



## Office of Inspector General

### Audit Report

# SUPERFUND

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

**E1SKF7-08-0011-8100240**

September 30, 1998

Inspector General Division	Central Audit Division
Conducting the Audit:	Denver, Colorado
	Western Audit Division
Inspector General Divisions Contributing to the Audit	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

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September 30, 1998

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#### **MEMORANDUM**

SUBJECT: EPA Had Not Effectively Implemented



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
- 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
- Has EPA developed an effective quality assurance training program?

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.



AGENCY COMMENTS AND OIG EVALUATION

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

Comprehensive Environmental Response, Compensation, and  
Liability Act of 1980  
Code of Federal Regulations  
Environmental Protection Agency  
Office of Emergency and Remedial Response  
Office of Inspector General  
Office of Research and Development

Office of Solid Waste and Emergency Response

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.

In July 1998, EPA issued a revised Order 5360.1 CHG 1 that superseded the 1984 Order. Attached to the July 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

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

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

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

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

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.

Revision) issued by the Comptroller General of the United States.

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

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## **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

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

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

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

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

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 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

### **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

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

### **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

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

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

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

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

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

2-2. Work collaboratively with EPA organizations to oversee and ensure consistent implementation of a cohesive, mandatory Agencywide quality assurance

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

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

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

## **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.

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:

<b>Data Quality Objectives Process</b>
1 State the problem.
2 Identify the decision.
3 Identify inputs to the decision.

**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

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

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.

## Office of the Inspector General - EPA Had Not Effectively Implemented Its Superfund Q..

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.

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.

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 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

d. Sharing regionally-developed tools, procedures, best practices, and successes with QAD and with headquarters and regional

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.

#### **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.

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

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**

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

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

### **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

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

## Office of the Inspector General - EPA Had Not Effectively Implemented Its Superfund Q..

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

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

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.

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.

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

#### **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.

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

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

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

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

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

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

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
- 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.

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
  
- Included defensible or optimal plans for collecting data.
- Reviewed or approved project plans.

*Special Review of EPA Region 9 Data Quality Oversight at The Aerojet Superfund Site, Report No. E1SKG5-*, 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

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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,

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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 \_\_\_ 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

**ORD Comments on OIG Draft Report**  
**Audit No. E1SKF7-08-001-XXXX**  
**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 . . .**

\_\_\_\_\_ 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

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

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

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

EPA corrected the fiscal 1992 Agency level material weakness regarding

**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. . . .**

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\_\_\_\_\_ 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**

\_\_\_\_\_ : 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

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

**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.**

\_\_\_\_\_ 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

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

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\_\_\_\_\_ : 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

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 . . .**

\_\_\_\_\_ : 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

**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 . . .**

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\_\_\_\_\_ See explanation in # 5, above. The words "regional material weakness" inaccurately combines two

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.**

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\_\_\_\_\_ See explanation in #5, above. The words "ORD material weakness" inaccurately combines two

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

**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**

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

**RESPONSE: We suggest that the recommendation be deleted.**

\_\_\_\_\_ As noted in the attached table, ORD believes that QAD has sufficient access to ORD senior

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



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

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**

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\_\_\_\_\_ : 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.

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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

2. The term "regional Superfund staff" is open to interpretation as to whether it includes regional \_\_\_\_ 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.

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Rec #			
	<p style="text-align: center;"><i>EPA Quality Assurance Manual</i> throughout the Agency.</p>		<p>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</p>
	<p>Work collaboratively with EPA organizations to oversee and ensure that a cohesive, mandatory Agencywide quality assurance program is consistently implemented.</p>		
	<p>To further institutionalize EPA's quality assurance program, require QAD to develop a strategic plan and annual performance plan including appropriate performance measures and the level of resources</p>		
	<p>Place QAD, which is responsible for EPA's quality assurance organizational level where it can be an effective and independent advocate for the program as specified by the July</p>		<p>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.</p>
	<p>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</p>		<p>A memorandum will be sent to Assistant and Regional Administrators directing them to review any available management</p>

	<p>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</p>		<p>General agreement with recommendation. Memoranda will be prepared and distributed:</p> <ol style="list-style-type: none"> <li>1. Clarify equivalence of "acceptance or performance criteria" to "data quality"</li> <li>2. Clarify management responsibility to define, within their organization, minimum training requirements for staff with QA responsibilities.</li> <li>3. Clarify management responsibility for implementing quality systems that fully meet the requirements established in the Order and Manual.</li> </ol>	<p>12/98</p> <p>3/99</p> <p>12/98</p>
	<p>Establish and implement a method of ensuring adherence to minimum criteria for an adequate systematic planning</p>		<p>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.</p>	

<p>Establish and implement minimum training requirements for staff in all EPA programs</p> <p>implementation of data quality assurance</p>		<p>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</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>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</p>	
<p>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</p>		<p>Annual reports on QA program status will be prepared for the</p>	

**(The First portion of OSWER response not visible in HTML format - please view PDF document below)**

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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.

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"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, 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.

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"In concert with QAD, develop and implement a plan to institutionalize the Superfund program's required data

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

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"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.

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"Provide Superfund staff with sufficient tools to implement EPA's data quality objectives policy in the Superfund

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

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

As previously noted, OERR has completed this task. However, OERR will request QAD to provide the software

## Office of the Inspector General - EPA Had Not Effectively Implemented Its Superfund Q..

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 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

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 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

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"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

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

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"Top OERR and regional managers had not ensured staff adequately performed Superfund quality assurance

OSWER is concerned with the absolute nature of this statement and would prefer it be qualified to read: 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

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

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"Develop a plan with a realistic cycle for OERR staff to perform management and technical assessments in the

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"Develop a strategy to ensure corrective actions in response to OIG audits and EPA management assessments

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.

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"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

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"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

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.

Please ensure each of the subtitles in this section are appropriately qualified since all the Regions were not

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"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.

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Office of Inspector General

Inspector General (2410)  
Deputy Assistant Inspector General for  
Internal Audits (2421)  
Headquarters Audit Liaison (2421)  
Divisional Inspectors General for Audit

Headquarters Offices

Assistant Administrator for Solid Waste and Emergency Response (5101)  
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Division Director, Analytical Operations and Data Quality Center (5202G)  
Division Director, Regions 5/7 Accelerated Response Center (5202G)  
Assistant Administrator for Research and Development (8101)  
Director, National Center for Environmental Research and Quality Assurance (8701)  
Division Director, Quality Assurance Division (8724R)

Agency Followup Coordinator (3304)

Associate Administrator for Regional Operations and State/Local Relations (1501)  
Associate Administrator for Congressional and Legislative Affairs (1301)  
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