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

SEP 11 2003

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Approval of the Quality Management Plan for the Office of Solid Waste and Emergency Response

FROM: Reggie Cheatham
Acting Director, Quality Staff
Office of Environmental Information (2811R)

TO: Devereaux Barnes
Director, Office of Program Management
Office of Solid Waste and Emergency Response (5103T)

I am pleased to approve the Quality Management Plan (QMP) for the Office of Solid Waste and Emergency Response (OSWER). Approval is valid for a period not to exceed five years from the date of this memorandum. Please remember that organizational and/or mission changes may make it necessary for you to revise and resubmit the QMP before the five-year approval period expires, per Section 3.2.4 of the EPA Order 5360 A1.

You and your staff are to be complimented on developing a quality system that encompasses all of OSWER. The OSWER QMP was reviewed in accordance with the specifications contained in Chapter 3 of EPA Order 5360 A1 (May 2000), *EPA Quality Manual for Environmental Programs*. Many of the specifications required under this EPA directive were left to the implementation plans supporting the OSWER QMP which have not yet been developed. As such, we will expect to be informed as these implementation plans are developed and approved and would be happy to assist in the development process.

If there are any questions about the review and approval, please call me at (202) 564-6830.

Attachment

cc: Barry Breen (5101T)
Tony Jover (5103T)

OSWER Quality Management Plan
August, 2003

TABLE OF CONTENTS

1. Management and Organization

It is EPA policy that each EPA Headquarters Office, National Program Office, Region and components develop, implement and maintain a quality system that complies with the requirements of EPA Order 5360.1 A2

The EPA requires each organization to develop a Quality Management Plan (QMP). The QMP documents the organization's quality policy, describes its quality system, and identifies the environmental programs to which the quality system applies. The QMP is implemented following approval of the organization's executive leadership and the AA for the Office of Environmental Information (OEI).

This document contains the Office of Solid Waste and Emergency Response's QMP. It delineates the policy and management structure to be used in implementing the OSWER quality system. While this QMP includes general descriptions of each of the individual components' quality system structure, offices will separately develop a more detailed implementation plan covering their activities. These plans will be documented and included as part of the OSWER Quality Assurance Annual Report and Work Plan (QAARWP) and reviewed and approved by the Deputy Assistant Administrator.

1.1. Policy Statement

It is the policy of OSWER that environmental data generated, processed, or used for its program requirements will be of known and documented quality, will achieve prescribed acceptance or performance criteria, and be adequate and sufficient for their intended use. Senior management [which is presumed to include the Assistant Administrator, the Deputy Assistant Administrator and Office Directors] are responsible for providing adequate resources for meeting the responsibilities contained in the QMP.

To ensure that this policy is uniformly applied to the generation and processing of OSWER environmental data, the Quality Manager is delegated the authority and responsibility for overseeing the development and implementation of the OSWER QMP. This QMP is designed to ensure that quality is a consistent aspect of the generation, processing and use of environmental data. This authority covers in-house and extramural environmental data collection and processing as a result of:

a. OSWER in-house environmental measurement activity
b. Contracts and Interagency Agreements
c. Grants and Cooperative Agreements
d. Partnerships with industry, federal, state and local government, and regional offices

1.2. Office of Solid Waste and Emergency Response

OSWER is the organization charged under the authorities of the *Comprehensive Environmental Response and Compensation and Liability Act (CERCLA), the Resource and Conservation Recovery Act (RCRA), the Emergency Planning and Community Right to Know Act (EPCRA), 112r of the Clean Air Act (CAA), the Oil Pollution Act (OPA), Section 311 of the Clean Water Act (CWA), and multiple sections of the Defense Base Closure and Realignment Act of 1990*, to protect and enhance the quality of the nation's land resources and to ensure the clean up of polluted sites to achieve the protection of the public and where possible full reuse of the land. It is the mission of OSWER to provide policy, guidance and direction for:

- safely managing waste,
- preparing for, and preventing chemical and oil spills
- cleaning up contaminated property,
- responding to environmental emergencies,
- and providing technical assistance to all levels of government establishing programs that safeguard our air, water, and land from the uncontrolled spread of waste.

OSWER is organized into program offices reporting to and staff offices attached to the Assistant Administrator's Office. The program office components are the Office of Superfund Remediation and Technology Innovation, the Office of Solid Waste (OSW), the Office of Underground Storage Tanks (OUST), the Office of Program Management (OPM) and the Office of Emergency Preparedness, Prevention and Response (OEPPR), the Office of Brownfields Cleanup and Redevelopment (OCBR); and the staff office components are the Federal Facilities Restoration and Reuse Office (FFRRO) and the Innovations, Partnerships and Communications Office (IPCO). [All references to Office include all organizational units unless otherwise stated.] The OSWER Quality Manager (QM) is located within the Office of Program Management and reports directly to the Office Director; however, the QM also reports to the Assistant Administrator and the Deputy Assistant Administrator on Quality issues.

Each Office has a Quality Officer, who is the quality manager for the program and is responsible for managing the day-to-day implementation of the quality system; acting as liaison between the Office and the Quality Staff within OEI on matters of policy; assisting in developing the OSWER QA Annual Report and Work Plan (QAARWP), including the implementation plan; managing component resources designated for the Quality System; and maintaining records of pertinent activities performed by the component. The quality officers within OSWER also coordinate the development of and revisions to OSWER's Quality Management Plan, as needed, to ensure its continued effectiveness, and engage senior management in decision-making regarding quality improvements within OSWER.

Each Office within OSWER has a unique set of statutory and programmatic responsibilities which govern how they are organized and how they accomplish those tasks. These Offices have the flexibility to develop their quality program to meet their unique organizational needs, integrated with the OSWER QMP. The programs and functions of these offices, as they relate to the quality system are outlined below.

1.2.1 Office of Program Management

The Office of Program Management is the administrative arm of the Assistant Administrator. This office is organized into four staffing groups: Acquisition and Resources Management (ARMS), Organizational and Management Integrity (OMIS), Policy and Regulatory Management (PARMS), and Information Management and Data Quality (IMDQS). These entities have key roles to play in the quality system.

Acquisition and Resources Management Staff (ARMS) is responsible for budget and contract management within OSWER. As part of their acquisition oversight responsibilities, they have responsibility for assisting staff in following the appropriate procedures for acquisition of goods and services, and in awarding and managing of grants to ensure their conformance with Agency and Federal rules and guidelines. ARMS support the Senior Resource Official (SRO) by reviewing all Procurement Initiation Notice (PIN) packages over $1,000,000 prior to the SRO approving or concurring on the pins, and in reviewing assistance and interagency agreement packages exceeding $250,000 prior to SRO approval. In addition, ARMS review all packages citing CERCLA 311(c) as its authorizing statute to ensure that activities under the grant are limited to research activities, as the law specifies. ARMS provide training to OSWER assistance agreement project officers to ensure compliance with EPA regulations and Office of Grants and Debarment policy and guidance. Streamlining of procurement process has reduced the role of ARMS in reviewing the complete procurement package, including the evaluation of the project for environmentally related data collections. This responsibility is now left to the project officer and Quality Officer for the organization requesting the acquisition.

Policy Analysis and Regulatory Management Staff (PARMS) are responsible for management of the regulatory development process, including policies and guidance which further the implementation of regulations, and as such, will have the responsibility for ensuring that the policies and guidance documents of the programs include, where appropriate, the requirements of the quality system in developing rules and regulations, guidance documents, and other regulatory control documents developed within OSWER. PARMS are also responsible for the Quality System Peer Review process.

Organizational and Management Integrity Staff (OMIS) are responsible for human resources management and management integrity requirements within OSWER and as such has the responsibility for assuring that appropriate quality requirements are addressed in management integrity activities, including OIG and GAO audits, FMFIA reviews, ethics and other integrity issues. They also review appropriate position descriptions and personnel performance standards. This staff is being proposed for relocation to the Deputy Assistant Administrator's office in the coming year.

Information Management and Data Quality Staff (IMDQS) is responsible for managing the information management and data quality programs within OSWER. These areas include information security, ADP acquisitions, Information Quality Guidelines and quality assurance and as such is responsible for assuring that information management activities reflect the requirements of the quality system and incorporate, as appropriate, controls in the direct operation of information systems to support the quality system.

OPM's quality program is a component of the OSWER QMP, and will prepare an implementation plan and document it in the QAARWP.

1.2.2 Office of Solid Waste

The Office of Solid Waste provides the Assistant Administrator of OSWER with guidance in the specific area of management of solid waste and hazardous wastes and the issues relating to the Resource Conservation and Recovery Act (RCRA). The Office of Solid Waste (OSW) contributes to the Agency's goal of protecting human health and the environment. Its principal responsibility is to build a national waste management program, implemented through EPA Regional Offices and State Programs, to manage solid and hazardous waste in the United States. OSW implements this program through the promulgation of regulations, policies, and guidance that apply to facilities and persons generating, transporting, treating and disposing of hazardous and solid waste and by developing national policies and programs to support resource conservation through pollution prevention and environmentally sound recycling.

All of OSW's functions, activities, and quality assurance tools are geared to help achieve the objective (described above) of building a national waste management program that contributes to the Agency's goal of protecting human health and the environment. Specific examples are the development and maintenance of national data bases containing waste program information; development of national standards and guidance; development of risk and economic modeling analyses to support particular standards and policies; technical assistance for Regional, State and Tribal programs; waste sampling in support of selected activities; coordination with other offices, agencies and national associations on quality assurance topics; implementing quality

assurance review procedures; and compliance assistance. Most of these examples are crosscutting in that they are implemented throughout OSW, often in several divisions. The first section below provides a general description of the OSW divisions, followed by a section describing major functions and quality assurance tools.

In order to fulfill its mission, OSW is currently organized into the following six divisions: Communication, Information, Resources Management Division (CIRMD), Economics, Methods and Risk Analysis Division (EMRAD), Hazardous Waste Identification Division (HWID), Hazardous Waste Minimization and Management Division (HWMMD), Municipal and Industrial Solid Waste Division (MISWD) and the Permits and State Programs Division (PSPD). OSW maintains a QA staff of one quality officer (QO) and five division quality coordinators which meet periodically as a group. OSW's QO reports to the EMRAD's Director, but, on quality issues, reports to the Office Director. While more detailed information can be found in the Office's implementation plan, a general description of each division follows:

Communication, Information, Resources Management Division (CIRMD): The CIRMD is responsible for managing an outreach and communication program to increase public awareness about hazardous and solid waste programs; managing the national RCRA information systems which include the technology aspects of the Waste Information Needs initiative, national RCRA data systems, RCRA Confidential Business Information, telecommunications components of the Agency Working Capital Fund, and operation of the office local area network; and providing administrative, budget and contract management support to the Office.

Economics, Methods and Risk Analysis Division (EMRAD): The EMRAD is responsible for evaluating toxicological and exposure data; developing health and ecological risk assessment support; applying multimedia fate and transport models to assist in the evaluation of the ecological and human health impacts of solid waste management systems. The division also develops and evaluates sampling, statistical, and analytical methods to support RCRA regulations and policies and develops and implement the RCRA quality assurance program.

Hazardous Waste Identification Division (HWID): The HWID is responsible for conducting industry studies to determine which wastes should be listed as hazardous; identifying the "characteristics" of hazardous wastes; evaluating delisting petitions; developing regulations and guidance regarding medical wastes, used oil, generators and transporters of hazardous wastes, and hazardous waste recycling; and defining what are Solid Wastes.

Hazardous Waste Minimization and Management Division (HWMMD): The HWMMD is responsible for encouraging the minimization of hazardous waste requiring treatment and disposal and for identifying the hazardous waste generation, treatment, storage, and disposal data that must be reported under RCRA. Implementation of its mission includes the Waste Minimization National Plan, the Land Disposal Restriction Plan, the EPA combustion, and the Waste Information Needs Projects.

Municipal and Industrial Solid Waste Division (MISWD): The MISWD is responsible for ensuring safe management of municipal, industrial and extractive wastes by providing technical guidance to industry, Regional, State and Tribal officials, and the general public.

Permits and State Programs Division (PSPD): The PSPD is responsible for the nationwide implementation of a program to control hazardous wastes, including the permitting of facilities and authorizing States to operate their programs in lieu of a Federal Program.

Major Functions and Quality Assurance Tools:

Waste Program Information: OSW manages several data bases of waste program information for use by the Agency and other stakeholders in analyzing national statistics concerning waste quantities, waste management practices and component constituents in wastes. A major example is the RCRA Information data base. In addition, special data bases have been compiled under particular studies, such as the 1996 National Hazardous Waste Constituent Survey and the 2001 Surface Impoundment Study. OSW also provides information to assist stakeholders through the RCRA Docket, the RCRA hotline and the Internet.

Standards and Guidance: Several OSW divisions regularly develop national regulatory standards and guidance, for use by regulated parties, Regions and States in implementing their waste management programs. These guidance and standards may be targeted to particular chemicals, groups of chemicals, listed waste streams, or waste management practices such as land disposal restrictions or cleanup programs. These represent the standards and goals for the national waste management program. In developing national standards, OSW assesses risks averted and costs of compliance, using "state of the science" analytic procedures such as peer-reviewed fate and transport models, and using data sources of the highest quality available. Use of these analytic tools helps improve the overall efficiencies of OSW's regulatory standards in defining national goals for waste management.

Technical support and assistance to Regions, States, Tribes and Communities: Technical support and assistance are important activities through which OSW helps Regions, States and Tribes achieve quality assurance objectives in their waste management programs. OSW also provides assistance to municipalities and communities concerning recycling and other programs.

Sampling data: OSW conducts direct sampling of wastes as part of selected regulatory efforts and studies, in order to accurately characterize the hazardous constituents, if any, present in certain waste streams. These sampling data are acquired using carefully defined data quality objectives and quality assurance project plans.

National Coordination on Quality Assurance Procedures: OSW's Methods and QA Team coordinate at the national level with other EPA programs, other Federal agencies and private sector organizations to help maintain the "state of the science" quality of laboratory analytical procedures for waste materials. OSW provides regular training programs and co-sponsors a national symposium with ORD, grantees and other organizations which is an opportunity for practitioners to convene for training, presentations and discussions of papers. OSW participates in ORD's National Environmental Laboratory Accreditation Program (NELAP) and in the Intergovernmental Data Quality Task Force (an interagency task force to achieve consistent data quality standards.)

Additional OSW Quality Assurance Review Procedures: OSW's QAM and QACs coordinate internal quality assurance procedures for the Office. For example, OSW ensures that quality assurance mechanisms are described in contract statements of work and individual work assignments, as appropriate. The QAM and QACs review quality assurance project plans to ensure the adequacy of the procedures described in them and they meet regularly to discuss cross-program quality assurance goals.

Compliance Assistance: Fundamentally, it is regulated parties and other stakeholders who have the initial, primary responsibility for assuring the quality of their data submissions for use in studies, rulemakings, and permit applications, and also for their on-site records of operating conditions. OSW works with Agency offices such as OECA and ORD's NELAP to help ensure that the various stakeholders develop and submit high quality data. OSW's role at the Headquarters level is primarily to review guidance for accurate regulatory and policy interpretations and to assist Regions with their compliance and enforcement activities. These data system reviews are implemented directly by Regions and States through a regular program of inspections, lab audits, and compliance or enforcement activities.

OSW's quality program is a component of the OSWER QMP and the Office will prepare an implementation plan and document the plan in the QAARWP.

1.2.3 Office Of Superfund Remediation and Technology Innovation

The Office of Superfund Remediation and Technology Innovation (OSRTI) is in the process of reorganization. The first phase of reorganization was completed at the end of June. This phase involved adding the Technology Innovation Office to OSRTI and moving the oil and removal functions to OEPPR. Given that a second phase of the former Office of Emergency and Remedial Response (OERR)[1] reorganization is expected to take place this fall, other organizational changes are expected that will affect OSRTI's quality assurance activities. OSRTI's quality program is a component of the OSWER QMP, and the effect of the reorganization on quality responsibilities and the development of a quality implementation plan will be documented in the QAARWP. Within OSWER, the OSRTI is the National Program Manager (NPM) responsible for managing the Superfund program in accordance with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986. In its capacity as Superfund NPM, OSRTI manages the Superfund remedial program response program, develops policy, and manages budgetary resources.

Several activities performed by OSRTI in its role as the Superfund NPM include:

- Issuance of procedural, scientific, and technical regulations and guidance;
- Procurement, management, and oversight of in-house and extramural projects;
- Oversight of regional Superfund program implemention; and
- Development and implementation of Superfund's quality assurance (QA) program for environmental data collection and environmental technology programs (collectively known as environmental data collections, or EDOs or environmental programs).

OSRTI is responsible for providing oversight in the development and implementation of remedial response actions in support of Superfund. OSRTI comprises fourteen centers and four Senior Process Managers responsible for providing support to Superfund program in strategic areas. A number of cross organizational teams support the work of OSRTI. One of these cross center teams is the Quality Enhancement Standing Team, which promotes sound quality practices within OSRTI. The Director of the Regions 5/7 Center serves as the mentor for this team and as the Quality Officer for OSRTI. While more detailed information can be found in the individual annual implementation plan, a general description of each center follows:

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[1] In the first phase of the OERR reorganization OERR was renamed to the Office of Superfund Remediation and Technology Innovation to reflect the changes in functional responsibility.

Analytical Operations and Data Quality Center (AO/DQC) oversees laboratory analyses for Superfund, other waste programs, and States through the Contract Laboratory Program. It also provides quality assurance oversight and develops laboratory protocols.

Community Involvement and Outreach Center (CIOC) develops policies related to community involvement in the Superfund process. It is responsible for interacting with Superfund stakeholders and external customers and is the OSRTI focal point for environmental justice issues.

Contracts Management Center (CMC) procures and manages OSRTI's mission support contracts. It provides national oversight and support for the Regional Superfund contracts; provides assistance in implementing OSRTI grants and IAGs; and develops and updates contract guidance and coordinates contract training.

Environmental Response Team (ART) Center located in Edison, New Jersey, Las Vegas, NV, and Cincinnati, OH, provides technical assistance to EPA, the U.S. Coast Guard, other Federal, local and state agencies, and foreign governments, in responding to environmental emergencies. Also, it serves as in-house technical consultant on Superfund and oil issues.

Five Regional Accelerated Response Centers, organized as Regions 1 & 9, 2 & 6, 3 & 8, 4 & 10, and 5 & 7. The Region 5 & 7 Accelerated Response Center is where the Office Quality Officer and quality expert are located. Staff in these centers provide Regional support and guidance to Regions, including development of policy and technical guidance; assistance in obtaining HQ approvals where appropriate; review of draft decision documents; assistance in listing of sites; and a variety of other issues.

Human and Organization Services Center (HOSC) manages the Office docket and directives systems, directs FOIA compliance and coordination, coordinates striped border reviews, manages all human resources matters, coordinates administrative services, and oversees EPA's Interagency Agreement with NTIS to handle all publication, inventory, and distribution of Superfund documents.

Information Management Center (IMC) designs and maintains CERCLIS and WasteLAN and supports headquarters and regional databases and systems, including headquarters automation. It collects and makes available general information and reports on sites (financial, demographic, and geographic) and the program.

Planning, Analysis and Resources Management (PARM) Center coordinates budget, program planning and program analysis functions throughout the organization. It develops program measures for Regions, conducts qualitative analyses of program, including FMFIA and GPRA.

State, Tribal and Site Identification Center (ST/SIC) coordinates all aspects of developing core capabilities between State and Tribal Superfund programs. Works with States and Tribes on site identification and manages the NPL listing process.

Senior Process Managers (SPMs) responsible for coordination activities across the centers in the following key program areas: Risk, Response Decision, Emergency Response, Pipeline Integration, and Reauthorization/Reform.

The Superfund Reform Coordinator manages OSRTI's Superfund reauthorization and administrative reform activities and keeps Regions informed on process and activities.

Both Centers and Teams undertake projects to improve OSRTI as an organization. These projects involve cross center/cross office/regional coordination, seek customer feedback and employ reviews to evaluate the implementation of guidance. The Technology Innovation Program (TIP) has recently entered OSRTI, as a staff office. The activities of the TIP are summarized below.

Technology Innovation Program. The mission of the Technology Innovation Program (TIP) is to advocate more effective, less costly approaches to assessing and cleaning up contaminated waste sites, soil, and groundwater. TIP disseminates technical and market information in an effort to remove policy and institutional impediments to adopting the new technologies and modernized strategies that comprise these "smarter solutions." A large part of TIP's activities revolves around building partnerships among private and public sector entities to coordinate information exchange and education, to facilitate resource-sharing for research and demonstration projects, and to avoid duplication of efforts. Ensuring the quality (technical and programmatic accuracy and completeness) of the information that TIP gathers and disseminates is critical to maintaining TIP's credibility as an agent for progressive change within OSWER.

TIP does not collect environmental data itself, nor directly oversee its collection. TIP is a user of secondary data. TIP does fund, or partner with various parties to sponsor, projects through which environmental data are collected. For such projects TIP requires that the implementing party prepare a Quality Assurance Project Plan that is reviewed and approved by the Quality Officer that oversees the implementing party.

OSRTI's quality program is a component of the OSWER QMP, and it will prepare a detailed implementation plan and document it in the QAARWP.

1.2.4 Office of Underground Storage Tanks

The Office of Underground Storage Tanks (OUST) is distinct within the Agency's Office of Solid Waste and Emergency Response, in both program design and approach. Due to the large universe of regulated active tanks (696,205) and the large number of confirmed releases (over 436,494), the program is designed to be highly decentralized in its implementation. EPA/OUST has allowed the states tremendous flexibility in structuring their particular programs, accepting large variations in how specific tasks are accomplished. The principal role of OUST regarding Regional implementation of the Underground Storage Tank/Leaking Underground Storage Tank (UST/LUST) program is that of national oversight. While OUST has national program leadership responsibilities and oversight, and performs many technical assistance functions, states are the primary implementing agencies. OUST is primarily a user (not a producer) of information gathered by the states (and in the limited case of tribal lands and some states, the Regions) from owners/operators of USTs, although OUST does perform data quality checks on the states' information.

Release Prevention/Detection for Underground Storage Tank Systems

Owners and operators of underground storage tanks (USTs) are required by Federal UST regulations to maintain proper documentation either at the UST site, or at a readily available alternative site. This is not environmental data collection subject to EPA's quality requirements. It is also important to note that this documentation generally involves testing records for the UST system, rather than a record of the equipment at the facility. A record of the actual equipment at a facility is reported to the state.

Corrective Action for Leaking Underground Storage Tanks Systems

Environmental monitoring is performed for the presence of contaminants at potential or known release sites. In accordance with the flexibility accorded to states in carrying out the program, OUST has not developed specific national guidance on how to conduct environmental monitoring during the corrective action process. LUST cooperative agreement guidance (OSWER Directive 9650.10) requires that states develop and implement quality assurance practices in accordance with 40 CFR Part 31.45. Specifically, the directive states, "[the details of the State's QA procedures should be appropriate to the circumstances of the releases for which the QA procedures will be applied, and should be designed to meet state program objectives." In the limited instances where states use contractors for environmental data collection, these efforts must be included in the scope of the states' quality assurance plans developed under the

LUST cooperative agreements. The LUST cooperative agreements are negotiated, awarded and actively managed by the Regions. Products produced under the cooperative agreements are subject to EPA Regional review and approval.

OUST's National Contract For Remediation Of Leaking Underground Storage Tanks In Indian Country

OUST's national remediation contract does have environmental measurement work, e.g., site assessments, soil and groundwater sampling, testing existing monitoring wells, and, therefore, includes QA/QC requirements in the contract. Specifically, the contract clause, Section E, Inspection and Acceptance, Subsection E.2, Higher-Level Contract Quality Requirement, requires that the remediation contractor comply with the following QA/QC requirements: (1) Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4); (2) Develop and submit a contract-level Quality Assurance Project Plan (QAPP). The remediation contractor developed, submitted and received EPA approval for the contract-level QAPP. (3) Develop and submit project-specific supplement to Programmatic Quality Assurance Project Plan for each applicable project. For the existing regional work assignment, the remediation contractor developed, submitted and received EPA approval for the project-specific supplement to its Programmatic QAPP. Future regional work assignments will follow this process. 4) Develop and submit a Quality Assurance Report at the end of the period of performance. The remediation contractor will develop and submit the final QA Report at the end of the contract's period of performance (September 30, 2006).

UST State Grants and LUST Cooperative Agreements

OUST utilizes the UST State Grant and LUST Trust Fund guidance documents as quality management practices for informing the UST/LUST Regional Program Managers of their quality management responsibilities. UST State grants and the LUST Cooperative Agreements are awarded in compliance with 40 CFR Part 31.

Headquarters and the Regional Division Directors also discuss the status of QA/QC as part of the Regional Strategic Overview process. The Regional Strategic Overviews describe the status of each state program in the Region, including a checklist of basic program elements, and identify the areas that the region will focus on over a two-year period. These areas include: working with states on national priorities, including near term needs and plans to improve the number of facilities in significant operational compliance with the leak detection requirements and with the spill, overfill, and corrosion protection regulations, reduce the backlog of cleanups to be completed, and address MTBE, as well as other challenges to ensure that good tank management

becomes common business practice. Regions are responsible for state program oversight and evaluation, and review and approval of formal applications for state program delegation. This review ensures that the state program is "as stringent as" the federal program and that the state has the enforcement capability to implement the program.

OUST's Approved Quality Management Plan

OUST had already submitted its Quality Management Plan (QMP) and received OEI's five-year approval in January 2000. Under the OSWER Quality Management Plan, OUST's QMP will be the quality implementation plan. The approved plan is comprehensive. The UST/LUST Regional offices incorporate their UST/LUST work into their Regional Quality Management Plans that govern their Regional environmental data collection. OUST's current QMP provides a programmatic perspective; that is, how the national program handles quality assurance and provides oversight of quality management issues. Under this plan, the Quality Officer for OUST reports to the Deputy Office Director for OUST.

1.2.5 Office of Brownfields Cleanup and Redevelopment (OBCR)

The Office of Brownfields Cleanup and Redevelopment (OBCR) is the national manager of EPA's Brownfields program. OBCR develops and promulgates policy; manages resources; oversees program implementation at the regions. The grantees in the Brownfields Program collect environmental data for the purpose of making decisions affecting human health and the environment. What follows is a brief description of the program, whereas more detailed information will be provided in our quality implementation plan and documented in the QAARWP.

On January 11, 2002, President Bush signed into law the Small Business Liability Relief and Brownfields Revitalization Act (Public Law 107-118; H.R. 2869) became law on January 11, 2002. The law will enable EPA to increase its support to Brownfields communities, especially in the area of conducting cleanups, to assist state and tribal brownfields programs. The new law will permit future support to brownfields projects that were not previously eligible; such as sites contaminated by petroleum, drug labs, or lands that are mine scarred.

EPA's Brownfields Program empowers states, communities, and other stakeholders in economic development to work together in a timely manner to prevent, assess, safely clean up, and reuse brownfields in a sustainable manner. Brownfields are real property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant. Brownfields properties are generally lightly contaminated or uncontaminated. States, cities, communities, or local non-profit entities typically lead the redevelopment of a Brownfields property, including appropriate environmental assessments and responses.

EPA, with assistance from the Federal partners of the Brownfields Initiative, encourages and promotes these Brownfields redevelopment efforts. OBCR and the Brownfields Teams at the regions develop policy statements, Memoranda of Understanding or Agreement, Cooperative Agreements, Assistance Agreements and Interagency Agreements with Brownfields redevelopment entities and other stakeholders to provide notice of EPA policy and intent, technical assistance, and grants under the authority of CERCLA. Some of the technical assistance and funds received from EPA are used by Brownfields site managers for environmental assessments that include collecting environmental data. Brownfields site cleanups are usually performed under the lead of a State, especially under State voluntary cleanup programs.

In September 1998, the publication, **Quality Assurance Guidance for Conducting Brownfields Site Assessments,** was issued. This guidance informs Brownfields site managers of important quality assurance concepts and issues, and provides a process for identifying the type and quality of environmental data needed to present a clear picture of the site's environmental conditions. It describes key principles and best practices for Brownfields site assessment quality assurance and quality control. It is based on experience gained from managing the Brownfields Program, and on EPA's body of knowledge developed from managing programs performing assessment and response under CERCLA, RCRA, etc. The guidance covers data quality objectives and process, quality assurance programs and plans, sampling design strategies, field and laboratory controls, document control, and provides a model Quality Assurance Project Plan. Copious references identify sources of additional information, including current relevant EPA documents. This guidance has been well disseminated to EPA regional Brownfields staff, managers of Brownfields sites, Federal partners supporting Brownfields site assessments, and other interested stakeholders. Regional Brownfields staff work with recipients of Assistance Agreements, Cooperative Agreements, and Interagency Agreements to ensure the tenets of this guidance are applied to Brownfields site assessments.

The OBCR Quality Officer/quality coordinator reports to the Director of the OBCR, is a member of the OSWER Quality Team and fulfills the relevant responsibilities identified in this QMP, including all of the Quality Officer responsibilities. Because environmental assessment data is collected by Brownfields site managers who are interfacing with regional Brownfields staff and the data are not reported to OBCR, the site-specific functions of the quality coordinators are performed by regional Brownfields staff, supported as appropriate by the OBCR Quality Officer/quality coordinator and in compliance with their approved regional QMP. OBCR ensures effective implementation of the quality system by management system reviews of the regional programs and regular communication via electronic media and meetings.

1.2.6 The Office of Emergency Prevention, Preparedness and Response

[Note: The former Chemical Emergency Preparedness and Prevention Office in OSWER was reorganized as of June 25, 2003 to include program elements formerly of OSWER's Office of Emergency and Remedial Response. The Quality Assurance Implementation plan for the new organization will be developed as part of the new organization's planning. The functions below include all the new Office's functions.]

The temporarily-named Office of Emergency Prevention, Preparedness and Response within OSWER is responsible for administering sections of three statutes: CERCLA, the Emergency Planning and Community Right to Know Act (EPCRA) and Section 112r of the Clean Air Act. The new office will continue those responsibilities and add ones described below, notably concerning the Oil Pollution Act and Emergency Response functions.

– The Office provides leadership, advocacy and assistance in the federal contingency planning for EPA's role in responding to major disasters or terrorist threats;
– In partnership with regions, federal, state and local governments, industry, environmental groups, and labor, supports the state and local role in preparing for and preventing chemical accidents under EPCRA and the Clean Air Act;
– Provides policy leadership and regional support for the Agency's response to domestic releases or threats of releases of hazardous substances and oil resulting from accidents or terrorist actions and conducts inter- and intra-agency coordination for Agency emergency responses and removal actions; and,
– Develops policy, guidance, and regulations to implement the Agency's oil pollution prevention program responsibilities.

Specific areas of involvement:

Federal Contingency Planning – This is primarily a coordination role with the other federal partners on the National Response Team under the National Contingency Plan. Implementation of the federal planning support is performed by the Office's Deputy Emergency Coordinator and staff who report directly to the Office Director.

Emergency Planning and Community Right-to-know Act -- The office's state planning support is centered in the State Emergency Response Commissions (SERCs), created under EPCRA, in all the States, territories, the District of Columbia and Native American tribes. The local planning support primarily addresses the Local Emergency Planning Committees (LEPCs) that work under the SERCs to develop local contingency plans and work with regulated facilities to prevent and prepare to respond to chemical accidents.

112r of the Clean Air Act (as amended in 1990 and by the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (CSISSFRRA) of 1999) – Under this Act, regulated facilities are required to prepare and implement risk management programs and document and submit Risk Management Plans (RMPs) for the prevention of chemical accidents. In order to streamline the receipt of RMPs and facilitate their distribution to SERCs, LEPCs, EPA Regions, the Chemical Safety Board and the public according to the law, the EPA provides collection and distribution support via a network of computer applications (the RMP system), the RMP Reporting Center, and Federal Reading Rooms.

The State and local program for EPCRA and CAA 112(r) is designed to be highly decentralized in its implementation. EPA has allowed the states flexibility in structuring their particular programs, accepting variations in how the SERCs, LEPCs and other local agencies are constituted and how the CAA is administered. While EPA has national program leadership responsibilities and oversight, and performs many technical assistance functions, states are intended to be the primary implementing agencies. EPA, state and local agencies may conduct audits (both on and off site) which can include reviewing the accuracy of the data reported but resources permit auditing of only a small percentage of the reporting population.

Emergency Response (ER) This is a newly acquired function for the Office. It provides policy leadership and regional support for the Agency's response to accidents or terrorist actions. This area conducts inter- and intra-agency coordination for Agency emergency responses and removal actions, including preparing information for senior Agency management, Congress, the pubic, and media and acting as liaison with other offices within EPA, and other federal agencies. In the event of a terrorist incident, in conjunction with the appropriate region(s), it provides technical advice and support to the FBI during the crisis management phase under the Federal Concept of Operations Plan for Terrorism Response (CON Plan) and provides the lead for ESF #10 under the Federal Response Plan.

The ER coordinates with elements within EPA and with other federal and state agencies in planning and conducting emergency response and homeland security training and exercises, providing oversight to the Preparedness for Response Exercise Program (PREP) established under the Oil Pollution Act, which includes working with other federal agencies in writing PREP Guidelines and conducting a uniform and coordinated nationwide exercise program for vessels and facilities.

The ER also is responsible for development and interpretation of emergency response, removal action, and homeland security program policy, guidance, and procedures; community outreach; and budget support and strategic planning.

Policy and procedure development responsibilities include: developing and maintaining program policies, guidance, and procedures related to emergency response, removal actions, and homeland security; developing and conducting training for regional offices on new policy areas; reviewing and analyzing draft legislation and regulations, policies, and procedures developed by other EPA offices and federal agencies that could impact the emergency response and removal program; compiling and analyzing data and information from field experience for use in evaluating and revising program policy and procedures.

Oil Pollution Act (OPA) – The program develops guidance and policies related to the facilities covered by the Act; provides monitoring research and development in government and private industry; leads efforts to implement new and innovative oil spill response technology and other tasks supporting the oil pollution response and prevention program, including data collection efforts; develops policy and economic studies, prepares guidance, and coordinates public participation on issues relating to the prevention of oil pollution.

1.2.7 Federal Facilities Restoration and Reuse Office

To overcome contamination at Federal facilities, EPA's Federal Facilities Restoration and Reuse Office (FFRRO) works with DoD, DOE, and other Federal entities to help them develop creative, cost-effective solutions to their environmental problems. FFRRO's overall mission is to facilitate faster, more effective, and less costly cleanup and reuse of Federal facilities. By focusing on teamwork, innovation, and public involvement, FFRRO and its Regional counterparts improve environmental cleanup, while protecting and strengthening the conditions of human health, the environment, and local economies.

FFRRO is a user of secondary data (not a producer of environmental data). FFRRO's quality program is a component of the OSWER QMP, and will develop an implementation plan document it in the QAARWP. The principal role of FFRRO regarding Regional implementation of a Quality System is oversight for national consistency. The Intergovernmental Data Quality Task Force (IDQTF), chaired by FFRRO, prepared a *Uniform Federal Policy for Implementing Environmental Quality Systems* (www.epa.gov/swerffrr/pdf/ufp_v1_final.pdf). The Policy was approved by the Assistant Administrator for Solid Waste and Emergency Response, the Assistant Deputy Undersecretary of Defense (Environment) and the Assistant Secretary of Energy for Environment, Safety and Health. It is jointly published under the following numbers:

EPA: EPA-505-F-03-001
DoD: DTIC ADA 395303
DOE: DOE/EH-0667

The use of this Policy by DoD and DOE in establishing quality systems, along with its use by EPA in overseeing those quality systems, is the basis of consistency within the federal community.

Responsibilities of FFRRO include:

- Supporting policy development and implementation regarding restoration and reuse of federal facilities,
- Facilitating participation by stakeholders in cleanup and reuse activities,
- Providing outreach and training to promote faster, more effective and less costly cleanups,
- Providing national acquisition of Regional Oversight Contract services,
- Supporting development of national, Intergovernmental Quality Assurance policy and guidance, including definition of roles and responsibilities,
- Developing and implementing a national Quality System for federal facilities, and
- Providing programmatic oversight of the implementation and continuing function of federal facilities Quality Systems in the Regions and at other Federal Agencies.

Responsibilities of other Federal Departments, Agencies and Instrumentalities include:

- Developing and implementing national Quality Systems that comply with Intergovernmental Quality Assurance policy,
- Requiring and overseeing the implementation and continuing function of Quality Systems in field and subordinate organizations, and
- Requiring the development and effective use of Quality Assurance Project Plans (or the equivalent) through the use of systematic planning.

Responsibilities of EPA Regional Offices include:

- Developing and implementing a program that ensures that federal facility Quality Systems comply with Intergovernmental Quality Assurance policy,
- Overseeing the effectiveness of Quality Systems implemented at federal facilities within the Region,
- Reviewing and approving Quality Assurance Project Plans for federal facility environmental data operations in the Region, and
- Overseeing the effectiveness of federal facility management of environmental data operations, including performance of all requirements in Quality Assurance Project Plans.

A number of activities related to oversight of federal facilities were specified in a Memorandum from James E. Woolford, Director of the Federal Facilities Restoration and Reuse Office and Nancy Wentworth, Director of the Quality Staff in 1999 that established specific actions that

Regions must implement to enhance the quality and oversight of our data collection and environmental decision making processes. The Memorandum reiterated the concept that ensuring reliable data quality is the responsibility of all personnel, not just one program or the quality assurance staff.

The requirements established by the Memorandum, and included by reference in this Quality Management Plan are quoted below:

> "15. Regional federal facility program managers and staff must routinely consult with Regional quality assurance personnel throughout the cleanup process. EPA Regional programs must clearly define and establish the roles and responsibilities of Regional QA staff and federal facility staff relative to the processes by which the lead federal (non-EPA) agency develops and implements data quality requirements for a cleanup agreement, permit, order, etc. Particular attention must be given to the roles and responsibilities relative to site-specific documentation on environmental data provided by other federal agencies that support response decisions. Please note that although a QAPP or similar document may not be specifically included as a deliverable in, for example, a Federal Facility Agreement (FFA) under the CERCLA National Contingency Plan (NCP), QAPPs are required and the lead federal agency is required to obtain EPA concurrence on them where the CERCLA process is being followed.[2] At a minimum, QA Officers and federal facility Superfund staff should work together to ensure that requirements are based on well defined data quality objectives (DQOs) and the appropriate documentation for each data collection activity is gathered to support the implementation of environmental response decisions."
>
> "16. Regional QA Managers must assess the effectiveness of the hazardous waste Quality System for federal facility cleanups implemented according to the Regional Quality Management Plan (QMP). A recommended approach to accomplish this requirement is through annual management system reviews (MSRs) of federal facility response programs. Also, the MSR can be used as an opportunity to set clear expectations and controls on core management and QA and quality control activities that can improve the coordination and integration of oversight of data quality activities. In particular, this would be appropriate action when an internal or external audit of the federal facility program identifies problems with the quality of environmental data collection systems or shortcoming with compliance with the QMP. For example, a Region should establish corrective measures on the management controls for environmental data

[2]Federal Register, Vol. 55, No. 46, March 8, 1990, Sections 300.415(b)(4)(ii), 300.430(b)(8) and 300.435 (b).

collection systems to include requirements for quality management plans that discuss the nature, frequency, and the roles and accountability of cross-functional managers/staff oversight of cleanup projects."

"17. At the facility/site level, EPA federal facility RPMs [Remedial Project Managers] are expected to work with the Regional QA staff and the federal agency lead counterparts to identify measures to detect data integrity problems. Although other federal agencies are designated lead authorities under Executive Order 12580 to address cleanup and related data integrity requirements, EPA has responsibility to establish data quality oversight procedures or practices that ensure that unreliable data are not used in decision making at federal facility cleanups and property transfers. For example, the systematic use of effective data verification and validation protocols; the use of data quality review tools/checklists; the training of data reviewers to heighten their awareness of indicators of fraudulent practices; and the use of qualified labs may also help in reducing the likelihood of both data integrity problems and fraudulent practices."

1.2.8 Innovations, Partnerships and Communications Office

The Innovations, Partnerships and Communications Office is a direct report organization within the immediate office of the Assistant Administrator and carries out the Innovations initiative, reviews and coordinates communications within the immediate office and provides support to partnership initiatives designed to further the AA's priorities. This office does not collect, produce or use environmental data. Its function is to provide communications support to the AA and the DAA and is included for purposes of providing a complete view of OSWER's organizational structure.

1.3. Key OSWER Management Personnel

1.3.1 OSWER Assistant Administrator

The OSWER Assistant Administrator has overall responsibility for OSWER programs and assuring that those program work according to Agency policy and has final authority within the organization on issues of quality. The direct responsibility for assuring data quality on an operational basis rests with line management. Ultimately, the AA is responsible for implementing QA policy in OSWER and for resolving QA issues identified through the QA program. The AA also provides leadership and visibility for quality to all OSWER programs and partners.

1.3.2 OSWER Principal Deputy Assistant Administrator

The OSWER Principal Deputy Assistant Administrator (DAA) has overall responsibility for managing OSWER's Quality System according to Agency policy. While the direct responsibility for assuring data quality rests with line management, the Principal DAA has responsibility for assuring that senior managers fulfill their roles in the quality system.

Major QA related responsibilities of the DAA include: approving the budget and planning processes; assuring that OSWER develops and maintains a current and germane QMP; ensuring adherence to the document by OSWER senior management and, where appropriate, other EPA offices and stakeholders; establishing policies to ensure that QA requirements are incorporated in environmental data collections; and taking corrective action that may be required from evaluation findings from the OSWER Quality Manager or other quality system reviews; and maintaining an active line of communication with the QM and Quality Team. The Principal DAA delegates the responsibility of the quality system development and implementation in accordance with Agency policy to the Office Directors. Oversight of the OSWER Quality program is delegated to the Quality Manager in the Office of Program Management.

1.3.3 Quality Board

This is a group of Senior level managers who meet on a periodic basis to provide direction and support to the organization in carrying out its responsibilities under the Quality Management Plan. The Board is the forum which addresses conflicts or disputes which impact the entire organization and makes recommendations concerning resources and priorities for quality improvements. The IRM Steering Committee for OSWER functions as the Quality Board.

1.3.4 Quality Manager

The Quality Manager (QM) is the AA's Quality Representative and as such is delegated management of the OSWER quality system and, as such, has direct access to the OSWER AA and DAA on all matters pertaining to Quality. In OSWER the QM is the staff director for the Information Management and Data Quality staff. Oversight of the OSWER quality program is delegated to the QM. Oversight includes coordination of activities on quality, dissemination of new or changed policies and procedures to appropriate Quality Officers and senior managers, and direct liaison with the Quality Staff in OEI on issues of quality which affect the organization or its components. Individual responsibilities are detailed in the Quality Manager's performance standards. The QM is the chair of the Quality Board and provides support and leadership to the Quality Team. The QM is independent of the data collections about which he has oversight.

Responsibilities include:

- collecting for submission to OEI, the annual QAARWP;
- interpreting Agency quality policy and developing the quality policy for OSWER in accordance with Agency policies and direction from management;
- assisting staff in developing quality documentation and in providing answers to technical questions;
- tracking the QA/QC status of all programs;
- assisting in solving quality-related problems at the lowest possible organizational level;
- recommending required management-level corrective actions; and
- serving as the program's liaison with the Quality Staff.

1.3.5 Office Directors for Program Components

The Office Directors serve as the Director of an OSWER program office and as the senior manager, with oversight of the Quality Officer and the quality program in their component. Major quality responsibilities include:

- appointing a Quality Officer, independent of the environmental data activities which are subject to the quality system, who will oversee the routine functioning of the quality system within the component and to be a member of the Quality Team for OSWER;
- developing the quality system within their organization and providing it with required resources and ensuring that Quality Officers are assigned for particular tasks or activities;
- meeting regularly with their Quality Officer to provide feedback and guidance;
- approving recommendations for continuous improvement to the quality system; and
- advocating quality as an objective and working to overcome barriers;
- ensuring that managers and staff follow the OSWER QMP;
- resolving disputes and conflicts which may arise within their organization, and

- submitting an implementation plan to the Senior Resources Official for review and approval; and
- submitting the Office's contribution to the annual QAARWP to the OSWER Quality Manager for submission to OEI.

1.3.6 OSWER Line Managers

Other key quality staff are the managers, supervisors, team leaders and project managers which we are identifying collectively as Line Managers. These people are responsible for ensuring that subordinate personnel are trained and follow the policies of the QMP and each is responsible for the quality of the data collected in his or her program or project. Line Managers are the quality advocates and key personnel for producing quality data.

1.3.7 Quality Team

The Quality Team (QT) is made up of the Quality Manager (QM) and the Quality Officer in each program component. The Team reports to the Quality Board and is responsible for developing the OSWER QMP and ensuring that OSWER management and staff within their respective organizations understand and adhere to its requirements. Team meetings are an opportunity for all Quality Officers to meet and discuss issues across OSWER. In addition to having the responsibilities noted above, the QT members and supporting staff carry out many varied support functions within OSWER. They support environmental data collection and analysis activities, both internal and external to EPA, including Regional Offices, state and local agencies, and businesses. Individual responsibilities are detailed in the employee's performance standards. While membership in the team is limited to the officers in each component, meetings are open to the quality coordinators in program offices. The leadership of the Team will rotate periodically among the members.

Responsibilities of the Team include:

- developing an OSWER QMP and revising it as necessary;
- developing and reviewing quality policies and procedures;
- coordinating the review and submission of the QA Annual Report and Work Plan to OEI;
- ensuring training or quality information such as quality requirements, protocols, and technology are made available to staff;
- ensuring that data collections are covered by appropriate quality planning documentation (e.g., project plans and performance acceptance criteria);
- identifying evolving quality issues;

- promoting quality within OSWER and with cooperating organizations; and
- providing quality leadership to other staff and organizations external to OSWER.

The QT has the authority to carry out these responsibilities and to bring to the attention of the senior managers of program offices any issues associated with these responsibilities.

Team Mission

The Office of Solid Waste and Emergency Response Quality Team is dedicated to ensuring that environmental data collections are of a quality that meets or exceeds requirements for informed environmental decision-making. The Team remains committed to providing the OSWER AA information, guidance, and expertise to ensure decisions are made to protect the public and the environment. The Team recognizes that quality products will be achieved through effective communication, training, cooperation, and a desire to produce the best results possible.

1.3.8 Quality Officers

The Quality Officers are the program quality managers within each of the seven OSWER Offices and serve as their office's representative on the Quality Team. The Quality Officers and the OSWER Quality Manager make up the Team. These officers are identified by different titles in the program components. The Quality Officers' responsibilities, which should be incorporated into their performance standards, include:

- Developing an implementation plan describing their quality system and submitting it for management approval;
- implementing the OSWER QMP within their respective components;
- acting as a conduit for information on quality to staff;
- representing the component's interests on the Quality Team;
- assisting the QM in developing and interpreting quality policies and procedures;
- coordinating the Office's input to the QMP and the Quality Assurance Annual Report and Work Plan (QAARWP);
- developing, facilitating, and providing training to staff on their quality responsibilities:
- reviewing Quality Assurance Project Plans (QAPPs) for program projects, as well as work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements that are performed on behalf of EPA within their component;
- reviewing and approving Quality forms for contracts and cooperative assistance agreements, as appropriate; and
- providing technical assistance to the coordinators or other staff on an as needed basis.

Each Quality Officer has the authority to carry out these responsibilities and to bring to the attention of his or her respective Office Director any issues related to these responsibilities. The review of QAPPs and other quality forms for implementing the quality system may be delegated by them to quality coordinators within their Offices. This reassignment will be outlined in the implementation plan, if it occurs. These officers are generally independent of the data collection activities that they oversee.

1.3.9 Quality Coordinators

The quality coordinators are the staff who provide quality support and assistance to the program staff, under the general auspices of the QM and the Quality Officers, and as determined by their respective Office directors. These staff may report directly to their respective QM or Quality Officer or they may provide support in the sub-units of their components. In most cases, only OSW and OSRTI, because of their size, and the QM because of his or her responsibilities will have need for a coordinator in addition to a Quality Officer. The activities of the coordinators in the offices will be further detailed in their Office implementation plan. The coordinator for the QM assists and supports the QM in implementing the Quality System in OSWER.

Responsibilities of coordinators, which should be incorporated into their performance standards in the coming year, if not already accomplished, may include:

- remaining current on Quality developments;
- providing technical support to staff in developing projects;
- if delegated responsibility, approving QAPP's; and
- providing staff support to the QT, as appropriate to their responsibilities.

1.3.10 Project Officers, Contract Officer's Representatives, Grants and Cooperative Agreement Officers

OSWER Project Officers, Contract Officer's Representatives, Grants and IAG Officers are responsible for including appropriate quality requirements within their contracts of work, grants and IAG's. Any uncertainty regarding these requirements should be discussed with the Quality Officer or other representative of the quality system and their concurrence regarding the applicability of such requirements obtained. These staff are responsible for assuring that all data collection activities obtained through grants, cooperative agreements, contracts or other agreements meet quality requirements and they determine the quality criteria to be applied, based on the intended use of the data. These personnel working together with the OSWER Line Managers are responsible for much of the quality assurance that is done within the programs.

Responsibilities include:

- developing, or assisting in the development of QAPPs using a systematic planning process;
- negotiating with contractors, appropriate QA representatives, and other technical personnel when needed;
- submitting QAPP plan for review and approval prior to project initiation;
- ensuring the implementation of QAPPs;
- ensuring that standard operating procedures (SOP) for each data collection operation are reviewed and approved;
- reviewing project QA/QC outputs; and
- developing, or ensuring the development of quality reports.

2. OSWER Quality System

2.1. OSWER Quality System Components for Environmental Data Collections

In order to meets its stated mission using environmental measurement data, OSWER has implemented a quality program that is designed to ensure that the environmental measurement data is of known and documented quality and can be used for its intended purpose. The following elements assist in the assurance of data quality and are described below:

- Quality Management Plan,
- Implementation Plans
- Quality System Audits,
- Systematic planning process,
- QA project plans,
- Standard operating procedures,
- Data quality assessments.

Various reviews to determine the successful application of quality in OSWER environmental data processes will be discussed in Section 9 and 10.

2.2. Quality System for Other OSWER Data Programs

OSWER is committed to adopting quality management principles and to continuous improvement of its programmatic and administrative processes. OSWER will work towards systematizing process improvements in its overall data management operations, administrative systems, contracts and grants management, regulatory development, information and data quality guidelines, and systems development during the life cycle of this QMP. OSWER will identify tools to allow it to evaluate its progress towards quality management in it programs.

2.3. Quality Management Plan

EPA policy requires that all Agency organizational units document their quality program in an approved Quality Management Plan (QMP). This document describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted. This QMP is developed in accordance with EPA Requirements for Quality Management Plans (QA/R-2). The QMP is developed for use by all OSWER staff, as detailed in Section 3. In addition, components of OSWER have or will develop implementation plans which further detail the activities of their program with respect to implementing a quality system in OSWER. These plans will be documented and updated in the annual QAARWP and incorporated by reference in this document when complete. The OSWER QMP will reside on the OSWER Intranet for easy access to all OSWER staff. A hard copy will also be filed in the records system of the QM. Approval for the QMP will include the OSWER Quality Manager, Office Directors, the OSWER AA and DAA. It is then submitted for approval by the Director of Quality Staff under delegation from the Assistant Administrator for the OEI. This approval is valid for up to five years, pending substantive changes to the organization's quality system during the interim.

The QMP and Quality System will be reviewed every year by the QT to determine if the information remains adequate to satisfy OSWER's quality needs. A briefing of the findings will be provided to the Quality Board and senior management. If the Board determines changes are required, they will be incorporated into the QMP. Changes will be documented and communicated to all OSWER staff, appropriately archived, and included in the applicable QAARWP. A copy of revisions will be sent to the QS in order to keep their copy of the OSWER QMP current. Every 5 years, based upon the original approval date, the QMP will undergo a thorough review, in its entirety, and go through the approval cycle. Since the QMP undergoes yearly reviews, this would simply be another yearly review with the addition of approval signatures.

2.4. Quality Implementation Plans

As part of the implementation of the QMP, each office must develop an implementation plan which outlines how they will organize and manage their quality system to ensure that the requirements identified in the QMP are implemented. This plan will be developed by the component primarily using the requirements in the QAARWP to describe its quality system. This includes identification of qualified quality staff, organizational responsibilities, training plans and accomplishments, resources, records contacts, and any other issues that need to be identified in order to move the system forward. The implementation plans will also address, as

applicable to their lines of business, procedures for developing, reviewing, and approving SOPs; records management processes; procedures for performing internal assessments; how the component will ensure that Quality Officer will be independent of data collection/use; and procedures for review/approval of QMPs for grants/contracts.

For those organizations which need additional details in their implementation plan, they may create their own more detailed procedures document which specifically address each of the requirements contained in the QMP and how they are implemented in their organization. In this case, the implementation plan provided as part of the QAARWP will provide a summary of this detail. Either a summary of the implementation plan or the plan itself will be submitted in a memorandum from the Office Director to the Deputy Assistant Administrator for review and approval. The Quality Manager is responsible for briefing the DAA and the Quality Board on the implementation plans prior to approval. Although the implementation plans will be discussed and reviewed annually as part of the QMP annual review and the QAARWP submission, their approval by the DAA will last for the five years of the QMP.

2.5. Quality Systems Audit

A quality system audit (QSA) is a qualitative assessment of data collections and/or organizations to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the quality of needed environmental data. It is used to determine the effectiveness of, and adherence to the QA program and the adequacy of resources and personnel provided to achieve and ensure quality in all activities.

An internal assessment of the OSWER Quality program will be conducted every year by the Quality Team, with emphasis on one or more components. Results of the review will be documented and the Quality Board briefed on the results. It is the responsibility of the QM, working with the Quality Team to follow up to determine the status of corrective actions identified as part of the assessment. We intend to coordinate within OSWER, as well as outreach to organizations to conduct these assessments and audits in the least burdensome manner possible. It is our expectation that the QS will conduct a QSA on alternate years.

2.6. Systematic Planning Process

The Systematic Planning Process (SPP) clarifies project technical and quality objectives, defines the appropriate type of data, and specifies tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. A systematic planning process is required for all environmental data collections and it must be documented, sufficient to allow for external review of the process. Systematic planning is based on a common sense, graded approach to ensure that the level of detail in planning is

commensurate with the importance and intended use of the work and the available resources. A QAPP is one example of how an SPP may be documented. The process should be appropriate to the importance and complexity of the project and will follow the guidance in *EPA Manual 5360, §3.3.8.1*.

The SPP is used to facilitate the planning of data collection activities. It asks the data user to focus their planning efforts by specifying the use of the data (the decision) and the decision criteria. The process for developing performance acceptance criteria:

- establishes a common language to be shared by decision makers, technical personnel, data generators and, where appropriate, statisticians in their discussion of program objectives and data quality.
- provides a mechanism to pare down a multitude of objectives into major critical questions.
- facilitates the development of clear statements of program objectives and constraints which will optimize data collection plans.
- provides a logical structure within which an iterative process of guidance, design, and feedback may be accomplished efficiently and cost effectively.

Development of performance acceptance criteria is a normal part of the systematic planning process and should be accomplished based on cost-effectiveness and realistic capabilities of the measurement process. The SPP assists the user in defining the purpose for an environmental data operation and sets the framework for the design, implementation, and quality assurance of the project. Once performance acceptance criteria are defined, where appropriate, a Quality Assurance Project Plan (QAPP) can be developed. When a project requires a rigorous approach to the decision making process a Data Quality Objective process should be followed. When one is determined necessary, it is the responsibility of the party responsible for collecting the data to define allowable uncertainty and to develop DQOs with the interested principals. To facilitate these determination, the Quality Staff (QS) of EPA developed specific guidance for DQOs in 1984, 1994 and again in 2000: *Guidance for the Data Quality Objectives Process (EPA QA/G-4)*, and *Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (EPA QA/G-4HW)* (Final - EPA/600/R-00/007, January 2000). By using the SPP to plan environmental data collections, EPA can improve decisions-making and the quality of data being collected.

2.7. Quality Assurance Project Plans

The Quality Assurance Project Plan (QAPP) is a formal document describing in comprehensive detail the necessary QA/QC, and other technical activities that must be implemented to ensure that the results of work performed will satisfy the stated performance criteria developed in the SPP. The information in this section applies equally to in-house and extramural QAPPs. If a

contract is involved, it is the responsibility of the Contract Officer's Representative (COR) to adhere to this policy. If it is a data collection performed under a grant, other type of assistance agreement or directly by EPA personnel then it is the person whose role is identified in the agreement as responsible for the data collection who must ensure a QAPP is developed. This person also bears the responsibility of providing copies of the approved QAPP to each individual who has a major responsibility for the data collection and of explaining the elements of the QAPP to these individuals. The Project Officer should ensure that the grantee or recipient of the assistance agreement is aware of their data quality obligations.

In most cases in OSWER, environmental data collections are performed in the Regions. QAPPs are prepared by the organization collecting the data, including EPA, other Federal agencies, contractors, and grantees. OSWER's role with regard to these activities is to ensure OSWER regional staff and other Federal agencies, contractors, grantees and permittees which engage in environmental programs comply with the National policy.

OSWER will use a graded approach to its quality program in order to meet the diverse needs of its programs and activities, as discussed in *EPA Requirements for Quality Assurance Project Plans (EPA QA/R5)*. As noted above, most of these quality determinations are performed at the regional level under the auspices of the regional QMP. Each program component develops its graded approach in consultation with the Quality Team and these approaches will be documented in the component's implementation plan. These plans will be updated as times change and will be part of our continuous improvement in this area and the progress will be reported as part of our QAARWP.

2.7.1 QAPP Review and Approval

QAPPs are prepared, reviewed and approved in accordance with *EPA Requirements for Quality Assurance Project Plans*. Copies of this guidance document, and others are available on the internet. These documents identify and define the elements that must be addressed in all formal QAPPs.

Each Office must identify and document its process for review and approval of any QAPPs prepared. The process should provide for a review and approval, separate from the preparer of the QAPP. These processes will be documented in the component's implementation plan. While these implementation plans have not yet been developed by the programs, these actions will be done as part of our continuous improvement in this area and then documented in this year's QAARWP.

Any revisions required to the original QAPP can be included in a second or subsequent revision or an addendum. However, sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes affect the collection of environmental

data, an addendum to the approved QAPP must be submitted that describes the changes and the appropriate QA/QC techniques necessary to meet quality objectives. When the vehicle for data collection is a contract or grant, the COR or the grants officer and the appropriate Quality Officer must approve the changes. QAPP preparers are urged to consult with the Quality Officer or coordinator during the preparation but prior to obtaining formal approval of the QAPP and any changes thereto.

All environmental data collections to be accomplished by OSWER staff (e.g any federal or SEE employee retained for OSWER services and located at the OSWER offices) must be covered by an approved QAPP prior to the start of the collection. The Grant and Federal Assistance Regulations 40 CFR 1 parts 30.53 and 31.45 document the quality approval requirements when a grant project entails environmental data collections and the project officers for the grants are responsible for ensuring that those requirements are addressed..

The QAPP signature and approval page will include the signatures of the QAPP preparer, COR or other responsible party, and the approving Quality Officer. If documented in the program implementation plan, the Quality Officer may delegate approval of the QAPP to a qualified and trained coordinator.

2.7.2.1 In-house Quality Assurance Project Plans.

All environmental data collections to be accomplished by OSWER staff (e.g any federal or private employee retained for OSWER services and located at the OSWER offices) must be covered by an approved QAPP prior to the start of the collection. Mission requirements in Emergency Response may involve the use of template QAPPs. These should only be used where there is an immediate need to protect life, health and safety. Development of a project specific QAPP should be accomplished as soon as possible following the emergency. Program QAPP templates may be used where routine or repetitive activities are being done. However, these templates must be reviewed and amended, where appropriate, before commencing work.

2.7.2.2 Extramural Quality Assurance Project Plans

The Grant and Federal Assistance Regulations 40 CFR 1 parts 30.53 and 31.45 document the QA requirements when the project entails environmental data collections. A QAPP, the level of which is determined by the grants project officer, will be required in these instances.

2.7.2.3 Other Federal Agency Quality Assurance Project Plans

Other Federal departments, agencies or instrumentalities performing environmental data collections under the authority of RCRA, CERCLA, or subject to the requirements of the Federal Facilities Compliance Act are required to prepare QAPPs. In some cases, such as federal facility

sites on the NPL, EPA approval of the QAPP is required. However, this approval process is primarily an activity of the regions, performed under the auspices of the regional QMPs. OSWER's role is generally one of oversight.

2.7.2 QAPP Archive

QAPPs should be filed with the Office Document Control Officer (DCO) or records management system. All original copies of the QAPPs and any subsequent revisions will be secured by the DCO or records manager. The Quality Officer will maintain a copy for the quality program files. If possible, a disk copy of QAPPs should also be acquired and maintained according to records disposition schedules.

2.8. Standard Operating Procedures

Standard operating procedures (SOPs) are written documents that detail the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. It is an approved method for performing certain routine or repetitive tasks. SOPs are protocols for all routine activities, especially those that are involved in the environmental data collections, which generally involve repetitious operations performed in a consistent manner.

SOPs should ensure consistent conformance with organizational practices, serve as training aids, provide ready reference and documentation of proper procedures, reduce work effort, reduce error occurrences in data, and improve data comparability and credibility while ensuring that decisions using such data can be defended. They should be sufficiently clear and written in a step-by-step format to be readily understood by a person knowledgeable in the general concept of the procedure. Staff preparing OSWER SOPs are encouraged to follow the QS document entitled *Guidance for the Preparation of Standard Operating Procedures (SOPs) EPA QA/G-6*.

In general, approval of SOPs occur during the approval of the QAPP. Individuals with appropriate training and experience with the particular SOPs in the QAPP need to review the SOPs. A method for maintaining SOPs and archiving obsolete documents should be addressed in the QAPP. Internal SOPs must be approved by the supervisor of the personnel responsible for writing the document. SOPs developed by external organizations should be approved by the responsible party to the grant or contract.

2.9. Data

Assessment of data's usability provides important information that allow the decision maker to determine whether the data produced from an environmental data collection support their intended use as outlined in the Systematic Planning Process. The QS have developed a document entitled *Guidance for Data Quality Assessment: Practical Methods for Data Analysis EPA QA/G-9* which can be used to assist in the DQA process. This process is used in a limited fashion because of its resource requirements. However, OSWER, while not requiring the use of QA/G-9 supports the importance of data review, validation, verification and comparison of data in all projects under OSWER's purview. OSWER also requires its component organizations to comply with the Information Data Quality Guidelines in the development and dissemination of its information, whether created by EPA, its agents or third parties.

3. Personnel Qualifications and Training

3.1. Personnel Qualifications

The staff members of OSWER are expected to have met the educational, work experience, and training requirements for their positions, as outlined by the Office of Personnel Management in their position descriptions. Quality responsibilities are outlined in position descriptions and performance plans of staff and managers, as appropriate.

3.2. Training Policy

It is the responsibility of senior management and Line Managers to ensure that staff involved in quality activities are appropriately trained and qualified for their assignments. Training may consist of classroom lectures, workshops, teleconferences, and on-the-job training. Courses may be required before an employee may engage in certain activities, such as health safety, Confidential Business Information (CBI), and contracts and grants management, or optionally, as in leadership or teamwork. Additionally, certain training may be highly relevant to the effective performance of certain work responsibilities, such data collection methods, the development of QAPPs, or acceptance or performance criteria for data collection and analyses. While these types of training are optional for many employees, for those employees engaged in environmental data collection activities, such training is required where the experience of the employees does not provide them with the ability to fulfill their responsibilities.

Training needs are identified each year by OSWER employees, as part of their self-evaluation process. This process is meant to help ensure that the staff members remain current in their technical fields, that they have opportunities for growth, and that they are able to meet the challenges of changing agency vision and goals. It is the responsibility of the employee's supervisor or management to review the training needs of their employees to ensure they are

properly trained for the requirements of their position. It is the responsibility of OSWER senior management to anticipate, identify, and communicate effectively, to both OSWER management and staff, changes in the OSWER vision and goals. It is also the OSWER senior management responsibility to establish a systematic measurement system [Performance Planning, Employee Rating Feedback, Opportunity & Recognition Management System - PERFORMS] to identify and comply with mandatory (statutory and regulatory) training requirements, to assess success of current non-mandatory training, and to identify opportunities for future cost-effective improvements. The annual performance review process is one mechanism for accomplishing this goal and for assuring compliance with any training requirements needed by the employees for success in their job performance. It is the Line Manager's responsibility to encourage OSWER staff to gain any desired training which may enable them to improve their ability to perform their duties.

3.2.1 Mandatory Training

COR and Assistance Agreement Project Officers' Training OSWER has established a procedure for assuring that contracts and assistance agreements are effectively managed. One aspect of effective management is assuring that staff have mandatory training before they engage in contract or assistance agreements management. The OSWER AA is the responsible official. Each OD has been further delegated responsibility for assuring staff compliance with training requirements. CORs and Assistance Agreement Project Officers must take certification courses and refresher courses in order to serve in an official capacity. The Office of Administration and Resources Management's Contracts Management Division have further oversight responsibilities of the CORs' work and Grants Administration Division have further oversight responsibilities of the Assistance Agreements Project Officers' work.

Quality Awareness Training Basic quality awareness training is required for OSWER officials with QA responsibilities. This includes Office Directors, CORs, Quality Officers, quality coordinators, as well as staff who are primary or secondary environmental data users. This training is provided by the Quality Officers within OSWER. The Quality Team will document, as part of the QAARWP a schedule of such training. OSWER will consider expanding this training to include all mid and senior level employees as part of its assessment of how to implement a quality system beyond environmental data activities.

3.2.2 Recommended Quality Training

It is OSWER policy that all staff who need additional quality training to perform their jobs will be provided the opportunity to obtain that training in order to meet the requirements of their position. Additionally, quality training needs should be reviewed annually as part of their performance review and in light of any changes to their positions or the quality curriculum.

Formal quality training is offered through the EPA Institute, EPA Quality Staff as well as in OSWER, the Technology Innovation Office.

In addition, OSWER uses contractors and academic institutions to develop and provide training for data collection activities that support regulatory efforts throughout OSWER, as well as the states and Regions. These training courses are obtained and administered by the various program components on an as-needed basis or as resources allow.

4. Acquisition and Assistance

OSWER must ensure that the items and services it acquires are procured and administered within EPA regulations, are delivered in a timely fashion, and are within the required specifications. The Acquisition and Resource Management Staff (ARMS) in OSWER assists staff in following the appropriate procedures for acquisition of goods and services to ensure their conformance with Agency and Federal rules and guidelines. ARMS provides training to OSWER assistance agreement project officers to ensure compliance with EPA regulations and Office of Grants and Debarment policy and guidance.

The procurement of services by the Office follows the Federal Acquisition Regulation, the U.S. Environmental Protection Agency's (EPA's) Acquisition Regulations for Contracts, and Part 30 of Title 40 of the Code of Federal Regulations (40 CFR 30) for assistance agreements. This section describes the process used to ensure activities related to grants and contracts produce results of acceptable quality.

4.1 Acquisition

In OSWER, ARMS supports the Senior Resource Official (SRO) by reviewing all Procurement Initiation Notice (PIN) packages over $1,000,000 prior to the SRO approving or concurring on the PINs. Several years ago, the Office of Acquisition Management streamlined the pre-award procurement process to promote and facilitate dialogue early in the pre-award process between the requiring office and the contract service center prior to preparation of many key documents. As a result, ARMS and the SRO now review only the PIN package, rather than a 32 point procurement package which was previously required. The PIN includes preliminary information about the procurement, some management certifications, the contract statement of work and management controls to address sensitive and vulnerable services.

All issued requests for proposals (RFPs) that include environmental measurements are required to include, as a portion of the proposal, a quality assurance project plan (QAPP). An evaluation criterion is devoted to determining whether the offerer will have a quality system in place to ensure that the quality of the service or product desired by the Agency will be delivered. An appropriate QMP is evidence of this. An independent quality assurance/quality control (QA/QC) function is required with the appropriate expertise and with procedures to assess the quality of all deliverables and to correct any deficiencies in meeting specifications. For laboratory services, the ability to attain the desired levels of precision and accuracy is evaluated by the use of performance evaluation (PE) samples. Performance on these samples constitutes a portion of the evaluation criteria. For environmental data collection activities, compliance with the good laboratory practices (GLPs) is required.

The project officer consults the program office's quality officer to determine whether the project involves these data. This ensures that all environmentally-related measurements, which are funded by EPA, or which generate data mandated by EPA will be scientifically valid, defensible and of known and documented quality. The project officer indicates his review by completing a quality assurance form and obtaining the concurrence of the Quality Officer. Both the project officer and the Quality Officer are required to sign this form; however, ARMS is not involved in this review. ARMS provides assistance as needed.

4.2 Assistance Agreements

In OSWER, ARMS supports the SRO in reviewing assistance and interagency agreement packages over $250,000, prior to SRO approval. This threshold is lower than the Agency standard of SRO review required for all funding actions over $1,000,000. In addition, ARMS reviews all packages citing CERCLA 311(c) as its authorizing statute to ensure that activities under the grant are limited to research activities, as the law specifies. OSWER can approve all CERCLA packages that are considered "social science research" while all other forms of research must be approved by the Office of Research Development (ORD).

For grants and cooperative agreements, quality assurance must be addressed in decision memorandums. Many assistance agreements involving environmental data collection are awarded in the regions under the auspices of the regional QMP. In Headquarters, proposals often are solicited through the Federal Register or an EPA web site and are selected through a competitive process. After a recipient is selected to receive an award, a QAPP following OEI guidance is developed by the recipient, if environmental data is involved. The QO approves the QAPP before funding is allowed. If a QAPP has not been approved prior to the award, a term or condition is included in the agreement requiring plan approval and outlining steps that must be taken for final approval. For agreements that require a QAPP, the PO must indicate in the decision memorandum that there will be environmentally related measurements or data generation under the agreement and describe the status of the plan. The extent of monitoring once an agreement has been awarded is negotiated between the PO and QAM. The recipient

activities are monitored through periodic reports and audits. The PO approved the adequacy of the final report.

5. Document and Records Management

Federal agencies are required to create and preserve Federal records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures and essential transactions of the agency, and all records necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities (44 U.S.C. 3101). As with all entities that handle federal records, organizations that perform environmental data collections must establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records.

OSWER's records management function is a decentralized process in which the core responsibility for managing federal records is assigned to each Office. Each Office is responsible for establishing a system to ensure that completed work meets EPA documentation requirements. The systems established in each office must conform to the requirements of Chapter 10 of Directive 2100 and may be reviewed by the National Records Management Program on a periodic basis to assist in improving those systems. Each Office is responsible for identifying a Records Management coordinator, as defined in Chapter 10 of that directive. The records management process within each Office will be addressed in the implementation plan.

OSWER has identified an OSWER records liaison official responsible for the coordination of the distributed implementation and maintenance of OSWER's records management system. This individual is responsible for the following activities:

- providing for awareness training of OSWER personnel on records management requirements;
- providing advice and assistance, as needed, on records issues which arise in OSWER; and,
- managing disposition and retention process for OSWER records.

6. OSWER Information Management

The Environmental Protection Agency's ability to fulfill its mission is dependent upon a strong information technology infrastructure. Mission objectives rely on an infrastructure that is capable of supporting environmental information and dynamic communication among EPA offices. One of the most critical components of the EPA infrastructure is information technology (IT). The hardware, software, and communications components that are encompassed by IT

form the foundation for environmental information and EPA-wide communication. The management of IT, therefore, is critical to the success of the EPA. OEI through National Technology Services Division (NTSD) is responsible for managing the EPA's IT infrastructure and components. In that role, OEI has established IT policies and standards to manage and ensure that IT components integrate properly into the infrastructure. The Clinger-Cohen Act also laid down certain requirements for IT budgeting, planning, development and implementation, which have been incorporated into the Agency's guidance on these matters. OSWER follows the OEI guidance with regard information resources management.

6.1. System Development

OSWER has several mission critical systems [as defined in Directive 2100], i.e. CERCLIS, RCRA Info, and RMP Systems. In addition, OSWER has numerous Level 2, 3, and 4 systems which are the primary responsibility of the initiating office. It is OSWER policy to follow the requirements and guidance of EPA Directive 2100 in developing, installing, testing, using, maintaining, controlling and documenting major software systems. OSWER has issued Life Cycle Development Guidance that the program offices can use in developing and managing their systems. The Agency is in the process of revising its LCD guidance and OSWER will follow that guidance when issued. Change management is a function designed and managed at the system operational level. We operate in accordance with the Clinger-Cohen Act which requires that information technology be acquired, maintained and operated in an effective and efficient manner which supports program management goals. Each program developing such systems is responsible for ensuring the systematic and careful acquisition and development of those systems it funds. Under a 2003 memorandum to all OSWER Office Directors from the Associate Deputy Assistant Administrator, the Senior Information Resources Management Official is responsible for reviewing and approving most information resource acquisitions.

Information management system development, improvements, and updates formerly were required to comply with OARM's *System Design and Development Guidance*, EPA Directive 2182, dated April 30, 1993, to include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers, prior to the design of the system. Although this directive expired in 1996, it continues, along with OSWER's Life Cycle Development Guidance to be used to assist program staff in developing systems in accord with EPA Architecture Road Map and applicable federal acquisition requirements, including OMB Circulars and Federal Information Processing Standards (FIPS). Once OEI issues replacement Lifecycle Development Guidance, OSWER will follow the requirements identified through that guidance. Further, OSWER has security plans in place for its mission critical systems and is developing plans for all major systems which serve key mission objectives. These security plans are intended to ensure the integrity of the data contained therein. Without such assurance, the quality of the data could be compromised.

6.2. Data Standards

All Federal agencies are required to adhere to federally mandated data standards, regulations and executive orders. Further, it is the policy of OSWER to the extent practicable, to comply with applicable guidance, and internal policy documents concerning data standards. These include:

- Environmental Data Registry and any applicable implementing guidance; it is the responsibility of each individual Program Office to be aware of the current standards and regulations.
- The National Institute of Standards and Technology (NIST) develops standards and guidelines to achieve the most effective use of Federal information. The FIPS are the Federal data standards for all data exchange among agencies.
- The EPA Data Standards Program is established and documented in the *Information Resources Management Policy Manual*. Within EPA, data standards policy is developed under the direction of the OEI. In general, EPA's data-related policies apply to all EPA organizations and personnel, including contractors, grantees, Senior Environmental Employee Program participants, fellows, and other personnel assigned to EPA who design, implement, and maintain information management systems for OSWER and EPA.

7. Quality Planning

It is OSWER policy to plan its programs and projects effectively. Quality planning must occur at three levels to ensure that OSWER meets its programmatic and quality goals: (1) Office-wide, (2) program-specific, and (3) project-level. OSWER's focus is on office-wide and program specific planning, since most project-level activities occur at the regional level. OSWER will work with Agency processes to develop a more formalized approach to reviewing program and project planning. Project level quality is ensured generally in the Regions under the auspices of the regional QMPs and by other Federal Agencies, with oversight from the appropriate HQ program offices. OSWER participates in Agency-wide planning through its contribution to the EPA strategic and operating plans and development of GPRA goals and objectives. Quality planning must be an integral part of the development and implementation of OSWER's operating plan and GPRA goals.

7.1. Office-wide Planning

The OSWER operating plan, developed by OSWER and its Planning and Budget staff, is the foundation upon which all programmatic activities and corresponding data collections are based. Annual program plans, tied to the budget process, identify the types of data operation that should occur.

OSWER will review the QMP annually and, at a minimum will update it every five years. As part of the Quality Assurance Annual Work Plan (QAARWP), OSWER and its components will report the status of their implementation plans and their planned operational activities in those areas where the organization will focus its quality management efforts for the upcoming year. OSWER determines those areas on which it will focus its efforts by reviewing activities from the previous year. Based on this review and on the available budget, OSWER will include in the QAARWP plans to correct any deficiencies in its quality activities. OSWER must increasingly coordinate the collection and use of environmental data and related activities across many EPA, Federal, state, local, academic, and private organizations. This close coordination is essential to ensure that data are of known type and quality and can be shared where data objectives are similar.

7.2. Program-specific Planning

Programs are functional work areas authorized by statute and Congressional direction. The OSWER programs covered by this QMP approach program level planning in a variety of ways. These efforts are coordinated with other offices as appropriate. Program specific planning processes are identified in individual implementation plans and documented in the annual QAARWP's.

7.3. Project-level Planning

A project is an organized set of related activities within a program. When a program begins a project, the initiating program will organize a project team. If the project involves environmental data collections, the team will include members who have knowledge or experience in the following areas: sampling, analysis, statistics, and QA/QC. It is the responsibility of the team leader and his/her supervisor to ensure that these areas of expertise are adequately represented on the team and that project-level planning addresses the needed components of quality planning. All projects will be subject to the same requirements, whether they are done extramurally or in-house; however, these requirements will follow a graded approach applicable to any individual project. Any project-level systematic planning will be addressed in the QAPP's. Most of OSWER's programmatic activity at the project level is in the Regions and other federal agencies and this systematic planning will be accomplished and documented according to the regional QMP. Projects will follow appropriate EPA quality

guidance regarding incorporation of quality requirements in the particular activity and should always consult with the appropriate Quality Officer for technical assistance, if there is uncertainty regarding how to apply quality requirements.

8. Implementation of Work Processes

The procedures described in this Section on the implementation of work process must be followed within all Offices in OSWER.

8.1. Program Implementation

OSWER developed the QMP as a means of documenting how the organization will plan, implement, and assess the effectiveness of quality applied to environmental programs. All Offices within OSWER are responsible for the implementation of the QMP and for oversight of quality implementation in the Regions & other Federal agencies. The level of management involvement required is determined by each program office.

All EPA organizations conducting environmental programs must submit an approved QAARWP to the director of the QS by November 1 each calendar year. The purpose of the QAARWP is to inform Agency senior management about the status and effectiveness of the organization's quality program. The QAARWP documents the findings of management's assessment of the organization's Quality System, documents performance during the immediate past fiscal year, and provides the work plan for the upcoming fiscal year's priorities for the organization's quality system. In OSWER, the QAARWP will also document the implementation plans for the component offices.

8.2. Project Implementation

It is OSWER policy that its environmental data collections be supported by a QAPP. See Section 2.7 for additional detail. The COR or other responsible party such as the grants officer, project officer, project team leader in the case of assistance agreements or in-house projects is responsible for obtaining approval and then implementing the QAPP. The responsible parties immediate supervisors are responsible for ensuring the responsible party as described above, perform these duties in compliance with the specific regulations and guidance. Regions and other Federal agencies are responsible for developing and implementing QAPPs for projects conducted under their authority. The ongoing surveillance of the project status by these entities, as well as by the OSWER staff as part of the planning process, will help ensure that the product meets the needs of the intended user. The role of the OSWER Quality program is generally in oversight and technical assistance in the implementation process and this oversight and technical assistance is integrated into the management and program processes to the fullest extent practicable.

9. Assessment and Response

The Office of Solid Waste and Emergency Response, in full coordination with its program and regional components anticipates using assessments to evaluate compliance with the requirements of this QMP and the regional Quality Management Plans. This focus on quality systems is designed to improve the quality of environmental data collections. The assessments are an independent process of evaluating the ability of an organization to function as documented. The assessments help ensure the integrity of environmental data collection programs. These collected environmental data are the basis for regulatory and guidance development and for compliance assessment, across and the entire Agency. OSWER plans to use *G-10, Guidance for Developing a Quality Assurance Training Program* to determine and develop training requirements for those involved in assessment and response activities, including management systems reviews and audits. Until that guidance is implemented, the OSWER supervisors must use their judgment to ensure that each time they assign someone to an assessment and response activity, the individual assigned has the correct technical expertise; and the appropriate audit and/or management systems review training. OSWER intends to include quality as a component of its management and other compliance reviews of the programs and regions. Further, as part of their implementation plans, the program offices will address their use of assessments in their implementation plans.

9.1. Auditing

An audit or assessment is a systematic and objective examination of a program or project to determine whether environmental data collection activities and related results comply with the project's QAPP or other data quality planning documents, are implemented effectively, and are suitable to achieve the project's data quality goals. The frequency and level of detail of an audit must be appropriate to the importance or criticality of the data and the program or project.

9.1.1 Technical Systems Audits

A Technical Systems Audits is a systematic and objective examination of an intramural or extramural project to determine: whether environmental data collection activities and related results comply with the project's QAPP; whether the procedures defined by the QAPP are implemented effectively; and whether they are sufficient and adequate to achieve the QAPP's data quality goals. TSA's are employed during the data collection activity at the project level. This activity in OSWER is most often performed by the Regions and by other Federal Agencies, as that is where the bulk of data collection takes place. HQ's role is one primarily of oversight for compliance with the QMP.

9.1.2 Surveillance

Surveillance is an ongoing monitoring and verification of the status of a project and an analysis of records to ensure that specified requirements are being fulfilled. It occurs when the product user oversees the actions of the producer, on a real-time basis, during development of the product. One purpose of surveillance is to identify potential problems as quickly as possible, and to institute corrective action such that a suitable product is developed for the user. Effective use of surveillance will reduce the negative impact on both producer and user in developing an acceptable product. Surveillance may occasionally be used on projects within OSWER.

9.1.3 Readiness Review

This is a systematic, documented review of the readiness of the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work. This activity is not routinely performed at HQ, except under the circumstances of an environmental emergency response. When otherwise performed, it is generally used at the Regional and other Federal agency level.

9.1.4 Data Quality Assessments

Not all technical assessments fit the definition or attributes of "audits" precisely. In the context of EPA use and the application of these assessments to environmental programs, they contain some of the general characteristics of audits but usually are more subjective and may lack the specific measurable criteria typically expected of audits. One type of technical assessment which does have the rigor of an audit is known as a DQA.

DQA is the statistical analysis of environmental data, to determine whether the quality of data is adequate to support the decision. Data are appropriate if the level of uncertainty in a decision based on the data is acceptable. The guidance in Section 10.2 should be used by personnel in OSWER, but primarily by Regions and other Federal agencies, when accomplishing statistical data quality assessments.

An assessment of data quality whether statistical or by analysis of the success in meeting the objectives of the QAPP should be accomplished routinely when using data for environmental decision-making.

9.1.5 Audit Planning

Audit planning is a necessity in order to conduct efficient audits. An audit plan for all types of audits will include the following items:

- Audit title

- Audit number - Year and number of audits can be combined, as in 91-1, 91-2
- Date of an audit
- Scope - establishes the boundary of the audit, and identifies the groups and activities to be evaluated. The scope can vary from a general overview, to total system, to part of a system, and will affect the length of the audit
- Purpose - What the audit should achieve
- Standards - Standards are criteria against which performance is evaluated. These standards must be clear and concise and should be used consistently when auditing similar facilities or procedures. The use of audit checklists is suggested to ensure that the full scope of an audit is covered and provides consistency when auditing the same activity more than once
- Audit team - Team lead and members
- Auditees - People who should be available for the audit from the audited organization. This should include the program officer, principal investigator, organization QA representative(s), other management, and technicians as necessary.
- Documents - Documents that should be available in order for the audit to proceed efficiently. Too often, documents are asked for during an audit, when auditors do not have the time to wait for these documents to be found. Documents could include QMP's, QAPPs, SOPs, control charts, raw data, QA/QC data, previous audit reports, etc
- Time line - A time line of when organizations (auditors/auditees) will be notified of the audit in order for efficient scheduling and full participation of all parties.

The audit plan document is not a major undertaking and, in most cases, will be a one-page table or report. However, the document represents thoughtful and conscious planning for an efficient and successful audit. The audit plan should be made available to the organization audited, with adequate lead time to ensure that appropriate personnel and documents are available for the audit.

9.1.6 Audit Reporting

A debriefing will occur at the completion of the audit. Positive and negative aspects of the audited activity will be discussed between the audit team and management of the area audited, and, if necessary, the technical personnel performing the measurement activity. Copies of the draft audit summary and findings should be provided to all those in attendance. Necessary action to improve the measurement system/organization will be discussed with audit participants.

The final audit report will include:

- Audit title and number and any other identifying information
- Names of audit team leaders, audit team participants and audited participants

- Background information about the project, purpose of the audit, dates of the audit, particular measurement phase or parameters that were audited, and a brief description of the audit process
- Summary and conclusions of the audit and corrective action
- Attachments or appendices that include all audit evaluation forms and audit finding forms

The final audit report should be completed within five working days of completion of the audit. It is the responsibility of the review team lead to forward final audit reports to the appropriate participants. The audit report should have restricted distribution, in order to foster constructive working relationships. Follow-up meetings may be held as appropriate to discuss significant concerns.

9.2. Response Actions

The audit reports will be discussed with the audited organization, and action(s) necessary to rectify and control the situation will be developed. Line management may be asked to assist in problem resolution, as necessary. A mechanism for tracking this information at the program level will be developed and included in the audit file. OSWER audit tracking is accomplished in the Organization and Management Integrity Staff. If major deficiencies are found, follow-up audits may be required and should be discussed and coordinated with the audited organization.

9.3. Peer Review

Peer review is well established as a mechanism for assuring the quality, credibility, and acceptability of both individual and institutional work products of scientific and technical nature. OSWER uses a network of designated peer review coordinators to help ensure that OSWER managers are appropriately considering and supporting peer review for their scientific and technical work products and Peer Review Leaders are implementing the proper peer review procedures set forth in the EPA Peer Review Handbook. OSWER has an office-wide Peer Review Coordinator in the Policy and Regulatory Management Staff who ensures dissemination of the latest peer review policy information to OSWER offices, participates on an EPA Peer Review Advisory Group to ensure cross-cutting OSWER issues and positions are raised, and coordinates preparation of the annual peer review report to the Office of Research and Development (ORD) database.

Each office within OSWER also has a designated peer review coordinator, who interacts with OSWER managers and Peer Review Leaders within their offices on a day-to-day basis to promote and support the appropriate use of peer review. During the annual peer review reporting process, these office-level coordinators help ensure that managers have identified all of their scientific and technical work products and considered peer review where warranted. Each

OSWER office has its own process for identifying their scientific/technical products and making decisions regarding peer review. With the support of the OSWER Peer Review Coordinator, the office-level coordinators also provide peer review training to managers and staff in their organizations.

In accordance with the Peer Review Handbook, it is the Decision-Makers that are primarily responsible for assuring compliance with the agency's peer review policy. Within OSWER, front-line decision-makers have been assigned in each of the offices, generally at the division/center level in larger offices and at the office director/deputy office director level in the smaller offices. It is their job to ensure peer reviews are conducted for major scientific/technical work products and that needed resources for peer reviews are included in their budget requests. These decision-makers will be identified in the program's implementation plan. The OSWER and office-level peer review coordinators support them in that effort.

10. Quality Improvement

The intent of this section of the QMP is to develop and foster the culture that recognizes and embraces the concept that quality must be incorporated into all work functions. In this effort, OSWER will be continually striving for improvement. This section describes how OSWER will detect and prevent quality problems and describes the process for ensuring continuous improvement. This process will be discussed for both program and project levels.

10.1. Program Review and Improvement

Program improvement and quality management for OSWER and its programs cannot be solely accomplished by any particular group. It requires the sustained commitment of all levels of management to emphasize and encourage continuous improvement by staff in their development and implementation of projects, initiatives, and ongoing programs. The system established by the QMP cannot be the responsibility of any one group or individual. Quality improvement must be everyone's job and must be incorporated into the everyday, ongoing work of the Office.

A role of the Quality Team (QT) is to provide technical assistance to the various units of the program as they embark on quality improvement projects and to review and comment on the processes that exist or processes which do not incorporate the quality objectives of OSWER. The QT meets to discuss cross-cutting issues and to look at ways of improving the organizational philosophy about QA. Of particular benefit is the representation of all the Offices within OSWER on the QT. This provides unique views of the quality process and to which programs it applies. By discussing new aspects of quality, the Team has the opportunity to continuously improve the individual programs.

The Quality Board will also provide a perspective on the continuous improvement process and issues will be presented to the board when a resolution cannot be reached at the program level. The Board will also provide advice and recommendations to OSWER management on ways to improve the quality processes within OSWER.

OSWER Management will rely on the regular internal program reviews undertaken in response to issues or problems identified. OSWER Management will also rely on Quality System Audits conducted by the QS and IG audits as external program reviews to improve our processes. Any deficiencies identified through any of these mechanisms will be addressed through the development of appropriate action plans, which could include revision of the QMP, if necessary.

The QMP is reviewed annually by the QT and the Quality Board in order to determine if the document remains relevant to the OSWER mission. It is OSWER's policy that the QMP should guide the environmental programs within the organization in accomplishing their program mission in a high quality manner. The QAARWP serves as the assessment mechanism and the blueprint for the next year's actions at improving programs and at implementing any QMP revision needed to address changes to the OSWER mission.

10.2. Project Reviews and Improvement

Project reviews can be accomplished using the tools described in Section 9. There are two types of project reviews. The goal of the first type of project review is to detect and correct conditions that could adversely compromise the ability to use the products for its intended purpose. This goal will be accomplished by employing the principles of data quality objectives in the planning phase of the project, to translate the user's needs into defined product characteristics that, if met, both user and producer agree will satisfy the user's need. This will be documented and will form the basis for determining the success of the project. It is the duty of the project staff lead responsible for producing the product to ensure that this documentation is developed and the goals established for the project are met. For traditional environmental data collections, this is typically called a QAPP, or Site Test Plan.

For products such as a regulation, a similar process should be followed, but the measures of success will usually be more global and will include policy measures as well. It is the duty of the user staff lead to review and (ultimately) approve the proposed specifications prior to the start of the project, to provide timely notification to both the producer and his/her Line Manager if project needs change that could require product changes, and to promptly notify the producer if there is a problem with using the finished product. It is the user's Line Manager's responsibility to resolve potential budget increases that result. Where the producer and user are both in OSWER, it is the responsibility of the producer and user's Line Managers to ensure that a systematic process is in place to accomplish the goal of timely detection and correction of conditions that could adversely compromise the product's end use. It is the responsibility of the OSWER senior management to provide a work atmosphere that encourages this process and,

when the user is outside of OSWER, to take on the role of a key user (decision maker) during the planning phase, to ensure that the measures by which success of the project will be judged are conveyed to the project lead. There should be an assessment of data quality made at the end of the project, to ensure that the measures of success are met and to provide input to the second type of project review.

The goal of the second type of project is to look for ways to ensure that the customer receives future products within the required time frame, at acceptable quality, and for less cost (continuous process improvement). It is the responsibility of the OSWER senior management to provide both a work atmosphere that encourages process improvement and a budget system that documents and rewards cost-saving innovation. It is the responsibility of the Line Managers to ensure that a systematic planning process is implemented that categorizes typical work products of the group, documents historical costs, assesses the potential for process improvements, and ensures the implementation of improvement recommendations resulting from this systematic planning process. It is the responsibility of the project staff to actively participate in this systematic planning process by offering suggestions and by implementing recommended process improvements. Among the tools which are used include the customer survey and the focus group. A feedback mechanism should be developed and incorporated into projects as they are being designed.

The focus of improvement should be real-time “customer satisfaction”, product quality, timeliness, and effective use of resources.

This is to certify that the Quality Management Plan has been reviewed and approved by the following Senior Managers of OSWER :

Barry Breen
Principal Deputy Assistant Administrator
Office of Solid Waste and Emergency Response

Tony Jover
Quality Manager
Office of Solid Waste and Emergency Response

Devereaux Barnes
Director
Office of Program Management
Office of Solid Waste and Emergency Response

Mike Cook
Director
Office of Superfund Remediation and Technology Innovation
Office of Solid Waste and Emergency Response

Robert Springer
Director
Office of Solid Waste
Office of Solid Waste and Emergency Response

Cliff Rothenstein
Director
Office of Underground Storage Tanks
Office of Solid Waste and Emergency Response

Ann Marie McDonough

for Linda Garczynski
Director
Office of Brownfields Cleanup and Redevelopment
Office of Solid Waste and Emergency Response

Stephen O'Hare for

Debbie Dietrich
Director
Office of Emergency Preparedness, Prevention and Response
Office of Solid Waste and Emergency Response

J E Woolford

James Woolford
Director
Federal Facilities Restoration and Reuse Office
Office of Solid Waste and Emergency Response

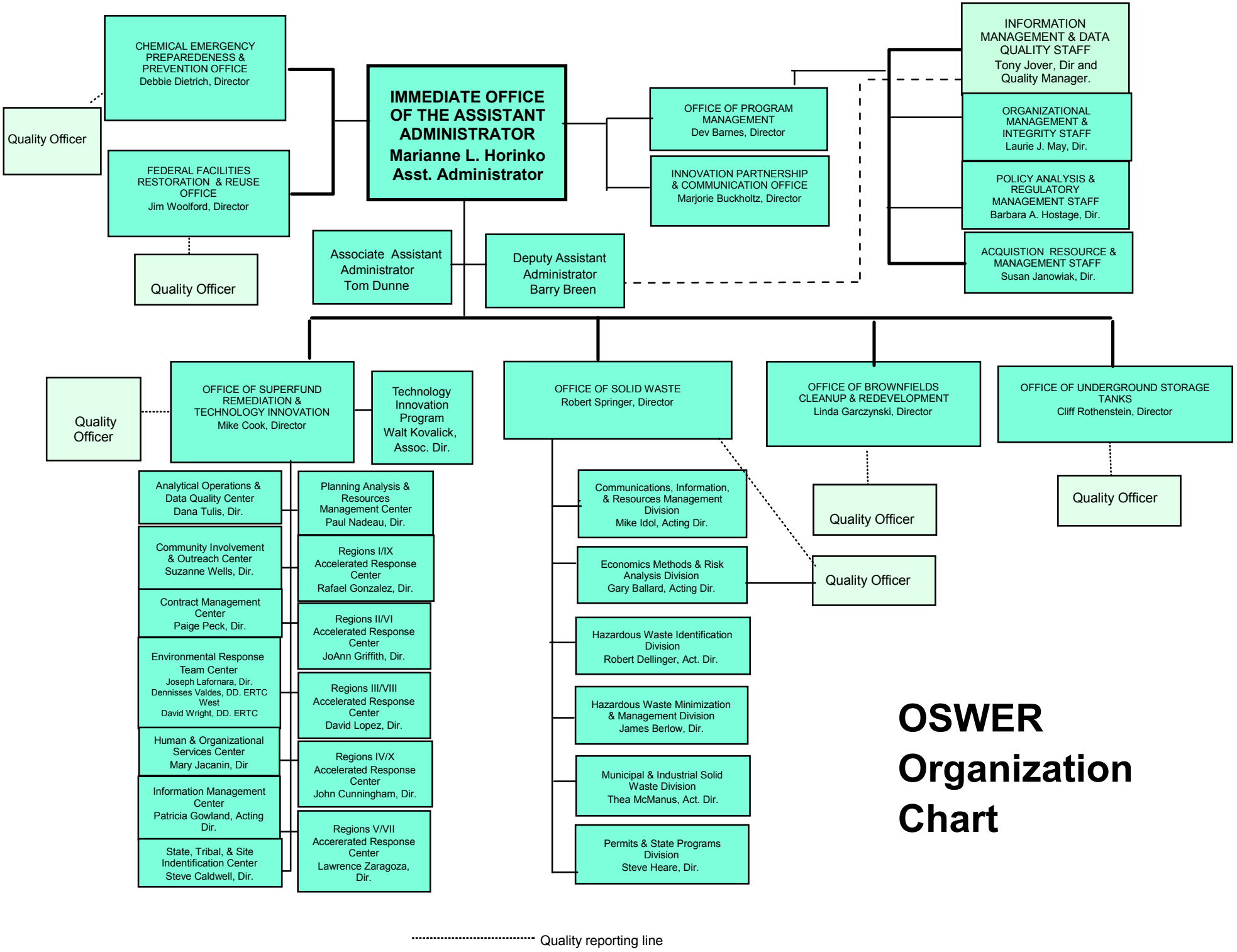
AND

9/11/03

Director
Quality Staff
Office of Environmental Information

Appendix A - Organization Chart for OSWER Quality System

See attached.


CHEMICAL EMERGENCY PREPAREDENESS & PREVENTION OFFICE
Debbie Dietrich, Director
Quality Officer
FEDERAL FACILITIES RESTORATION & REUSE OFFICE
Jim Woolford, Director
Quality Officer
IMMEDIATE OFFICE OF THE ASSISTANT ADMINISTRATOR
Marianne L. Horinko
Asst. Administrator
Associate Assistant Administrator
Tom Dunne
Deputy Assistant Administrator
Barry Breen
OFFICE OF PROGRAM MANAGEMENT
Dev Barnes, Director
INNOVATION PARTNERSHIP & COMMUNICATION OFFICE
Marjorie Buckholtz, Director
INFORMATION MANAGEMENT & DATA QUALITY STAFF
Tony Jover, Dir and Quality Manager.
ORGANIZATIONAL MANAGEMENT & INTEGRITY STAFF
Laurie J. May, Dir.
POLICY ANALYSIS & REGULATORY MANAGEMENT STAFF
Barbara A. Hostage, Dir.
ACQUISTION RESOURCE & MANAGEMENT STAFF
Susan Janowiak, Dir.
Quality Officer
OFFICE OF SUPERFUND REMEDIATION & TECHNOLOGY INNOVATION
Mike Cook, Director
Technology Innovation Program
Walt Kovalick, Assoc. Dir.
Analytical Operations & Data Quality Center
Dana Tulis, Dir.
Community Involvement & Outreach Center
Suzanne Wells, Dir.
Contract Management Center
Paige Peck, Dir.
Environmental Response Team Center
Joseph Lafornara, Dir.
Dennisses Valdes, DD. ERTC West
David Wright, DD. ERTC
Human & Organizational Services Center
Mary Jacanin, Dir
Information Management Center
Patricia Gowland, Acting Dir.
State, Tribal, & Site Indentification Center
Steve Caldwell, Dir.
Planning Analysis & Resources Management Center
Paul Nadeau, Dir.
Regions I/IX Accelerated Response Center
Rafael Gonzalez, Dir.
Regions II/VI Accelerated Response Center
JoAnn Griffith, Dir.
Regions III/VIII Accelerated Response Center
David Lopez, Dir.
Regions IV/X Accelerated Response Center
John Cunningham, Dir.
Regions V/VII Accererated Response Center
Lawrence Zaragoza, Dir.
Quality Officer
OFFICE OF SOLID WASTE
Robert Springer, Director
Communications, Information, & Resources Management Division
Mike Idol, Acting Dir.
Economics Methods & Risk Analysis Division
Gary Ballard, Acting Dir.
Hazardous Waste Identification Division
Robert Dellinger, Act. Dir.
Hazardous Waste Minimization & Management Division
James Berlow, Dir.
Municipal & Industrial Solid Waste Division
Thea McManus, Act. Dir.
Permits & State Programs Division
Steve Heare, Dir.
Quality Officer
OFFICE OF BROWNFIELDS CLEANUP & REDEVELOPMENT
Linda Garczynski, Director
Quality Officer
OFFICE OF UNDERGROUND STORAGE TANKS
Cliff Rothenstein, Director
Quality Officer
OSWER Organization Chart
Quality reporting line