



**Office of Inspector General
Audit Report**

SUPERFUND

**EPA Had Not Effectively Implemented
Its Superfund Quality Assurance Program**

Report No. E1SKF7-08-0011-8100240

September 30, 1998

Inspector General Division
Conducting the Audit:

Central Audit Division
Denver, Colorado

Inspector General Divisions
Contributing to the Audit:

Western Audit Division
San Francisco, California

Mid-Atlantic Division
Philadelphia, Pennsylvania

Program Offices Involved:

Office of Research and Development

Office of Solid Waste and Emergency
Response

Regional Offices Involved:

Regions 1 - 10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 30, 1998

OFFICE OF
THE INSPECTOR GENERAL

MEMORANDUM

SUBJECT: EPA Had Not Effectively Implemented
Its Superfund Quality Assurance Program
Audit Report No. E1SKF7-08-0011-8100240

FROM: Michael Simmons /s/ *Michael Simmons*
Deputy Assistant Inspector General
for Internal Audits

TO: Henry Longest
Acting Assistant Administrator
for Research and Development

Timothy Fields
Acting Assistant Administrator
for Solid Waste and Emergency Response

Attached is our final report on issues that impact the Agencywide quality assurance program and Superfund environmental data collection activities. The report includes recommendations to the Assistant Administrators for Research and Development and for Solid Waste and Emergency Response.

Action Required

In accordance with EPA Order 2750, the primary action official is required to provide us with a written response to the audit report within 90 days of the final audit report date. Since this report deals primarily with the management of the quality assurance program, we designated the Assistant Administrator for Research and Development as the primary action official. As such, the primary action official should take the lead in coordinating the Agency's official response so that the 90-day timeframe is met. For corrective actions planned but not completed by the response date, reference to specific milestone dates will assist in deciding whether to close this report.

We have no objections to the further release of this report to the public. This audit report contains findings that describe problems the Office of Inspector General (OIG) has identified and corrective actions OIG recommends. This audit report represents the opinion of OIG and the findings contained in this audit report do not necessarily represent the final EPA position. Final determinations on matters in this audit report will be made by EPA managers in accordance with established EPA audit resolution procedures.

In this particular audit, OIG did not measure the audited offices' performance against

the standards established by the National Contingency Plan (NCP). The findings contained in this audit report are not binding in any enforcement proceeding brought by EPA or the Department of Justice under section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to recover costs incurred not inconsistent with the NCP.

If your staff have any questions, please have them contact Jeff Hart, Audit Manager in our Denver Office, at 303-312-6169, or Bill Samuel, Audit Liaison, at 202-260-3189. Please refer to report number E1SKF7-08-0011-8100240 on any correspondence.

Attachment

EXECUTIVE SUMMARY

INTRODUCTION

U. S. Environmental Protection Agency (EPA) managers are required to make important decisions on complex issues that have significant environmental, social, health, and economic impacts and consequences. To support these decisions, EPA must collect data to gain a better scientific understanding of the environmental issues being addressed. Although the collection of the data is necessary and in many cases required by law, it is expensive. Each year EPA and the regulated community spend about 5 billion dollars collecting environmental data. The EPA quality assurance program was intended to help EPA organizations conduct their data collection operations more efficiently and cost effectively by incorporating scientific and systematic planning into the process.

To date, Superfund is the only EPA program for which we have completed quality assurance audits. Because our audit work showed that Superfund weaknesses resulted from how the EPA quality assurance program was implemented in the regions, we anticipate that similar weaknesses in other EPA program offices may exist. Accordingly, we expanded our work to review implementation of some comprehensive aspects of the Agencywide quality assurance program in order to make recommendations to improve potential data weaknesses in other programs.

OBJECTIVES

Our overall purpose was to determine if EPA had developed and implemented a quality assurance program to ensure that environmental data used to support decision making in the Superfund program was of sufficient quality to satisfy the intended purpose. Our specific objectives were:

- Has EPA effectively developed and implemented its mandatory Agencywide quality assurance program to obtain quality data from Superfund field sampling?
- Is EPA appropriately implementing its policy

to develop data quality objectives to support Superfund decision making?

- Is EPA's oversight of Superfund field sampling adequate to ensure data of known and adequate quality?
- Has EPA developed an effective quality assurance training program?

RESULTS IN BRIEF

EPA's Quality Assurance Division and the Superfund program had developed many critical elements necessary for a strong and effective quality assurance program. However, EPA managers had not demonstrated their commitment to a cohesive, centrally-managed, mandatory Agencywide program by fully developing and effectively implementing the program to obtain Superfund and other data of known and adequate quality. Because EPA needs scientifically sound environmental data to achieve its overall mission and effectively implement its strategic plan, EPA required a consistent and effective quality assurance program for all programs, including Superfund. However, the program was not as successful as it could have been because senior EPA managers in the Offices of Research and Development and Solid Waste and Emergency Response and in the regions had not always fully supported the Agencywide program by establishing and implementing minimum project planning, oversight, and training requirements; providing necessary tools and resources; and asserting their authority to fully implement the program. Without an effective Agencywide program, EPA could not fulfill its mission which includes ensuring environmental data of known and adequate quality.

RECOMMENDATIONS

We recommend the Acting Assistant Administrator for Research and Development design a strategy to institutionalize the quality assurance program; place EPA's top quality assurance manager at an organizational level where that individual can be an effective and independent advocate; improve oversight, including improved management assessments, to ensure the program is

effectively implemented; develop minimum quality assurance requirements; and report annually on Agencywide program effectiveness.

We recommend the Acting Assistant Administrator for Solid Waste and Emergency Response require Office of Emergency and Remedial Response quality assurance staff to continue performing regional management and technical assessments to ensure that the data quality objectives policy is being adequately implemented in the Superfund program to improve project planning, provide Superfund staff with sufficient tools to implement EPA's data quality objectives policy, place the Superfund quality assurance manager at an organizational level where that individual can be an effective and independent advocate, and implement EPA guidance on quality assurance training.

**AGENCY COMMENTS
AND
OIG EVALUATION**

With a few exceptions, EPA generally agreed with our findings and recommendations. EPA offered comments to clarify some issues and recommendations, and we have modified our report as appropriate. We summarize EPA comments at the end of each chapter highlighting those significant issues on which we and EPA disagreed. We also include the full text of the comments as Appendices I and II.

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ABBREVIATIONS

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency
OERR	Office of Emergency and Remedial Response
OIG	Office of Inspector General
ORD	Office of Research and Development
Order	EPA Order 5360.1 entitled <i>Policy and Program Requirements to Implement the Mandatory Quality Assurance Program</i> , dated April 1984
OSWER	Office of Solid Waste and Emergency Response
QAD	Quality Assurance Division

CHAPTER 1

INTRODUCTION

PURPOSE

U. S. Environmental Protection Agency (EPA) managers are required to make important decisions on complex issues that have significant environmental, social, health, and economic impacts and consequences. To support these decisions, EPA must collect data to gain a better scientific understanding of the environmental issues being addressed. Although the collection of the data is necessary and in many cases required by law, it is expensive. Each year, EPA and the regulated community spend about 5 billion dollars collecting environmental data. The EPA quality assurance program was intended to help EPA organizations conduct their data collection operations more efficiently and cost effectively by incorporating scientific and systematic planning into the process.

Our overall purpose was to determine if EPA had developed and implemented a quality assurance program to ensure that environmental data used to support decision making in the Superfund program was of sufficient quality to satisfy the intended purpose. Our specific objectives were:

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- Is EPA appropriately implementing its policy to develop data quality objectives to support Superfund decision making?
- Is EPA's oversight of Superfund field sampling adequate to ensure data of known and adequate quality?
- Has EPA developed an effective quality assurance training program?

To date, Superfund is the only EPA program for which we have completed quality assurance audits. Because our audit work showed that Superfund weaknesses resulted

from how the EPA quality assurance program was implemented in the regions, we anticipate that similar weaknesses in other EPA program offices may exist. Accordingly, we expanded our work to review implementation of some comprehensive aspects of the Agencywide program in order to make recommendations to improve potential data weaknesses in other programs.

BACKGROUND

EPA Quality Assurance
Program

In May 1979, the EPA Administrator recognized the importance of environmental data quality by issuing a policy statement intended to establish a centrally-managed, mandatory Agencywide quality assurance program. The goal of the program was to produce environmental data that was "...scientifically valid, defensible, and of known precision and accuracy...." This policy was to apply to EPA and to non-EPA organizations performing work on behalf of EPA through extramural agreements. The Assistant Administrator for Research and Development was delegated primary responsibility for "...developing the national quality assurance program and directing and coordinating its implementation...." Program offices and regional offices were also responsible for program implementation. The policy recognized two primary requisites for implementation of the program. First, the program required direct attention by top managers for Agencywide implementation; and second, the program needed sufficient resources and authority to support the national program effort. The Office of Research and Development (ORD) was to report annually to the Administrator on the program progress and efficacy.

Superfund Quality
Assurance Program

In April 1984, EPA Order 5360.1 (Order), entitled *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*, was issued to guide implementation of the policy. The stated goal of the program was to "...ensure that all environmentally related measurements supported by the EPA produce data of known quality...." EPA defined data of known quality as

data that was thoroughly documented, verifiable, and defensible. The Order established ORD's Quality Assurance Division (QAD) to serve as the "central management authority" for this program. Specifically, QAD is responsible for developing and ensuring the Agencywide program is effectively implemented.

In July 1998, EPA issued a revised Order 5360.1 CHG 1 that superseded the 1984 Order. Attached to the July 1998 Order is the *EPA Quality Manual* that contains mandatory requirements for implementing the new Order. Although we based our audit on the 1984 Order, we also have made some references to the 1998 Order.

All EPA organizations governed by the Order are required to document their quality systems in quality management plans. This plan is a policy statement describing how an EPA organization will comply with the requirements in the Order.

EPA stated in its 1997 strategic plan that it "...will continue to implement its mandatory Quality Assurance Program" to ensure high quality environmental data. The plan identified one of its purposes as ensuring that, "National efforts to reduce environmental risk are based on the best available scientific information." The plan recognized that in the past, significant concerns had been expressed about the adequacy of EPA's ability to assess risk, and that improvements were needed. The plan indicated a need for guidance "...leading to more defensible environmental decisions."

EPA developed a "data quality objectives" process as its systematic planning tool to help ensure it consistently collected the type and quality of data needed to support technical decisions. The data quality objectives process is based on the scientific method and thus contributes to EPA's goal of sound science. EPA requires site-specific project plans to include a data quality objectives section to document the project's defined goal and planning outputs.

The Comprehensive Environmental Response,
Compensation, and Liability Act of 1980 (CERCLA)

established the Superfund program to respond to releases or the threat of releases of oil and hazardous substances which threatened public health or the environment. CERCLA was revised and expanded by the Superfund Amendments and Reauthorization Act of 1986. Section 105 of both acts required revision and republication of the National Contingency Plan to reflect the responsibilities and powers created by the Superfund acts. The National Contingency Plan established procedures and standards for responding to the threat or actual release of oil or hazardous substances.

The National Contingency Plan regulates the Superfund Removal and Remedial Program through Part 300 of 40 Code of Federal Regulations (CFR). Sections 300.415, 300.420 and 300.430 require sampling and analysis plans that provide a process for obtaining environmental data of sufficient quality and quantity to support decision making. EPA must review and approve sampling and analysis plans at most Superfund sites. Sampling and analysis plans consist of: (1) a field sampling plan, and (2) a quality assurance project plan. A field sampling plan describes the number, type, and location of samples and the type of analysis required. The quality assurance project plan describes policy, organization, and functional activities necessary to develop adequate data. The data is used for planning and documenting removal or remedial activities. EPA staff often use the terms “sampling and analysis plan,” “field sampling plan,” and “quality assurance project plan” interchangeably. Throughout this report, we have used the term “project plan” to refer to all these types of plans.

The Superfund quality assurance program is the joint responsibility of the Office of Solid Waste and Emergency Response (OSWER), the Office of Emergency and Remedial Response (OERR), and the regions. OERR is the national program manager responsible for managing the Superfund program in accordance with CERCLA. OERR’s October 1996 approved quality management plan states that, “Both OERR and Regional offices are responsible for reviewing and evaluating Superfund QA [quality assurance] activities.” OERR and regions are responsible for tailoring principal elements of the

Agencywide program to the Superfund program.

OERR's quality management plan documents its quality assurance program for Superfund environmental data collection activities and outlines the program's policies, requirements, organizational responsibilities, and functional structure. Specifically, the plan stated that the OERR quality assurance program goals would be "...achieved through proper planning, organization, review, communication of objectives, auditing, reporting, and corrective action."

SCOPE AND METHODOLOGY

We conducted seven regional audits in Regions 3, 8, 9, and 10 that examined some aspect of Superfund field sampling quality assurance. We also reviewed quality management plans and management assessments for all 10 regions that described and evaluated regional quality assurance programs. As a result of Superfund quality assurance problems that had national implications, we expanded our audit to examine the framework of the quality assurance program and its implementation in regional Superfund offices. Therefore, we conducted work at ORD's QAD and OSWER's OERR. We also supplemented our previous regional audit work using results from a questionnaire sent to all regional quality assurance managers. We conducted our work between April 1997 and July 1998. We performed our audit in accordance with *Government Auditing Standards* (1994 Revision) issued by the Comptroller General of the United States.

See Exhibit 1 for methodology details. See Exhibit 2 for prior audit coverage.

CHAPTER 2

A CONSISTENTLY IMPLEMENTED QUALITY ASSURANCE PROGRAM WOULD STRENGTHEN SUPERFUND ENVIRONMENTAL DATA

EPA had not institutionalized a cohesive, centrally-managed, mandatory Agencywide quality assurance program that was consistently implemented. Although QAD had developed many critical elements necessary for an effective program, it had not fully developed and implemented the program or reported on the program's effectiveness. The Order makes QAD responsible for developing requirements and overseeing implementation of EPA's centrally-managed, mandatory program. However, senior ORD managers had not asserted their authority by requiring all EPA organizations to comply with specific, minimum requirements. As a result, EPA did not have a fully effective Agencywide program, and EPA senior managers did not consistently ensure that data collected in support of Superfund decisions and perhaps other programs was of known and adequate quality.

EPA HAS ADEQUATE AUTHORITY TO PUT IN PLACE A STRONG PROGRAM

ORD's Assistant Administrator has authority to establish, direct, and coordinate a centrally-managed Agencywide quality assurance program. EPA's 1979 policy statement and 1984 Order clearly established the intent to develop and implement a centrally-managed Agencywide program that would promote national consistency in data quality. The July 1998 Order remains consistent with the 1984 Order regarding a centrally-managed, mandatory Agencywide program. The July 1998 Order states, "The Quality Assurance Division (QAD) is designated by the AA [Assistant Administrator]/ORD to serve as the central management authority for this [quality assurance] program."

40 CFR Part 1 describes EPA’s organization and provides general quality assurance information. 40 CFR Part 1, Subpart B, Section 1.45 authorizes ORD, as the headquarters program office, to put in place necessary tools for EPA organizations to implement a strong quality assurance program. 40 CFR Part 1, Subpart A, Section 1.5 describes EPA’s organization and responsibilities. EPA’s “...basic organization consists of Headquarters and 10 Regional Offices.” Headquarters maintains overall planning, coordination, and control of EPA programs, while regions are responsible for executing the programs. EPA has about 40 internal organizations in addition to states, tribes, and other agencies that must comply with EPA’s quality assurance program requirements.

**ORD HAD NOT
INSTITUTIONALIZED
ITS PROGRAM**

ORD had not institutionalized its program by ensuring QAD had a strategic plan that addressed EPA’s sound science program goal and objectives, and by providing adequate staff and resources at a level of authority and visibility to effectively develop and implement the program.

**EPA Lacked A Documented
Quality Assurance Strategic
Plan**

EPA lacked a quality assurance strategic plan describing the program’s mission and goals. Such a plan would serve as a needed framework for quality assurance planning and resource allocation decisions. Because EPA relies on environmental data to make decisions that impact human health and the environment, EPA’s September 1997 Strategic Plan recognized the need for a mandatory Agencywide quality assurance program. However, ORD’s overall strategic plan did not fully identify Agencywide program goals. Also, although QAD is tasked with developing and implementing the Agencywide program, it did not have its own specific strategic plan that identified Agencywide program goals. The QAD Director agreed that QAD would benefit from developing a strategic plan, but competing priorities prevented preparing one. Also, ORD did not require QAD to develop Government Performance and Results Act goals, objectives, and sub-objectives because QAD’s budget did not meet ORD’s dollar threshold for requiring such performance measures.

A QAD strategic plan would provide all quality assurance managers and program staff the direction necessary to implement a cohesive Agencywide program. The plan would establish the national strategies for achieving quality assurance goals and objectives in the future. QAD should also identify the resources needed to accomplish QAD's performance goals and measures used to assess whether the goals are met. Without a plan, QAD could not determine the adequacy of its resources.

Staffing Levels Did Not
Demonstrate Program
Commitment

Regional staff perceived that EPA senior managers were not committed to the quality assurance program because senior managers had not provided QAD adequate resources to fully develop and assess the effectiveness of the program. Regional staff also perceived that ORD senior managers had not ensured the program was appropriately staffed to fulfill its responsibilities including developing and issuing policy and guidance documents, developing generic quality assurance training materials, and conducting and issuing timely management assessments.

The results of a questionnaire we sent to all regional quality assurance managers showed that staff perceived that QAD lacked senior management support and national leadership in quality assurance due to what regional staff perceived was a low level of resources invested in the program. The QAD Director stated that staff resources have been strained as a result of QAD being given additional tasks. As of March 1998, the proposed QAD staffing plan included 20 staff positions of which 17 were filled to conduct work in the areas of: (1) quality assurance, (2) peer review, and (3) the National Environmental Laboratory Accreditation Program. However, without a workload model or divisional strategic plan, we were unable to assess the adequacy of QAD's resources to accomplish its goals.

The QAD Director stated that lack of adequate resources prevented QAD from developing and timely issuing adequate guidance to establish an effective program. In response to our questionnaire, four regional quality assurance managers responded that guidance documents had been untimely and some were still draft. For example, although QAD's training guidance document QA/G-10, *Quality Assurance Training for Environmental Data*

Operations, was a critical component of the program, it was in draft form in 1996 and still not finalized in September 1998.

QAD's training program and management assessment program suffered when staff were reassigned from quality assurance activities to peer review activities. In February 1997, at the request of the Deputy Administrator, QAD staff conducted an evaluation of "the implementation of the Agency's peer review policy." The peer review evaluation occurred at the same time that the QAD staff were trying to prepare for QAD's National Quality Assurance Training that was held in August 1997. As a result, some QAD staff were not properly prepared for their presentations at the training conference and did not clearly communicate quality assurance concepts, principles, and requirements.

Organizational Placement Did
Not Demonstrate
Program Commitment

ORD senior managers had not demonstrated their commitment to the quality assurance program by ensuring that QAD was organizationally located at an appropriate level to timely and effectively accomplish its responsibilities. The July 1998 Order states that all quality assurance managers should function "independently" and "...report[s]...to the senior manager having executive leadership authority for the organization...." A July 1998 EPA Science Advisory Board report agreed that "quality assurance managers are most effective when they report to the highest career professional in an organization...". Although QAD is responsible for developing and implementing an Agencywide program, QAD reports to a manager one level below the ORD Assistant Administrator. In our opinion, QAD may not be organizationally located within the reporting chain at the proper level to accomplish its goals.

Regional EPA quality assurance staff had the perception that quality assurance importance was diminished because QAD and regional quality assurance program offices were inappropriately located and staffed within their respective organizations. In response to our questionnaire, some regional quality assurance managers stated that QAD and their regional offices were located within organizations with little visibility or apparent authority. Regional quality assurance managers further commented that QAD was not

perceived to have any real authority to direct a centrally-managed program and could be ignored. Regional quality assurance staff perceived the program lacked support for adequate resources because it was not a media program with an independent source of funding. For example, QAD's management assessments reported that in 7 of 10 regions, the quality assurance managers experienced difficulty in negotiating and securing adequate resources for the program from the media program offices.

In our opinion, QAD was unable to ensure the revised July 1998 Order and manual were issued promptly because QAD was not placed at an organizational level high enough to ensure timely comments and issuance. For example, QAD began circulating the revised Order and *EPA Quality Manual* in mid-1995 for all quality assurance managers' and other top EPA managers' review, but QAD was unable to obtain final management comments and complete revisions until mid-1997. QAD did not obtain final approvals for these documents until late July 1998.

**QAD DEVELOPED MANY
CRITICAL ELEMENTS
OF AN EFFECTIVE
PROGRAM**

Despite competing priorities and organizational barriers, QAD developed many critical elements necessary for a strong and effective quality assurance program. QAD developed and: (1) continually worked to improve its preferred systematic planning approach, namely the data quality objectives process; (2) issued many of its planned requirements and guidance documents; and (3) disseminated training modules and provided training assistance.

Since 1984 when EPA first introduced the requirement for data quality objectives, QAD has worked diligently to develop and improve its preferred 7-step data quality objectives process. The process is a systematic planning approach to developing data quality objectives for project managers to determine the type, quantity, and quality of data needed to support EPA decisions. QAD has continued evolving the process at the request of EPA project managers who wanted a more user-friendly process.

In addition to the July 1998 Order and manual, QAD has developed and issued other policy and guidance documents necessary to implement a strong and effective quality assurance program. As of April 1998, QAD developed 17 requirements and guidance documents to address program needs. Requirements documents are designed for the non-EPA community that is subject to EPA's quality assurance program through appropriate extramural regulations. QAD developed three requirements documents but issued none in final form. Guidance documents are supplemental documents describing suggested methods for implementing the requirements for both EPA and non-EPA organizations. QAD developed 14 guidance documents and issued 6 in final form.

QAD developed and disseminated extensive quality assurance training materials. The training modules consisted of briefing slides but did not include speaker notes. QAD is in the process of developing speaker notes to further assist training presenters. QAD had also fully developed six training courses. For its March 1998 national training held in Denver, Colorado, QAD developed a comprehensive project planning course that walked trainees through the data quality objectives process. In response to our questionnaire, regional quality assurance managers commented that QAD had been responsive to their requests for training assistance.

EPA corrected the fiscal 1992 material weakness regarding environmental data quality in fiscal 1997 primarily by ensuring adequately documented organizational quality management plans existed in each EPA organization, developing model generic quality assurance performance standards for managers, and issuing a revised quality assurance Order and manual. However, as discussed below, QAD must take additional actions to establish a fully effective program. In addition, as discussed in Chapters 3, 4, and 5, substantive implementation problems remain in the regions and perhaps in other EPA organizations.

**EPA'S PROGRAM HAD
NOT PROVEN FULLY
EFFECTIVE**

QAD had not adequately specified minimum EPA quality assurance program requirements or effectively overseen program implementation to ensure that EPA had a cohesive, mandatory Agencywide program. In addition, QAD did not annually report to the Administrator on the "progress and efficacy" in implementing the Agencywide program as required by EPA policy.

**QAD Did Not Adequately
Specify Minimum
Requirements**

Though tasked with developing and assessing the effectiveness of the Agencywide quality assurance program, QAD had not adequately specified minimum program requirements and had allowed individual EPA organizations too much flexibility in implementing the program. Developing a sound foundation for a strong program includes both developing the overall program framework and specifying certain minimum requirements. QAD referred to its requirements as guidance. We found that some regional Superfund program offices did not effectively implement QAD's guidance partly because many elements were not required. (Specific Superfund examples follow in Chapters 3, 4, and 5). The QAD Director stated that the July 1998 Order and manual should improve program effectiveness in the future because these new documents clearly state the program requirements. We agree that the new documents now require much of what had been optional.

QAD had not required minimum quality assurance elements be followed by EPA organizations. For example, although QAD spent over 10 years improving and refining its 7-step data quality objectives process, it did not require and had not persuaded all EPA organizations to use this preferred process as intended. QAD's 7-step process is flexible and provides a systematic planning approach that would benefit EPA organizations if used as intended. Also, QAD had not required EPA organizations to list the minimum training courses required for each EPA employee to ensure a basic quality assurance understanding. Because the quality management plan is a planning and management tool, listing minimum training courses would provide managers a gauge with which to measure minimum required quality assurance skills. To their credit, some regional offices took the initiative and listed specific training courses as required in their regional plans.

QAD may have unintentionally obscured its requirements regarding data quality objectives in its July 1998 revision of the Order. Data quality objectives, not to be confused with the “data quality objectives process” which has always been optional, have been mandatory since 1984. In a May 1984 memorandum with attachment, the Deputy Administrator required under the EPA Order that data quality objectives be a “necessary element” in data collection project plans. However, EPA’s revised July 1998 Order made no mention of data quality objectives or of EPA’s preferred data quality objectives process. The QAD Director explained that QAD chose to replace the term “data quality objectives” in the Order with “acceptance or performance criteria” to avoid confusion between mandatory objectives and the optional objectives process.

Although QAD had authority to make the data quality objectives process mandatory for all programs, both the initial and July 1998 Orders were silent about data quality objectives. Both Orders delegated all authority for overseeing and ensuring implementation of an Agencywide quality assurance program to the ORD Assistant Administrator and the QAD Director. In commenting on a draft of the new Order, we suggested in a January 12, 1998, memorandum to the EPA Central Directives Officer, Organization and Management Consulting Services, that the Agency mandate use of the data quality objectives process and specify the process requirements in the new Order. QAD agreed that all environmental measurements and data collection must be based on a systematic planning approach that provides sound, clearly-defined criteria and objectives so that the usability of the data can be determined. Although QAD stated that data quality objectives (referred to as “acceptance or performance criteria” in the July 1998 Order) are needed for EPA data collection activities, the Director explained that QAD chose not to make the objectives process mandatory for all EPA programs because some steps in the process did not apply to all EPA programs. Instead, the July 1998 Order allows programs the flexibility of using any “systematic planning approach” to develop data quality objectives as long as the process meets certain criteria.

Although the objectives process is mandatory in the Superfund program, we found, as discussed in Chapter 3, that Superfund staff generally did not follow the process or a comparable planning process. We have serious concerns that allowing more freedom of decision in a process that has never been clearly understood or implemented is a serious step backward for ensuring consistent collection of quality data in EPA programs.

QAD Did Not Effectively
Oversee Program
Implementation

QAD had not effectively fulfilled some quality assurance oversight responsibilities. QAD's quality assurance responsibilities included approving EPA organizations' quality management plans, conducting and documenting management assessments to confirm compliance with the plans, and tracking corrective actions. However, QAD approved quality management plans that did not require specific training courses or use of the data quality objectives process or alternative systematic planning process with defined criteria. QAD also approved a quality management plan that showed quality assurance staff reporting directly to a manager responsible for data collection activities (a potential conflict of interest) and, in five cases, geographically separated from the regional program staff. Geographic separation would make it difficult for quality assurance staff to timely review project plans or provide other technical assistance. In response to our questionnaire, regional quality assurance managers stated that they perceived that geographic separation de-emphasized the importance of quality assurance. Although QAD staff performed management assessments, QAD staff had not confirmed that organizations were using data quality objectives, an important performance aspect of the quality assurance program. QAD acknowledged and regional quality assurance managers were concerned that QAD's final management assessment reports were untimely. Regional quality assurance managers also stated that they perceived QAD's untimely management assessment reports as further evidence that quality assurance was not really important. QAD staff stated that they had not tracked management assessment corrective actions.

QAD's organizational management assessments, conducted during fiscal 1994-1997, identified concerns, but QAD did not always use the information to effectively oversee the

Agencywide implementation of the quality assurance program. QAD reported findings in its management assessments under two categories. QAD reported some findings as “sufficiently significant” that required corrective action and other findings as “minor” which did not require corrective action. Major findings QAD identified included inadequate training, weak state programs, limited resources, non-compliance with quality management plans, no systematic planning, and inadequate regional quality assurance assessments. QAD’s management assessments found all these major weaknesses were evident in two regions. In our opinion, the two regions did not have adequate programs and QAD should have recommended the regions report their programs as weaknesses under the Federal Managers’ Financial Integrity Act process. All 10 regions had at least one of these major weaknesses identified in their programs. Regional quality assurance programs appear even less acceptable considering collectively QAD’s sufficiently significant and minor findings.

QAD Had Not Reported On The Program’s Effectiveness

Although QAD performed management assessments of EPA organizations, it had not summarized the results of its work to report on the effectiveness of the program’s Agencywide implementation in accordance with a January 1979 policy statement. The policy required “...annual, or more frequent, reports to the Administrator on the program progress and efficacy.” The QAD Director explained that while QAD had not separately reported to the Administrator on the overall effectiveness of the program, QAD had reported program implementation weaknesses to EPA’s senior leadership council through the Federal Managers’ Financial Integrity Act reporting process. However, except for the fiscal 1996 report, these reports did not meet the annual reporting requirement discussed above or include a summary of the results of QAD’s organizational management assessments. QAD conducted individual EPA organizational management assessments and reported its findings to the respective organizations. Had QAD summarized its findings, it would have reported to the Administrator that in 9 of 10 regions, staff did not understand basic quality assurance policy, practices, and procedures. Although the QAD Director stated that annual reporting to the Administrator is no longer required, we could find no evidence that EPA had rescinded the 1979

policy. Furthermore, we believe the 1979 policy remains appropriate and necessary.

QAD had at least two reporting means available. QAD could have: (1) summarized and reported on the collective results of its individual management assessments each time it completed a review cycle, and (2) used some of the results reported by EPA organizations in their Quality Assurance Annual Report and Work Plan reports. The QAD Director explained that EPA organizations' annual reports were generally incomplete and not comparable until 1996 or 1997. However, ORD used such a collective reporting approach before in December 1992 to report environmental data quality as a material weakness.

**ORD SHOULD ASSERT
ITS AUTHORITY TO
PROMOTE
CONSISTENCY**

ORD senior managers had not asserted their authority and supported QAD to require all EPA organizations to comply with specific quality assurance requirements. Although 40 CFR and the EPA Order authorized ORD to establish, direct, and coordinate the Agencywide program, it appeared that ORD managers chose not to assert their authority and have QAD impose requirements on EPA organizations, particularly EPA regions. EPA has about 40 internal organizations in addition to states, tribes, and others. Each of the organizations was developing and implementing potentially separate programs because QAD had not clearly established minimum Agencywide requirements necessary to institutionalize a cohesive quality assurance program. Program managers could not be held accountable for minimum performance requirements because QAD had not established firm program requirements or clearly identified QAD expectations for organizations' quality management plans.

The QAD Director stated that whether QAD had a fully developed Agencywide quality assurance program or not, EPA's accountability systems are such that QAD did not have the authority to make other organizations implement the program requirements. In our opinion, the Agency

cannot have an effective program unless ORD and QAD assert their authority and establish clear quality assurance requirements.

ORD acknowledged that during the period when the new Order and manual were being developed and in draft form (i.e., from May 1995 to July 1998), some EPA organizations were using these new documents, some were using documents from the 1980s, and others were using a combination of both. This led to many variations in program implementation, which ORD hopes have been eliminated by the July 1998 issuance of the final new Order and manual.

CONCLUSION

QAD has worked diligently and made considerable progress in developing an effective Agencywide quality assurance program. However, without fully developed quality assurance requirements, EPA must assess potentially separate quality assurance programs and cannot hold managers accountable to implement a consistent, effective program. QAD reported in its management assessments that significant and widespread problems existed because each EPA organization interpreted the program requirements differently. However, QAD had not asserted its authority to require greater consistency and improvements where problems existed.

RECOMMENDATIONS

We recommend that the Acting Assistant Administrator for Research and Development:

- 2-1. Develop a strategy to communicate and a timetable to implement the requirements in the July 1998 Order and *EPA Quality Assurance Manual* throughout the Agency.
- 2-2. Work collaboratively with EPA organizations to oversee and ensure consistent implementation of a cohesive, mandatory Agencywide quality assurance program.

- 2-3. To further institutionalize EPA's quality assurance program, require QAD to develop a strategic plan and annual performance plans including appropriate outcome-based performance measures and the level of resources needed.
- 2-4. Place EPA's top quality assurance manager, who is responsible for the Agencywide quality assurance program, at an organizational level where that individual can: (1) be an effective and independent advocate, as specified by the July 1998 Order; and (2) improve oversight, including improved management assessments, to ensure the program is effectively implemented
- 2-5. Recommend to each regional administrator and national program manager that they review the most recent QAD and regional quality assurance management assessments for their unit conducted by QAD, national program managers, and regional quality assurance groups to determine whether the regional administrator or national program manager should identify quality assurance implementation as a weakness in their unit as part of the Federal Managers Financial Integrity Act process.
- 2-6. Issue a memorandum to clarify that "acceptance or performance criteria" ,as referred to in the July 1998 Order, were formerly known and referred to as "data quality objectives."
- 2-7. Establish and implement a method of ensuring adherence to minimum criteria for an adequate systematic planning process.
- 2-8. Establish and implement minimum training requirements or specific courses for staff in all EPA programs implementing or

overseeing implementation of data quality assurance activities.

- 2-9. Enhance oversight conducted by QAD by:
- a. Not approving EPA organizations' quality management plans which do not include enough specifics to ensure a sound quality program.
 - b. Verifying that EPA organizations are actually using the data quality objectives process or an adequate alternative systematic planning process to identify environmental data needs.
 - c. Preparing and issuing timely management assessment reports.
 - d. Tracking organizations' implementation of corrective actions identified in management assessment reports.
- 2-10. To elevate the visibility of quality assurance progress in support of the Agency's stated goal of sound science, prepare an annual report to the Administrator on the "progress and efficacy" in implementing the Agencywide quality assurance program.

**AGENCY COMMENTS
AND OIG EVALUATION**

EPA generally agreed with our findings and recommendations. EPA offered comments to clarify some issues and recommendations, and we have modified our report as appropriate. We highlighted below those significant issues on which we and EPA disagreed. We also included the full text of the comments as Appendices I and II.

ORD stated that while QAD centrally manages ORD's Agencywide quality assurance responsibilities, QAD is not

responsible for centrally managing the Agency's quality assurance program. We find this statement confusing and contradictory. We agree ORD/QAD should not be expected to implement the program on a day-to-day basis. However, we strongly believe that EPA policy statements beginning in 1979 and continuing through the July 1998 Order clearly demonstrate that ORD is responsible for developing and implementing a single, centrally-managed program. By "implementing," we mean that we believe ORD and QAD clearly have the authority to establish and should establish firm, mandatory, minimum Agencywide requirements including but not limited to requiring certain planning processes and specific training courses for certain staff. ORD and QAD can and should ensure requirements are implemented by a variety of methods including but not limited to the tracking and reporting of non-compliance to appropriate management officials.

ORD disagreed that QAD was not placed at the appropriate level within ORD. ORD stated that QAD staff have "Access to senior ORD officials...whenever there is a need to work with senior level managers in other organizations." We believe that the July 1998 Order clearly requires that the senior EPA quality assurance manager (currently designated as the Director, QAD) report directly to either the EPA Assistant Administrator for Research and Development, or possibly the EPA Administrator. The July 1998 EPA Science Advisory Board reached a similar conclusion.

CHAPTER 3

DEVELOPING PROJECT SPECIFIC DATA QUALITY OBJECTIVES WOULD IMPROVE SUPERFUND PLANNING AND DECISION MAKING

Senior EPA managers had not consistently implemented EPA's policy to develop project specific data quality objectives for Superfund environmental data collection activities. EPA policy and the Superfund National Contingency Plan required EPA to develop data quality objectives for data collection activities. The policy was only minimally successful in the Superfund program because QAD and OERR managers and regional administrators had not provided staff sufficient direction or tools to implement EPA's data quality objectives policy. Without the consistent use of a systematic planning process with clear criteria, such as EPA's 7-step data quality objectives process, EPA cannot ensure that staff planning adequately and appropriately defined the Superfund data type and quality needed.

EPA REQUIRED CONFIRMED DATA QUALITY OBJECTIVES

An EPA policy memorandum governing the Agencywide quality assurance program required project specific data quality objectives and management assessments to confirm their use. In May 1984, 1- month after the Order was finalized, an EPA policy memorandum specifically required national program managers to develop data quality objectives for data collection activities effective September 1984. The policy stated, "Data quality objectives are descriptors of the quality of data needed to support a specific environmental decision or action." The policy specifically required QAD to perform management assessments to ensure that program offices had established and were using data quality objectives. OERR also required its quality assurance manager to conduct management assessments to ensure compliance with the policy.

Although EPA's July 1998 Order does not make specific reference to the term "data quality objectives," the

Superfund National Contingency Plan still requires Superfund project plans to include data quality objectives. Specifically, the National Contingency Plan, in Parts 300.415, 300.420, and 300.430, required that project plans describe the "...policy, organization, and functional activities and the data quality objectives and measures necessary..." to achieve the intended purpose of each Superfund data collection activity.

Both QAD and OERR issued guidance on a data quality objectives process to facilitate decision making. In September 1994, QAD finalized EPA QA/G-4, *Guidance for the Data Quality Objectives Process*. The guidance outlined a 7-step data quality objectives process emphasizing "...a strategic planning approach based on the Scientific Method..." OERR's Superfund data quality objectives guidance followed the same presentation as the QAD data quality objectives process and promoted use of the 7-step process as described below:

DATA QUALITY OBJECTIVES PROCESS	
1	State the problem.
2	Identify the decision.
3	Identify inputs to the decision.
4	Define the study boundaries.
5	Develop a decision rule.
6	Specify limits on decision errors.
7	Optimize the design for obtaining data.

QAD, OERR, and regional administrators have overall responsibility to ensure data quality objectives are included in project plans for environmental data collection activities.

**MANAGERS HAD NOT
CONSISTENTLY
IMPLEMENTED
EPA'S DATA QUALITY
OBJECTIVES POLICY**

Senior EPA managers had not consistently implemented EPA's policy to develop data quality objectives for all Superfund environmental data collection activities. Office of Inspector General (OIG) and other evaluations showed that EPA's Superfund program had not fully developed and

implemented project specific data quality objectives as an integral part of a Superfund site's planning process. Although QAD, OERR, and regional administrators had overall responsibility to ensure such objectives were the foundation of environmental data collection activities, none had ensured through management assessments that the objectives were adequate to achieve a project's intended purpose. The QAD Director told us QAD had never intended to conduct technical assessments of projects' specific data quality objectives.

Evaluations Disclosed Data
Quality Objectives
Policy Was Not Fully
Implemented

Although EPA policy required project specific data quality objectives since 1984, OIG audits and evaluations showed that the Superfund program had not fully implemented the policy. We evaluated 61 project plans and found that 48 (79 percent) showed the objectives had not been developed or had not been adequately documented in the project plans. Two regions had QAD-approved quality management plans that did not require data quality objectives as the foundation of environmental data collection activities. Lead agency staff at one federal facility site stated that they believed EPA staff overseeing the site discouraged use of the data quality objectives which hampered the lead agency's efforts to develop objectives.

A September 1988 National Academy of Sciences multi-year study of EPA's quality assurance program identified data quality objectives concerns that we confirmed have continued after approximately 10 years. The National Academy of Sciences report endorsed EPA's accelerated institutionalism of the data quality objectives process and recommended "...holding management accountable for key portions of the QA [quality assurance] program." The report criticized that EPA was taking longer than was reasonable to effectively implement data quality objectives.

QAD, OERR, And Regional
Administrators Had Not
Identified Data Quality
Objectives Were Lacking

Although QAD, OERR, and regional administrators had overall responsibility to ensure data quality objectives were the foundation of environmental data collection activities, none ensured through management assessments that project specific data quality objectives were adequate to achieve a project's intended purpose. The QAD director stated that QAD performed management assessments to confirm regional compliance with regional quality management plans

and not for specific performance criteria, such as data quality objectives. The QAD director stated that evaluations of performance were the responsibility of the program office. OERR had competing priorities and had not invested adequate resources to conduct management assessments that would evaluate project specific data quality objectives. QAD's management assessments reported that 6 of 10 regions had not performed regional management assessments of regional program performance. (Recommendations regarding management assessments can be found in Chapters 2 and 4.)

**MANAGERS HAD NOT
PROVIDED ADEQUATE
DATA QUALITY
OBJECTIVES
DIRECTION OR TOOLS**

Managers Had Not Provided
Adequate Direction

Senior Superfund managers had not provided staff sufficient direction or tools to develop project specific data quality objectives. Superfund managers had not clearly communicated the importance and necessity of data quality objectives or the data quality objectives process as a planning tool for environmental data collection activities, or stressed their requirement. Superfund managers had also not emphasized or made available the necessary tools to promote data quality objectives, such as training and interactive software packages.

Senior Superfund managers had not clearly communicated the importance and necessity of data quality objectives or the data quality objectives process as a planning tool for environmental data collection activities. OIG audits showed that some regional project managers did not spend the time and resources necessary to properly plan their Superfund projects. For example, OIG reported in Region 9 that for the 5 removal actions reviewed, none had used the required 7-step data quality objectives process to design project plans. Also, Region 9 analyzed about 420 samples for one removal action that were not used to make the decision indicated in the project plan--the suitability of leachate for discharge. Another OIG report showed that at a California Superfund site managed by a responsible party, EPA spent over \$2 million in oversight costs and the responsible party spent over \$100 million on studies and cleanup. However, the project plan showed that the potentially responsible party had not developed adequate data quality objectives during its planning process.

As an example of the deficiencies, we noted the data quality objectives for one Superfund site plan clearly stated a need to conduct a sampling study. However, the objectives did not identify the point at which enough information would be collected and a decision could be made. Appropriate objectives for this project should include statements of the problem (i.e., the project/task objectives); specific inputs needed; a decision statement (i.e., a point at which remedial action should be taken); risks associated with the decision, if the critical sample results were too close to the action level; and an optimal design.

When Superfund managers advocate quality assurance expertise be used, project managers benefit from the outcomes of a collaborative approach. For example, Region 4 staff stated the regional approach to developing data quality objectives worked well for them because Region 4 required that the appropriate staff (including the quality assurance experts) be involved up front during a project's planning stage and that all project plans be reviewed by the regional quality assurance experts. Because of the thorough review process using a mixed team of appropriate staff, Region 4 quality assurance staff stated that the Region's data quality objectives were well documented in project plans and adequate for the intended purpose.

Superfund managers had not stressed that data quality objectives were required and that the EPA 7-step process was OERR's adopted approach. Although senior Superfund managers promoted EPA's recommended process as the most effective way to obtain data of known quality, some managers did not require its use or clearly define an alternate process. OERR's data quality objectives guidance followed the recommended process and considered it a practical approach. The guidance also allowed flexibility using a "graded approach" that considered the decisions to be made and the amount of confidence needed. Some project managers stated they considered the EPA 7-step data quality objectives process to be rigid, complex, burdensome, and onerous and were unaware of the flexibility available in the process.

Managers Had Not Provided
Adequate Tools

EPA managers had not emphasized or made available the necessary tools to promote data quality objectives such as

training, technical assistance including statisticians, interactive software packages, and any other regionally-developed tools. OIG audits showed that Superfund staff did not have a good understanding of data quality objectives and needed better training. In response to an OIG questionnaire, three regional quality assurance managers stated that their regions had not provided training. OIG audits showed that some project managers' perceptions were that quality assurance technical assistance was not always readily available or constructive. Only 2 of 10 regions had statisticians available to assist Superfund project managers in developing objectives. However, headquarters Superfund quality assurance staff told us that statistical expertise is available through Superfund contracts. Although EPA developed interactive software to assist project managers in developing data quality objectives, it had not widely distributed the software package with accompanying guidance. Also, at least one region developed its own comprehensive standard operating procedures and quality assurance manual that could assist other regions but had not widely shared its accomplishments.

In response to data quality objectives training evaluations received after its August 1997 training conference, QAD changed its training format and made the training more interactive. In August 1997, QAD presented quality assurance training in sessions using a modular format. A March 1998 QAD conference provided three courses: Implementing Data Quality Objectives, Quality Assurance Project Plans, and Data Quality Assessment. The training was interactive and had participants develop data quality objectives, document the objectives in the project plans, and assess the validity of the data. The training used software developed by QAD and its contractor and known as the Data Quality Objectives Decision Error Feasibility Trials software. Although the software and related guidance had been available since September 1994, EPA had not widely distributed the software or advocated its use to Superfund project managers.

With senior managers' support, Region 4's quality assurance experts developed a May 1996 Standard Operating Procedures and Quality Assurance Manual that included sections on data quality objectives and sampling designs and

techniques. Although Region 4 staff had access to the regional procedures, the majority of the other regions were unaware of Region 4's guidance.

CONCLUSION

Without consistently developing data quality objectives using a systematic planning process with clear criteria, such as EPA's 7-step process, EPA cannot ensure that staff planning adequately and appropriately defined the data type and quality needed to support Superfund decision making. Although EPA had developed an effective data quality objectives process, Superfund staff were poorly equipped to use the process. Consequently, Superfund cleanup decisions had been made which might have been approached differently had senior Superfund managers and staff strongly advocated the available process and tools.

RECOMMENDATIONS

We recommend:

The Acting Assistant Administrator for Research and Development:

- 3-1. Develop a strategy to encourage Agencywide use of EPA's 7-step data quality objectives process as EPA's recommended systematic planning process as stated in the July 1998 *EPA Quality Manual*.

The Acting Assistant Administrator for Solid Waste and Emergency Response:

- 3-2. In concert with QAD, develop and implement a plan to institutionalize the Superfund program's data quality objectives process.
- 3-3. Advocate the benefits of developing data quality objectives using an across-organization team approach.

- 3-4. Provide Superfund staff with sufficient tools to implement EPA's data quality objectives policy in the Superfund program by:
 - a. Making data quality objectives training more effective by integrating available quality assurance courses to provide a comprehensive understanding of data quality objectives.
 - b. Making automated tools (such as the Data Quality Objectives Decision Error Feasibility Trials software or other interactive modeling software) available to appropriate staff and encouraging use through training and examples of success.
 - c. Increasing awareness as to what expertise is available to provide staff technical assistance in areas such as statistics either through realignment of regional resources or contractor support.
 - d. Sharing regionally-developed tools, procedures, best practices, and successes with QAD and with headquarters and regional Superfund staff.
- 3-5. Recommend to each regional administrator that they review the most recent QAD, OERR, and regional quality assurance management assessment results for their unit to determine whether the regional administrator should identify quality assurance implementation as a weakness in their unit as part of the Federal Managers Financial Integrity Act process.

**AGENCY COMMENTS
AND OIG EVALUATION**

EPA generally agreed with our findings and recommendations. EPA offered comments to clarify some issues and recommendations, and we have modified our report as appropriate. We highlighted below those significant issues on which we and EPA disagreed. We also included the full text of the comments as Appendices I and II.

OSWER stated that OERR had distributed some data quality objectives direction and tools such as guidance and software. However, we concluded that these actions were insufficient to ensure program success.

OSWER stated that we had overstated the impact of the Superfund program's lack of data quality objectives direction and tools, and recommended that we add some qualifiers. We disagreed and we clarified in our report that our audit work covered all 10 regions. We believe our audit results are representative of all 10 regions and accurately reflect the condition of the quality assurance program throughout the Superfund program

CHAPTER 4

INCREASED EPA OVERSIGHT WOULD STRENGTHEN SUPERFUND QUALITY ASSURANCE EFFECTIVENESS

Top OERR and regional managers had not uniformly ensured staff adequately performed Superfund quality assurance oversight to ensure environmental data was of known and adequate quality. The Order assigns specific oversight responsibilities to national program managers and regional administrators. Senior Superfund managers had not adequately or consistently demonstrated their commitment to Superfund quality assurance oversight activities. Without appropriate oversight of data collection activities, EPA could not ensure data collected at Superfund sites was of sufficient quality to support decision making.

OVERSIGHT IS REQUIRED FOR AN EFFECTIVE SUPERFUND QUALITY ASSURANCE PROGRAM

The Order assigns responsibilities to national program managers and regional administrators to ensure an appropriate level of oversight to establish an effective Superfund quality assurance program. Specific oversight responsibilities require that they ensure: (1) all projects requiring environmental data collection are covered by an acceptable, approved quality assurance project plan and that the plan is implemented; (2) adequate management assessments are performed to determine compliance with quality assurance requirements; and (3) quality assurance is an identifiable activity with resources adequate to accomplish program goals.

The Superfund National Contingency Plan at CFR Part 300.415, 300.420, and 300.430 requires oversight activities by requiring that EPA review and approve sampling and analysis plans prior to conducting data collection activities.

**SENIOR SUPERFUND
MANAGERS HAD NOT
CONSISTENTLY
IDENTIFIED
OVERSIGHT
WEAKNESSES**

OERR and regional administrators had not adequately or consistently identified quality assurance oversight weaknesses or acted on weaknesses identified by others. OERR had not performed adequate oversight by conducting management assessments that would ensure national consistency in how the Superfund quality assurance program was implemented. OERR had also not used the results of QAD management assessments to confirm weaknesses were corrected and to prepare for its own management assessments. Finally, regional administrators had not ensured weaknesses identified by regional staff, QAD, and OIG were corrected.

OERR Had Not Adequately
Fulfilled Its Quality
Assurance Oversight
Responsibilities

The OERR quality assurance manager served as the focal point for developing Superfund quality assurance policies and guidance and conducting regional Superfund quality assurance management assessments. One objective for conducting management assessments of regional Superfund data collection activities was to ensure consistency in how the regions performed quality assurance oversight responsibilities.

OERR had not adequately fulfilled its oversight responsibilities to conduct timely management assessments of the 10 EPA regions' Superfund program offices. In fiscal 1995, OERR conducted management assessments in all 10 regional Superfund emergency removal programs. Time-critical removals have minimal quality assurance requirements up-front. However, OERR had not diligently conducted management assessments in its Superfund remedial cleanup program. These cleanups are more long-term and non-time critical in nature and have important quality assurance requirements.

Although OERR's quality assurance manager had participated on two joint remedial management assessments in 1995 with QAD, he had not conducted any OERR-initiated remedial assessments until April 1998. OERR's quality assurance manager prepared an internal workplan to assess all 10 regions during fiscal 1998. However, competing priorities caused him to delay his assessments by several months. In April 1998, the quality assurance manager completed the first of the planned regional management assessments in Region 5.

Completed management assessments would identify whether Superfund staff were performing their work in accordance with quality assurance requirements. Although the Superfund program required the development of data quality objectives, OIG reports showed that 79 percent of regional project plans we reviewed did not include adequately documented data quality objectives or had no data quality objectives at all. QAD management assessments also showed that regional Superfund staff did not ensure that states, tribes, and other external organizations had followed EPA quality assurance requirements. EPA oversight of external organizations is especially important because the Superfund program relies heavily on secondary data from these organizations. Had OERR conducted its planned management assessments earlier, it could have identified inconsistencies in how regions implemented the Superfund quality assurance program and sought corrective action.

Headquarters Superfund staff told us that OSWER will address quality assurance implementation weaknesses through the Field and Analytical Services Teaming Advisory Committee established in March 1998.

OERR Had Not Acted On
QAD Identified
Quality Assurance
Weaknesses

OERR had not used the results of past QAD management assessments to help meet its objective to ensure consistency in how the regions performed quality assurance oversight responsibilities. Although QAD's assessments addressed overall regional weaknesses, OERR could have followed up to identify those weaknesses that specifically affected Superfund environmental data collection activities. QAD reported that six regions had not performed adequate oversight. For example, QAD heavily criticized EPA regional oversight of state and tribal programs. Some regions had not, until recently, required states and tribes to submit quality management plans and had not consistently performed oversight of state and tribal quality assurance performance. Because OERR had not aggregated Superfund weaknesses, it did not improve or promote a consistently implemented Superfund quality assurance program.

Regional Administrators
Had Not Ensured All
Previously
Identified Oversight
Weaknesses Were Corrected

Regional administrators had not ensured all weaknesses identified by regional quality assurance managers, QAD, and OIG were corrected. Weaknesses identified by regional staff in their Superfund management assessments were not corrected and continued to affect program operations, despite having corrective action plans in place to address the weaknesses. For example, the Region 8 quality assurance manager performed a Superfund management assessment simultaneously with an OIG fiscal 1995 Region 8 audit of Superfund field sampling activities. Both reports showed incomplete training and inadequate oversight practices. OIG completed a 1998 followup audit of these same issues and found problems continued, despite a corrective action plan to address both the regional quality assurance manager's and OIG's findings. An OIG Region 9 report showed that Region 9 did not adequately oversee a site being cleaned up by a responsible party. The project manager did not approve the most recent project plan and did not ensure that the potentially responsible party complied with important conditions in the project plan and in the guiding consent decree.

**SUPERFUND
MANAGERS HAD NOT
DEMONSTRATED
QUALITY ASSURANCE
OVERSIGHT
COMMITMENT**

Headquarters Superfund quality assurance staff agreed that senior managers had not demonstrated their commitment to quality assurance oversight by providing necessary guidance and authority to perform an adequate level of oversight of Superfund quality assurance activities. OERR and regional administrators had not ensured sufficient guidance was available and ensured quality assurance managers were appropriately located within their respective organizations to effect needed changes.

OERR and Regions Lacked
National or Regional
Guidance Describing
Oversight Responsibilities

Although OERR is the national program office tasked with developing national guidance, it had not issued specific oversight guidance or procedures. The OERR quality assurance manager planned to use the results of completed management assessments to develop guidance. However, because he had not yet completed the management assessments, he had not determined weaknesses in

oversight activities that guidance would address. We found that little actual guidance existed to require or guide the project managers in their oversight role.

OIG audits showed that Superfund project managers were unaware of regional oversight guidance that would help them fulfill their quality assurance requirements. For example, although Region 8 developed an oversight policy memorandum as a corrective action to a 1995 OIG report, the 1998 OIG followup audit showed that some project managers still had not followed the policy and some project managers did not recall having seen the policy.

Organizational Location Of
Quality Assurance
Managers Undermined Their
Authority

OERR senior managers had not emphasized quality assurance importance and provided adequate resources and flexibility for the OERR quality assurance manager to conduct necessary management assessments. The July 1998 Order states that each EPA organization with environmental data or environmental technology responsibilities must have:

A quality assurance manager (QAM), or person assigned to an equivalent position, who functions independently of direct environmental data generation, model development, or technology development responsibility; who reports on quality issues to the senior manager having executive leadership authority for the organization; and who has sufficient technical and management expertise and authority to conduct independent oversight of and assure the implementation of the organization's quality system in the environmental programs of the organizations.

We interpret this statement to mean that the quality assurance manager must be organizationally located outside EPA operational units (e.g., Centers or Divisions) that have responsibility for environmental data collection and must have direct reporting authority to the senior management in charge of overall program operation.

The OERR quality assurance manager's quality assurance responsibilities compete with other responsibilities

outlined in his performance agreement. He is a staff member in 1 of 14 headquarters Superfund organizational units (i.e., “process centers”) reporting to the manager of his unit. His responsibilities are not limited to quality assurance as his workload includes many competing management priorities. As the OERR quality assurance manager, if he had unresolved concerns, the OERR quality management plan stated that he could access the OERR Director “...through the normal chain-of-command, but formal direct access outside the chain-of-command is available if needed.” In our opinion, each quality assurance manager needs open, uninhibited, direct communication lines to their respective senior managers. Otherwise, senior managers risk sending the message to other Superfund staff that Superfund quality assurance is not important. Headquarters Superfund quality assurance staff agreed that the quality assurance function should be completely independent of any line organization and at a level at least equal to those managers responsible for operations.

The OERR quality assurance manager cannot ensure consistency in the Superfund program if the position is not perceived by regional Superfund offices as having adequate authority and is not at a level high enough to effect needed changes. OERR reviewed draft proposals about where to place various office functions prior to its reorganization in October 1995. We reviewed one draft proposal that suggested the OERR quality assurance function become a separate OERR process center reporting directly to the OERR Director. On the surface, the draft proposal seemed to be a viable approach that would have emphasized the significance of the Superfund quality assurance program and goals. We did not see other evidence to explain why this language was eliminated. We also found that the approach may address some Superfund authority concerns about quality assurance importance.

Regional quality management plans showed that quality assurance managers and staff were not appropriately located within their respective regions to accomplish their quality assurance objectives. In one region, the quality assurance staff reported to a manager directly responsible

for data collection activities--a clear conflict of interest. While in five regions, quality assurance managers were located in the regional laboratories and not in the regional offices, making oversight difficult. One of these laboratories was located over 200 miles from the regional office which may have strained communication and undermined the quality assurance program's authority over functions located in the regional office.

CONCLUSION

Without adequate headquarters oversight, OERR could not ensure the Superfund quality assurance program met its objectives for a consistently implemented program with sufficient guidance. Without documented and appropriate oversight of data collection activities, regions could not ensure data collected at Superfund sites was of known quality and sufficient for project-specific decision making. Because the Superfund program has often been criticized and subjected to litigation, it cannot afford to rely on data that it had not ensured was of known and adequate quality. EPA must perform adequate and effective oversight or risk making inaccurate decisions that could affect human health and the environment.

RECOMMENDATIONS

We recommend:

The Acting Assistant Administrator for Solid Waste and Emergency Response:

- 4-1. Develop a plan with a realistic cycle for OERR staff to perform management and technical assessments in the regions. Include in the plan the staffing resources necessary to carry out the plan. Invite regional Superfund and quality assurance managers to participate as members of OERR's assessment team.
- 4-2. Continue conducting joint management assessments with QAD and obtain QAD regional management assessment results to

ensure that regional Superfund staff satisfactorily perform their quality assurance activities.

- 4-3. Work with regional Superfund and quality assurance staff to develop adequate oversight procedures to ensure data is of sufficient quality to support decision making.
- 4-4. Develop an OSWER strategy to ensure corrective actions in response to OIG audits and EPA management assessments are fully implemented.
- 4-5. Develop guidance to effectively implement the Superfund quality assurance program including specific quality assurance responsibilities for regional project managers.
- 4-6. Place the Superfund quality assurance manager and staff at an organizational level where they can be an effective and independent advocate for the program.
- 4-7. Clearly and formally delegate quality assurance program authority to the headquarters Superfund quality assurance manager.

The Acting Assistant Administrator for Research and Development:

- 4-8. Coordinate management assessments with the national program managers to ensure that regional staff satisfactorily perform their quality assurance activities. At a minimum, provide regional management assessment results to the appropriate national program managers and their respective quality assurance managers.

- 4-9. Address the placement of regional quality assurance managers in management assessments to encourage regional administrators to place their quality assurance managers at an organizational level where they can be an effective and independent advocate for the program.

**AGENCY COMMENTS
AND OIG EVALUATION**

EPA generally agreed with our findings and recommendations. EPA offered comments to clarify some issues and recommendations, and we have modified our report as appropriate. We highlighted below those significant issues on which we and EPA disagreed. We also included the full text of the comments as Appendices I and II.

OSWER stated that we had over-generalized in several cases and recommended that we add some qualifiers. We have included qualifiers where appropriate, and we clarified in our report that our audit work covered all 10 regions. We believe our audit results are representative of all 10 regions and accurately reflect the condition of the quality assurance program throughout the Superfund program.

OSWER disagreed that its Superfund quality assurance manager was not placed at the appropriate level within OSWER. Although OSWER stated its quality assurance manager “has direct access to” top OERR management, the quality assurance manager does not report directly to the OERR Director or Deputy Director. Furthermore, the quality assurance manager is in a unit with environmental data responsibilities.

OSWER also stated its Analytical Operations/Data Quality Center could continue to provide independent technical assessments because “. . . the Analytical Operations/Data Quality Center (AOC) was designed to include oversight and implementation of quality assurance activities for both CLP [Contract Laboratory Program] and non-CLP data.” However, the Analytical Operations/Data Quality Center is responsible for

analyzing environmental data. We believe that the organizational placement of the senior Superfund quality assurance manager in a unit with environmental data collection, analysis, or oversight responsibilities is a conflict of interest. The July 1998 Order clearly intends for the quality assurance manager position to be independent of organizations responsible for environmental data collection activities, as well as having direct access to top management.

CHAPTER 5

EFFECTIVE TRAINING WOULD PROVIDE A BETTER FOUNDATION FOR THE SUPERFUND QUALITY ASSURANCE PROGRAM

OERR and regional administrators had not fully identified Superfund-specific quality assurance training needs and provided necessary training. EPA Order 5360.1 requires national program managers and regional administrators to identify and provide training to ensure staff directly involved in data collection activities have an adequate understanding of quality assurance. Senior Superfund managers were not held accountable for fulfilling training requirements and had not demonstrated their commitment to training. Without assessing staff skills and fully identifying training needs, EPA could not develop an effective quality assurance training program to provide the skills necessary to ensure that data collected in support of Superfund decision making was of known and adequate quality.

EPA REQUIRES QUALITY ASSURANCE TRAINING

Two major EPA authorities require quality assurance training. The Order requires national program managers and regional administrators to identify program-specific quality assurance training needs and to provide this training. The Order specifically requires training "...for all levels of QA [quality assurance] management, to assure that QA responsibilities and requirements are understood at every stage of project implementation." Also, the Superfund National Contingency Plan, Section 300.120 (g) (1), requires lead agencies to ensure that project managers are appropriately trained to fulfill their Superfund responsibilities. We interpreted the Superfund citation to include quality assurance training.

Two headquarters offices oversee Superfund quality assurance training requirements. QAD, as the quality assurance coordinator, established requirements applicable to all programs including Superfund. The requirements specify that EPA organizations must describe their individual training

requirements in their quality management plans. The plans must "... describe the organization's process for establishing training requirements, identifying training needs, assigning priorities to them, and satisfying them." As the Superfund national program manager, OERR oversees that specific Superfund training requirements are included in regional plans and are appropriately implemented. Headquarters Superfund quality assurance staff agreed quality assurance training should be mandatory.

As the accountable officials for regional quality management plans, regional administrators must ensure that regional plans include the necessary training requirements in accordance with QAD's guidance and that regional Superfund staff receives the training.

**OERR AND SOME
REGIONAL
ADMINISTRATORS HAD
NOT IDENTIFIED AND
PROVIDED NECESSARY
TRAINING**

OERR and some regional administrators had not fully identified and provided the quality assurance training necessary to ensure a consistent and effective Superfund quality assurance program. Specifically, OERR had not used management assessments effectively to improve the Superfund quality assurance training program. In addition, some regional administrators had not fully implemented an effective Superfund quality assurance training program.

OERR had not used management assessments effectively to identify deficiencies in the Superfund training program or to improve training that when provided would heighten project managers' skills. Had OERR conducted its planned regional management assessments, it could have identified that regional plans did not specify minimum, basic training requirements. We found that only 4 of 10 regional plans provided specific quality assurance training requirements for Superfund staff. The six remaining regional plans addressed training only generally and did not specifically identify Superfund staff classifications that needed the training or the type of training needed. Although OERR's quality assurance manager developed questions designed to determine the skills of project managers, OERR did not provide or ensure training was provided. QAD's and regions' internal management assessments identified similar deficiencies. However, OERR had not collectively used the

results of those assessments to ensure a consistently and effectively implemented Superfund quality assurance training program.

Some regional administrators had not fully implemented an effective Superfund quality assurance training program to ensure the appropriate staff developed the understanding and skills necessary to fulfill their responsibilities and make sound decisions. Quality management plans for 6 of 10 regions did not specify which Superfund staff classifications were required to complete quality assurance training, identify staff training needs, or specify minimum training courses required. In the four regional plans that listed specific training courses, OIG audits showed that senior Superfund managers in at least two regions had not ensured Superfund staff completed the required training. OIG questionnaire results showed that regional quality assurance training was not a high priority in all regions. For example, three regional quality assurance managers commented that no data quality objectives training had been provided in their regions. Yet, a thorough understanding of data quality objectives is key to correctly implementing the data quality objectives process.

**SOME SENIOR
MANAGERS WERE NOT
ACCOUNTABLE AND
DID NOT
DEMONSTRATE THEIR
COMMITMENT TO
SUPERFUND QUALITY
ASSURANCE TRAINING**

Some senior Superfund managers were not held accountable for fulfilling quality assurance training requirements and had not demonstrated their commitment to an effective training program. Although some senior Superfund managers had not taken quality assurance training courses or ensured Superfund staff attended necessary training, they were not held accountable to ensure that they and staff completed training. As a result, in Region 8, training attendance problems that we identified in 1995 continued to be a problem in a 1998 followup audit. Also, QAD regional management assessments reported that in 9 of 10 regions, staff, including Superfund, did not understand basic quality assurance/quality control concepts, principles, and practices. OERR and regional administrators had not demonstrated their commitment to an effective quality assurance training program. They also had not used available information to work collaboratively to identify and fulfill Superfund training needs.

CONCLUSION

When senior managers attend management quality assurance courses, they send a message to Superfund staff that quality assurance training is important and a necessary tool to enhance staff skills. However, even when regions have criteria requiring Superfund staff to take specific training but have not held senior Superfund managers accountable to take or ensure staff take the required training, the incentive for staff is diminished. Without assessing staff skills and fully identifying training needs, OERR and regional administrators could not develop an effective training program to provide skills necessary to ensure that data collected in support of Superfund decision making was of known and adequate quality.

RECOMMENDATIONS

We recommend the Acting Assistant Administrator for Solid Waste and Emergency Response through OERR work:

- 5-1. With QAD and regional administrators to implement a Superfund quality assurance training program which:
 - a. Identifies the skills necessary to perform Superfund-specific quality assurance responsibilities.
 - b. Includes quality assurance performance language for appropriate headquarters and regional staff.
 - c. Assesses each headquarters and regional staff member's quality assurance skills with respect to established standards.
 - d. Identifies minimum Superfund quality assurance training requirements for headquarters and regional staff and includes these requirements in quality management plans.

- e. Ensures headquarters and regional Superfund staff needing quality assurance training complete required training.
 - f. Assesses and modifies training based on participants' course evaluations.
- 5-2. To assist regions in providing the necessary training when regional training does not prove entirely effective.
- 5-3. To provide senior OERR and regional Superfund managers with sufficient training for them to understand the importance and necessity of the quality assurance program.

**AGENCY COMMENTS
AND OIG EVALUATION**

EPA generally agreed with our findings and recommendations. EPA offered comments to clarify some issues and recommendations, and we have modified our report as appropriate. We highlighted below those significant issues on which we and EPA disagreed. We also

included the full text of the comments as Appendices I and II.

OSWER may have misunderstood our recommendations in this chapter in determining its corrective actions. Therefore, we modified the recommendations to clarify our intentions and will work with management to develop appropriate, specific corrective actions.

ORD stated that there is no requirement for quality management plans to include a list of specific training courses, and we agree. However, we believe ORD and QAD should use their authority to establish firm, mandatory, Agencywide requirements for any activities related to quality assurance including specific training courses for certain staff. ORD and QAD can and should ensure requirements are implemented by a variety of methods including but not limited to the reporting of non-compliance to appropriate management officials.

EXHIBIT 1

METHODOLOGY

Methodology

Our first objective was to determine if EPA had developed and implemented its mandatory Agencywide quality assurance program.

Our review of the EPA quality assurance program included:

- Review of the development of EPA policies, procedures, and practices for the program.
- Extensive discussions with QAD staff including feedback on emerging audit issues.
- Review of program guidance and requirement documents.
- Review of QAD performance in meeting its responsibilities to develop and oversee implementation of the program.
- Review of OERR development and oversight of Superfund quality assurance programs to ensure environmental data of known quality.

Our second objective was to determine if EPA had implemented its policy to develop data quality objectives to support Superfund decision making. Our review of data quality objectives development and use included:

- Results of audits of Regions 8, 9, and 10.
- Review of national oversight performed by QAD and OERR to ensure that national policy to develop and use the data quality objectives process were implemented.
- Review of all regional quality management plans for requirements.
- Review of all QAD regional management assessment reports.
- Assessment of responses to an OIG questionnaire sent to all regional quality assurance managers.

Our third objective was to determine if EPA organizations were conducting adequate oversight of quality assurance activities. Our review of EPA oversight of the quality assurance program included:

- Results of audits of Regions 3, 8, 9, and 10.
- Review of national oversight performed by QAD and OERR.
- Interviews with QAD and OERR staff regarding oversight responsibilities.
- Review of quality management plans for oversight procedures and practices for all regions and OERR.
- Review of annual quality assurance reports and work plans for oversight planned and accomplished.
- Review of all QAD regional management assessment reports.

Our fourth objective was to determine if EPA had developed an effective quality assurance training program. Our review of EPA quality assurance training included:

- Review of the training program developed by QAD.
- Participation in and assessment of two national training events provided by QAD.
- Interviews with QAD and OERR staff regarding training.
- Review of quality management plans for training requirements in each region and OERR.
- Review of annual quality assurance reports and work plans for training planned and accomplished.
- Review of all QAD regional management assessment reports.
- Assessment of responses to a questionnaire sent to all regional quality assurance managers regarding regional training requirements and programs.
- Results of audits of Regions 3 and 8.

PRIOR AUDIT COVERAGE

Regional Audits

OIG conducted seven audits since 1995 that addressed various aspects of the EPA quality assurance program. Three divisional OIG offices conducted audits in four EPA regions. A brief description of the seven audits are provided below. Complete copies of the audit reports are available from OIG.

Environmental Data Quality at Superfund Removal Actions in Region 9, Report No. E1SFF7-09-0058-8100223, dated September 4, 1998, issued by the Western Audit Division. This audit was performed to determine if Region 9 had sufficient procedures to ensure that Superfund environmental data was of known and adequate quality for response actions. The audit found that the Region had not:

- Used the complete data quality objectives process.
- Developed project plans capable of preventing or detecting inappropriate data.
- Included defensible or optimal plans for collecting data.
- Reviewed or approved project plans.
- Performed adequate oversight to ensure project plans were implemented.

Region 8 Needs to Further Strengthen Its Superfund Field Sampling Quality Assurance Controls, Report No. E1SKG7-08-5001-8100082, dated March 25, 1998, issued by the Central Audit Division. This audit was a followup to the 1995 Region 8 report summarized above. The audit reviewed the Region's improved procedures and processes for review, approval, and implementation of Superfund field sampling quality assurance activities. Although improvements were made, the audit disclosed that the Region:

- Continued to have unapproved project plans.
- Often did not develop data quality objectives as required by EPA national and regional policy and

- by Superfund regulations.
- Had not significantly improved project managers' oversight of field sampling.
- Had not ensured training effectiveness or that staff attended training.

Region 3 Superfund Field Sampling Activities, Report No. E1SKF6-03-0104-7100140, dated March 27, 1997, issued by the Mid-Atlantic Audit Division. This audit was performed to determine if Region 3 had adequate quality assurance and quality control procedures for environmental data. The audit found that:

- The Region had taken 12 years to comply with the requirement to prepare a quality management plan.
- Regional staff had not documented review of sampling documents.
- Superfund staff had not completed required training.

Laboratory Data Quality at Federal Facility Superfund Sites, Report No. E1SKB6-09-0041-7100132, dated March 20, 1997, issued by the Western Audit Division. The purpose of the audit was to determine if EPA had sufficient procedures in place to ensure that laboratory data was of known quality under federal facility agreements. The audit covered Regions 8, 9, and 10 and disclosed that:

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

Special Review of EPA Region 9 Data Quality Oversight at The Aerojet Superfund Site, Report No. E1SKG5-09-0110-6400044, dated March 28, 1996, issued by the Western Audit Division. This review was conducted to review quality assurance procedures at a responsible party-lead Superfund site. The audit found that:

- Data quality objectives had not been developed for the site.
- The quality assurance project plan was not approved by EPA as required.
- Responsible party had not complied with important provisions of the quality assurance project plan and with its consent decree.
- EPA had not performed oversight of the potentially responsible party's performance.

Environmental Data Quality at DOD Superfund Sites in Region 9, Report No. E1SKF5-09-0031-5100505, dated September 26, 1995, issued by the Western Audit Division. This audit was performed to determine if Region 9 was ensuring that laboratory data was of known and acceptable quality under Federal facility agreements with Department of Defense. The audit found that:

- Quality assurance project plans were not generally designed to detect the laboratory quality problems.
- Quality assurance project plans were not always officially approved or fully implemented.
- Region 9 did not sufficiently monitor compliance with quality assurance project plans or perform sufficient oversight to determine the quality of laboratory data.
- Quality assurance project plan inadequacies were not corrected after data problems were found.

Implementing Controls Would Improve Region 8's Superfund Field Sampling Activities, Report No. E1SKG4-08-0045-5400034, dated January 27, 1995, issued by the Central Audit Division. This review was performed to determine if Region 8's procedures and processes for review, approval, and implementation of Superfund field sampling activities were adequate. The review disclosed that:

- Superfund field sampling was not effectively performed.
- Project plans were not consistently approved.
- Required training was not completed.
- EPA staff did not always perform effective oversight.
- Timely technical assistance was not always available.

APPENDIX I

ORD RESPONSE



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF
RESEARCH AND DEVELOPMENT

September 4, 1998

MEMORANDUM

SUBJECT: Response to OIG Draft Report of Audit No. E1SKF7-08-001-XXXXX
EPA Had Not Effectively Implemented Its Superfund Quality Assurance
Program

FROM: Henry L. Longest II *Deborah Y. Dietrich for*
Acting Assistant Administrator (8101R)

TO: Michael Simmons
Deputy Assistant Inspector General
for Internal Audits
Office of Inspector General (2421)

Purpose

This memorandum responds to the Office of Inspector General's (OIG's) Draft Report of Audit No. E1SKF7-08-001-XXXXX, EPA Had Not Effectively Implemented Its Superfund Quality Assurance Program, dated August 6, 1998.

Discussion

In general, we find the draft report reasonable and we concur with most of the recommendations for which we have cognizance. However, there are a few points which we feel still merit clarification in the report.

First, the Office of Research and Development (ORD) is responsible for developing quality assurance (QA) and quality control (QC) requirements and for overseeing

implementation of the Agencywide Quality System. We have assigned the operational responsibility for these activities to the Quality Assurance Division (QAD). That is, they centrally manage ORD's Agencywide quality-related responsibilities. They are not responsible for centrally managing the Agency's QA program. The statements referring to QAD as the central management authority for QA should be corrected to reflect this definition of their responsibilities.

Second, a number of the recommendations imply that ORD has either the responsibility for implementing the quality system across the Agency or that ORD has the authority or means to ensure that organizations implement effective quality programs (see recommendations 2-2, 2-7, 2-8). While ORD can develop processes for organizations to use in systematic planning of environmental monitoring programs and in developing minimum training requirements and providing training courses to staff, ORD must rely on the senior managers in those organizations to ensure that the tools provided are effectively utilized within their organizations. We will work closely with senior managers across the Agency to ensure that they understand their responsibilities and work to fully implement their quality systems.

Third, the report recommended (recommendation 2-4) that we place QAD at an organizational level where it can be an effective and independent advocate for the QA program. Although we considered this action, we feel that a reorganization is unwarranted. Access to senior ORD officials is available to QAD staff whenever there is a need to work with senior level managers in other organizations. There are a number of other actions that we will take to improve the QA practices, and we propose to address these actions in our corrective action plan.

We also have a number of comments which, if addressed, will improve the quality of the report. These detailed comments are attached and speak to the primary report findings and recommendations.

We appreciate the opportunity to respond to this draft report. We believe that your attention to the issues identified in the report will help to improve the Agency's QA program. Attached is ORD's corrective action plan. Should your staff have any questions, or require additional information, please contact Nancy Wentworth on (202) 564-6830.

Attachments:

1. ORD Comments
2. Corrective Action Plan

cc: Tim Fields (5101)
Bill Samuel (2421)
Deborah Dietrich (8101R)
Lek Kadeli (8102R)

ORD Comments on OIG Draft Report

Audit No. E1SKF7-08-001-XXXXX

EPA Had Not Effectively Implemented Its Superfund Quality Assurance Program

1. On page ii, paragraph 2, the draft report states:

We recommend the Acting Assistant Administrator for Research and Development place the EPA quality assurance manager at an organizational level where that individual can be an effective and independent advocate;

RESPONSE: We request the following change to this portion of the draft report:

. . . place the Quality Assurance Division at an organizational level where . . .

Discussion: To be consistent with the report text, we believe that the statements about the quality assurance manager refer to the Quality Assurance Division, not an individual. See additional comments on this recommendation and in the corrective action plan under recommendation 2-4.

2. On page 2, paragraph 2, the draft report states:

...The Order established ORD’s Quality Assurance Division (QAD) to serve as the “central management authority” for this program. Specifically, QAD is responsible for developing and ensuring the Agencywide program is effectively implemented.

RESPONSE: We request the following change to this portion of the draft report:

Specifically, QAD plays a central role in developing the Agencywide program and overseeing its implementation. Senior managers are responsible for ensuring the implementation of the program within their organizations.

Discussion: The statement about “central management” of the QA program is not intended to require QAD to centrally manage the QA program, but that it is the single organization within ORD that tracks and reports on the status of the Agencywide program. This change should be made throughout the report. See also page 5, ¶ 1, line 5, ¶ 2, lines 3 and 7.

3. On page 6, paragraph 3, the draft report states:

A QAD strategic plan would provide quality assurance managers and program staff the direction necessary to implement a cohesive Agencywide program. The plan would establish the national strategies for achieving quality assurance goals and objectives in the future. QAD should . . .

RESPONSE: We request the following change to the draft report:

A quality assurance strategic plan would provide quality assurance managers and program staff the direction necessary to implement a cohesive Agencywide program. The plan would establish the national priorities for achieving QA goals and objectives in the future. QAD should . . .

Discussion: The paragraph should clearly state whether the recommended strategic plan is a QAD plan or a plan for the Agency's QA program. The plan will state the national priorities for quality system implementation. Also, it should be noted that it is the responsibility of organizations across the agency to actually implement the required actions.

4. On page 8, paragraph 5, the draft report states:

... Requirements documents are external policy documents describing what actions must be taken to meet the Order's requirements by non-EPA organizations conducting EPA work. QAD has developed three requirements documents and issued none in final form. Guidance documents are internal policy documents describing methods for implementing the requirements for both EPA and non-EPA organizations. . . .

RESPONSE: We request the following changes to this portion of the draft report:

Requirements documents are designed for the non-EPA community that is subject to EPA's QA program through appropriate extramural regulations. The requirements documents provide additional descriptive information on how to comply with the regulations. QAD has developed three requirements documents and issued none in final form; these documents could not have been completed until the revised Order and Quality Manual were issued and conforming changes made to the regulations. Guidance documents are policy documents containing non-mandatory information that could be useful to both EPA and non-EPA organizations. . . .

Discussion: The Order and Quality Manual apply to EPA organizations, while regulations (40 CFR 30, 40 CFR 31, 48 CFR 15) invoke the QA requirements for non-EPA organizations. The regulations are further clarified by the requirements documents. The guidance documents provide additional information to whomever chooses to use them.

5. On page 9, paragraph 2, the draft report states:

EPA corrected the fiscal 1992 Agency level material weakness regarding environmental data quality in fiscal 1997 . . .

RESPONSE: We request the following change to this portion of the draft report:

EPA corrected the fiscal 1992 material weakness regarding environmental data quality in fiscal 1997. . . . As a result, Agency organizations with incomplete QA programs were required to declare weaknesses for those programs and report on them individually. However, as discussed below. . . .

Discussion: FMFIA weaknesses are either material (reported to The President and Congress), Agency-level (reported to the Administrator), or [in our case] ORD-Level (reported to the AA/ORD). The words “Agency level material weakness” inaccurately combines two terms.

6. On page 9, paragraph 4, the draft report states:

Though tasked with developing and assessing the effectiveness of the Agencywide quality assurance program, QAD did not adequately specify minimum program requirements and allowed individual EPA organizations too much flexibility in implementing the program. Developing a sound foundation for a strong program includes both developing the overall program framework and specifying certain minimum requirements. QAD referred to its requirements as guidance. We found that some regional Superfund program offices did not effectively implement QAD’s guidance partly because many elements were not required. (Specific Superfund examples follow in Chapters 3, 4, and 5). The QAD Director stated that the July 1998 Order and manual should improve program effectiveness in the future because these new documents now require much of what had been optional.

RESPONSE: We request the following changes to this paragraph:

Though tasked with developing and assessing the effectiveness of the Agencywide QA program, QAD has only recently specified uniform program requirements in the new Order and Quality Manual. These new documents should eliminate much of the variability between Agency programs that has occurred because of the “draft” status of the documents. During the transition period while the new documents were under preparation and review, some Regional Superfund program offices did not effectively implement QAD’s documents, partly because many elements were not required. (Specific Superfund examples follow in Chapters 3, 4, and 5.) The QAD Director stated that the July 1998 Order and Manual should improve program effectiveness in the future because these new documents clearly state the program requirements.

Discussion: While the Order and Manual were under development and being reviewed for Agency implementation, QAD had no basis for requiring activities that were not explicitly covered in the 1984 Order. Therefore, there has been a period of transition where some organizations implemented the program as it was being described in the new program

documents and others adhered strictly to the 1984 requirements. Approval of the new Order and Manual will require all organizations to adhere to the same requirements, albeit after additional transition time.

7. On page 9, last paragraph, the draft report states:

QAD had not required minimum quality assurance elements be followed by EPA organizations. For example, although QAD spent over 10 years improving and refining its 7-step data quality objectives process, it did not require and had not persuaded all EPA organizations to use this preferred process. QAD's 7-step process is flexible and provides a systematic planning approach that would benefit EPA organizations if used as intended. Also, QAD had not required EPA organizations to list in their quality management plans the minimum training courses required for each EPA employee to ensure a basic quality assurance understanding. Because the quality management plan is a planning and management tool, listing minimum training courses would provide managers a gauge with which to measure minimum required quality assurance skills. To their credit, some regional offices took the initiative and listed specific training courses as required in their regional plans.

RESPONSE: We request the following changes to this portion of the draft report:

Until the issuance of the Order and Quality Manual, QAD had not required minimum QA elements be followed by EPA organizations. For example, . . . as intended. The revised Order and Quality Manual require organizations to state the process that they will use to define QA-related training needs of their staff. QAD does not require EPA organizations to list in their Quality Management Plans the minimum training courses required for each EPA employee to ensure a basic QA understanding. The Quality Management Plan is a planning and management tool and listing minimum training courses could provide managers a gauge with which to measure minimum required QA skills. To their credit, some regional offices took the initiative and listed specific training courses as required in their regional plans.

Discussion: As noted, the Quality Management Plan is a planning and management tool used to define the processes on how activities would be conducted within the organization; it is not intended to describe the details of each of the processes and procedures.

8. On page 10, paragraph 3, the draft reports states:

Although QAD had authority . . . Both Orders delegated all authority for implementing an Agency-wide quality assurance program to the ORD Assistant Administrator and the QAD Director . . .

RESPONSE: We request the following changes to this portion of the draft report:

Although QAD had authority . . . Both Orders delegated all authority for

**overseeing implementation of the Agency-wide QA program to the ORD
Assistant Administrator and the QAD Director.**

Discussion: ORD and QAD have responsibility for overseeing implementation, not directly implementing the Agency-wide QA program. The AA/ORD is, of course, responsible for ensuring implementation of the QA program within ORD.

9. On page 10, last paragraph, the draft report states:

QAD had not effectively . . . QAD’s quality assurance responsibilities included approving EPA organizations’ quality management plans, conducting and documenting management assessments to confirm compliance with the plans, and tracking corrective actions. However, QAD approved quality management plans that did not require specific training courses or use of the data quality objectives process or alternative systematic planning process with defined criteria . . .

RESPONSE: We request the following changes to this portion of the draft report:

QAD had not effectively . . . QAD’s quality assurance responsibilities included approving EPA organizations’ Quality Management Plans, conducting and documenting management assessments to confirm compliance with the plans, and tracking corrective actions. However, QAD approved Quality Management Plans that did not require use of the data quality objectives process or alternative systematic planning process with defined criteria . . .

Discussion: The Quality Management Plan is a process and planning document, and there is no requirement that it include a list of required courses for individuals with QA responsibilities. If you believe it necessary, additional rationale should be provided in the report text.

10. On page 11, paragraph 2, the draft report states:

... In our opinion, the two regions did not have adequate programs and QAD should have recommended the regions report their programs as regional material weaknesses . . .

RESPONSE: We request the following change to this portion of the draft report:

... In our opinion, the two regions did not have adequate programs and QAD should have recommended the regions report their programs as weaknesses under the Federal Managers’ Financial Integrity Act process . . .

Discussion: See explanation in # 5, above. The words “regional material weakness” inaccurately combines two types of weaknesses.

11. On page 12, paragraph 2, the draft report states:

...However, ORD used such a collective reporting approach before in November 1991 to report environmental data quality as an ORD material weakness.

RESPONSE: We request the following change to this portion of the draft report:

...However, ORD used such a collective reporting approach before in November 1991 to report environmental data quality as a material weakness.

Discussion: See explanation in #5, above. The words “ORD material weakness” inaccurately combines two types of weaknesses.

12. On page 12, paragraph 3, the draft report states:

ORD senior managers had not asserted their authority and supported QAD to require all EPA organizations to comply with specific quality assurance requirements. Although 40 CFR and the EPA Order authorized ORD to establish, direct, and coordinate the Agencywide program, it appeared that ORD managers chose not to assert their authority and have QAD impose requirements on EPA organizations, particularly EPA regions. EPA has about 40 internal organizations in addition to states, tribes, and others. Each of the organizations was developing and implementing potentially separate programs because QAD had not clearly established minimum Agencywide requirements necessary to institutionalize a cohesive quality assurance program. Program managers could not be held accountable for minimum performance requirements because QAD had not established firm program requirements or clearly identified QAD expectations for organizations’ quality management plans.

RESPONSE: We suggest the following changes to this paragraph:

While QAD was developing the new Order and Quality Manual, ORD senior managers did not assert their authority and support QAD to require all EPA organizations to comply with specific QA requirements. Although 40 CFR and the EPA Order authorized ORD to establish, direct, and coordinate the Agencywide program, it appeared that, during this transition period, ORD managers chose not to assert their authority and have QAD impose requirements on EPA organizations, particularly EPA regions. EPA has about 40 internal organizations in addition to states, tribes, and others. Each of the organizations was developing and implementing potentially separate programs because at that time, QAD had not clearly established minimum Agencywide requirements necessary to institutionalize a QA program. Program managers could not be held accountable for minimum performance requirements because QAD had not established firm program requirements or clearly identified QAD expectations for organizations’ Quality Management Plans. With the issuance of the revised Order and Quality Manual, clearer specifications for acceptable programs have been defined.

Discussion: During the period when the Order and Manual were being developed, some

organizations were using the new material, some were using the 1980's material, and others used a combination of both. This lead to many variations in program implementation, which we hope, have been eliminated by issuance of the final Order and Manual.

13. On page 13, recommendation 2-2, the draft report states:

- 2-2. Work collaboratively with EPA organizations to oversee and ensure that a cohesive, mandatory Agencywide quality assurance program is consistently implemented.

RESPONSE: We suggest the following change to this recommendation:

- 2-2. Work collaboratively with EPA organizations to oversee the implementation of the mandatory Agencywide QA program.**

Discussion: Agency senior managers are responsible for the implementation of their QA programs. The programs are required to contain certain components and processes, but the details of design and implementation of the components and processes are the responsibility of the managers and the organization. There will continue to be variability between programs based on statutory and regulatory differences.

14. On page 13, recommendation 2-4, the draft report states:

- 2-4. Place QAD, which is responsible for EPA's quality assurance program, at an organizational level where it can be an effective and independent advocate for the program as specified by the July 1998 Order.

RESPONSE: We suggest that the recommendation be deleted.

Discussion: As noted in the attached table, ORD believes that QAD has sufficient access to ORD senior management to function effectively.

15. On page 13, recommendation 2-5, and on page 20, paragraph 3-5, the draft report states:

- 2-5 . . . should identify quality assurance implementation as a material weakness in their unit as part of the fiscal 1998 Federal Managers' Financial Integrity Act process.

RESPONSE: We request the following change to this recommendation:

- 2-5 . . .should identify QA implementation as a weakness as part of the fiscal 1998 Federal Managers' Financial Integrity Act process.**

Discussion: See explanation in #5, above. The words "material weakness in their unit" are confusing. Material weaknesses are reported to The President and Congress.

16. On page 14, recommendation 2-7, the draft report states:

4-8. Coordinate management assessments . . . At a minimum, provide regional management assessment results to the appropriate national program managers.

Discussion: For this recommendation to be effective, the findings and recommendations from the regional assessments should be provided directly to the national program managers. See also a corrective action plan for this recommendation.

20. On page 27, paragraph 3, the draft report states:

Two headquarters offices oversee Superfund quality assurance training requirements. QAD, as the quality assurance coordinator, established requirements applicable to all programs including Superfund. The requirements specify that EPA organizations must describe their individual training requirements in their quality management plans. The plans must "... describe the organization's process for establishing training requirements, identifying training needs, assigning priorities to them, and satisfying them." As the Superfund national program manager, OERR oversees that specific Superfund training requirements are included in regional plans and are appropriately implemented. Headquarters Superfund quality assurance staff agreed quality assurance training should be mandatory.

RESPONSE: We request the following changes to the draft report:

Two headquarters offices oversee Superfund QA training requirements. QAD, as the QA coordinator, established requirements applicable to all programs including Superfund. The requirements specify that EPA organizations must describe their processes for defining individual training requirements in their Quality Management Plans. The plans must "...describe the processes and the management and/or staff responsible for...identifying, designing, performing, and documenting technical, quality, and project management training." (See section 3.3.4, Quality Manual.) As the Superfund national program manager, OERR oversees that specific Superfund training requirements are included in regional plans and are appropriately implemented. Headquarters Superfund QA staff agreed quality assurance training should be mandatory.

Discussion: The Quality Management Plan describes the process used by an organization to determine training needs. It is not expected to contain the specific training requirements for all staff and managers.

21. On page 29, recommendation 5-1e, the draft report states:

- e. Develops and delivers an effective quality assurance training program that meets minimum mandatory Agencywide requirements and incorporates these requirements into minimum Superfund training requirements.

RESPONSE: We request the following change to this recommendation:

- e. **Develops and delivers an effective QA training program that meets the organization’s needs and incorporates these materials into Superfund’s training program.**

Discussion: The Agency quality system does not establish mandatory training requirements. Instead, it requires managers to ensure that training needs are defined within their organizations and that those needs are met.

General comments that apply throughout document:

1. Use of the term “quality assurance manager” is sometimes confusing regarding which QA manager is being considered. In most cases, the term is modified by “regional” or “OERR,” but there are times when its meaning is confusing.
2. The term “regional Superfund staff” is open to interpretation as to whether it includes regional QA staff or not. Use of the term should be clarified. When comments and recommendations are directed to regional staff, the recommendations need to clearly state that staff with QA responsibilities are included.
3. A more common use is Agency-wide, not Agencywide.

**ORD Corrective Action Plan to OIG Draft Report of Audit
No. E1SKF7-08-001-XXXXX
EPA Had Not Effectively Implemented Its Superfund Quality Assurance Program**

Rec #	Draft Report Recommendation	Action Official	Corrective Action	Due Date
2-1	Develop a strategy to communicate the requirements in the July 1998 Order and <i>EPA Quality Assurance Manual</i> throughout the Agency.	Director, Quality Assurance Division (QAD)	A communication strategy detailing the background of the QA program, the recent changes and how they affect different user communities, and a plan for communicating the requirements to the users will be prepared and implemented.	12/98
2-2	Work collaboratively with EPA organizations to oversee and ensure that a cohesive, mandatory Agencywide quality assurance program is consistently implemented.	AA/ORD with support from QAD	QAD will continue to conduct management assessments of QA program implementation and raise successes and deficiencies to appropriate senior managers' attention.	ongoing
2-3	To further institutionalize EPA's quality assurance program, require QAD to develop a strategic plan and annual performance plan including appropriate outcome-based performance measures and the level of resources needed.	Director, QAD	QAD will develop a strategic plan for its areas of responsibility, including performance measures and resource estimates. QAD will then prepare a performance plan for the upcoming year based on the priorities and resources provided.	12/98
2-4	Place QAD, which is responsible for EPA's quality assurance program, at an organizational level where it can be an effective and independent advocate for the program as specified by the July 1998 Order.	AA/ORD	We have considered this recommendation but do not believe this action to be warranted. QAD has access to ORD senior managers whenever needed for purposes of discussions with other senior managers across the Agency.	N/A

Rec #	Draft Report Recommendation	Action Official	Corrective Action	Due Date
2-5	Recommend to each regional administrator and national program manager that they review the most recent QAD and regional quality assurance management assessments for their unit conducted by QAD, national program managers, and regional quality assurance groups to determine whether the regional administrator or national program manager should identify quality assurance implementation as a material weakness in their unit as part of the fiscal 1998 Federal Managers Financial Integrity Act process.	AA/ORD	A memorandum will be sent to Assistant and Regional Administrators directing them to review any available management assessments (conducted by QAD, conducted internally, conducted by OIG of similar organizations or programs) to determine whether they should identify any component of their QA program as a weakness under the Integrity Act.	9/98
2-6	Issue a memorandum to clarify that “acceptance or performance criteria” as referred to in the July 1998 Order were formally known and referred to as “data quality objectives,” and clearly specify minimum Agencywide quality assurance training and other program requirements.	AA/ORD	General agreement with recommendation. Memoranda will be prepared and distributed: 1. Clarify equivalence of “acceptance or performance criteria” to “data quality objectives.” 2. Clarify management responsibility to define, within their organization, minimum training requirements for staff with QA responsibilities. 3. Clarify management responsibility for implementing quality systems that fully meet the requirements established in the Order and Manual.	12/98 3/99 12/98
2-7	Establish and implement a method of ensuring adherence to minimum criteria for an adequate systematic planning process.	AA/ORD	Recommend deletion. See actions in 2-9b. QAD will include in its management assessments explicit consideration of the use of systematic planning, and will report to managers on the results of the assessments. It is these managers who are responsible for ensuring implementation.	Ongoing

Rec #	Draft Report Recommendation	Action Official	Corrective Action	Due Date
2-8	Establish and implement minimum training requirements for staff in all EPA programs implementing or overseeing implementation of data quality assurance activities.	AA/ORD	Non-concur as written. QAD will develop a guidance document outlining a process to be used to define training needs. It is the program managers' responsibility to ensure that the needs within their organization are defined and met.	3/99
2-9	<p>Enhance oversight conducted by QAD by:</p> <p>a. Not approving EPA organizations' quality management plans which do not include enough specifics to ensure a sound quality assurance program.</p> <p>b. Verifying that EPA organizations are actually using the data quality objectives process or an adequate alternative systematic planning process to identify environmental data needs.</p> <p>c. Preparing and issuing timely management assessment reports.</p> <p>d. Tracking organizations' implementation of corrective actions identified in management assessment reports.</p>	<p>Director, NCERQA</p> <p>Director, NCERQA</p> <p>Director, NCERQA</p> <p>QAD</p>	<p>Quality Management Plans that are submitted for Agency approval will be reviewed against the criteria established in Chapter 3 of the Quality Manual.</p> <p>Management assessments will include explicit review of the use and effectiveness of systematic planning processes.</p> <p>Draft assessment reports will be completed within 60 days of completion of data collection.</p> <p>Corrective actions will be tracked using QA annual reports and work plans. Where proposed schedules are not being met, senior management will be notified of the status.</p>	<p>Ongoing</p> <p>Ongoing</p> <p>Ongoing</p> <p>Ongoing</p>

Rec #	Draft Report Recommendation	Action Official	Corrective Action	Due Date
2-10	To elevate the visibility of quality assurance progress in support of the Agency's stated goal of sound science, prepare an annual report to the Administrator on the "progress and efficacy" in implementing the Agencywide quality assurance program.	AA/ORD	Annual reports on QA program status will be prepared for the Administrator.	1/98
3-1	Develop a strategy to encourage use of EPA's 7-step data quality objectives process as EPA's recommended systematic planning process as stated in the July 1998 <i>EPA Quality Manual</i> .	QAD in conjunction with OERR	QAD will work with OERR to develop a strategy to enhance use of systematic planning, including the data quality objectives process and alternative processes for defining acceptance and performance criteria.	3/99
4-8	Coordinate management assessments with the national program managers to ensure that regional staff satisfactorily perform their quality assurance activities. At a minimum, provide regional management assessment results to the national program managers' quality assurance managers.	Director, QAD	QAD will continue to involve QA managers from related organizations in its management assessment teams. Relevant results of regional management assessments will be forwarded to national program managers for their consideration.	Ongoing
4-9	Address the placement of regional quality assurance managers in management assessments to encourage regional administrators to place quality assurance managers at an organizational level where they can be an effective advocate for the program.	Director, NCERQA	QAD will continue to evaluate the effectiveness and the location and organizational support of QA managers in the Regions as part of the management assessments.	Ongoing

APPENDIX II

OSWER RESPONSE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 10 1998

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: OSWER Response to OIG Draft Report on Superfund Quality Assurance Program, Audit Report No. E1SKF7-08-0011-XXXXXX

FROM: Timothy Fields, Jr. *Timothy Fields, Jr.*
Acting Assistant Administrator

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

Thank you for the opportunity to review the draft report on Superfund's Quality Assurance Program. I appreciate the fact that you have been working closely with the Office of Emergency and Remedial Response (OERR) staff on developing this report and have already incorporated many of their comments in both the body of the text and in the recommendations. I will be focusing our comments on the findings and recommendations for OSWER, presented in Chapters 3 through 5. Our comments are structured in the same format as they are presented in the draft report. We note the Section on which we are commenting and the specific statements with which we have concerns, and then follow with OSWER's comments. We established this format, since OIG did not number the Sections in each of the Chapters. For the final report, we recommend you establish a numbering system.

Chapter 3 - Findings

Opening Paragraph and Opening Paragraph for Section Entitled: MANAGERS HAD NOT PROVIDED ADEQUATE DATA QUALITY OBJECTIVES DIRECTION OR TOOLS

"The policy was only minimally successful in the Superfund program because QAD and OERR managers and Regional Administrators had not provided staff sufficient direction or tools to implement EPA's data quality objectives policy."

This is an overstatement since OIG has not audited all of the Regions, but focused on Regions 3, 8, 9 and 10. It would be appropriate to qualify this statement as: *In some Regions*, this policy was only minimally successful. Furthermore, OERR did provide some direction and tools to the

Regions -- both the Superfund Data Quality Objectives guidance and QAD's Data Quality Objectives Decision Error Feasibility Trials (DEFT) software were distributed to Regional staff.

Managers Had Not Provided Adequate Direction

“Also, Region 9 collected and analyzed about 420 samples that were unnecessary for decision making.” I am concerned that this misstatement remains in the report. As staff in OERR previously indicated to you, these analyses were vital to ascertain the performance of a wastewater treatment system used as part of a Superfund site cleanup. These samples were necessary for overall site management and decision making.

“Superfund managers had not stressed that data quality objectives were required and that the EPA 7-step process was OERR's adopted approach.” It is an overstatement to indicate that Superfund managers had not stressed data quality objectives; you need to qualify this statement by adding, *In some Regions*, to the beginning of the sentence. Since OERR also wants to ensure Regional flexibility, EPA's 7-step process is one example of an approach that can be followed. However, we do agree that the Regions need to be aware of this flexibility as you state later in that paragraph.

Chapter 3 - Recommendations

Recommendation 3-2

“In concert with QAD, develop and implement a plan to institutionalize the Superfund program's required data quality objectives process.”

OSWER agrees with this recommendation. OERR will work with QAD to develop a plan by March 31, 1999.

Recommendation 3-3

“Advocate the benefits of developing data quality objectives using an across-organization team approach.”

OSWER agrees with this recommendation. OSWER will provide this recommendation to the Regions in a Quality Assurance (QA) memorandum from the Acting Assistant Administrator, OSWER to the Regional Administrators and Superfund Division Directors by December 31, 1998.

Recommendation 3-4

“Provide Superfund staff with sufficient tools to implement EPA's data quality objectives policy in the Superfund program by:

a) “Making data quality objectives training more effective by integrating available quality

assurance courses to provide a comprehensive understanding of data quality objectives.”

OSWER agrees with this recommendation. This work will be conducted in concert with Recommendation 3-2 and will be completed by March 31, 1999.

b) “Making automated tools (such as the Data Quality Objectives Decision Error Feasibility Trials software or other interactive modeling software) available to appropriate staff and encouraging use through training and examples of success.”

As previously noted, OERR has completed this task. However, OERR will request QAD to provide the software again by January 31, 1999. OSWER will inform Regional management of the availability of the software in OSWER’s QA letter to the Regions as discussed in Recommendation 3-3.

c) “Making more expertise available to provide staff technical assistance in areas such as statistics either through realignment of regional resources or contractor support.”

As the recommendation is currently written, OSWER does not agree with it. It is implying that OERR provide additional resources for Regional quality assurance responsibilities. As you know, OERR is currently addressing many competing priorities and at this time does not project that this can be accomplished. However, if the recommendation is rewritten as, *Increase awareness that expertise is available to provide staff technical assistance in areas such as statistics either through realignment of Regional resources or contractor support*, OSWER will support it in the QA memo to the Regions expected by December 31, 1998.

d) “Sharing regionally-developed tools, procedures, best practices, and successes with all EPA programs and regions.”

As the recommendation is currently written, OSWER does not agree with it. It is not OSWER’s responsibility to reach out to all EPA programs and regions. However, if the recommendation is rewritten as, *Sharing regionally-developed tools, procedures, best practices, and successes with QAD and Superfund staff*, OSWER can support it. QAD serves as the central point of contact on QA issues for the Agency. For Superfund-specific issues, this can be accomplished by September 30, 1999 when OERR’s Regional Quality Assurance reviews are completed, and OERR develops guidance to address concerns and share successes revealed during the QA reviews.

Recommendation 3-5

“Recommend to each regional administrator that they review the most recent QAD, OERR, and regional quality assurance management assessment results for their unit to determine whether the regional administrator should identify quality assurance implementation as a material weakness in their unit as part of the fiscal 1998 Federal Managers Financial Integrity process.”

OSWER does not agree that quality assurance concerns should be raised to the level of a material weakness, especially in light of the work that OERR is pursuing on quality assurance activities (e.g., QA reviews, guidance, memorandums). Additionally, training is available to the Regions from the Quality Assurance Division which hopefully will alleviate the problem in the future. However, OSWER is willing to work with QAD on a memo to the Regional Administrators requesting that they review the QA management assessment results to determine whether a material weakness exists in their Region. QAD's proposed date for this memo is September 30, 1998.

Chapter 4 -Findings

Opening Paragraph

“Top OERR and regional managers had not ensured staff adequately performed Superfund quality assurance oversight...”

OSWER is concerned with the absolute nature of this statement and would prefer it be qualified to read: Regional managers had not *uniformly* ensured staff adequately performed Superfund quality assurance oversight. It is the responsibility of Regional managers, not OERR, to oversee day-to-day operations in the Regions.

SENIOR SUPERFUND MANAGERS HAD NOT IDENTIFIED OVERSIGHT WEAKNESSES

The first paragraph and the title of this section contain numerous absolute statements that need to be qualified. The title should be modified to reflect that Senior Superfund managers had not *consistently* identified oversight weaknesses. This continues for the rest of the paragraph; as we stated earlier, the OIG audit did not cover all ten Regions, nor was every file in each of the Regions reviewed; therefore these statements need to be qualified.

OERR Had Not Fulfilled Its Quality Assurance Oversight Responsibilities

Again, we would like to see the subtitle include a qualifier such as, OERR had not *completely* fulfilled its Quality Assurance Oversight Responsibilities.

The statement that “Removals have minimal quality assurance requirements up-front due to the time-critical nature of the activity,” is not accurate. As a reminder, the removal program also includes non-time critical actions, and these longer term cleanups do follow QA requirements up-front.

Regional Administrators Had Not Ensured Previously Identified Oversight Weaknesses Were Corrected

Again, we would like to see this subtitle qualified since OIG observations are based on limited examples in a limited number of Regions.

SUPERFUND MANAGERS HAD NOT DEMONSTRATED QUALITY ASSURANCE
OVERSIGHT COMMITMENT.

OSWER continues to be concerned with the above phrase. As previously noted, OERR recognizes the importance of data quality assurance and the necessity of management involvement in such issues. Stephen Luftig, Director, OERR, Larry Reed, Deputy Director, OERR, and Dana Tulis, Director, Analytical Operations and Data Quality Center, will continue to be involved in OERR's quality assurance program. Duane Geuder and Joan Fisk, both of whom have been involved in quality issues for Superfund for many years, have committed a large percentage of their time to working towards the kind of improvements to our Superfund Quality System that have been identified as problem areas by the OIG.

Furthermore, I established the Field and Analytical Services Teaming Advisory Committee (FASTAC) in my March 16, 1998 memorandum, *Sources for Analytical Services Under Contracts 2000*. FASTAC is comprised of Headquarters, Regional Superfund, and Regional Science and Technology managers who are charged to address field and analytical issues that cut across the Superfund program and analytical support organizations. Quality Assurance is one of the implementation issues being addressed by FASTAC.

Organizational Location of Quality Assurance Managers Undermined Their Authority

As previously discussed, OSWER believes the Superfund Quality Assurance Manager is working at the appropriate organizational level. When OERR reorganized three years ago, the Analytical Operations/Data Quality Center (AOC) was designed to include oversight and implementation of quality assurance activities for both CLP and non-CLP data. AOC has and will continue to provide independent technical assessments for analytical services outside of the CLP program. Furthermore, FASTAC is addressing the Superfund Quality Assurance program, with emphasis on planning activities. Larry Reed is the FASTAC Chair and Dana Tulis has the lead for FASTAC implementation. OERR is also establishing quality assurance leads in each of OERR's Regional Centers.

Chapter 4 - Recommendations

Recommendation 4-1

“Develop a plan with a realistic cycle for OERR staff to perform management and technical assessments in the regions. Include in the plan the staffing resources necessary to carry out the plan. Invite regional Superfund and quality assurance managers to participate as members of

OERR's assessment team.”

OSWER agrees with the recommendation and the plan will be complete by December 31, 1998.

Recommendation 4-2

“Consider joint management assessments with QAD to ensure that regional Superfund staff satisfactorily perform their quality assurance activities. At a minimum, obtain QAD regional management assessment results.”

OSWER agrees with this recommendation. OERR just completed a joint assessment with QAD for the Region 10 review. In the past, OERR's Quality Assurance manager has participated in QAD reviews as well.

Recommendation 4-3

“Work with regional Superfund staff to develop adequate oversight procedures to ensure data is of sufficient quality to support decision making.”

OSWER agrees with this recommendation. OERR will be developing such guidance once the Regional QA reviews are complete. The guidance, as previously noted, should be completed by September 30, 1999. OERR will also work with Regional QA staff. The Recommendation should probably be broadened to include Regional QA staff as well.

Recommendation 4-4

“Develop a strategy to ensure corrective actions in response to OIG audits and EPA management assessments are fully implemented.”

OSWER agrees with this recommendation. OSWER will request a strategy from each of the Regions in the QA memo that I will be issuing to the Regions by December 31, 1998. The regional plans will be requested by February 28, 1999.

Recommendation 4-5

“Develop guidance to effectively implement the Superfund quality assurance program including specific quality assurance responsibilities for regional project managers.”

OSWER agrees with this recommendation. This will be addressed by OERR's QA guidance expected by September 30, 1999.

Recommendations 4-6 and 4-7

“Place the Superfund quality assurance manager and staff at an organizational level where they can be an effective advocate for the program.” “Clearly and formally delegate program authority to the headquarters Superfund quality assurance manager.”

OSWER believes this is already the case. The Superfund Quality Assurance Manager does not directly report to AOC, which is responsible for operations of the QA program. The Quality Assurance Manager has direct access to OERR's Office Director and Deputy Directors, and routinely reports to the Deputy Director responsible for QA issues. All memorandums concerning improvements and modifications to the QA program will be disseminated under OERR's Office Director or when appropriate, under my signature.

Chapter 5 - Findings

Please ensure each of the subtitles in this section are appropriately qualified since all the Regions were not audited. "OERR and Regional Administrators had not identified and provided necessary training," should only refer to *some* Regional Administrators. Similarly, *some* "Senior managers were not held accountable and did not demonstrate their commitment to superfund quality assurance training."

Chapter 5 - Recommendations

Recommendation 5-1

"Implement quality assurance training for environmental data operations." This recommendation consists of seven subtasks.

OSWER supports the overall recommendation; however, we do not agree that OERR is the lead on each of the subtasks. The overall recommendation can be implemented by September 30, 1999.

a) "Identifies the skills necessary to perform Superfund-specific quality assurance responsibilities."

OERR will work with QAD to establish these in concert with the Regions.

b) "Establishes quality assurance performance language for appropriate staff."

If QAD provides these, OERR will share them with their Regional managers.

c) "Assesses each staff member's quality assurance skills with respect to established standards."

This is clearly a Regional management responsibility.

d) "Identifies minimum Superfund quality assurance training requirements for staff to perform their responsibilities and includes the requirements in regional quality management plans."

OERR can work with QAD in establishing training requirements. The Regional managers will need to include the requirements in the regional quality management plans.

e) “Develops and delivers an effective quality assurance training program that meets minimum mandatory Agency wide requirements and incorporates these requirements into minimum Superfund training requirements.”

OERR will work with QAD.

f) “Ensures Superfund staff needing quality assurance training complete required training.”

Regional management will need to ensure that staff needing quality assurance training complete required training.

g) “Assesses and modifies training based on participants’ course evaluations.”

OERR will work with QAD and the Regions.

Recommendation 5-2

“Assist regions in providing the necessary training when regional training does not prove entirely effective.”

OSWER agrees with this recommendation and can provide assistance as resources allow.

Recommendation 5-3

“Provide senior managers with sufficient training for them to understand the importance and necessity of the quality assurance program.”

OERR will provide this recommendation to the Regions and request it be accomplished by September 30, 1999.

Thank you for incorporating our comments. We look forward to reviewing the final report.

cc: Stephen Luftig, OERR
Larry Reed, OERR
Dana S. Tulis, OERR
Henry Longest, ORD
Nancy Wentworth, ORD
Superfund National Policy Managers
Regional RS&T Division Directors
Bob Cianciarulo, Region 1
Elizabeth Harris

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