data use	3
Analytical levels* defined by objectives not accurately incorporated into the QAPP for some data uses	1
Total	14

*The OSWER directive defining analytical levels was rescinded in 1993 after OSWER Directive 9355.9-01 was issued. OSWER Directive 9355.9-01 revised the DQO process and replaced analytical levels (along with other elements) with acceptable decision errors and data categories.

Poor DQOs Cause Problems

When DQOs are not defined, the project runs the risk of collecting inappropriate quality data or expending too much for sampling. In this regard, we found that the initial sampling costs were much higher than the resampling costs, possibly indicating that initial DQOs may have been inadequate or incomplete.

For example, we believe the lack of sound DQOs increased sampling and analysis costs at Hunters Point Naval Shipyard. DQOs at Hunters Point did not establish acceptable error rates or confidence requirements for determining the sample size. Nonetheless, the Navy collected over 1,200 samples during the fall of 1990; the cost was about $2.5 million. After major data problems were encountered, the Navy was forced to resample. However, costs were $1 million, less than half the initial costs of $2.5 million. We believe this lower resampling cost indicates the initial sampling effort was excessive.

Problems with DQOs occurred because the Federal agencies had not effectively used the DQO process to establish QAPP requirements. Key decision makers and technical experts were oftentimes not participating in the process. Further, cleanup managers believed the process needed more structure and specific guidance documentation.

QAPP Not Used For Critical Data

We noted that a QAPP was not used to collect data to fill critical gaps in support of Fort Wainwright's postwide risk assessment. Additional field sampling was conducted at Fort Wainwright in 1995 to fill critical data gaps for the risk assessment.

> *"The postwide risk assessment, scheduled for completion in 1996, is intended to provide a comprehensive evaluation of potential human health and ecological risks across the post."*
>
> ***- Final Postwide Field Sampling Plan for Fort Wainwright, Alaska***

We were told the additional field sampling was conducted under Operable Unit (OU) 5's remedial investigation and feasibility study QAPP. However, this QAPP only established DQOs and quality assurance activities for OU 5. It did not establish requirements for the collection of critical data needed for the postwide risk assessment. Consequently, DQOs and quality assurance requirements had not been established for critical risk assessment data.

Three Effective Data Quality Activities

Our review found that three data quality activities were particularly effective in detecting inappropriate quality data:

- Independent data validation, using EPA functional guidelines or their equivalent;
- An independent laboratory audit before work starts and periodically throughout the project; and,
- A requirement to provide magnetic media of raw data, when needed.

While 8 of the 19 QAPPs reviewed required at least one of these activities, the other 11 QAPPs did not require any of the three quality assurance activities we found effective.

As shown in the following chart, EPA or the Federal facility used these three activities to find data problems at seven of the nine Federal facilities we reviewed.

Quality Assurance Activities Used To Identify Unacceptable Data

Site	Data Validation	Laboratory Audits	Magnetic Tape Audits
March Air Force Base		●	●
Hunters Point Naval Shipyard	●		
Travis Air Force Base		●	
Sacramento Army Depot	●		
Luke Air Force Base	●		●
Rocky Mountain Arsenal		●	
Fort Wainwright	●		

(Quality assurance activities are defined at Appendix E.)

Data Validation Found Effective

Data validation identified data quality problems at four of the sites we reviewed. Data validation is used to ensure that laboratory data is of known and documented quality. It involves reviewing data against a set of criteria to provide assurance that data is adequate for its intended use. It is absolutely essential at key decision points, such as determining the boundaries of groundwater contamination.

EPA has data validation guidelines, known as National Functional Guidelines, for its own contract laboratory program. Generally, the QAPPs we reviewed called for data validation that corresponded with EPA data validation guidelines. According to EPA guidelines, data validation includes a review of documentation such as raw data, instrument printouts, chain of custody records, and instrument calibration logs.

For example, data validation was effective in finding data problems at Sacramento Army Depot. Twenty percent of the data for the Depot's Burn Pits Operable Unit was required to be validated; however, prior to our review, the data had not been validated. Subsequently, we requested that Region 9 validate critical data from

the March 1991 sampling round, resulting in the rejection of volatile organic compound analyses. Further, our Engineering and Science Staff determined that all samples taken in March 1991 should be rejected because of a defect in the sampling technique.

> *"The sample results [for volatile organic compounds] are rejected due to serious deficiencies in the ability to analyze the sample and meet quality control criteria. The presence or absence of the analyte cannot be verified."*
>
> ***-Region 9 Quality Assurance Section May 19, 1995***

These rejected samples were critical because they were used in the public health risk assessment, remedial investigation, feasibility study, and record of decision. This data was also used to determine the contaminants of concern, determine the cleanup levels for the contaminants, and select the cleanup remedy.

Laboratory Audits Resulted in Data Being Rejected

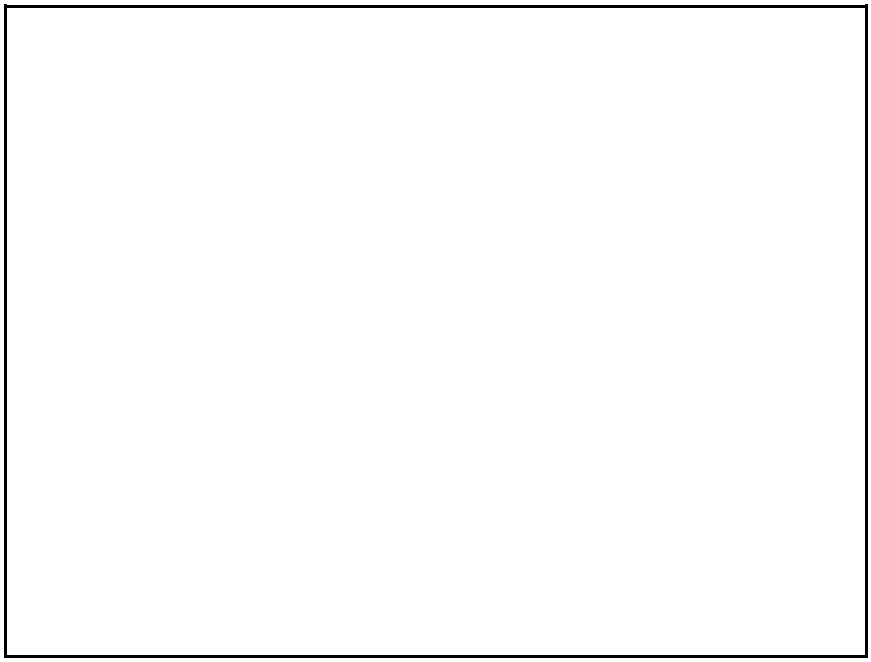
Laboratory audits identified inappropriate quality data at three of the seven sites with data quality problems. On-site laboratory audits are designed to identify technical areas which may cause laboratories to improperly identify or quantitate chemicals. Audits normally evaluate a technical expertise, standard operating procedures, facility and equipment sufficiency, and possible sources of sample contamination.

> *"Eureka Laboratory is not in compliance with the requirements of the ...[Chemical Quality Assurance Plan], the contract under which they are performing work and good laboratory practices. Data produced for certification has been found to be altered and may be required to be repeated prior to acceptance by [the Program Manager for Rocky Mountain Arsenal]."*
>
> ***- Rocky Mountain Arsenal August 1993 Audit Report on Eureka Laboratories***

One example of the effective use of laboratory audits was at Rocky Mountain Arsenal in EPA Region 8. The Arsenal effectively used laboratory audits of their contract laboratories to find poor data and to avoid using laboratories with problem performance.

To illustrate, in June 1995, the Rocky Mountain Arsenal conducted an audit of a Texas laboratory. This audit found that the laboratory was performing poorly and had not shown the expected improvements. Also, changes made at the laboratory did not effectively identify or eliminate the problems. As a result, the

Arsenal stopped sending samples to the laboratory, and did not use data previously analyzed by the laboratory. The Arsenal paid the laboratory about $485,000 for the unused data analyses.



South Plants Area
On-Post Operable Unit, Rocky Mountain Arsenal, Colorado

We believe that on-site laboratory audits are one of the better quality assurance activities if they are performed: (i) before samples are sent to the laboratory; and (ii) periodically throughout the sampling process. We also believe QAPPs should allow unannounced audits so that laboratory performance at the time of the audit is representative of routine operations.

Magnetic Tapes Should be Available

Magnetic tape audits were used to verify the extent of data quality issues at two of the seven sites with data quality problems. Tape audits are routinely conducted by EPA in monitoring its contract laboratories. At a minimum, we believe magnetic data should be available so that tape audits can be done when warranted.

Magnetic tape audits can identify poor laboratory practices but have limited usefulness. These audits, in conjunction with data audits, are used to assess the authenticity of the data generated and the implementation of good automated laboratory practices. However, magnetic tape audits generally can only be used for data generated by gas chromatography and mass spectrometry laboratory equipment.

For example, Region 9 used magnetic tape audits at March Air Force Base to detect major data quality problems. The Region used this technique after double-blind performance evaluation samples identified data problems. The tape audits found deficiencies and pervasive fraudulent work. This led to Eureka Laboratories pleading guilty to falsifying test results and two of its chemists being convicted of fraud in May 1995.

> *"These audits [magnetic tape audits] are used to assess the authenticity of the data generated and assess the implementation of good automated laboratory practices."*
>
> ***-AFCEE Quality Assurance Project Plan, February 1996***

We believe it is critical that the requirement for the availability of magnetic tapes be written into QAPPs and laboratory contracts. To illustrate, Travis Air Force Base found potential problems with data from one laboratory. However, we were advised that the laboratory refused to provide magnetic tapes of raw data for audit because contract specifications did not require availability of magnetic data. Thus, Region 9 could not determine whether the data was of appropriate quality for its intended purpose. Resultant laboratory data problems delayed the cleanup more than 2½ years.

In summary, we believe magnetic tape audits should be performed if major deficiencies are found by other methods, such as data validation or performance evaluation samples. However, in order to do so, Federal agencies must be able to obtain magnetic data. This means including the requirement for magnetic data availability in QAPPs and laboratory contracts.

Lack of Guidance

EPA's guidance document for the preparation of quality assurance project plans, QAMS 005/80, did not require data validation, laboratory audits, and magnetic tape availability. To ensure these quality assurance items are addressed in QAPPs, and required when appropriate, EPA guidance should be modified to require their inclusion, when DQOs require high-quality data.

> *"EPA believes that the appropriate content and level of detail in the QAPP may be best achieved by having the QAPP requirements reviewed and confirmed by the EPA project manager with the assistance and approval of the EPA QA Manager."*
>
> ***-EPA QA/R-5***

Assistance from Regional Quality Assurance Staff

EPA's regional quality assurance staffs are a good source of expertise to improve QAPPs. However, we found 13 of 19 QAPPs were not reviewed and approved by the regional quality assurance staffs. QAMS 005/80 did not require QA staff to review QAPPs. However, interim final QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, August 1994, includes a requirement for EPA QA managers to assist EPA project officers in reviewing and approving QAPPs. Even though QA/R-5 is not expected to be finalized until late 1997, it has been embraced EPA-wide, with the exception of Region 10.

Best Practices

During our audit we found "best practices" for developing DQOs, validating data, tracking laboratories, contracting with laboratories, and reporting quality assurance findings. These best practices merit inclusion in Federal quality assurance programs whenever possible.

DQO Development

The environmental restoration contractor at Hanford developed an effective planning procedure for defining DQOs. This procedure, shown at Appendix F, involves key decision makers, including EPA, in the development of objectives. The outcome of this procedure was a set of DQOs with the level of detail and information needed by the QAPPs and field sampling plans. EPA should refine its process to include many of the aspects of this procedure.

Computerized Data Validation

Another best practice is the use of computerized data validation. EPA has developed two computerized data validation programs to verify laboratory performance. They are called Computer-Aided Data Review and Evaluation (CADRE) and electronic Data Transfer and Validation System (e-Data).

Region 9 has tested both systems for use at Federal facilities. The Region found that CADRE not only identified the same problems that manual data validation did, but was more objective and consistent. A drawback to CADRE was that, as a computer program, it could not visually inspect raw data to identify anomalies.

Region 9 also did a study of e-Data with the Navy at Pearl Harbor. Among other things, the study found that e-Data:

- Was able to quickly load, process and identify outlying quality control data much more efficiently than manual procedures;

- Did not make any transcription or recording errors; and
- Reduced the effort required to distribute and process data.

Neither program was able to accommodate deviations from the prescribed agency standard format for electronic data deliverables. Another drawback is that the laboratories needed computer systems that produce data in the proper format.

Although there are some problems with electronic data validation, tests have shown that computerized data validation can be much more efficient than regular data validation as shown in the following table:

Comparison of Data Validation Methods

	CADRE	Manual
Time to Validate	4 hours	35 hours
Turn Around Time	1 week	1 month
Cost to Validate	$150	$1,200

Source: Region 9 study.

Army Validation and Tracking System

The U.S. Army Corps of Engineers (the Corps) implemented a laboratory validation and tracking system. This system required laboratories to be "validated" before contracts were awarded. The validation process typically included an on-site audit and performance evaluation samples. (Performance evaluation samples are samples spiked with known quantities of contaminants used to measure a laboratory's analytical performance.)

The tracking system monitored laboratory validation information related to Corps' contracts. This system tracked laboratory information such as a business profile, performance evaluation sample results, and laboratory validation status.

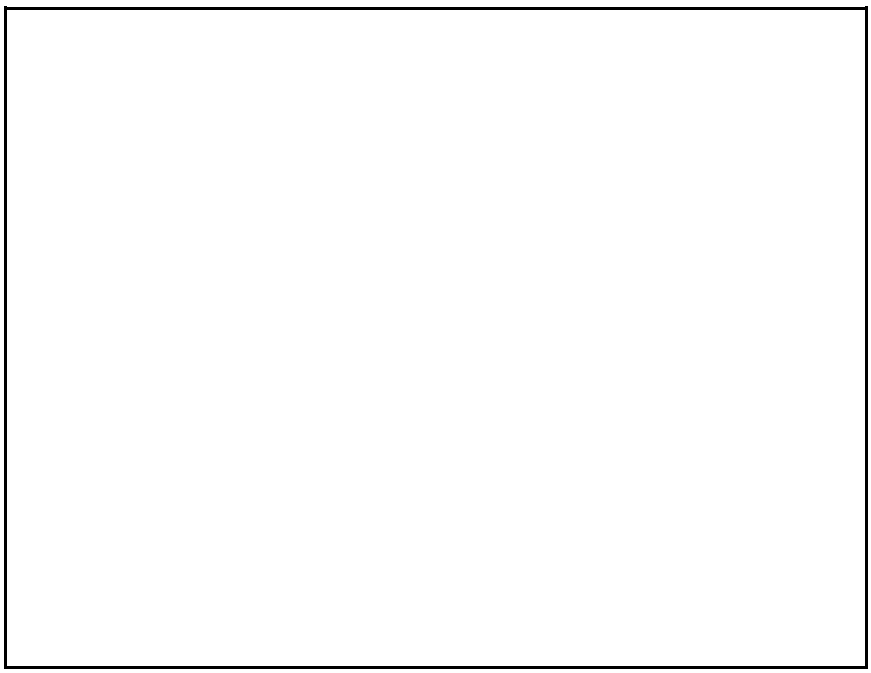
Contracting Directly with Laboratories

Another best practice that increased control over environmental data was directly contracting with laboratories, instead of subcontracting through environmental engineering firms. Rocky Mountain Arsenal contracted directly with its laboratories. This allowed the Arsenal to have more control over the laboratories. The Arsenal also included many "best practices" in its laboratory contracts, including laboratory audits and performance evaluation

samples. Further, it included a clause that said no more work would be sent to the laboratory if it did not meet the minimum requirements for operational and documentation requirements.

Meaningful Quality Assurance Report

The Travis Air Force Base QAPP established an effective format for the quality assurance report. The report showed the results



Storm Water Treatment Plant
Travis Air Force Base, California

of the PE samples, laboratory audits, and data validation. The report included information on the findings, corrective actions required, and the effects on data quality assurance. The report was included with the remedial investigation reports for EPA's review. An example of one of these reports is included in Appendix G.

EPA OVERSIGHT INSUFFICIENT

EPA regions were not providing sufficient oversight on Federal facilities' implementation of QAPP requirements.

Region 8

For example, we found that Region 8 did not have a copy of the current QAPP for Rocky Mountain Arsenal at the time of our audit in June 1996. The original QAPP was implemented during 1989 and had substantially changed since that date. Without the current

QAPP, the Region was unable to adequately oversee the Arsenal's compliance with quality assurance requirements.

> *"...Regional Administrators shall:...Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable QA project plan and that the plan is implemented...."*
>
> ***-EPA Order 5360.1***

Region 9

Region 9 did not monitor the data validation requirement specified in the QAPP for the Sacramento Army Depot's Burn Pits Operable Unit. The QAPP required 20 percent of the data to be validated according to EPA national functional guidelines. However, we found that no data was validated.

Subsequent data validation resulted in the rejection of critical analyses. After we determined data was not validated, we requested that Region 9 validate critical data from the March 1991 sampling round. This validation resulted in the rejection of volatile organic compound analyses.

These rejected samples were critical because they were used in the public health risk assessment, remedial investigation, feasibility study, and record of decision. This data was also used to determine the contaminants of concern, determine the cleanup levels for the contaminants, and to select the cleanup remedy.

Region 10

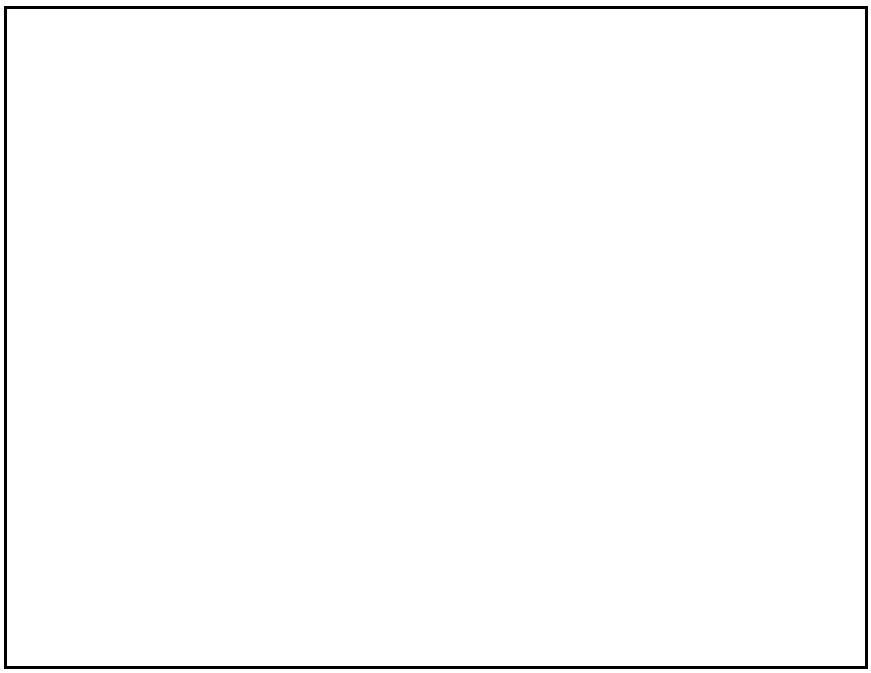
Region 10 did not monitor compliance with the laboratory audit requirement specified in the QAPP for Fort Wainwright Operable Unit (OU) 2. The QAPP required laboratories to be validated by the Army Corps prior to their use and every 18 months thereafter. This validation process included laboratory audits. We found that the Army had not complied with this requirement.

> *"Based on the PE sample results and the information gathered during the on-site inspection, National Environmental Testing-Santa Rosa Division is not considered to be qualified to perform chemical analyses for the U.S. Army Corps of Engineers at this time."*
>
> ***- Army Corps of Engineers' April 1996 Audit Report of NET - Santa Rosa***

The Army was almost a year late performing an audit of one of the laboratories for OU 2. The Army should have audited the laboratory in May 1995, when the laboratory's validation from the Army expired. However, the Army extended its validation to May 1996 without conducting an audit. When the Army conducted the audit during March 1996, it found significant performance deficien-

cies and concluded that the laboratory was not qualified to perform analyses for the Army. Region 10 was unaware of the untimely audit because copies of the relevant audit reports had not been obtained and reviewed.

Unfortunately, the laboratory was used to analyze samples collected in October 1995 for Fort Wainwright's postwide risk assessment; this assessment was used to more completely define contamination in the Chena River at Fort Wainwright.



Chena River
Fort Wainwright, Alaska

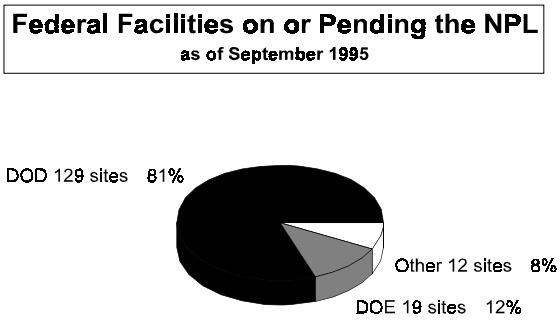
We believe the laboratory's analysis of these samples was questionable because of the audit's conclusion about the laboratory.

Cause

EPA oversight was insufficient because regional remedial project managers were generally relying on the Federal facilities to ensure that QAPP requirements were met. To ensure that data of appropriate quality is obtained, regional remedial project managers must monitor compliance with QAPP requirements. In addition, EPA quality assurance staff should assist the project managers with this oversight in order to make sure that significant data quality issues are identified and addressed.

FEDERAL QUALITY SYSTEMS NOT EVALUATED

EPA had not fully assessed DOD's or DOE's environmental data quality systems on a department-wide basis. We believe the extent of EPA's oversight should be based on the adequacy of DOD's and DOE's data quality systems. We found weaknesses in both DOD's and DOE's data quality systems that substantiate the need for increased EPA oversight.



DOD and DOE are responsible for most of the Federal sites on the Superfund National Priorities List. Under the National Contingency Plan, DOD and DOE have unique investigative and cleanup responsibilities for NPL cleanups. As lead agencies, they are responsible for ensuring data quality.

EPA is responsible for reviewing DOD and DOE remedial investigations and feasibility studies and must agree with their cleanup remedies. In order to make an informed judgement of remedy, EPA must ensure the data supporting environmental decisions is of known quality. We believe the degree of EPA oversight should also depend on the effectiveness of a Federal department's data quality system.

Except for some efforts made by Region 9, EPA had not evaluated DOD's or DOE's data quality systems. Our review indicated such an evaluation would identify significant deficiencies in their data quality systems. These deficiencies have allowed poor-performing laboratories to analyze samples at Federal facility Superfund sites, as discussed in the following paragraphs.

DOD Not Tracking Laboratory Performance

DOD did not have a system for tracking laboratory performance. Although it had established a Tri-Service Chemical Quality Assurance Work Group to enhance communication among the military services, DOD had not established a system to share laboratory audit results. Consequently, laboratory audits that found serious problems were not always shared with other military services or Federal agencies. For example, an Air Force-contracted evaluation of Eureka Laboratories found serious deficiencies with

laboratory performance and procedures. However, the evaluation was not shared with the other services or Federal agencies.

Moreover, the DOD Inspector General found that DOD facilities were not using effective quality assurance activities for their laboratory support services.

DOE Has Problems with Quality Assurance

The DOE Office of Inspector General found problems with the DOE's commercial laboratory quality assurance evaluation program. In its June 1995 audit report, the OIG found that:

> *"Both Department and contractor officials stated that some laboratories failed to qualify or were suspended from work for one site but continued to test samples for other sites. These officials told us that even when they learned of these failures or suspensions, they did not notify other known laboratory customers."*

Deficiencies in DOE's Commercial Laboratory Quality

- Some laboratories failed to qualify or were suspended from work for one site but continued to test samples at other sites.
- Some laboratories were not evaluated to determine their ability to provide analytical services.
- Methods used to perform evaluations and report results varied among contractors.

-Audit of DOE's Commercial Laboratory Quality Assurance Evaluation Program, DOE Inspector General, June 1995

Because of problems with Federal quality assurance systems, it is our opinion that laboratory analyses conducted to date at DOD and DOE Superfund sites cannot be presumed to be of appropriate quality for cleanup decision making. This should be a national concern since DOD and DOE have over 90 percent of the Federal facility Superfund sites on or pending inclusion on the National Priorities List.

LABORATORY EVALUATIONS NOT SHARED

One reason that the extent of data quality problems were not identified was because neither EPA or any other component of the Federal government had an effective forum or system for sharing laboratory evaluations. Laboratory evaluations, such as audits, are one of the most useful tools for judging the technical capabilities of a laboratory. On-site audits typically evaluate a laboratory's

technical expertise, standard operating procedures, and facility and equipment sufficiency.

No Federal System

There was no system within the Federal government to share laboratory evaluations. Such a system could avoid the use of incompetent laboratories and could also help cut costs by preventing duplicate audits.

For example, if the Air Force had shared audit results with the Army, it is likely that $3.8 million in rejected data and associated costs could have been avoided. The Army, Navy, and Air Force paid for five audits of Eureka Laboratories between January 1991 and October 1992. The first Air Force audit, done in January 1991, found major problems with Eureka Laboratories, which was used to analyze samples at 28 DOD installations.

An Army manager at Rocky Mountain Arsenal told us that Eureka Laboratories would not have been used if he had been aware of the Air Force audit. Rocky Mountain Arsenal ultimately rejected samples analyzed by Eureka Laboratories, at a cost of about $3.8 million. This rejection also set back the Arsenal's water monitoring program about 1 year.

> *"If I had known about the AFCEE [Air Force Center for Environmental Excellence] audit, I would not have used Eureka Laboratories."*
>
> ***-Army Representative***
> ***Rocky Mountain Arsenal***
> ***February 1996***

We were told EPA and Federal departments have shared laboratory information in the past to identify poor quality analyses. For example, EPA told us it provided information to DOE which led to allegations of laboratory fraud at Hanford.

Need to Track Performance Data

EPA and other Federal agencies have recognized the need to track laboratory performance data. For example, in 1986 OSWER Directive 9240.0-2 established a system for tracking all Superfund analytical services, including Federal facility laboratories. OSWER later rescinded this requirement for Federal facilities, although these facilities accounted for nearly 60 percent of the Superfund priority sites undergoing investigation or study in 1995.

Some of the items the system might include are laboratory audits, accreditation status, and performance evaluation samples. In our opinion, EPA is the logical proponent for such a system because of its experience in tracking laboratory performance and its oversight

role at Superfund cleanups. We recognize there could be legal limitations on the type of information that could be shared and who it can be shared with.

EPA Notification Procedures Lacking

There were no procedures for exchanging laboratory performance information between EPA's contract laboratory program and other EPA laboratory programs, such as those for Federal facilities. EPA also lacked procedures for ensuring that fraudulent or poor quality data was not used at Federal facility Superfund sites. For example, after Eureka Laboratories pleaded guilty to fraud in May 1995, EPA did not request its regions to evaluate the impacts of this laboratory's work at Federal facilities, although the laboratory was used at 28 DOD installations.

EPA OVERSIGHT ROLE NOT DEFINED

We believe one of the primary reasons for weaknesses in data quality was that EPA's oversight role at Federal facility Superfund sites was not well defined, especially at sites where DOD and DOE were involved. This condition was due to ambiguous legal authorities under CERCLA section 120 and Executive Order 12580.

Under CERCLA section 120, issued in 1986, EPA was to review remedial investigations and feasibility studies (RI/FS) prepared by other Federal agencies. The extent of this review was not defined by CERCLA.

Executive Order 12580, issued in 1987, gave DOD and DOE cleanup responsibilities at their National Priorities List sites. The National Contingency Plan (40 CFR 300) further defines these responsibilities. However, it did not describe EPA's oversight responsibilities for these cleanups.

In 1991, the Office of Solid Waste and Emergency Response (OSWER) issued Directive 9835.1(c), Guidance on Oversight of Potentially Responsible Party Remedial Investigations and Feasibility Studies. According to this directive, EPA should oversee Federal facility cleanups to the same degree as private industry cleanups. However,

> *"While oversight of Federal facilities should be to the same degree as oversight of non-Federal PRPs [potentially responsible parties], it is important to note certain distinctions that may affect the RI/FS [remedial investigation/ feasibility study]."*
>
> ***-OSWER Directive 9835.1(c), July 1991***

this directive did not address how EPA's oversight responsibilities are impacted by DOD's and DOE's authorities under Executive Order 12580, nor how site-specific data quality activities should be coordinated.

EPA Oversight During the RI/FS

Because of ambiguous legal authorities, EPA's authority to oversee data quality during the RI/FS process may be questioned in the absence of a Federal facility agreement. In fact, on a national basis, there were 31 Federal facility Superfund sites without a Federal facility agreement. For example, EPA did not have an agreement with the Concord Naval Weapons Station. As a result, EPA's comments on the work plan for the remedial investigation had to be provided to the State of California for inclusion in the state's comments.

We believe it is imperative that EPA become involved overseeing data quality during the RI/FS process because:

- Federal agencies must be viewed as having an inherent conflict-of-interest between their desire to have sites removed from the NPL, but at the lowest cost.

Reasons for EPA Oversight of Data During RI/FS

- Federal agencies are not independent; they are responsible for pollution and must pay for cleanup.
- Most environmental data is collected during the RI/FS.
- EPA must rely on data to make an informed judgement of the remedy.
- EPA and Federal agency partnerships during the RI/FS allow parties to focus on critical issues.

- Most of the environmental data used in determining the remedial action is collected during the RI/FS. EPA must agree with the remedial action.

- EPA cannot determine if a remedial action is appropriate without evaluating the quality of the underlying data.

- Joint partnerships between EPA and the Federal agency during the RI/FS process allow all parties to focus on key issues that are critical. Such partnerships support the targeting of oversight activities to the priority sites, and provide a means to resolve substantive issues prior to action.

To clarify EPA's oversight responsibilities at Federal facility Superfund cleanups, it is our opinion that Executive Order 12580

requires modification. The modification should identify EPA's oversight responsibilities for RI/FS activities, including environmental data quality. Further, EPA's RI/FS guidance, such as OSWER Directive 9835.1(c), needs to be revised to define EPA's specific oversight responsibilities at Federal facilities and how site-specific data quality activities should be coordinated.

ENVIRONMENTAL DATA QUALITY A MATERIAL WEAKNESS

EPA had not fully documented its quality systems. In our opinion, documenting these systems will help ensure sufficient quality assurance systems are in place, including those for data quality at Federal facilities.

Since 1992, environmental data quality has been a material weakness in EPA's management control system. The weakness was reported because many EPA activities had not documented their quality systems in acceptable quality management plans.

A quality management plan describes the entire organization-wide quality management system. Quality management plans are required by American National Standard ANSI/ASQC E4-1994 and EPA Order 5360.1.

A quality management plan had not been developed by EPA's Federal Facilities Restoration and Reuse Office. This office has responsibility for guidance and policy for Superfund cleanups at Federal sites. In addition, as of September 30, 1996, EPA's Office of Research and Development had not approved quality management plans for three EPA regions, although most of these regions had plans approved in the past. However, as of February 21, 1997, 9 of the 10 regions had approved plans. The other regional plan was under development.

PERFORMANCE MEASURES NOT ESTABLISHED

EPA had not established performance measures for environmental data quality at Superfund sites. Because environmental data quality is at the heart of EPA decision-making, we believe performance measures should be developed that measure how well the data quality process was planned and carried out.

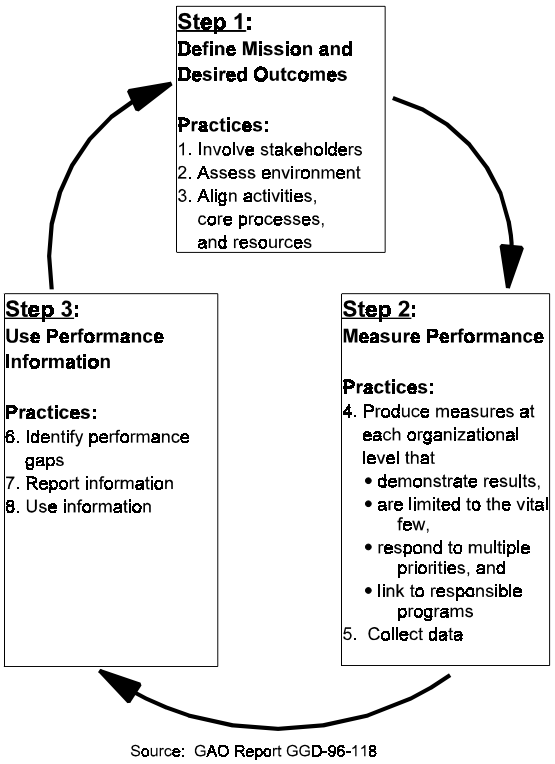
> *"...the active involvement of agencies' top officials in setting goals, measuring performance, and using performance information is critical..."*
>
> ***-General Accounting Office testimony, June 1995***

> *"Developing effective performance indicators is the heart of the process."*
>
> ***-KPMG Peat Marwick Government Services***

The Government Performance and Results Act, enacted in 1993, requires Federal agencies to measure performance. The Act seeks to fundamentally change the focus of Federal management and accountability from a preoccupation with inputs to a greater focus on the outcomes that are being achieved. Under this Act, agencies are to set strategic goals by 1997, and measure performance and report on the degree to which goals are met by 2000. The Office of Management and Budget has recognized the need to reach consensus on outcome-oriented goals and has been strongly encouraging agencies to begin implementing the Act's requirements well before 1997.

EPA should develop performance measures for the quality of environmental data. Environmental data form the basis for most policy, technical, and regulatory actions at EPA. Thus, it is critical that the collected data are of the type, quantity, and quality needed to make decisions with the desired degree of confidence. Management should be confident that data do not lead to an incorrect decision and that the data can withstand scientific and litigative scrutiny.

Steps to Measure Performance



Source: GAO Report GGD-96-118

RECOMMENDATIONS

We recommend that:

The Assistant Administrator for Solid Waste and Emergency Response

1. Work with Regions to ensure that Federal facility Superfund QAPPs:

   a. Include QAPP requirements that are based on well-defined data quality objectives.

   b. Are prepared for each data collection activity that is used for decision making.

2. Ensure that regional quality assurance personnel are involved in the entire QAPP process, from development of the QAPP to compliance with the QAPP.

3. Issue guidance that specifies regional oversight responsibilities for Federal facility Superfund cleanups. Ensure this guidance addresses the oversight of laboratory data quality and includes a requirement for site-specific plans that discuss the nature, frequency, and responsibility for data quality oversight activities.

4. Assess the adequacy of DOD's and DOE's environmental data management systems.

5. Establish procedures for ensuring fraudulent or poor quality data is not used at Federal facility cleanups.

6. Fully identify the impacts of the Eureka Laboratories fraudulent and poor laboratory practices on Federal facility cleanups.

7. Develop a national quality management plan.

8. Develop performance measures for the environmental data quality system, and compare actual performance of the system to these measures.

9. Issue program-specific QAPP guidance to ensure that the following quality assurance measures are included when high-quality data is required by data quality objectives:

a. The use of EPA national functional guidelines or their equivalent for data validation. The data validation should represent all matrices, analysis types, and laboratory decision points, and be based on the data quality objectives.

b. Data validation performed by a party independent of both the laboratory and its parent company.

c. On-site laboratory audits before work is started and periodically throughout the project. Also, the guidance should specify that the audits will be conducted by an activity independent of the laboratory and will include both announced and unannounced audits.

d. Magnetic data maintained and made available to regions. In addition, magnetic tape audits should be required if major deficiencies are found by other quality assurance methods, such as data validation or performance evaluation samples.

10. Continue the development of electronic data validation, expand its capabilities, and encourage its use.

11. Create a forum for sharing environmental laboratory evaluations, such as laboratory audits, among Federal agencies.

12. Publicize best practices used in Federal facility agreements, QAPPs, and laboratory contracts to make EPA regions and other Federal facilities aware of them.

The Assistant Administrator for Research and Development

13. Refine the data quality objectives process by:

a. Ensuring the early involvement of key decision makers.

b. Using checklists to identify all necessary activities.

c. Identifying specific documentation requirements.

d. Using the model developed at the Hanford site as a guide.

14. Work with the Federal Facilities Restoration and Reuse Office and regions to develop acceptable quality management plans.

The Assistant Administrator for Enforcement and Compliance Assurance

15. Request that Executive Order 12580 be modified to expressly identify EPA's oversight role for environmental data quality.

AGENCY COMMENTS

The Offices of Solid Waste and Emergency Response, Research and Development, and Enforcement and Compliance Assurance generally agreed with the findings and recommendations. Their complete responses are at Appendix A.

OSWER Response

OSWER agreed improvements needed to be made in the current quality assurance oversight process. However, it cautioned that EPA must not undermine recent initiatives to streamline the Superfund process. It also stated *"...We believe that having sound information to base cleanup decisions is critical, but we also must recognize the responsibilities delegated under Executive Order 12580 to other Federal agencies. While we must improve our efforts, so too must other Federal agencies improve their accountability..."*

OSWER agreed to coordinate with EPA regions and the Departments of Defense and Energy to assess the adequacy of DOD's and DOE's environmental data quality systems by November 30, 1997. OSWER, EPA regions, DOD, and DOE will also develop a framework for the minimum quality assurance program that the Federal facilities should have in place. This framework will incorporate currently available quality assurance guidance and information. EPA will complete the design of the quality assurance framework and the initial implementation by May 31, 1998.

Each EPA region will be responsible for verifying that its Superfund Federal facilities have established and are maintaining the quality assurance program. OSWER also agreed to develop a quality management plan, encourage the use of electronic data validation, develop a mechanism to share laboratory audit information, and encourage the dissemination quality assurance best practices.

ORD Response

The Office of Research and Development agreed to amend its DQO guidance and work with OSWER's Federal Facility Restoration and Reuse Office and regions as they develop and implement quality management plans. ORD will also provide training in the Agency's quality management system.

ORD pointed out that *"...There is no system, no matter how well conceived and documented, that cannot be circumvented by unexpected environmental conditions, unintentional mistakes by staff, or intentional malfeasance."*

OECA Response

The Office of Enforcement and Compliance Assurance and OSWER, working with EPA regions and other Federal departments, will undertake a program to improve the quality of RI/FS work the Federal departments conduct. *"Consistent with our long-held 'enforcement first' principles, we applaud the IG for supporting the need for strong EPA oversight."*

OECA viewed the best approach to improving data quality at Federal facilities as the cooperative, yet aggressive, approach detailed in OSWER's comments. OECA said it remains ready to pursue amending the Executive Order if EPA fails to secure the improvements OSWER actions seek.

AUDIT SCOPE

This section describes the audit scope and methodology, including our review of the 1995 Integrity Act Report to the President and Congress and prior audit coverage.

Scope and Methodology

We performed our audit in accordance with Government Auditing Standards issued by the Comptroller General. Our field work was conducted between December 5, 1995 and July 31, 1996. The audit covered management procedures in effect as of September 30, 1995.

We interviewed officials in EPA's Offices of

- Solid Waste and Emergency Response;
- Enforcement and Compliance Assurance; and
- Research and Development.

We obtained and reviewed EPA oversight guidance, reports, and analyzed resultant data. We also contacted the DOD and DOE Offices of Inspector General to identify audits of these departments' laboratory quality assurance systems.

We selected Regions 8, 9, and 10 for review because they oversee about 40 percent of the Federal facility Superfund sites including:

- DOE's Hanford Nuclear Reservation, one of the two largest DOE cleanups; and
- Rocky Mountain Arsenal, one of the largest cleanups in DOD.

Seven of the sites included in the audit were selected because of known or possible problems with laboratory data quality. A complete list of the entities contacted in the audit is shown in Appendix H.

We interviewed responsible regional and Federal facility officials. We also reviewed the internal controls associated with regional oversight of laboratory data quality, including Federal facility agreements, QAPPs, and quality assurance reports. The internal control weaknesses we found are described in this report, along with recommendations for corrective actions.

Federal Managers' Financial Integrity Act

In planning our audit, we reviewed EPA's 1995 Integrity Act Report to the President and Congress, which reports compliance with the Federal Managers' Financial Integrity Act. EPA reported that environmental data quality has been a material weakness since 1992. As detailed in this report, we believe internal controls over laboratory data quality at Federal facility Superfund sites could be improved by correcting this weakness.

Prior Audit Coverage

We issued an audit report titled Environmental Data Quality at DOD Superfund Sites in Region 9 in September 1995. The results of this audit are included in this report. Region 9 had taken actions to implement the audit report recommendations. In this respect, Region 9 initiated a memorandum of understanding between its Federal Facilities Cleanup and Quality Assurance Management offices to establish responsibilities and time frames for implementing the report recommendations.

Other departments had also audited laboratory analyses for environmental data. For example, the Department of Energy Office of Inspector General addressed laboratory quality assurance in two reports: Audit of the Department of Energy's Commercial Laboratory Quality Assurance Evaluation System, issued in June 1995, and Audit of Testing Laboratory Support to the Environmental Survey Program, issued in December 1990. Both of these reports identified weaknesses in the Department's laboratory quality assurance system.

The DOD Inspector General issued a report called Laboratory Support Services for Environmental Testing on February 21, 1997. The report identified problems with environmental laboratory services.

In 1996, Army Audit Agency reported that the Army paid more than necessary for its laboratory analyses. Air Force Audit Agency issued two reports on environmental contract quality assurance in 1994 and 1995. These reports showed that contractor oversight was inadequate at Air Force cleanups.

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APPENDIX A

Program Office Responses to Draft Report

Attached are the responses from the program offices to our draft report. We issued the draft report on October 28, 1996. We received initial responses from the program offices during December 1996. After meeting with program officials from OSWER and ORD on January 28 and 29, 1997, we revised our draft report. The OSWER and ORD responses were subsequently resubmitted in February 1997, based on our revised draft.

Program Office Responses to Draft Report

It should be noted that the program offices' comments relative to specific sections of our report may no longer be relevant due to changes we made between the draft and final report. Many of these changes were made as a result of the program offices' comments.

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FEB 24 1997

MEMORANDUM

SUBJECT: OSWER Response to Audit Report EISKB6-09-0041:
Draft Audit of Laboratory Data Quality Oversight at Federal Facility Superfund Sites

FROM: Timothy Fields, Jr.
Acting Assistant Administrator

TO: Michael Simmons
Deputy Assistant Inspector General for Internal Audit
Office of Inspector General

The purpose of this memorandum is to transmit the Office of Solid Waste a Emergency Response (OSWER) comments on the findings and recommendations contained in the revised Office of the Inspector General (OIG) Draft Audit Report EISKB6-09-0041 dated January 29, 1997. We provide more specific comments following our general comments below. We appreciate the opportuni to comment on this revised Draft Report and we are looking forward to continuing to work with the OIG on this audit.

GENERAL COMMENTS ON THE DRAFT REPORT

OSWER generally agrees with the recommendations in the revised Draft Report. Many of our comments to the original Draft Report are no longer appropriate due to the changes in the revised Draft Report. We appreciate opportunity to discuss our earlier comments with the OIG and feel that the revised report is a better report than the earlier version. Many of our original comments have been omitted, as they have been addressed, or change in this response.

The Draft Report calls for additional oversight of other Federal agencies cleanup program by Environmental Protection Agency. Although it appears tha improvements are needed in quality assurance/quality control (QA/QC) oversight, we need to be careful as to not undermine recent initiative to streamline the Superfund process. We believe that having sound information base cleanup decisions is critical, but we also must recognize the responsibilities delegated under Executive Order 12580 to other Federal agencies. While we must improve our efforts, so too must other Federal

agencies improve their accountability. The very nature of the relationship that EPA has with other Federal agencies, such as Department of Defense (DO and Department of Energy (DOE), as defined by law, and Executive Order, lim the scope and authority that EPA has to dictate QA/QC procedures to other Federal agencies.

We agree with the Office of Enforcement and Compliance Assurance's respor that we should continue to explore options for addressing the recommendatio including possible future amendments to Executive Order 12580. Prior to taking such an approach, however, we recommend that EPA first try to correc the problems through our own efforts, in conjunction with other Federal agencies. If these prove ineffectual, then we should consider amending the Executive Order.

COMMENTS ON THE DRAFT REPORT

1)Page 9: "In this regard, we found that the initial sampling costs were much higher than the resampling costs, possibly indicating that DQOs m be inadequate."

Comment: It would be helpful if more information were provided with this example to show what the connection is between the sampling costs and DQOs since there are many reasons why the resampling costs would be lower t second time around.

2)Page 10: "Our review found that the following four (three) data quality activities were particularly effective in detecting inappropriate quality data:"

Comment: The following are general comments concerning the three data quality activities that are recommended.

a) Independent data validations, in accordance with EPA functional guidelines or their equivalent. We assume that "independent" means that th validators are working independently from the data generators. Adequate quality assurance programs normally require independent data validation. W agree that there should be documented appropriate guidelines for validating data.

b) Independent laboratory audits before the work starts and periodically throughout the project. Usually, on-site audits are viewed as unique opportunity to evaluate the laboratory in-person based on their personnel, procedures, documentation, and facility. They are useful in providing an insight into the laboratory's capabilities to perform specific analyses.

It is often beneficial to perform an on-site audit when the laboratory is being considered for work (or has been awarded the work) for which it do

not have a performance history with the Federal facility and/or Department. The Contract Laboratory Program (CLP) normally performs a laboratory audit before contract award and once a year during the contract (CLP contracts usually last two to three years). When evaluating a lab for a new contract if the laboratory has a good performance history under a similar current contract the EPA program office uses its discretion on whether to perform a pre-award on-site audit.

c) Provide magnetic media of raw data, when needed. Audits of magnet media (commonly referred to as tape audits) are used to detect manual chang in the electronic copy of the raw data and inconsistencies between the electronic copy and hard copy. The inconsistencies indicate poor laborator practices or possibly laboratory fraud. Tape audits are usually limited to GC/MS data (i.e., volatile and semi-volatile organics) that are generated b systems that are capable of taping. Tape audits are not currently availabl for inorganic data (e.g., metals, anions), or radionuclides. They are not generally performed for GC data (e.g., pesticides/PCBs). The auditor is als required to have access to systems capable of reprocessing the tape. Requiring magnetic records of the raw data is a potentially costly requirem for all program participants. The CLP routinely audits two tapes annually from each laboratory with a current contract for organics analysis. These audits cost approximately $5000 each. This cost does not include laborator resources to generate and ship the tape or EPA's resources to manage the contract and review audit results.

3)Page 15: Magnetic tapes audits were effective in detecting major da quality problems at March AFB.

Comment: It is not clear from the OIG audit text that tape audits are performed in conjunction with data audits to reconstruct an analytical run. It is only after an analytical run is compared with the data package that a true evaluation of the data deliverable can be made.

4)Page 16: The chart titled "QA Requirements in QAPPs".

Comment: The first column is labeled "No QA Requirements". This shou be changed to indicate that none of the three QA activities specified were included, not that the quality assurance project plan (QAPP) contained no Q requirements. (This has been agreed to but was not changed due to time constraints.)

5)Page 25: The OIG notes that there are no procedures for exchanging laboratory performance information.

Comment: While that is true, it should be noted that the DOE investigation which led to allegations of laboratory fraud at Hanford was started because EPA informed DOE that EPA was investigating the lab for fra

RESPONSE TO RECOMMENDATIONS

OIG Recommendations (page 26): We recommend that the Assistant Administrator for the Office of Solid Waste and Emergency Response:

OIG Recommendation #5: Assess the adequacy of DOD's and DOE's environmental data management systems. (Recommendation previously omitted.

OSWER Response: The results of the assessment of DOD's and DOE's environmental data management systems will assist EPA in responding to the other recommendations contained in this audit. It is important to determine the adequacy of DOD's and DOE's current environmental data management syste and to use this information to establish the baseline for the environmental data management systems. From this assessment, EPA should be able to determine what in the systems should be changed, the level of effort from E DOD, and DOE to effect the change, and a reasonable time frame in which to design and implement the changes. The baseline assessment can then be used measure improvement in the systems.

EPA HQ in coordination with the EPA Regions and DOD and DOE will asses the adequacy of DOD's and DOE's environmental data management systems. The assessment will be completed by November 30, 1997.

OIG Recommendation #1: Make sure that the Regions have QAPP requirements that are based on well-defined data quality objectives.

OIG Recommendation #2: Ensure that QAPPs are prepared for each data collection activity that is used for decision-making.

OIG Recommendation #3: Make sure that the quality assurance personnel are involved in the entire QAPP process, from development of the QAPP to compliance with the QAPP.

OIG Recommendation #4: Issue guidance that specifies regional oversig responsibilities for Federal facility Superfund cleanups. Ensure this guidance addresses the oversight of laboratory data quality and includes a requirement for site-specific quality management plans that discuss the nature, frequency, and responsibility for data quality oversight activities

OIG Recommendation #6: Establish procedures for ensuring fraudulent o poor quality data is not used at Federal facility cleanups. In this respec the impacts of the Eureka Laboratories fraudulent and poor laboratory practices on Federal facility cleanups should be fully identified.

OIG Recommendation #7: Develop a national quality management plan.

OIG Recommendation #8: Develop performance measures for the environmental data quality system and compare actual performance of the sys to these measures.

OIG Recommendation 9: Issue program-specific QAPP guidance to ensure that the following quality assurance measures are included when high-qualit data is required by data quality objectives:

9a: The use of EPA national functional guidelines or their equivalent for data validation. The data validation should represent all matrices, analysis types, and laboratory decision points, and be based on the data quality objectives.

9b: The data validation requirements by a party independent of both t laboratory and its parent company.

9c: On-site laboratory audits before work is started and periodically throughout the project. Also, the guidance should specify that the audits will be conducted by an activity independent of the laboratory and will include both announced and unannounced audits.

9d: Magnetic data maintained and made available to regions. In addition, magnetic tape audits should be required if major deficiencies are found by other quality assurance methods, such as data validation or performance evaluation samples.

OSWER Response: We agree that these recommendations are generally appropriate. OSWER's response to Recommendation #4 provides the core to th response to recommendations #1, 2, 3, 6, 8, and 9. In coordination with th EPA Regions and DOE and DOD, OSWER will develop a framework for the minimum quality assurance program that the Federal facilities should have in place. This framework will incorporate currently available QA guidances/ informati This will avoid the generation of new QA guidances/ information when the existing documents are sufficient and in many cases are already being used.

Each EPA Region will be responsible for verifying that its NPL Federa facilities have established and are maintaining the Federal facilities' QA program. The QA program will specify that: 1)QAPP requirements are based o well-defined data quality objectives; 2)QAPPs are prepared for each data collection activity used for decision-making; 3) the quality assurance personnel are involved in the entire QAPP process; 4)procedures are used to minimize the production and use of fraudulent data and; 5) performance measures are used to evaluate the environmental data quality system; 6)data validation is performed where appropriate and is based on the DQOs; 7) the data validation is performed by a party independent of both the laboratory its parent company; 8) on-site audits are performed; 9)magnetic data is maintained and available to Federal facility and to Regions; 10) magnetic t audits are required where appropriate.

Although not suitable for all types of analytical data, we believe magnetic tape audits should be performed if major deficiencies are found by other methods, such as data validation or performance evaluation samples. However, in order to do so, Federal agencies must be able to obtain the magnetic data. This means including the requirement in the QAPP and the laboratory contract. To this end, EPA will work with DOD and DOE to includ this requirement in their laboratory contracts.

It is apparent that the most effective way to obtain performance of th delineated QA tools is for the Quality Assurance Programs of the DOD and DO to adopt and require their implementation. Therefore, a revision of their programs is necessary and will provide a firm commitment by these Federal agencies to the specific QA requirements stated. In addition, the Regions use the Federal Facility Agreements as an opportunity to include the QA/QC requirements in the Federal facility programs. EPA will complete the desig of the QA framework and the initial implementation by May 31, 1998.

Recommendation #6 recommends the establishment of procedures for ensuring fraudulent or poor quality data is not used at Federal facility cleanups. A quality assurance program should ensure that the data is the quality that is needed for decision-making. One goal of a QA program is to minimize the occurrence and use of fraudulent or otherwise inappropriate da All incidences of fraud cannot be detected even by the most effective quali assurance program. There are quality assurance tools discussed in this repo that can be used to minimize the production and use of fraudulent and poor quality data. OSWER intends to pursue the implementation of these tools wh they are useful, cost-effective, and available.

The second part of Recommendation #6, states that the impacts of the Eureka Laboratories fraudulent and poor laboratory practices on Federal facility cleanups should be fully identified. After Eureka Laboratories wa suspended for the fraudulent and poor laboratory practices, the director of Office of Emergency and Remedial Response (OERR) sent a letter, dated July 1995, to all the Regions. This letter notified the Regions of Eureka Laboratories fraudulent activities and asked the Regions to identify the impacts on their data. The letter did not specifically mention that the impact on Federal facility data should be identified. OSWER will send a ne letter to the Regions asking them to identify the impact of Eureka Laboratories fraudulent activities on Federal facility data. The responses from the Regions will be due by October 31, 1998.

OIG Recommendation #7: Develop a national quality management plan.

OSWER Response: OSWER’s Federal facility Restoration and Reuse Office (FFRRO) will develop a Quality Management Plan (QMP) that will ensure data appropriate quality is generated for FFRRO. FFRRO, working with OERR and i Regions, plans to complete the QMP by April, 1997, then submit it to Office Research and Development (ORD) for approval.

OIG Recommendation #10: Continue electronic data validation developments, expand its capabilities, and encourage its use.

OSWER Response: Electronic data validation has a lot of potential for saving resources, making the validation faster, cheaper and more consistent Unfortunately, the development and implementation of electronic data validation is very resource intensive. Electronic data validation continues be an important area of focus in Superfund. The Contract Laboratory Program continues to support this project and funding of the project continues, alb at a reduced rate due to budget cutbacks. EPA will continue to fund development of electronic data validation. In addition, we will encourage use through technical support and guidance. This is a continuous effort tha has no completion date.

OIG Recommendation 11: Sponsor a forum for sharing environmental laboratory evaluations among Federal agencies, such as laboratory audits.

OSWER Response: Any exchange of laboratory performance information ha to be considered in the context of what information EPA may legally release Recognizing the limitations on laboratory information that can be exchanged between Federal agencies, OSWER will evaluate the advantages, disadvantages and the logistics of exchanging laboratory audits between the Federal agencies. OSWER will evaluate our options for developing a standard audit form that can be used by EPA, DOD, and DOE to facilitate the sharing of audits. One option is to adopt the draft standardized audit that is being developed for the National Environmental Laboratory Accreditation Conferenc (NELAC). OSWER will develop a mechanism to share some laboratory audit information by April 30, 1998.

OSWER Directive #9240.0-29 dated November 8, 1995 specifically address for the CLP what information may be released concerning laboratories under investigation for alleged fraud. For exchanging information among the Fede agencies when laboratories are under investigation, OSWER plans on adopting the same basic approach as the CLP. OSWER will adopt this approach by May 1997.

OIG Recommendation 12: Publicize best practices used in Federal Facility Agreements, QAPPs, and laboratory contracts to make EPA regions an other Federal facilities aware of them.

OSWER Response: OSWER will encourage the dissemination of information concerning best practices used in Federal Facility Agreements, QAPPs, and laboratory contracts. OSWER will send out a request semiannually to each E Region asking for information on the best practices used in Federal Facilit Agreements, QAPPs, and laboratory contracts by the Region and/or the Federa Facilities in their Region. The information will then be disseminated through various forums including the Federal Facility Leadership Council,

Federal Facility Forum, and quality assurance conferences. OSWER will begi
this process by April 30, 1997.

CONCLUSION

The revised Draft Report makes valid points as to the potential improvements to the current QA/QC oversight process including defining EPA’ and the Federal facilities role in ensuring appropriate data are generated used for making decisions affecting cleanup. OSWER agrees to initiate some changes and to address the problems identified and will do so in a timely manner. OSWER will actively try to enlist DOD and DOE in this effort to improve the data quality systems at the Federal facilities. We look forwar to continuing to work with the OIG and other EPA Offices as we move to resp to the recommendations.

If you have any questions about our response, please contact Marianne Lynch at (202) 260-5686.

cc: Steven Herman, OECA
Robert Huggett, ORD
Stephen Luftig, OSWER/OERR
Jim Woolford, OSWER/FFRRO
Craig Hooks, OECA/FFEO
Hans Crump-Wiesner, OSWER/OERR
Nancy Wentworth, ORD
Johnsie Webster, OSWER/OPM
Federal Facilities Leadership Council

February 27, 1997

(Insert original)

MEMORANDUM

SUBJECT: Response to Draft OIG Report - Laboratory Data Quality at Federal Facility Superfund Sites (E1SKB6-09-0041)

FROM: Robert J. Huggett, Ph.D.
Assistant Administrator
for Research and Development (8101)

TO: Michael D. Simmons
Deputy Assistant Inspector General
for Internal Audit (2421)

Purpose:

This memorandum responds to the Office of Inspector General's Draft Report on Laboratory Data Quality at Federal Facility Superfund Sites (Report No. E1SKB6-09-0041), received on January 31, 1997.

Discussion:

We reviewed the draft report and generally concurred with the findings and recommendations. We do, however, have comments, attached, which, if addressed, will improve the quality and accuracy of the report. First, we have provided an overview segment which comments on the focus of the report. Second, in our review of the findings, we found certain inaccuracies which we noted in detail. We believe remedying these inaccuracies will greatly improve the report. You will be receiving separate responses to the draft report from the Offices of Enforcement and Compliance Assurance, and Solid Waste and Emergency Response. ORD is committed to working with these other Offices to address the recommendations of the draft report.

We appreciate your support for ORD's efforts to respond to this draft report. If you have any questions about the details of the response, please contact Nancy Wentworth, Director, Quality Assurance Division, at 202 260-5763, or Arnold Bloom, ORD OIG liaison, at 202 260-9496.

Attachment

cc: Elliott P. Laws (5101)
Steven A. Herman (2201A)
William Samuel (2421)
Katherine Thompson, OIG-Sacramento

ORD Comments on Draft Laboratory Data Quality at Federal Facility Superfund Sites (Report #E1SKB6-09-0041)

Introduction:

We appreciate the opportunity to review the draft report on Laboratory Data Quality at Federal Facility Superfund Sites. We have several comments and concerns about the content of the report. Our comments are organized into three sections: 1) Overview, 2) Clarifications and Errors, and 3) Recommendations. We concur with the stated recommendations, except as noted, and appreciate the OIG's attention to considering our thoughts to clarify and enhance the report's content and message.

Overview:

The report leads the reader to believe that quality assurance documentation, particularly the quality assurance project plan (QAPP), is intended to provide absolute assurance that data of the appropriate type and quality will be collected and used in decision making. Development and approval of a QAPP is one thing; proper implementation of the approved QAPP is quite another. Both are needed to confirm the success of the project. The QAPP, including relevant site-specific data quality objectives (DQO), is an effective tool for defining site-specific data collection activities and the controls needed to give reasonable and documented assurance that the activities occurred as planned. There is no system, no matter how well conceived and documented, that cannot be circumvented by unexpected environmental conditions, unintentional mistakes by staff, or intentional malfeasance.

Clarifications, Inconsistencies and Errors:

Page 5, Quality Assurance Division: QAD "overseeing implementation of" the Agency-wide mandatory policy for QA....., not "implementing" the program. The Program Office and Regions are responsible for implementation.

Page 7, QAPPs: The statements imply a deficiency in the design of the QAPP, while the text describes flaws in the application of the QAPP. We believe that a well written and correctly implemented QAPP will address the deficiencies noted in the report.

Page 8-9, DQOs were deficient, paragraph below box: "possibly indicating that initial DQOs may be inadequate or incomplete.

Page 10, Effective Data Quality Activities Identified: Three activities, not four.

Page 11, Data Validation Found Effective, para 1: In the second sentence, data should be "of known and documented quality."

Page D: Standard operating procedures, not standing operating procedures.

Page 15: Chart should be revised to delete PEs.

Page 15: Lack of guidance: QA R-5 is expected to be issued in Summer, 1997.

Page 24, Data Quality a Material Weakness: As of October 31, 1996, 7 Regions have approved Quality Management Plans. As of February 28, 1997, 9 Regions have approved QMPs; Region 7's plan is still under development.

Recommendations:

The Assistant Administrator for Research and Development

13. Refine the data quality objectives process by:

    a. Ensuring that early involvement of key decision makers.

    b. Using checklists to identify necessary activities.

    c. Identifying specific documentation requirements.

    d. Using the model developed at the Hanford site as a guide.

    Response: The Quality Assurance Division's (QAD) data quality objectives (DQO) guidance was not intended to be a static document, but was designed to be updated on a periodic basis. QAD will review the guidance and material noted in the report that was prepared for the Hanford, Washington, Department of Energy facility, and will issue appropriate addenda to its DQO guidance. QAD will complete this activity by August 1, 1997.

14. Work with the Federal Facilities Restoration and Reuse Office (FFRRO) and regions to develop acceptable quality management plans (QMPs).

    Response: QAD will continue its support to FFRRO and the regions as they develop and implement QMPs. QAD provides training in the Agency's quality management system and invites all organization to participate in the training.

Dec 13 1996

(Insert original)

MEMORANDUM

SUBJECT: **OECA Response to the EPA Office of Inspector General (IG) Draft Audit Report, *Laboratory Data Quality at Federal Facility Superfund Sites* (Oct. 1996) (the Draft Report)**

FROM: **Steven A. Herman**
Assistant Administrator
Office of Enforcement and Compliance Assurance

TO: **Michael Simmons**
Deputy Assistant Inspector General for Internal Audit
Office of Inspector General

The Draft Report offers thirteen recommendations: twelve addressed to OSWER and ORD and one to OECA. While finding inadequate EPA's oversight of environmental data quality at federal facilities, the IG acknowledged EPA's legal authority to conduct this oversight is "ambiguous." Draft Report, p. 22. To cure any inadequacy due to unclear oversight authority, the Draft Report recommends we endeavor to modify Executive Order 12580 to expressly identify EPA's oversight responsibilities for RI/FS activities, including environmental data quality. Draft Report, pp. 23, 28. This memorandum provides our response to this recommendation.

Legal Background: CERCLA and Executive Order 12580 fail to address whether EPA has Clear Authority to Oversee RI/FS at Federal Facilities

Executive Order 12580 (the EO) delegates certain functions CERCLA vests in the President to the heads of federal departments and agencies for "releases or threatened releases where either the release is on or the sole source of the release is from any facility or vessel under the jurisdiction, custody or control" of their departments and agencies. Although in several instances, the EO tailors its delegations based on the department or agency receiving the authority and if the site is on the NPL, it makes no distinction when delegating the president's RI/FS authorities. The EO delegates the President's 104(b)(1) investigation and study (RI/FS) authority, regardless of the department or agency or if the

site is on the NPL. With few exceptions, the Executive Order's framework allocates the President's authorities in an exclusive manner, with EPA not delegated any shared authority over the functions delegated to another department or agency. (A significant exception to this exclusive delegation framework is the new amendments to EO 12580 providing the federal natural resource trustee agencies with section 106 and 122 enforcement authorities. These new amendments supplement the authorities of federal agencies, while not diminishing EPA's authorities.)

As noted above, in receiving the President's section 104(b)(1) authorities, the heads of the federal departments acquire exclusive authority to conduct the RI/FS, including the data gathering and quality assurance activities. Section 120(e)(2) modifies this unfettered authority by requiring EPA to review the "**results**" of the RI/FS and enter into an Interagency Agreement (IAG) providing for the implementation of the remedial action (emphasis added). Section 120(e)(4) provides EPA with the ultimate authority to select the remedial action, should the head of the department and the EPA Administrator disagree. However, it is unclear whether EPA has the ultimate authority to alter the RI/FS, including the environmental data on which it relies.

Although section 120 does not require EPA and the other departments or agencies to enter into an IAG until the time for remedy selection (time of ROD), typically EPA negotiates federal facility agreements earlier in the process. This allows EPA to review and potentially dispute certain pre-ROD documents and studies. These generally include, for example, draft RI/FS reports and data from which the RI/FS reports are compiled. The Quality Assurance Project Plan (QAPP) is an example of a document over which EPA has no clear oversight authorities, but may review, based on the provisions of the federal facility agreement. However, if the environmental data are used to support a removal, or a remedial action at a non-NPL site, the federal department or agency need not enter into an IAG with EPA. Thus, EPA would have little leverage to gain review and comment authority over the environmental data or studies.

To summarize, the statute and the Executive Order fail to specifically delegate oversight to EPA, which weakens our ability to compel the federal agency to modify any pre-ROD document. EPA negotiates for pre-ROD oversight, based on the possibility that unless EPA reviews the RI/FS, EPA may not have sufficient information on which to approve the federal agency's ultimate remedy selection decision.

OECA and OSWER Are Taking Action to Clarify EPA's Oversight Authority for Federal Facility RI/FS Activities, including Data Collection and Quality Control Measures

In its responses to the Draft Report, OSWER provides details of their efforts to aggressively respond to the Draft Report's findings and recommendations. In particular, OSWER responds to recommendation 4 (issue guidance specifying regional oversight responsibilities and other related topics) by committing to develop, in coordination with

the EPA Regions and DOE and DOD, a framework for the minimum quality assurance program that the federal facilities should have in place. OECA and OSWER, working with the regions and the other federal departments and agencies, will undertake a program to improve the quality of the RI/FS work the federal departments and agencies conduct. Consistent with our long-held "enforcement first" principles, we applaud the IG for supporting the need for strong EPA oversight. At this time, OECA and OSWER view the best approach to improving the data quality supporting federal facility response actions is the cooperative, yet aggressive, approach detailed in OSWER's comments. However, OECA remains ready to pursue amending the executive order if we fail to secure the improvements the OSWER actions seek. OECA currently is reviewing several options for amendments to EO 12580, should that become necessary. Further, OECA is considering whether a memorandum of understanding or similar agreement may offer the best vehicle for clarifying EPA'S oversight authorities.

CONCLUSION

As the above demonstrates, in response to the IG's Draft Report, OECA, in cooperation with OSWER, EPA regions and federal departments and agencies, is actively pursuing methods to clarify EPA's authority over federal departments and agencies conducting RI/FS activities, including environmental data collection and quality assurance measures.

cc: Elliott P. Laws
Robert J. Huggett

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APPENDIX B

Acronyms

Acronym	Name
AFCEE	Air Force Center for Environmental Excellence
CADRE	Computer Assisted Data Review and Evaluation (Program)
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CLP	EPA's Contract Laboratory Program
DQO	Data quality objectives
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
e-Data	Electronic Data Transfer and Validation System
FS	Feasibility study
NPL	National Priorities List
OECA	Office of Enforcement and Compliance Assurance
OU	Operable unit
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
PE	Performance evaluation (samples)
QA	Quality assurance
QAPP	Quality assurance project plan
QC	Quality control
RI	Remedial investigation

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APPENDIX C

How Federal Facilities on the NPL are Cleaned Up

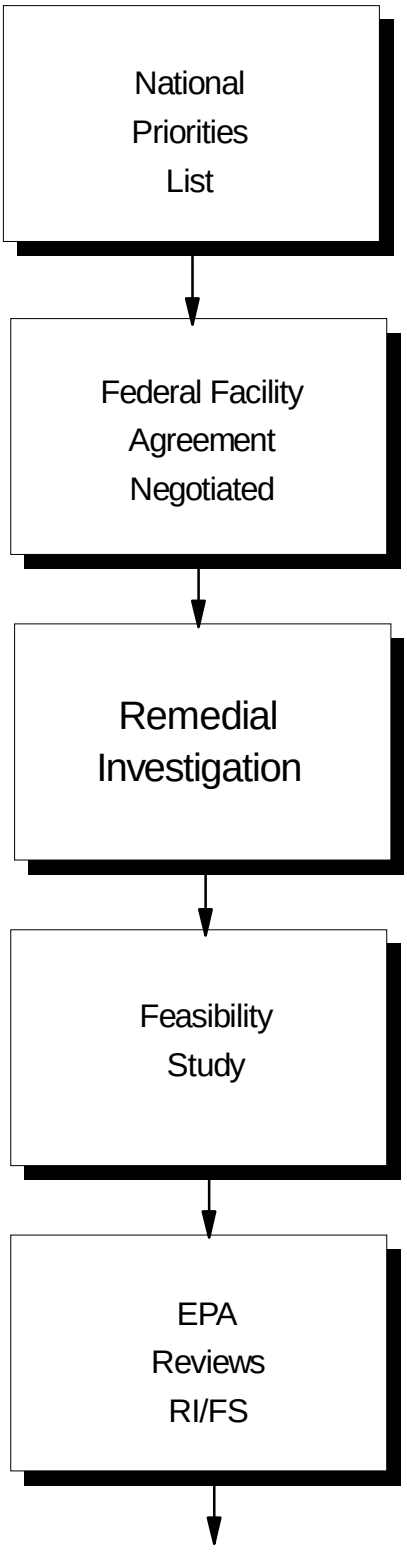
Facilities judged by EPA to present serious risks to human health and the environment are placed on this list.

EPA's policy is to sign a Federal facility agreement (FFA) before the Remedial Investigation/Feasibility Study (RI/FS) stage.

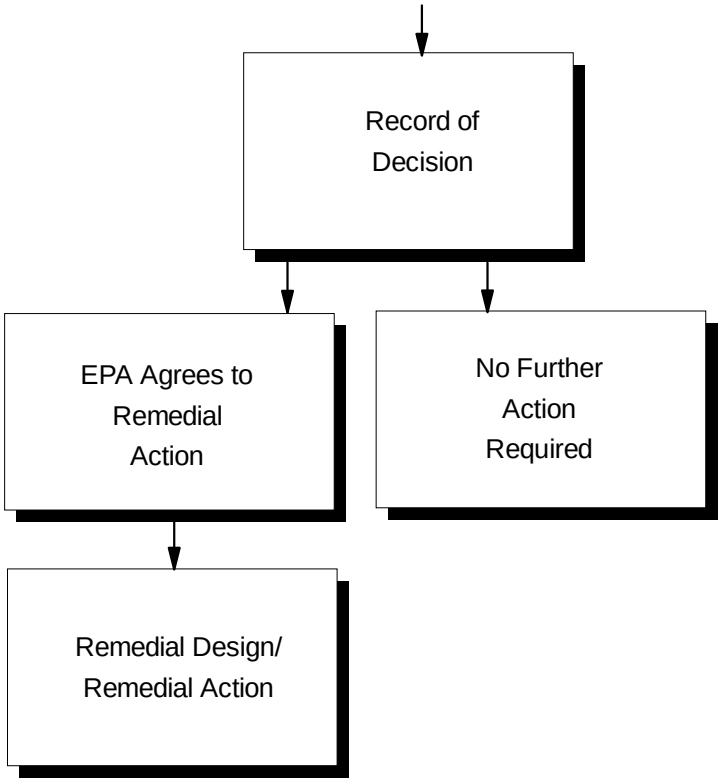
The responsible agency uses sampling and other analytical activities to determine the nature, extent, and significance of the contamination.

The responsible agency conducts feasibility studies to evaluate cleanup alternatives for the sites to determine which would provide the protection required.

EPA is required to review the RI/FS and enter into an FFA with the federal agency, if not already done.



The responsible Federal agency selects a cleanup method and, in the record of decision, documents the analysis that led to the selection.



Detailed design plans are chosen and the cleanup option is implemented by the responsible agency.

APPENDIX D

Data Quality Problems

Installation	Causes
March Air Force Base	Region 9's Request for Suspension of Eureka Laboratories dated November 1993 identified: *"Fraudulent under-reporting of tetrachloroethene concentration....Fraudulent reporting that method tuning criteria were met....Fraudulent reporting that initial calibration criteria were met....Fraudulent reporting that continuing calibration criteria were met....Fraudulent reporting that surrogate recovery criteria were met....Removing 'M Flags' from the paper trail....Pervasive unwarranted manipulation of calibration and sample quality control data."*
Hunters Point Naval Shipyard	The Executive Summary for Rejected Laboratory Data for CTO 0057, Hunters Point Annex RI/FS stated: *"However, full validation process identified gross methodology errors such as improper calibration procedures, improper procedures in violation of CLP, and numerous other laboratory QA problems. In addition, the full data packages were incomplete."*
Fernald Environmental Management Project	According to the U.S. Department of Energy's Office of Inspector General Report on Fernald Environmental Management Project Remedial Investigation and Feasibility Study (DOE/IG-0326) dated April 1993: "*Samples had been assigned duplicate identification numbers....The laboratory did not analyze some samples within EPA prescribed time limits, it lost other samples, and it questioned the integrity of the sample data.*"
Rocky Mountain Arsenal	According to Rocky Mountain Arsenal's report on their audit of Eureka Laboratories on August 12 and 13, 1993: *"The laboratory had obviously manipulated the instrument output, which immediately brings all GC/MS data output under question....A summary letter says that dilutions are to be made based on conductivity, but no conductivity measurements were found in the data package....There was not evidence of an initial calibration in data package....Several samples in this lot had numbers entered on the analyst worksheet that were incorrectly reported in the transfer file."*
Luke Air Force Base	According to Region 9's Memorandum of August 4, 1995, Subject: Confirmation of Manipulated Data at Luke Air Force Base: *"Manipulations of calibrations and surrogate recoveries for the semivolatile analyses were documented."*

Installation	Causes
Travis Air Force Base	According to an Air Force Center for Environmental Excellence contractor's report dated August 23, 1993: *"Weston's QA system for identifying out-of-control analytical data was in place but failed to prevent the reporting of such data for Travis Air Force Base....The specified calibration acceptance procedures were not being used....The required number of surrogates was not being used to QC samples for organic methods....Matrix spikes were not being used to control accuracy for organic methods....Laboratory-established control limits were not being used to QC the methods."*
Sacramento Army Depot	Region 9's data validation for the Burn Pits Operable Unit found that the sample results for volatile organic compounds were rejected due to serious deficiencies (defect in sampling technique) in the ability to analyze the sample and meet quality criteria. Region 9's data validation for the Groundwater Operable Unit found missing holding times and unacceptable calibrations impacting numerous compound analyses.
Fort Wainwright	The contractor's data validation reports said that pesticide peaks were not consistent and there were potential false positives and negatives.

APPENDIX E

Definitions of Quality Assurance Activities

Computerized Data Validation

Computerized data validation is a relatively new quality assurance measure that is more efficient than traditional manual data validation. EPA has developed two automated data validation programs: Computer-Aided Data Review and Evaluation (CADRE) and e-Data.

Data Validation

Data validation is a method for ensuring laboratory data is of known quality. It involves reviewing data against a set of criteria to provide assurance that data is adequate for its intended use.

EPA has data validation guidelines, known as national functional guidelines, for its own contract lab program. According to EPA guidelines, data validation includes a review of documentation such as raw data, instrument printouts, chain of custody records, and instrument calibration logs.

Laboratory Audits

Laboratory audits are on-site audits designed to identify technical areas which may cause laboratories to improperly identify or quantitate chemicals. Audits normally evaluate a laboratory's technical expertise, standard operating procedures, facility and equipment sufficiency, and possible sources of sample contamination.

On-site audits are frequently viewed as a unique opportunity to evaluate the laboratory in-person. They are useful in providing insight into the laboratory's capabilities to perform specific analysis. It is often beneficial to perform an on-site audit when the laboratory is being considered for work for which it does not have performance history with the Federal facility or department.

Magnetic Tape Audits

Audits of magnetic media are used to detect manual changes in the electronic copy of the raw data and inconsistencies between the electronic copy and paper copy. These audits are done in conjunction with data audits to reconstruct an analytical run.

Electronic data, often in the form of magnetic tapes, are an output of laboratory analyses. By obtaining magnetic tapes (or other electronic data) from a laboratory, audits can be conducted to help determine:

- If the laboratory is complying with its contract;

- The integrity of the laboratory's computer systems; and,
- The appropriateness of any software editing.

Electronic tape audits are usually limited to GC/MS data that are generated by systems that are capable of taping. Tape audits are not currently available for inorganic data or radio nuclides.

Performance Evaluation Samples

Performance evaluation (PE) samples are prepared by "spiking" a known concentration of chemicals into a contaminate-free media, such as water or soil. PE samples can be administered by two methods: "blind" or "double-blind." When a PE sample is blind, the laboratory is aware the sample is a PE, but does not know the chemical concentration levels.

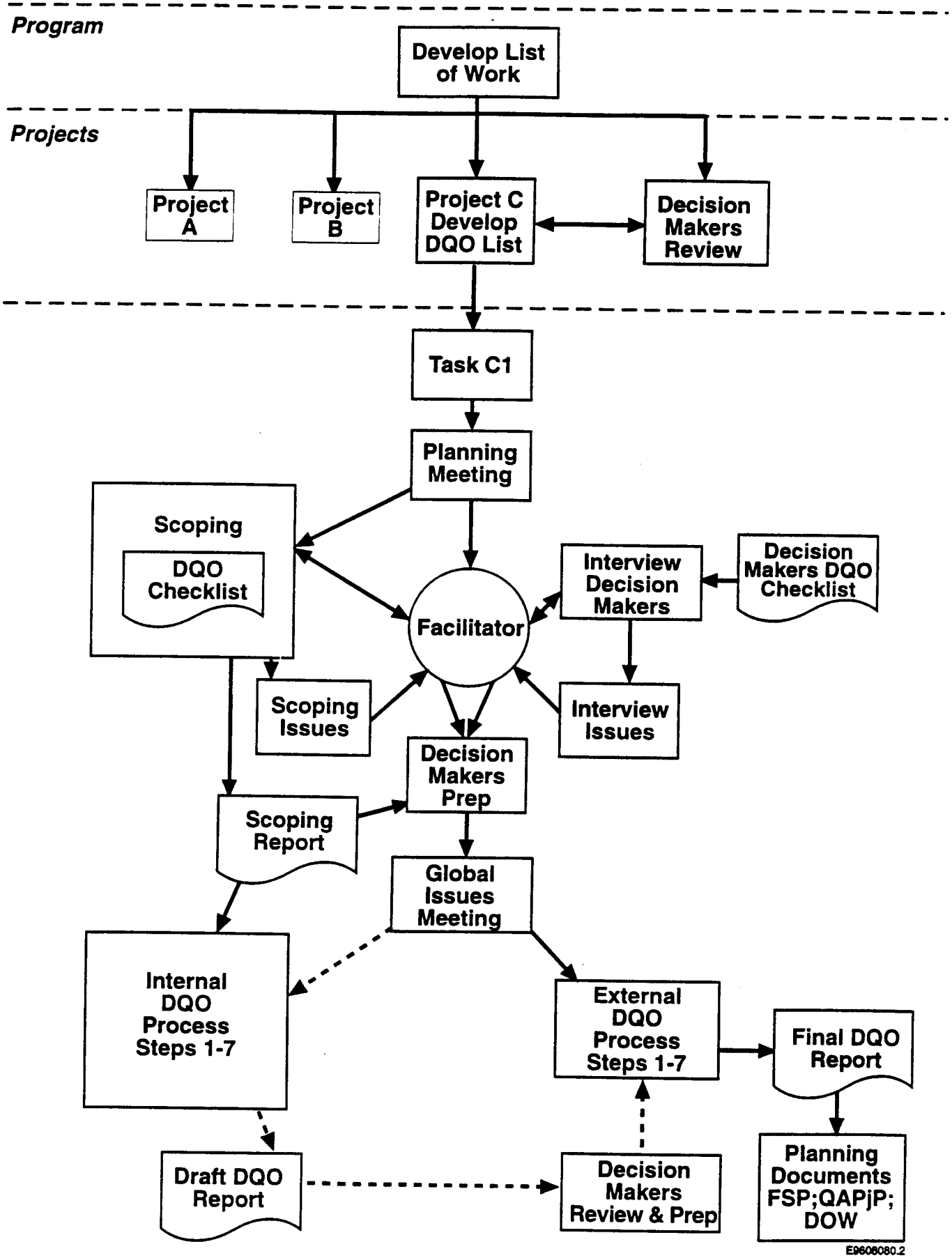
When a sample is double-blind, the PE sample is submitted as part of a field sample shipment, so that the laboratory is not only unaware of the concentration levels, it is also unaware that the sample is a PE. A laboratory's analysis of PE samples is used to evaluate its ability to produce accurate results.

APPENDIX F

Planning Procedure for Defining Data Quality Objectives

The following chart was prepared by Hanford Nuclear Reservation's environmental restoration contractor (ERC), Bechtel Hanford, Inc.

Bechtel Hanford's DQO Process


Program
Develop List of Work
Projects
Project A
Project B
Project C Develop DQO List
Decision Makers Review
Task C1
Planning Meeting
Scoping
DQO Checklist
Facilitator
Interview Decision Makers
Decision Makers DQO Checklist
Scoping Issues
Interview Issues
Decision Makers Prep
Scoping Report
Global Issues Meeting
Internal DQO Process Steps 1-7
External DQO Process Steps 1-7
Final DQO Report
Draft DQO Report
Decision Makers Review & Prep
Planning Documents FSP;QAPjP; DOW
E9606080.2

APPENDIX G

Example of Travis Air Force Base's Quality Assurance Report

Summary of Performance Evaluation Samples

Analysis	Labor-atory	Analysis Date	Problems Noted	Comments	Project Impact
SW8260 Volatiles by GC/MS (water)	RAS	May 1994	All volatile organic compounds were correctly identified. Of 19 PE analytes, only o-xylene and m,p-xylenes were outside the QAPP (LCS) and PE vendor acceptance criteria	No analytical anomalies found. A second PE sample was submitted	Sufficient data quality for all analytes. O-xylene was correctly identified and quantitated during second PE sample analysis.
			Six analytes were detected above the detection limit, but below the MRL which were false positives: acetone, 2-butanone, chloroform, chloromethane, d-ibromoethane, and 1,1-dichloroethene.	The majority of these low level detections were qualified as nondetects during data evaluations due to low-level blank contamination.	No impact.
SW8260	RAS	August 1994	All 19 PE analytes were correctly identified and all except benzene met QAPP and PE vendor QC criteria.	No analytical anomalies found.	Sufficient data quality. Benzene was in control in 2 other PE sample analyses.

Source: North Operable Unit RI Report, Travis Air Force Base, February 1995

The quality assurance report is discussed on page 16 of this report.

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APPENDIX H

Activities Contacted During the Audit

Activity	Location
Environmental Protection Agency, Headquarters	
! Office of Solid Waste and Emergency Response, Federal Facilities Restoration and Reuse Office	Washington, DC
! Office of Research and Development, National Center for Environmental Research and Quality Assurance	Washington, DC
! Office of Enforcement and Compliance Assurance Federal Facilities Enforcement Office	Washington, DC
Environmental Protection Agency	
! Region 8	Denver, CO
! Region 9	San Francisco, CA
! Region 10	Seattle, WA
Department of Defense	
! Office of the Assistant Deputy Under Secretary of Defense (Environmental Cleanup)	Washington, DC
! Office of Inspector General	Alexandria, VA
! Tri-Service Chemical Quality Assurance Work Group	Omaha, NE
! U.S. Army Corps of Engineers' Hazardous, Toxic, and Radioactive Waste Center	Omaha, NE
! U.S. Army Corps of Engineers, Alaska District	Anchorage, AK
! Air Force Center for Environmental Excellence	San Antonio, TX
! Naval Facilities Engineering Service Center	Port Hueneme, CA
! Concord Naval Weapons Station	Concord, CA
! Fort Wainwright	Fairbanks, AK
! Hunters Point Naval Shipyard	San Francisco, CA
! Luke Air Force Base	Glendale, AZ
! March Air Force Base	Riverside, CA
! Rocky Mountain Arsenal	Commerce City, CO
! Sacramento Army Depot	Sacramento, CA
! Tooele Army Depot	Tooele, UT
! Travis Air Force Base	Fairfield, CA

Activity	Location
! Air Force Audit Agency	Washington, DC March AFB
! Army Audit Agency	Alexandria, VA
Department of Energy ! Office of Inspector General	Germantown, MD
! Hanford Nuclear Reservation	Richland, WA
Interagency Steering Committee for Quality Assurance for Environmental Measurements	Los Alamos, NM

APPENDIX I

Report Distribution

Distribution	Individual or Activity
Office of Inspector General	! Acting Inspector General (2410)
EPA Headquarters	! Assistant Administrator for Administration and Resources Management (3101) ! Director, Office of Research Program Management (8102) ! Acting Associate Administrator for Regional Operations and State/Local Relations (1501) ! Associate Administrator for Congressional and Legislative Affairs (1301) ! Associate Administrator for Communication, Education, and Public Affairs (1701) ! Headquarters Library (3401) ! Director, Federal Facilities Restoration and Reuse and Office (5101) ! Director, Federal Facilities Enforcement Office (2261A) ! Director, National Center for Environmental Research and Quality Assurance (8201) ! Agency Followup Official, Attn: Director, Resource Management Division (3304)
Regional Offices	! Regional Administrators, Regions 1 through 10
External	! General Accounting Office ! DOD Inspector General ! DOE Inspector General

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