

QUALITY MANAGEMENT PLAN

USEPA REGION 2

FISCAL YEARS 2002-2007

U. S. ENVIRONMENTAL PROTECTION AGENCY - REGION 2

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INTRODUCTION

This Quality Management Plan (QMP) is intended to document the ongoing Quality Assurance (QA) policies, procedures, responsibilities and management systems that are in place to implement the Region 2 QA program. The QMP is revised every five years, or when significant changes are made to regional QA policies, procedures or management roles and responsibilities. In addition to the QMP, documentation of QA accomplishments and QA work plans are submitted to the Assistant Administrator for the Office of Environmental Information in the Region 2 Quality Assurance Annual Report and Work Plan (QAARWP) at the end of each fiscal year. Implementation of the Quality system applies to all Environmental Monitoring Projects (EMPs) where data for decision making purposes are to be collected.

1.0 MANAGEMENT AND ORGANIZATION

1.1 Mission and Organization

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

EPA requires each organization to develop a Quality Management Plan (QMP) that 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 Assistant Administrator for the Office of Environmental Information.

The Region 2 QMP has been prepared to describe the policy and management structure to be used in implementing the Region 2 quality system. This QMP is intended to include descriptions of each Division's quality system structure. Region 2 policy, as documented in this QMP, requires all environmental data generated and/or used by the Region to be of known quality, adequate for its intended use, with all aspects of its collection and analysis thoroughly documented; such documentation being verifiable and defensible.

The Region 2 Quality Management System is organized as a centralized Quality Assurance (QA) management system. The Regional Quality Assurance Manager (RQAM) is organizationally located within the Director's Office of the Division of Environmental Science and Assessment (DESA). As such, the RQAM is independent from any environmental monitoring management responsibilities, avoiding potential conflict of interest between performing data collection or analysis and quality assuring the data generated by these activities. To further support the independence of the RQAM, Region 2 has established direct access for the RQAM to the Deputy Regional Administrator (DRA) (incorporated in the RQAM's performance standards) to resolve any potential conflict of interest posed by the RQAM's organizational location in DESA (see Appendix A Organizational Chart for DESA). QA issues or disputes with program divisions are presented by the DESA Division Director to senior regional management for resolution.

1.2 Quality System Roles, Responsibilities, and Authorities

Overall responsibility for the QA Program in Region 2 rests with the Regional Administrator (RA), who is committed to ensure that QA is an identifiable activity with adequate resources allocated for accomplishment of program and Regional goals in the development and execution of all projects and tasks involving environmentally related measurements, both in-house and extramural. The responsibility for planning, oversight and policy recommendations is contained in the performance standards of the RQAM, the position being located in DESA. The regional organizational charts, available in Appendix A, illustrate the current reporting structure within the Region. Technical experts can be found at all management levels.

Specific QA responsibilities of the RQAM are to:

- a. Recommend policies and procedures for the management of QA/QC within the Region;
- b. Develop and revise the Regional QMP;
- c. Oversee the QA annual review and work plan process;
- d. Act as the official contact in the Region for all QA matters and communications from OEI Quality Staff, other Regions and Headquarters personnel, the States and Indian Nations and the private sector;
- e. Provide QA guidance and training to Regional and state personnel;
- f. Assist Region 2 program managers in their development of project data objectives and data quality objectives;
- g. Assist Region 2 personnel in the preparation and review of Quality Assurance Project Plans (QAPPs), Standard Operating Procedures (SOPs) and data quality assessments;
- h. Review and sign the QA Review Form for contracts;
- i. Conduct systems reviews, performance audits and data quality assessments;
- j. Review and approve QAPPs for Regional monitoring projects and inform Project Officer of said approval in a memo;
- k. Review and approve all Regional SOPs to ensure adherence to QA/QC policies;
- l. Review and approve all state, local, tribal and other grantees QMPs, and inform Grants and Contracts Management Branch of said approval in a memo;
- m. Oversee and provide QA advice and guidance to EPA grantees and contractors, ensuring conformance with their QMPs and other QA requirements;
- n. Oversee compliance with Regional QA Program requirements;
- o. Submit periodic reports to Regional management and OEI Quality Staff;
- p. Conduct certification evaluations of state drinking water laboratories;
- q. Review data submitted through the Contract Laboratory Program (CLP) and by potentially responsible parties when requested;
- r. Manage Regional information for the national proficiency testing programs;
- s. Act as a focal point for EPA methodology requirements;
- t. Review Alternate Test Procedure applications and quality assurance services; and,
- u. Ensure that QA activities or tasks that arise and are not covered in the QMP, are addressed appropriately

The RQAM delegates many of these responsibilities to regional QA Officers (QAOs) who are located in three Branches within DESA. The QAOs in the Hazardous Waste Support Branch perform centralized QA activities for regional RCRA permitting and corrective action programs, Superfund Brownfields, Emergency Response, Removal, Pre-remedial, Remedial programs, and the Region 2 Mobile Laboratory. QAOs in the Monitoring and Assessment Branch perform QA activities for RCRA enforcement, UST/LUST, Water, Air, FIFRA and TSCA programs. The QAO for the Region 2 Laboratory is located in the Laboratory Branch.

QA Officers (QAOs) serve under the general guidance of the Region 2 RQAM, but functionally report to their respective DESA Branch Chiefs, who inform the RQAM of their respective QAO activities. The RQAM is scheduled to: (1) hold quarterly meetings with the QAOs to discuss national QA concerns, (2) brief the DESA Division Director at weekly DESA Branch Chief meetings and, (3) participate in the monthly national RQAM Conference call between RQAMs and OEI Quality Staff. The DESA Division Director discusses current QA issues, when necessary, at weekly regional senior staff meetings with the RA.

1.3 Resources to Support the Quality System

The process for identifying and quantifying QA resources, comprising both staff and funds, needed to support given program activities begins with regional program managers, QAOs, and the RQAM when negotiating annual QA work plans. In general, the program managers' recommendations are based upon the program resource allocation models prepared by Headquarters and upon advice offered by the QAOs and RQAM. Resource allocations are assigned based upon annual work plans contained in MOUs developed jointly between DESA and regional program divisions (e.g. DEPP, DECA, ERRD). Recommendations are then made to the RA through the Office of Policy and Management (OPM). If the RQAM does not agree with those recommendations, suggestions for change are offered through the DESA Division Director. The RA allocates resources based on OPM's recommendations and any Division Director appeals. In rare instances, an appeal is made to Headquarters for additional resources. The final allocations of intramural, extramural and travel funds derived from these procedures are included in the annual Region 2 QAARWP submission to OEI.

1.4 Quality System Customers and Suppliers

The following briefly describes the environmental missions to which the Regional quality system is applied in each Division.

Caribbean Environmental Protection Division (CEPD)

For the Commonwealth of Puerto Rico and the Territory of the Virgin Islands, the Division is responsible for:

- Serving as a liaison with these governments on matters concerning environmental problems requiring EPA actions;
- Communicating EPA program objectives to local government agencies and providing scientific and technical assistance in meeting these goals;
- Supporting regional output commitments in air, water, pesticides, toxic substances, hazardous waste, emergency and remedial response, identifying local environmental problems and recommending pollution control measures; and,
- Overseeing environmental program grants in Puerto Rico and the Virgin Islands.

The Division does not currently have contracting responsibilities. Contracts for the type of projects addressed under the QMP are done at the Regional level.

The Division consists of a Division Director, a Deputy Division Director, two branches and a Virgin Islands (VI) Coordinator.

The VI Coordinator plans and coordinates activities necessary to implement regional programs, goals and objectives in the U.S. Virgin Islands, arranges for technical assistance, and supports delivery of needed emergency response actions.

The Enforcement and Superfund Branch conducts inspections, identifies violations and recommends enforcement actions under the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), Solid Waste Disposal Act (SWDA), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Toxic Substances Control Act (TSCA), and the Emergency Planning and Community Right to Know Act (EPCRA). The branch also carries out emergency response, immediate removal and long-term remedial actions for designated sites under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Superfund Amendments and Reauthorization Act (SARA), and performs emergency response actions under the Oil Pollution Control Act (OPA).

The Environmental Management Branch provides support to regional water and air programs.

The EMB provides oversight on the following programs: RCRA, CWA Section 106, CAA Section 105, CWA Section 205g, CWA SRF, SDWA PWSS, CWA Strategic Plan, San Juan Bay Estuary Program Oversight, SDWA Non-PRASA Initiative, CWA Watershed Initiative and Wetlands Protection Grant to the PR Environmental Quality Board (EQB), PR Department of Health (PRDOH), PR Department of Agriculture (PRDA), PR Department of Natural and Environmental Resources (PR DNER) and the US Virgin Islands Department of Planning and Natural Resources (DPNR). It also provides oversight of the Delegated Programs; CAA NSPS, NESHAP and Title V; CWA Grants and Pretreatment Program, CWA Territorial Pollutant Discharge Elimination System, FIFRA Pesticides Applicators Program, PWSS and Annual Updating of Municipal Landfill Program.

Communications Division (CD)

This Division is primarily concerned with:

- the development, implementation, and coordination of Congressional and Intergovernmental Relations;
- Public Affairs, Public Outreach and Environmental Education programs for Region 2; and
- advising the RA on all external communications of the Region's activities.

The Division is not directly involved with environmental monitoring programs.

The Division consists of two branches, a Policy Advisor and an Environmental Education Coordinator reporting to the Director.

The Intergovernmental Affairs Branch serves as a focal point within the Region for all matters involving Congressional and Intergovernmental liaison and the Region's international activities. The branch also provides periodic summaries to Regional officials concerning pertinent Federal, State and local legislative initiatives and regulatory development.

The Public Outreach Branch prepares press releases, briefing documents, fact sheets, speeches for the RA, articles for Regional and Headquarters publication, and coordinates the regional product review system. The branch also provides oversight and coordination for community relations activities conducted by the Region.

Division of Enforcement and Compliance Assistance (DECA)

The Division is responsible for:

- Ensuring compliance for the air, surface water, drinking water, ground water, solid and hazardous waste, Underground Storage Tanks(UST)/Leaking UST (LUST), and pesticides and toxic substances programs;
- Directing compliance and enforcement activities for the pesticides, toxics, Underground Injection Control (UIC), Asbestos Hazard Emergency Response Act (AHERA), and UST/LUST programs;
- Directing compliance and enforcement activities for the NPDES program;
- Negotiating compliance and enforcement elements of joint EPA/State strategic plans and state grant work plans/partnership agreements across all media and annual Memorandum of Agreements with HQ OECA and State/EPA Enforcement Agreements; and,
- Managing a comprehensive compliance assistance program under all environmental statutes, ensuring that compliance strategies are multi-media, wherever possible, and that environmental justice objectives are addressed.

The Division consists of five branches, two teams and a Deputy Division Director all reporting to the Director.

The Strategic Planning Team is responsible for development, coordination and monitoring of multi-media strategic planning for enforcement and compliance. The team develops and reports on performance measures and environmental indicators, and develops and coordinates environmental justice projects within the division. The Multi-Media Team is responsible for implementing, coordinating and monitoring comprehensive cross-program compliance assurance and enforcement activities within the division.

The Pesticides and Toxic Substances Branch is responsible for program planning, implementation and compliance assurance activities associated with the FIFRA, TSCA, Residential Lead-based Paint Hazard Reduction Act and Section 313 of EPCRA, and negotiating state grant work plan commitments.

The Air Compliance Branch is responsible for implementing a comprehensive compliance assurance program to address violations of the CAA, State Implementation Plans (SIPs), New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAPS), and AHERA. The branch manages state delegation of air enforcement functions and reviews for enforceability regional actions such as delegations, permit actions, and SIPs.

The RCRA Compliance Branch is responsible for implementing a comprehensive compliance assurance program to address violations of RCRA, Hazardous and Solid Waste Amendments (HSWA), SWDA, and the Federal Facility Compliance Act (FFCA). The branch manages state delegations of hazardous waste compliance and enforcement activities, and reviews, for enforceability, regional hazardous waste program actions.

The Water Compliance Branch is responsible for implementing a comprehensive compliance assurance program to address violations of RCRA, UST, CWA, NPDES, SDWA, UIC and Public Water System (PWS) programs and implementing regulations of these statutes. The branch also manages state delegation of water pollution control programs and oversight of state implementation of delegated responsibilities, reviewing for enforceability, regional CWA/SDWA actions.

The Compliance Assistance and Program Support Branch is responsible for implementing multi-media compliance assistance to the regulated community and the public. The branch also delivers information, education and technical assistance, in coordination with state compliance assistance programs, to promote responsible environmental behavior and prevent pollution. The branch encourages technological innovation within the regulated community to support compliance and pollution prevention, and promotes the transfer of alternative/innovative technologies to the regulated community and other stakeholders.

Division of Environmental Planning and Protection (DEPP)

The Division is responsible for:

- Developing and coordinating the implementation of joint EPA/State/Tribal multi-media strategic plans and recommending the award of program grants;
- Conducting environmental reviews in compliance with the National Environmental Policy Act;
- Developing and coordinating the implementation of place-based plans to achieve environmental goals and objectives;
- Working with the states to implement state air pollution control planning and permitting programs under the CAA;
- Working with the states and the U.S. Army Corps of Engineers to implement water pollution control planning and permitting programs under the CWA;
- Working with the states to develop and implement comprehensive ground water management programs;

- Managing the CWA construction grants program, coastal cities grants program and the State Revolving Fund loan program;
- Designating and managing ocean disposal sites, ensuring compliance with the Marine Protection Research and Sanctuaries Act (MPRSA);
- Working with the states to ensure an adequate and safe supply of drinking water in accordance with the SDWA;
- Working with the states to develop and manage the hazardous waste storage, treatment and disposal permitting corrective action programs under Subtitle C of RCRA and in
- implementing solid waste programs under Subtitle D of RCRA; and, minimizing exposure to radioactive materials and indoor air pollutants through oversight.

In addition to two Deputy Division Directors and three Senior Policy Advisors, the Division consists of six branches and a Long Island Sound (LIS) Office. The latter is jointly administered by Regions 1 and 2 to support the LIS Management Conference.

The Air Programs Branch develops and implements air programs under the CAA and related statutes.

The Water Programs Branch develops and implements selected water programs under the CWA, SDWA, and related statutes to develop and implement the wastewater permitting and pretreatment, construction grants, drinking water and wetlands programs.

The RCRA Programs Branch develops and implements RCRA programs under RCRA and related statutes.

The Community & Ecosystem Protection Branch develops and coordinates the implementation of place-based programs to address identified environmental problems, with particular emphasis on the multi-media nature of environmental problems. The branch also provides technical support in evaluating the fate and effects of pollutants in water, sediment and biota.

The Strategic Planning and Multi-Media Programs Branch is responsible for coordinating multi-media environmental reviews, working with DECA and other divisions as appropriate, developing multi-media strategic plans, administering program grants to the states, managing environmental data, facilitating pollution prevention and assessing risk.

The Radiation and Indoor Air Branch develops and implements an indoor radon program to reduce the risk of radon exposure to the general public, manages the State Indoor Radon Grant program, administers the Eastern Region Radon Training Center and supports the regional CERCLA program for sites having or suspected to have radionuclide contamination. The branch also manages the regional NESHAPs program and the development of radiological emergency response plans and develops and implements an indoor air program.

Division of Environmental Science and Assessment (DESA)

The Division is responsible for:

- Setting priorities and identifying necessary resources to collect environmental samples, analyze collected samples and evaluate the resulting data in support of regional and national Brownfields, Superfund, Air, Water, Pesticides and Toxic Substances compliance and ambient monitoring programs;
- Operating and maintaining the Region 2 Laboratory and the Region 2 Mobile Laboratory;

- Directing the implementation of the Regional QMP and special studies, investigations and surveys to support regional enforcement actions or define environmental quality problems;
- Providing scientific and technical advice and assistance to state, local and tribal governments,
- Providing oversight of funded programs in monitoring, analytical testing, quality assurance and PWS laboratory certification,
- Providing Regional Quality Assurance functions through the RQAM and QAOs;
- Providing a liaison between the Office of Research and Development and with the scientific community in other Federal Agencies and academia.

The RQAM, a Science Officer and a Regional Science Liaison to ORD, and three branches report to the Division Director.

The Laboratory Branch is responsible for the chemical, microbiological and biological testing of pollutants in support of CERCLA, SARA, RCRA, CWA, CAA, TSCA, FIFRA, MPRSA and SDWA. All analytical results are produced in accordance with the Regional QMP following EPA approved methods and protocols. The branch also provides consultation and technical assistance to other federal, state, local international and private laboratories.

The Monitoring and Assessment Branch is responsible for the collection and evaluation of all non-Superfund monitoring data and for QA activities associated with all monitoring and enforcement programs, except RCRA and Superfund. The branch conducts investigations and studies of surface, groundwater and air quality, RCRA-regulated facilities and industrial and municipal emissions and effluents. The branch is also responsible for providing quality assurance direction, assistance and evaluation of ambient and source monitoring data collection activities related to CWA, SDWA, MPRSA, and CAA. The branch reviews state monitoring and QA programs and coordinates national PE studies within the Region.

The Hazardous Waste Support Branch conducts Regional quality assurance programs for Brownfields, RCRA and CERCLA programs. The branch plans, coordinates and provides biological and chemical monitoring and QA technical assistance, and evaluates QA activities of EPA, state, tribal, local and other Federal and private laboratory and field operations in support of the Superfund program. The branch also develops and reviews data DQOs, QAPPs, QMPs and SOPs of state and local agencies and contractors. The branch serves as the focal point for EPA monitoring methodology requirements and QA services for Brownfields, CERCLA and RCRA programs, and operates and provides QA services for the Region 2 Mobile Laboratory conducting on-site analyses for Brownfields and Superfund investigations.

The Science Officer and Regional Science Liaison duties within DESA include providing advice to the RA, the Deputy RA and the Division Directors on matters concerning the Agency's scientific programs, problems or other issues; interacting with ORD; and, serving as liaisons with the scientific community of other federal, state, tribal and local agencies, academia and the private sector with respect to research and other science issues.

Emergency and Remedial Response Division (ERRD)

The Division is responsible for:

- Developing, implementing and coordinating Regional activities under CERCLA, SARA, and Brownfields legislation;

- Managing a comprehensive program for site evaluation, expediting response actions, immediate removals and long-term remedial actions, including cost recovery activities; and,
- Serving as the focal point for all emergency response and emergency contingency planning activities and spill control and monitoring programs under Section 311 of CWA, as amended by OPA.

One Deputy Division Director, three matrix managers and six branches report to the Division Director.

The New Jersey Remediation and the New York Remediation Branches are responsible for the management of remedial, enforcement and community relations activities at National Priorities List (NPL) sites in their respective states.

The Special Project Branch is responsible for the management of Superfund federal facilities activities, the pre-remedial activities and several special projects.

The Program Support Branch is responsible for contracts management activities, resource management/cost recovery activities, remedial technical support activities, including expertise services in the hydrogeologic and risk assessment areas, and the Region's Brownfields program management services. The branch also provides technical advice and assistance on innovative or developing field analytical techniques. .

The Response and Prevention Branch manages emergency response and oil and removal technical support activities.

The Removal Action Branch manages removal, removal enforcement and removal community relations activities.

Office of Policy and Management (OPM)

The Office is responsible for a full range of policy and administrative activities. Responsibilities include:

- Directing the accomplishment of the policy making and managerial phases of the RA's overall responsibility;
- Providing policy coordination and analytical support across Regional programs and with Agency-level efforts, such as compliance with the Government Performance and Results Act (GPRA);
- Coordinating cross-divisional programs such as innovation, data integration, and geographic information systems;
- Assuring efficient and effective management of resources in order to accomplish Regional objectives;
- Coordinating Region 2's lead region functions; and,

Providing policy and program coordination, integrated planning and budgeting, grants administration, contracts management, audit management, financial management, information systems, human resources management, equal employment opportunity, total quality and customer service coordination, health and safety and facilities management.

The Deputy Division Director, the Equal Employment Opportunity Officer and six branches report to the Assistant Regional Administrator.

The Policy, Planning and Evaluation Branch is responsible for developing the Region's analytical and policy formation capabilities by initiating special studies, reports and investigations, managing the development of long-

range strategies, coordinating the Region's innovation activities, managing discretionary grants, Federal Manager's Financial Integrity Act (FMFIA), audit coordination, regulatory review and the development of regional GIS capability.

The Grants and Contracts Management Branch provides centralized administrative support to all Regional assistance programs and is responsible for administrative review, award preparation, post-award management, development of grant terms and conditions, approval of grant payment request, closeout and oversight of grants, cooperative agreements, and Interagency agreements awarded in Region 2. The branch also carries out the full range of contract management (from award to closeout) for all regionally-managed contracts, including small purchase requests.

The Financial Management Branch conducts a full range of financial management activities to assure effective management and obligation of Region 2's budgetary resources. Superfund cost-recovery is also carried out by the branch.

The Information Systems Branch provides automatic data processing (ADP) and information management services; and, establishes and coordinates data integration initiatives and technical development/operational support for the Region's GIS. The branch is also responsible for implementing the Agency's Information Resources Management (IRM) policy and plans for future ADP hardware, software and services.

The Human Resources Branch develops and implements the Region's human resources management program. Working with program managers, the branch identifies recruitment sources, determines qualification requirements and evaluates applicants. The branch also plans and implements a regional program of employee development and training.

The Facilities and Administrative Management Branch provides general administrative support to the Region in the areas of safety and health services, security, motor vehicle management, telephones, etc. The branch also oversees the management of the Edison, New Jersey facility.

Office of Regional Counsel (ORC)

This office is concerned with the development, implementation and coordination of all Regional legal activities.

A Deputy Regional Counsel, two Associate Regional Counsels, and five branches report to the Regional Counsel who serves as this office's Director.

The Air Branch conducts all legal activities arising under the CAA and related statutes.

The Waste and Toxic Substances Branch conducts all legal activities arising under the FIFRA, SWDA, as amended by and often referred to as RCRA, TSCA, portion of EPCRA, and several other related pieces of legislation.

The Water, Grants and General Law Branch conducts all legal activities arising under the CWA, MPRSA, SDWA, OPA, the Ethics Reform Act of 1989 and various government-wide statutes of general applicability.

The New Jersey Superfund and the New York/Caribbean Superfund Branches conduct all legal activities arising under CERCLA, certain activities under EPCRA, and related activities arising under applicable federal, state and local laws.

1.5 Communication of the Quality System

The QMP is developed for use by all Regional staff. The QMP resides on the Region 2 Intranet for easy access to all Regional staff. Hard copies are also filed in the records system of the RQAM. Approval for the QMP includes the

RQAM, Division Directors, the RA and DRA. It is then submitted for approval to the Assistant Administrator, Office of Environmental Information. This approval is valid for up to five years unless substantial changes to the organization's quality system are made during the interim.

While the RQAM and the Quality Staff are the primary sources of information and communication, and provide quality leadership to other staff and organizations in the Region, each Division has the specific responsibilities for implementing the QMP identified in the following Table 1.

Region 2 DESA has constructed a website where quality system information (QMP, policies, SOPs, etc.) may be accessed both for the intranet (for internal users) and from the web (for outside users such as contractors, PRPs, etc.).

1.6 Management and Assessment of the Quality System

QA is intended to be an integral part of every Region 2 Program that is associated with environmental measurements. Program managers are responsible for ensuring that data collected by or for their program are of known quality, adequate for its intended use, and are responsible for ensuring that adequate resources are dedicated to that effort.

Division Directors are responsible for the implementation of all QA activities in their Division and must ensure that their staff adhere to the requirements noted in the Regional QMP. Acceptance of these responsibilities is indicated by signature on the Regional QMP. Division Directors' QA responsibilities and those of their staff are detailed in Table 1.

Table 1. QA Responsibilities and Communication

Role	Responsibilities
Division Directors (and Deputy Division Directors)	Ensure that QA is an identifiable component within the Division.
	Require, and participate in, the development of data quality objectives for all projects involving the generation and/or use of environmental data, and insure the balance between the need for data quality and the need to conserve resources.
	Ensure that adequate staff and other resources are allocated for environmental monitoring projects so project monitoring objectives can be achieved.
	In preparation for the QAARWP, perform internal assessment of the Division's QA activities to ensure conformance with the QMP, and report results to RQAM.
	Ensure that all products meet customer, division and Agency quality requirements.
Branch and Section Chiefs	Ensure implementation of systematic planning process for all projects.
	Have available, maintain and approve SOPs covering all routine tasks related to monitoring or data use (e.g. sampling, analytical, data handling practices, etc.).
	Ensure that QAPPs are prepared by their staff/contractors and meet the approval of the QAOs prior to initiation of monitoring, use of historical data and/or modeling activities.
	Ensure that staff/contractors are implementing the project QAPPs, including arranging for appropriate audits and reviews.
	Confirm that deficiencies highlighted in audits are corrected expeditiously.
	Identify program-specific and QA training needs and provide for that training.

Role	Responsibilities
Team Leaders, Technical Staff, Work Assignment Managers	Identify all EPA or EPA contractor monitoring and environmental data usage projects to QA staff.
	Complete and submit the QA review form for contracts.
	Ensure that work plans and contract deliverables include QA documentation such as QAPPs, QMPs, SOPs, QC performance results and data quality reports.
	Participate in the systematic planning process, and in developing related data acceptance criteria for incorporation into work plans and QAPPs.
	Ensure that all sampling, analytical and/or data handling practices are documented, represent good science and are adequately reviewed.
	Adhere to established methodologies, SOPs and QC protocols, reporting and documenting any deviations.
	Ensure that adequate checks and quality controls are established, rejecting all data not meeting these specified acceptance limits.
	Identify the need for technical and performance evaluation audits.
Grant Officers	Confirm that state, tribal and local grants involving environmental measurements or usage are not awarded if grantees do not have an approved QMP or QAPP.
Contract Officers	Ensure that contracts involving environmental measurements or data usage are in compliance with 48 CFR, Chapter 15, Part 1426, having a QA Review Form, and that monies are not released unless in compliance with EPA QA requirements.

Role	Responsibilities
<p>Contract Laboratory Program (CLP) Technical Project Officer</p>	<p>Participate in technical meetings in order to evaluate new analytical methods.</p>
	<p>Assist in evaluating contractor personnel, equipment and operations during the pre-award process, which involves discussion of any deficiencies that may occur.</p>
	<p>Conduct on-site evaluations of contract laboratories in Region 2 before contracts are awarded, and as follow-up to ensure corrective action has been taken to address deficiencies.</p>
	<p>Review quarterly blind PE sample data summaries and QA trend information.</p>
	<p>Serve as a focal point for resolving problems with CLP laboratories within Region 2.</p>
	<p>Serve as the regional contact for questions concerning the CLP and its services to both regional staff and commercial and public laboratories in the Region, as well as, States.</p>
<p>Regional Sample Control Center</p>	<p>Coordinate all activities associated with collecting and analyzing samples through the CLP, in addition to tracking non-CLP data.</p>
	<p>Ensure that contractors have an approved QAPP prior to scheduling laboratory space.</p>
	<p>Submit special analytical service requests to the Sample Management Office that includes methodology, QC requirements, matrices, etc, according to EPA protocols.</p>
	<p>Transmit unreviewed data to the RQAM for QA review and return reviewed data from the RQAM to the appropriate contractor.</p>
	<p>Maintain ERRD analytical records prior to archiving in Federal Records Center.</p>
	<p>Track data through CLP/Data Validation.</p>

2.0 QUALITY SYSTEM AND DESCRIPTION

The Regional QMP contains the QA policies, procedures, and management systems governing the Regional QA program. This QMP was developed, as all previous Regional QMPs, through an interactive process. Draft preparation and review of the document is accomplished by the RQAM, QAOs, and representatives from each of the regional program divisions. The draft QMP is then sent to each Division Director for review and clarification. The final document is then reviewed again and signed by all Division Directors, the RQAM, the Regional Administrator and the Deputy Regional Administrator before submitting it to the Assistant Administrator for OEI for final approval.

2.1 Documentation of the Quality System

The QMP is updated, in accordance with the EPA Quality Manual for Environmental Programs, EPA Manual 5360 A1, May 2000, when major changes have occurred within the Regional Quality System or every five years, whichever occurs first. Therefore, the adequacy of the QMP is reviewed annually during the annual QA internal review and planning process. Figure 1 illustrates the process used to develop the annual QAARWP which is then reported to OEI.

In addition, Regional policy mandates that all organizations receiving EPA funds for environmental collection/data usage through grants, cooperative agreements, contracts, or other financial assistance agreements must submit and have an approved QMP for their organization prior to dispersal of funds by EPA. The graded approach is applied to the level of detail required in specific QMPs. For continuing grants, cooperative agreements, contracts, or other financial assistance agreements, the RQAM and QAOs annually review these QMPs and QAARWPs to determine their adequacy. Several grantees have elected to resubmit their QMPs for EPA approval on an annual basis.

Figure 1. Process for Developing the Regional QA Annual Report and Work Plan (QAARWP) with Ideal Deadlines

Divisional representatives, with QA staff assistance, compile Division-level annual QA accomplishments of current year and priorities for next year (mid-August)

9

Division Directors review/approve accomplishments and issues/priorities for next year (September 1st)

9

RQAM compiles inputs from Divisions and works to set priorities based on personnel and budget (draft mid-Sept.)

9

RQAM briefs RA concerning QA accomplishments and priorities (mid-October)

9

RQAM submits QAARWP to OEI (November 1st)

2.2 Quality System Tools

Management Systems Reviews (MSRs)

Region 2's policy is to carry out an active audit and review program of major grantee and contractor monitoring programs. Because most monitoring activities have been delegated to the States, Regional reviews of the State's QA activities for all EPA funded programs are given high priority to ensure that adequate QA oversight is conducted by State QA counterparts to assure appropriate data of known and documented quality. MSRs of State QA Programs are routinely conducted on each State QA entity by the QA staff, generally on a biennial basis. Periodic programmatic reviews are also conducted and evaluations conveyed by the appropriate regional program management to State counterparts.

MSRs of major EPA contractors are scheduled on an annual basis. Priority focus for such reviews is based on problems uncovered during technical system assessment and prior MSR reports, and are conducted in accordance with the Region 2 MSR SOP.

An MSR is a review of an organization's environmental management system in order to verify implementation and maintenance of the approved QMP, QA organization and its activities, and the degree of management support afforded the program. Specifically, the review covers the following processes:

- a. Implementation of the QMP;
- b. QAPP development and approval, including adequacy of QAPP reviews, data review; and associated documentation;
- c. Implementation of the Systematic Planning Process;
- d. SOP development, approval, and documentation;
- e. Audits schedule and procedures;
- f. Tracking systems for QA activities and corrective actions;
- g. Managerial support, including financial and resource support; and,
- h. QA responsibilities of personnel, including project managers, field, laboratory and QA staff.

Regional guidance for MSR planning, performing and report writing/submission is available in a Regional SOP.

Systematic Planning Process

All program and project managers are responsible for (1) specifying, prior to the initiation of data collection and/or usage, their data quality needs; (2) providing adequate resources to ensure that the needs will be satisfied; and, (3) ensuring that the quality control and quality assurance requirements are written and satisfied for all Environmental Monitoring Projects (EMPs). This includes modeling projects and the use of historical data for decision making purposes.

All personnel involved with EMPs, including field, laboratory, project and data processing personnel, as well as, grant and contract officers, have the responsibility for ensuring the quality of the data associated with those measurements.

It is Regional policy that high level decision makers use a systematic planning process (SPP), i.e. the data quality objectives (DQOs) process, as a mechanism for balancing conflicting demands and data quality needs to ensure that environmental monitoring will effectively support decision making. Regional managers make decisions based on information provided by their staff, technical advisory committees and by regulatory requirements. QA staff must be involved in all planning sessions, such as scoping meetings. The process focuses attention on the relationship between data quality and the likely effectiveness of the final decision that will be based on the data. This allows the decision maker to balance the concrete costs of monitoring against the less tangible costs, or risks, of making a decision based on uncertain data.

The SPP clarifies project technical and quality objectives, defines the appropriate type of data, and specifies tolerable levels of uncertainty that will be used as the basis for establishing the quality and quantity of data needed to support decisions. When the DQO process for SPP is appropriate, it is the responsibility of the data user to define this allowable uncertainty and develop DQOs with the interested principals. An appropriate systematic planning process is required for all environmental data collections and the process must be documented.

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), the decision criteria, and the probability they can accept of making an incorrect decision based on the data. The process for developing performance acceptance criteria:

- Establishes a common language to be shared by decision makers, technical personnel, and 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; and
- 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 should be a normal part of the SSP, and be accomplished based on cost-effectiveness and realistic capabilities of the measurement process. EPA developed the following documents to assist this process: *Guidance for the Data Quality Objectives Process (G-4)*, August 2000, and *Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW)*, January 2000.

Quality Assurance Project Plans (QAPPs)

A QAPP is a technical planning document that defines the objectives, organization, field, laboratory and data methods, and the QA and QC activities necessary to meet the goals of an environmental monitoring project. It is Regional policy that all projects involving environmental data collection or usage, carried out by or for the Region, shall have QAPPs developed and approved prior to the initiation of any data collection. This applies to projects conducted or funded directly by the Region (termed in-house), as well as, those for which the Region has only oversight responsibility (i.e. state-lead projects) or work to be performed by potentially responsible parties (mandated in consent orders or agreements). If EPA either funds or directly carries out one component of an EMP (e.g. analysis), the entire study must have an approved QAPP.

Responsibility for the preparation and submission of a QAPP lies with the Project Officer (PO), whether he/she be the author, supervisor or contract officer of the project. Preparation of the document shall involve all key participants (QA, field, laboratory and project management). The PO is responsible for soliciting the necessary assistance. The plan should be submitted to the RQAM or his designee, ideally 30 days before the start of a project to afford sufficient time for review and coordination. It is the responsibility of the PO that no EMP starts before the QAPP has been approved. Figure 2 illustrates the process for preparation and implementation of QAPPs.

If changes to the work in progress are necessary, the QAPP will need to be revised by the PO and approved by the project QAO. For those projects that entail long term operations, the QAPP should be reviewed annually by the PO to determine whether the plan is still applicable as written.

To ensure their effectiveness, QAPPs are required to be prepared according to an approved format. Depending on the project and circumstances, several guidance documents are available: EPA QA/R-5, DESA QAPP guidance document, Region 2 CERCLA Quality Assurance Manual, and *Quality Assurance Guidelines for Modeling Development and Application Projects, a Policy Statement*. QA staff may, upon request and discussion, allow combination of the QAPP into another document, such as a CERCLA Field Sampling Plan (FSP) or a RCRA Waste Analysis Plan, to save duplication of effort. In programs such as CERCLA, it is the preferred practice.

When a group or continuum of monitoring projects is carried out for the same purpose and with the same personnel and procedures, a "generic" plan may be developed. Otherwise, QAPPs must be prepared and approved separately for each project.

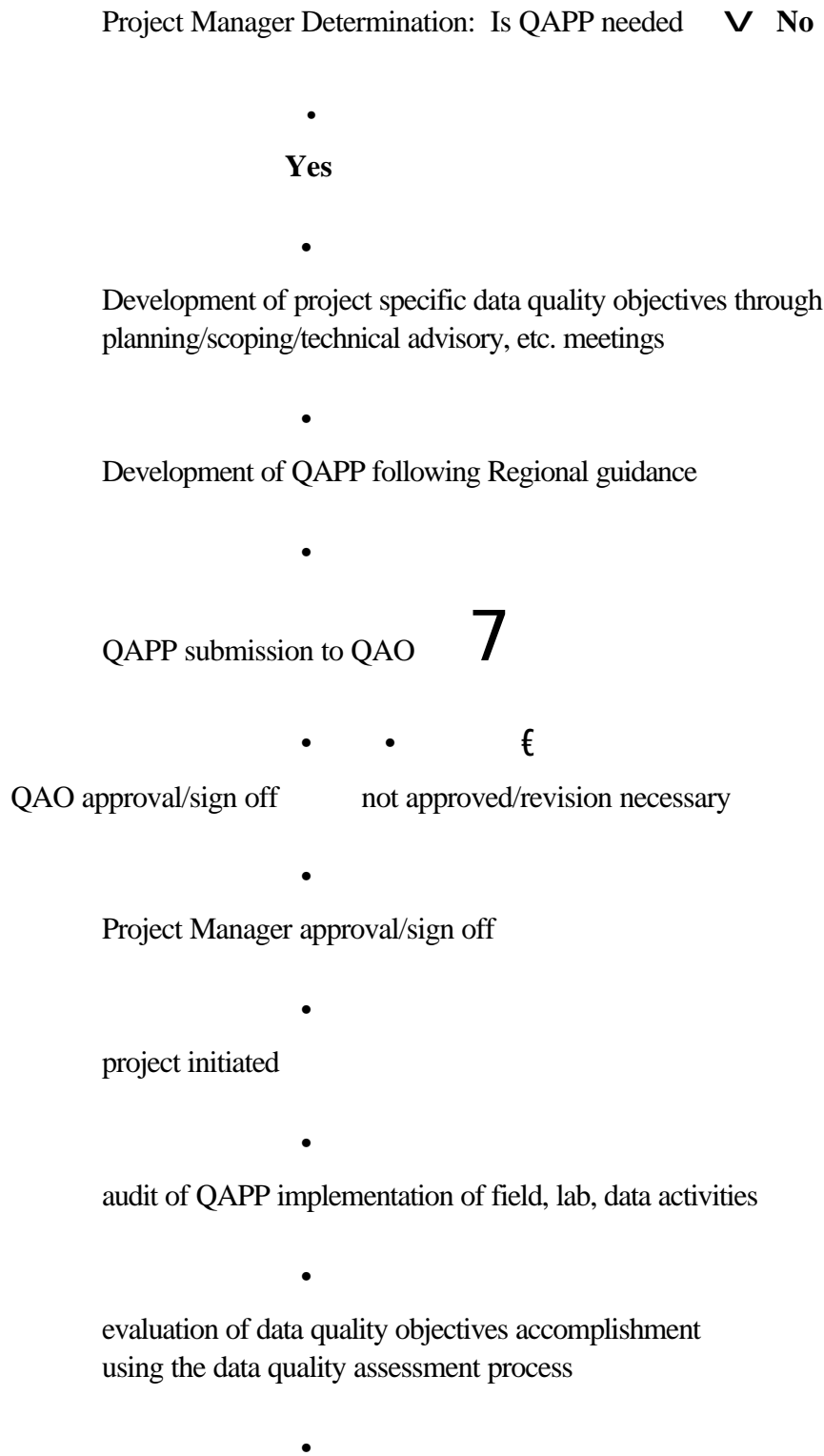
Emergency response groups will not have to prepare individual plans for response situations, but this shall not exempt them from the requirement for having generic QA plans approved and in place.

Review and approval of all EPA or EPA contractor QAPPs is the responsibility of the RQAM. The QA staff will review all QAPPs and recommend approval or approve (as per program delegation agreements) or request changes in writing.

For both in-house and extramural stack test programs and/or contracts, the production of a separate stack test protocol for each test project to be conducted is required. This protocol is the exact functional equivalent of a QAPP. *Guidelines for Stack Testing Protocol Development and Submittal* (December 1987 or later revisions), are distributed to sources and contractors by the RQAM to ensure that the protocols will satisfy all QA requirements. These test programs are handled in the same manner as other programs and projects with prior approval required. Air monitoring or testing projects may not begin until the RQAM has approved the stack test protocol.

QAPPs prepared by States or their contractors are approved by State QAOs. Copies of the approved plans are held on file, available for EPA review during the State MSR. For CERCLA and RCRA corrective actions, State approved plans and associated comments are submitted to the EPA PO.

Figure 2. Preparation and Implementation of Quality Assurance Project Plans



final report submitted

Standard Operating Procedures (SOPs)

SOPs are used to document routine or repetitive administrative and technical activities. They are considered an integral part of the QA system and are viewed as extensions both of the QMP and the QAPPs. They promote consistency within the programs, reducing work effort and improving data comparability, credibility and defensibility.

SOPs must be clearly written and detailed (such as a "cookbook"). They must be maintained in document control and kept current. SOPs must be signed by the preparer and the approving supervisor. They should be reviewed annually to ensure that they reflect current procedures and updated when necessary. Regional guidance on SOP preparation is available from the RQAM and national guidance: *Guidance for the Preparation of Standard Operating Procedures (G-6)*, March 2001, is available from QS.

SOPs must be readily available to all personnel and adhered to rigorously. Modifications must be documented and have written supervisory concurrence.

SOPs must be either part of the QAPP by direct attachment or by reference when they have already been made available. Any modifications to the SOP that will occur during the project must be detailed in the QAPP. All field monitoring, analytical and data handling procedures, not covered explicitly in a QAPP, must be in an approved SOP.

Technical Assessments

Technical assessments are audits/reviews of field, laboratory and/or data project-specific monitoring activities. To perform an audit, the auditor must be experienced in the activity being examined, familiar with the auditing/reviewing process and able to communicate effectively verbally and in writing. Whenever possible, audits are performed by a team of two or more individuals.

Most audits are conducted by the QA staff, but certain technical systems audits are conducted by program staff who are familiar with the particular activity and related QC activities. Outside experts can be called upon to assist the EPA QAO or PO in conducting the review. However, it is the EPA officer who will be in charge of the review and final determination of acceptability or non-acceptability.

An on-site technical systems audit (TSA) focuses on actual quality control activities of environmental data collection systems. The approved QAPP is used as a base. Equipment used to conduct TSAs must be calibrated and checked in accordance with Regional protocols to ensure accurate assessments. Various Regional SOPs are available that describe the initiation, preparation for and execution of an audit, as well as submission of an audit report for timely notification and response actions, some of which are referenced in Appendix E.

Specific review activities vary with the scope of the audit, but can include review of:

- a. Sample collection and analytical activities;
- b. Equipment calibration techniques and records;
- c. Decontamination and equipment cleaning;
- d. Equipment suitability and maintenance/repair;
- e. Background and training of personnel;
- f. Laboratory control charts, support systems, etc.;
- g. QC samples such as duplicates, trip and field blanks, method blanks, unknown performance evaluation samples, etc.;
- h. Sample containers, preservation techniques, chain of custody;
- i. Data logs, transfer, reduction and validation;
- j. Monitor Siting; and,
- k. Conformance with approved methodologies and/or SOPs.

If inadequate TSAs are carried out by a State, the Region may undertake direct auditing of that State's projects.

In addition to those conducted by regional personnel, primary consulting engineering contractors for responsible parties are required to conduct TSAs of activities according to EPA Region 2 SOPs. In addition, EPA remedial contractors and field investigation team contractors are required to conduct TSAs of their own field activities.

The Performance Evaluation (PE) audit is another means for evaluating a laboratory's performance. The laboratory must process a sample of specific pollutants in an appropriate matrix with the quantity and/or pollutant content being unknown to the analyst. Several nationally run studies are managed by the QA staff. These include the Water Supply (WS) and the Discharge Monitoring Report (DMR) QA studies, the National Performance Audit Program (NPAP) for ambient air, and the stationary air source, RCRA and FIFRA PE studies. The Region also participates annually in the WP and WS water PE studies and in the NPAP studies.

PE audits may also be conducted as needed to address particular study needs. This includes, for example, an audit of an ambient air monitoring operation in which cylinders of gas mixtures or audit devices are sent to field operators to check the calibration/operation of the monitors.

PEs, outside of nationally run studies, are scheduled on an as needed basis as determined by the QA staff in conjunction with Regional Program office and other DESA personnel. For example, PEs and audits of data quality (ADQs) are required for all air emission tests, but only as requested by the program office for ambient water testing. The RQAM may arrange for PE samples to be prepared in the Region or to be acquired elsewhere.

On an as-needed basis, PEs are submitted to all laboratories providing CERCLA analytical services, except for EPA's Superfund Contract Laboratories (CLP). PEs are required for all non-CLP laboratories which have not analyzed PEs within the last 6 months. Results of PE audits are submitted to ERRD project managers along with a recommendation of capability. The QA staff arranges PE audits for ERRD project managers. CLP Laboratories are required to participate in a quarterly PE program for maintaining certification. The CLP has begun instituting a single-blind PE sample program in some of the Routine Analytical Services (RAS) contracts.

An Audit of Data Quality (ADQ) evaluates whether sufficient information exists to support the assessment of collected data quality. ADQs are to be distinguished from data validation activities, which are part of the normal data generation process. The ADQ examines, in part, the actual data validation process. In Region 2, ADQs are not normally conducted alone, but rather are made part of a TSA.

In the ambient air monitoring program, ADQs are conducted, in part, by the appropriate air program branch through reviews of detailed printouts of data and QA parameters produced by required automated systems. Much of this review is also automated and is standardized nationwide.

TSAs are scheduled and selected across media and program types dependent upon the general priority guidance provided by EPA Headquarters for a particular fiscal year. When possible, TSAs are scheduled to coincide with actual field monitoring activities or laboratory analyses.

Data Quality Assessments

It is the responsibility of the PO to evaluate, statistically and scientifically, the project data, both during the project and after completion. This evaluation is required to determine whether the data being produced or produced are adequate for their intended use and whether the data collection design satisfies the project's data quality objectives. Data quality assessments are to be documented and filed with final project report documentation.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Establish Technical Proficiency and Quality Requirements at the Organization, Program, and Project Levels

Managers are responsible for ensuring that all personnel (including themselves) involved with environmental data have the necessary knowledge, skills and training, including certifications, for their tasks and functions, and that the EPA Program requirements, where available, are met. Personnel who collect and generate data include: analysts, laboratory technicians, field samplers, maintenance technicians, project managers, supervisors, statisticians, modelers, and Regional QA staff. Their training includes, but is not limited to, safety, ethics and QA training. Management is responsible for encouraging professional development beyond initial qualifications.

3.2 Evaluate Training Needs

Individual qualifications and training are identified during the initial personnel recruitment process. Additional training and development needs are identified upon hiring, and may be amended during individual performance evaluations. The RQAM evaluates programmatic and regional training needs based on interviews with program managers, program staff, and QAOs; review of MSR and TSA reports; and recognition of new or revised EPA QA policies and practices. Training needs of QAOs, regional program staff, state partner staff, and contractors are considered in developing a Region 2 training strategy.

3.3 Prioritize Training Resources

Training priorities are jointly developed and negotiated as part of the annual QAARWP development. Specific priorities arise out of program emphasis and results from MSR, TSA, and other internal and external assessments performed during the year.

3.4 Provide Training

As for QA training, currently all new employees are required to attend a three day new employee orientation course. During that orientation course, the Regional QA policy is explained, written guidance handed out, and they are reminded that the Regional QMP is available on the Region 2 website. Further, R2 QA staff present QA workshops, open houses, and training as needed or upon request.

Within the Region, the regional QAOs provide program specific QA training to project managers, and are also available to provide appropriate one-on-one training and technical assistance for Program Managers, Project Officers and Work Assignment Managers. This is routinely conducted through program-specific QA Open House sessions. EPA's QS are contacted by the RQAM when individuals require additional QA training beyond that available via regional staff. The RQAM schedules specific training in Agency QA and program areas necessary to provide innovative and cost-effective means for improving QA. Such training may be either on-site in Region 2 (e.g. FORMS II, Managing Uncertainty for Environmental Decision making) or at EPA headquarters or conference training sessions.

3.5 Provide Access to Information

The R2 DESA website contains a considerable amount of R2 QA material, as well as, links to other useful QA sites (including OEI-QS site). Access to the R2 DESA website can be from the intranet for internal users, but also from the internet for outside users (i.e., contractors, PRPs, etc.) The webpage connecting directly to the Region 2 QA documents and links is located at: www.epa.gov/region02/DESA/HSW. A listing of the contents accessible is as follows:

EPA order 5360.1 CGH 1 (1998) - Final
EPA Quality Manual for Environmental Programs (1998) - Final
QA/R-1: EPA Quality Systems Requirements for Environmental Programs

QA/R-2: EPA Requirements for Quality Management Plans
QA/R-5: EPA Requirements for Quality Assurance Project Plans

USEPA CLP Contract Laboratory Program (CLP), a listing of several CLP Guidance Documents:

National Functional Guidelines for Organic Data Review
National Functional Guidelines for Inorganic Data Review
Sampler's Guide to the Contract Laboratory Program

Region 2 RCRA and CERCLA Data Validation Standard Operating Procedures (SOPs):

SOP HW-2, Revision 11, January 1992:
Evaluation of Metals Data for the CLP Program

SOP HW-6, Revision 12, March 2001: CLP Organics Data Review and
Preliminary Review

SOP HW-7, Revision 3, March 1993: TCLP Data Validation

SOP HW-11, Revision 2, August 1993: Polychlorinated Dibenzodioxins/Polychlorinated Dibenzofurans
Data Review

HW-13, Revision 3.2, July 2001: Organic Data Review for Low
Concentration Water, EPA SOW OLC03.2

HW-15, Revision 2, May 1993: CLP Data Review for Analysis - Multi
Media High Concentration

HW-16, Revision 1.3, September 1994: Nitroaromatics and Nitroamines by HPLC

HW-17, Revision 1.3, November 1994: Validating Chlorinated Herbicides by Gas Chromatography

HW-18, Revision 0, August 1994: Validating Canisters of Volatile Organics in Ambient Air

HW-19, Revision 1, October 1994: Validating PCDDs and PCDFs by
HRGC/HRMS

HW-21, Revision 1, April 1995: Validating Semivolatile Organic
Compounds by SW-846 Method 8250A

HW-22, Revision 2, June 2001: Validating Semivolatile Organic Compounds by
SW-846 Method 8270C.

HW-23, Revision 0, April 1995: Validating Pesticide/PCB Compounds by SW-846 Method 8080A

HW-24, Revision 1, June 1999: Validating Volatile Organic Compounds by SW-846 Method 8260B

HW-25, Revision 2, September 1999: Validating Tetra - through Octa - chlorinated Dioxins and Furans
by Isotope Dilution (HRGC/HRMS) by

HW-29, Revised, October 2001: Measurement of Purgeable Organic Compounds in Water by Gas
Chromatography/Mass Spectrometry (GC/MS): Capillary Column, Acquired Using Method 524.2
(Revision 4.1, 1995)

Region 2 Useful QA Links:

Quality Assurance Guidance and Data Validation
Office of Solid Waste and Emergency Response (OSWER)
Contract Laboratory Program (CLP)
Superfund Technical Resources
Office of Solid Waste
Quality Assurance Division Links

OSWER Home Page
Brownfields Home Page
RCRA, Superfund & EPCRA Hotline Training Modules

CLP Home Page
CLP Statements of Work for Organic, Inorganic, and Low
Concentration Organic Analytical Services
Functional Guidelines for Organic Data Review and Inorganic Data Review
Sampler's Guide to the Contract Laboratory Program
Frequently Asked Questions about the CLP Program

Presumptive Remedies Home Page
Risk Assessment Guidance for Superfund (RAGS) Part D
Assessing Reports of Continuous Releases of Hazardous
Substances: A Guide for EPA Regions
Use of Soil Cleanup Criteria in 40 CFR Part 192 as Remediation
Goals for CERCLA Sites
Superfund Soil Screening Guidance

RCRA Orientation Manual
SW-846 On-Line
Methods Information Communication Exchange (MICE) Service
Performance Based Methods System

Assuring the Quality of Environmental Data at EPA
Quality Requirements for Extramural Agreements
Quality Management Tools
EPA Quality System Documents
Quality Assurance Division Computer-Based Training
EPA QA Contacts and Web sites
Brownfields Project Planning Guidance, Volumes 1 & 2

3.6 Documentation of Training

Documentation and maintenance of training records for personnel is the responsibility of management. The information should be maintained within the appropriate Division files and also submitted to the Human Resources Branch (HRB) for attachment to personnel records. The HRB maintains a listing of courses scheduled and this is available on the local area network or LAN.

For all courses, an evaluation form is required to be completed to evaluate both the effectiveness of the trainers and the appropriateness of the information given. This information is used to modify and improve the training courses.

4.0 PROCUREMENT OF ITEMS AND SERVICES

4.1 Planning and Control

Procurement of items must meet established administrative and QA requirements of the agency. In Region 2, OPM is responsible for ensuring that all procured items and services meet established requirements and perform as specified. Procurement documents or financial assistance agreements require suppliers to have a Quality System, consistent with EPA QA requirements, if the supplier is providing services or items that directly affect the quality of results or products for environmental programs.

Contractors, suppliers and financial assistance recipients are responsible for the quality of work performed or items and services provided by their subcontractors and suppliers.

4.2 Assessment and Verification

The Region 2 process for ensuring conformance with these requirements for contracts is based on the use of a QA Review (QAR) Form for each procurement request/order, except for incremental funding actions, when the acquisition is in excess of \$25,000 and is in one of the following object classifications: Research and Development Contracts, Program Contracts, Occupational Health Monitoring, Occupational Health and Safety Other, Laboratory Supplies, Scientific and Technical Equipment. In addition, the QAR Form must be submitted for procurements valued at less than \$25,000 that are for information collected or produced from measurements, analyses or models of:

- a. environmental processes or conditions;
- b. industrial, commercial, or personal processes or conditions of interest because of their relationship to the environment; or,
- c. experimental systems representing any such processes or conditions.

4.3 Procurement Documents and Records

The Grants and Contracts Management Branch (GCMB) is responsible for ensuring that no procurement document in the categories specified is implemented without the appropriate signatures.

The PO or other official responsible for the procurement, such as a Work Assignment Manager (WAM), will prepare and sign the QAR Form, indicating all relevant funding and QA information, in particular noting whether the project will involve environmental monitoring. If environmental data will be involved, the PO will sign and submit the QAR Form to the designated QA Officer within DESA who is responsible for monitoring the PO's program.

The QA Officer will then review and approve the level of quality assurance assessment that will be necessary for the project and return the form to the PO. The PO will then forward the completed QAR as part of the procurement request package to GCMB. If the QA Officer indicates on the form that QA requirements are applicable to a procurement and the potential value of the procurement exceeds \$500,000, the QA Officer, or designee, shall be a member of the Technical Evaluation Panel to evaluate QA aspects of the technical proposals.

If the form indicates that environmental data will NOT be involved, the PO should sign and submit the form as part of their procurement request package directly to GCMB.

For non-Region 2 EPA contracts, the PO or WAM submits all QARs to the originating Office. When such contracts do involve environmental monitoring, the PO or WAM is responsible for ensuring the inclusion of all subsequent QA documentation and activities.

Those agencies that receive grants or financial assistance, e.g., States or Tribal governments, under which environmental measurements will be performed are required to submit quality assurance information, i.e., a QMP or QAPP, dependent on the type of grant being considered. The RQAM or designee is responsible for the review and approval of the appropriate QA documentation before funds can be released.

For intergovernmental agreements whereby those agencies are receiving funds from EPA, a QAPP must be prepared, submitted and approved by the RQAM before monies can be released.

5.0 DOCUMENTATION AND RECORDS

5.1 Identification of Technical and Quality-Related Documents and Records Requiring Controls

Quality related documents and records requiring controls are as follows:

- Management System Reviews
- Technical System Audits
- Data Audits
- QAPPs
- SOPs
- QMPs
- Data Review and Validation Reports

5.2 Description of Systems for Controlling Technical and Quality-Related Documents and Records

Preparation, control, issuance, and implementation (including revisions or amendments) of QAPP(s), SOPs, QMPs are the responsibility of the appropriate program or project manager. . Quality related documents are submitted to appropriate regional QAOs for review and approval prior to issuance or implementation, and documentation of any subsequent revisions or amendments is also provided to QAOs. Maintenance of QA documents and records associated with a given environmental program or project is the responsibility of the Division that has primary responsibility for that program or project. In Region 2, DESA is responsible for records and documents associated with the Region 2 QA Program, while the various Divisions (including DESA) are responsible for their own environmental monitoring records and documents dealing with air, RCRA, etc. At a minimum, the final report and the QAPP for each project should be stored together by the PO, not the QAO, thus allowing a subsequent investigator to understand the full context of the data and the conclusions. Responsibility for removal of obsolete QA documents and records and replacement with current versions is the responsibility of the appropriate QAOs.

5.3 Tracking and Retrieval of Technical and Quality-Related Documents and Records

Short and long term storage is to be maintained in a place and for a period of time to be decided by each Division/Office Director in accordance with the EPA's OEI and the Records Management Manual, including the proposed revision of Agency record disposition schedules covering selected Agency-wide records.

6.0 COMPUTER HARDWARE AND SOFTWARE

The Information Systems Branch (ISB) is responsible for the planning, implementation, support and maintenance of the Region II Local Area Network (LAN) and electronic mail using Lotus Notes. ISB manages the Information Center/Help Desk and provides training and support for the Region's PCs and application software. The branch is also responsible for the approval, installation and support of all information technology (IT) related hardware and software. The branch provides database administration support for most major program systems in the region. ISB is responsible for the Region 2 Intranet website and share responsibility with the Communications Division for the EPA Region 2 public access website.

By including information technology in the QMP, there is a recognition of the full life cycle of the information collection process, which includes the storage, transmission, security and use of the information.

6.1 Process, Roles, and Responsibilities for Managing Changes to Hardware and Software Configurations, Configuration Testing and Documentation

Network Infrastructure: The Region 2 LAN infrastructure contains many components, beginning with the Wide Area Network (WAN) routers, and includes the cable infrastructure, remote access routers, Ethernet switches, file and print servers, applications servers (production and test), and web servers. These components, for the most part, include various levels of software, such as the operating systems (Novell 5x, Microsoft NT4x and Windows 2000 Enterprise Server, application components such as Lotus Notes (which itself has numerous components such as email, databases, etc.), Lotus SmartSuite, etc. There are dozens of different pieces of software, all of which must be managed according to applicable Agency standards in terms of security and interoperability.

Where appropriate, changes to any component of the network infrastructure will utilize specific Agency guidelines as well as information provided by the vendors to implement a change, such as the installation of new hardware or software, upgrades, patches, etc. Depending on the network component, ISB will implement in a test or pilot environment for as little as 24hrs to several months or more. The aggregation of the desktop software is known as the desktop image for a particular make/model PC. In Region 2, we have at least 5 different images and any change to any component will be tested on each image before it is implemented.

LAN Manager, LAN Administrator, Information Security Officer, Notes Administrator, Desktop Administrator, and the Webmaster are key points of contacts for IT services.

Documentation of the changes to the LAN infrastructure will be included as part of the Region 2 Disaster Recovery Operations Manual

Program Systems

There are numerous program systems in use in the region for which ISB will participate in the change management process, but for which it is not the primary system owner. Depending on the application, a program office may utilize the services of a contractor to modify an existing application, or develop a new one. The roles, responsibilities and contacts will vary, depending upon the system or application. For example, the Laboratory Information System is managed and operated by the DESA Laboratory, although ISB will provide support, insofar as, the operation of LIMS on the LAN and its conformance to Agency guidelines, especially as it pertains to network security.

6.2 Process, Roles, and Responsibilities for Developing and Evaluating Software

The OEI has published several documents that provide the basis for developing and evaluating software. These documents are as follows:

EPA Directive 2182 - System Design and Development Guidance (April, 1993)

<http://www.epa.gov/irmpoli8/sysdesn/>

Web Guide: Application Deployment

<http://www.epa.gov/webguide/deploy/index.htm> 1

Information Technology Architecture Roadmap

<http://basin.rtpnc.epa.gov/ntsd/ITARoadMap.nsf>

ISB uses these documents, as appropriate, to develop and evaluate software. The EPA Directive 2182 is old and out of date, and its utility is minimal, although it does offer some general concepts that are applicable. The branch uses new development tools such as Cold Fusion to perform rapid prototyping which allows meaningful interaction with the system owners. A member of the Information Systems Branch is assigned as the project lead for any system developed within the branch, or being developed by a contractor.

6.3 Process, Roles, and Responsibilities for Verifying that Data Being Compiled and the Quality Control and Maintenance that these Data are Appropriate for Intended Use

OEI has published several documents that provide the basis for data elements. These documents are as follows:

Environmental Data Registry (EDR) <http://www.epa.gov/edr/>

EPA Directive 2190 - Privacy Act Manual <http://www.epa.gov/irmpoli8/privacyact/>

The Information Systems Branch uses these documents as appropriate to review data and data elements. There are branches within every division that play a role in this activity, depending on the type of data. In most cases, they are the primary data owner, such as the Division of Enforcement and Compliance Assistance (DECA) for enforcement data, the Office of Policy and Management for financial and human resource data, etc.

6.4 Process, Roles, and Responsibilities for Developing Procedures to Ensure that Historical Files Are Documented and Can Be Recovered

U.S. EPA Directive 2100 - IRM Policy Manual- Chapter 10 - RECORDS MANAGEMENT July 1996
<http://www.epa.gov/records/policy/2100/2100-10.htm>

EPA Records Schedules <http://intranet.epa.gov/records/schedule/index.htm>

The documents referenced above provide the guidance that is used by the owners of the official records. They are responsible for ensuring that their historical files are properly documented and conform to official Agency records disposition schedules. The Information Systems Branch performs back-ups of all data that is stored on file servers in Region 2. However, data that is stored on PCs and laptops must be backed-up.

The Region 2 Records Management Officer in the Facilities and Administrative Management Branch provides assistance in the archiving and retrieval of official Agency records.

7.0 PLANNING

7.1 Management of Systematic Planning

Each program will identify annual priorities to be implemented in conjunction with Regional resource limitations, regulatory requirements and national and regional EPA goals. This is an interactive process involving DESA. Every attempt is made to coordinate the collection and use of environmental data with other federal, state, tribal and local governmental agencies, volunteer monitoring organizations and academic institutions. To this end, participation in cross-organizational planning groups is encouraged and technical advisory committees are formed for many site specific areas of concern. Informal development of data quality objectives is initiated within these focus groups. The Region has no statistician nor experienced modeler available on staff and must rely on headquarters personnel and outside peer review of proposed projects. Section 2.2 describes the systematic planning process in greater detail.

The QAARWP, produced at the end of each fiscal year, includes a detailed report on the previous year's QA activities and an QA annual work plan citing proposed activities for the next fiscal year. This is developed by the RQAM after participation in the development of program planning activities and is submitted to QS. This is also described in Section 2.1 and illustrated in Figure 1.

Individual project level planning is described above in Section 2.2. The QA Officer is available to participate in the project planning phase and as well as review of draft QAPPs in order to define the data quality needs of the project.

7.2 Elements of Systematic Planning Process

As described in Section 2.2.

8.0 MANAGEMENT OF WORK PROCESS IMPLEMENTATION

Section 2 describes the implementation of work processes within the Region.

9.0 ASSESSMENT AND RESPONSE

Management Self Assessment

An essential element in the development of QA planning for the next year is a careful review of the past year's activities, accomplishments, and problems. The RQAM and the QA staff conduct this review in conjunction with the divisional work plan planning process to ensure that the plans reflect any identified needs and concerns. At the same time, the relevance of the QMP is reviewed. The QAARWP is submitted to QS for review. Regional peer reviews are conducted on selected projects as determined annually by the peer review work group. Use of the DQA process, an additional form of self-assessment, is discussed in section 2.7.

The QAOs perform periodic Regional assessments, to review and comment on the implementation of the QA functions within each Division. The results of the review, including deficiencies and recommendations for addressing them are provided by the QAOs. Divisional follow-up is timely, appropriate and documented to the RQAM.

Management self assessment is exhibited by some of the grantees, such as New Jersey and New York. The Performance Partnership Agreement (PPA) grant process incorporates completion of a self assessment document.

Management Independent Assessment

In addition to reviewing and commenting upon the QAARWP, EPA's QS conducts an MSR of the Regional QA program on a triennial basis. Deficiencies requiring corrective action are appropriately addressed in a timely manner.

Management systems reviews of program activities are carried out routinely by the appropriate EPA headquarters program staff. For example, the drinking water certification program is reviewed annually either in person or by information requested to be submitted.

Independent assessments of delegated program and grantee activities are conducted through jointly conducted TSAs as well as the MSR process, as discussed in section 2.2.

Technical Self-Assessment

TSAs of EPA field, laboratory and data review activities are conducted by EPA QA and program staff as requested by the PO and/or program office or as determined by regional QA staff. Outside experts can be called upon to assist the EPA QAO or PO in conducting the self-review.

Technical Independent Assessment

The Headquarter's Office of Water conducts audits triennially for the purpose of recertification of the laboratory for drinking water analyses. Other reviews may be conducted by appropriate headquarters personnel. Also, regional participation in annual PE studies assess technical competency. Corrective actions are addressed in a timely manner, as appropriate for the process that identified the problem, i.e., MSR, and based on the type of problem, i.e., systemic or unique.

10.0 QUALITY IMPROVEMENT

Continual improvement is achieved by constant evaluation of program, project and individual performance in terms of ever changing environmental policies and objectives.

Program improvement and quality management for R2 and its programs is not accomplished by only the QA staff. 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 on-going programs. The system established by the QMP is the responsibility of all R2 employees. Quality improvement must be considered, and must be incorporated into the everyday, on-going work of the Office.

The role of the R2 QA staff is to provide technical assistance to the various units of the program as they initiate projects and to review and comment on the processes that exist or processes which do not incorporate the quality objectives of R2. The R2 QA staff meets regularly to discuss cross-cutting issues and to look at ways of improving the organizational implementation of QA. The R2 QA staff also provide a perspective on the continuous improvement process and provide advice and recommendations to program office managers on ways to improve the quality processes within R2.

10.1 Quality System Improvement Process

It is the responsibility of line management for assuring staff participation for all program reviews and to review annually all QA activities of their staff, e.g., determining that SOPs are in place and revised if necessary, that QAPPs are written and approved in advance of project start-up and that data quality assessments are made. All deviations and discrepancies noted during any independent or self-assessment review will be corrected promptly and modifications made, if necessary, to the Regional QMP. Additionally, the RQAM communicates results of audit, assessments, and reviews with program counterparts to identify areas of excellence, and areas needing corrective actions.

10.2 Corrective Action for Quality-Related Problems

Region 2 SOPs for conducting MSRs and laboratory or field TSAs mandate corrective actions be identified in review or audit reports, when appropriate. The RQAM and QAOs ensure that reports contain warranted corrective actions, and that such corrective actions are, in fact, implemented. The results of followup on corrective action are documented with the associated reports that initiated the requirement for corrective actions. The QAARWP will reflect progress made in these corrections.

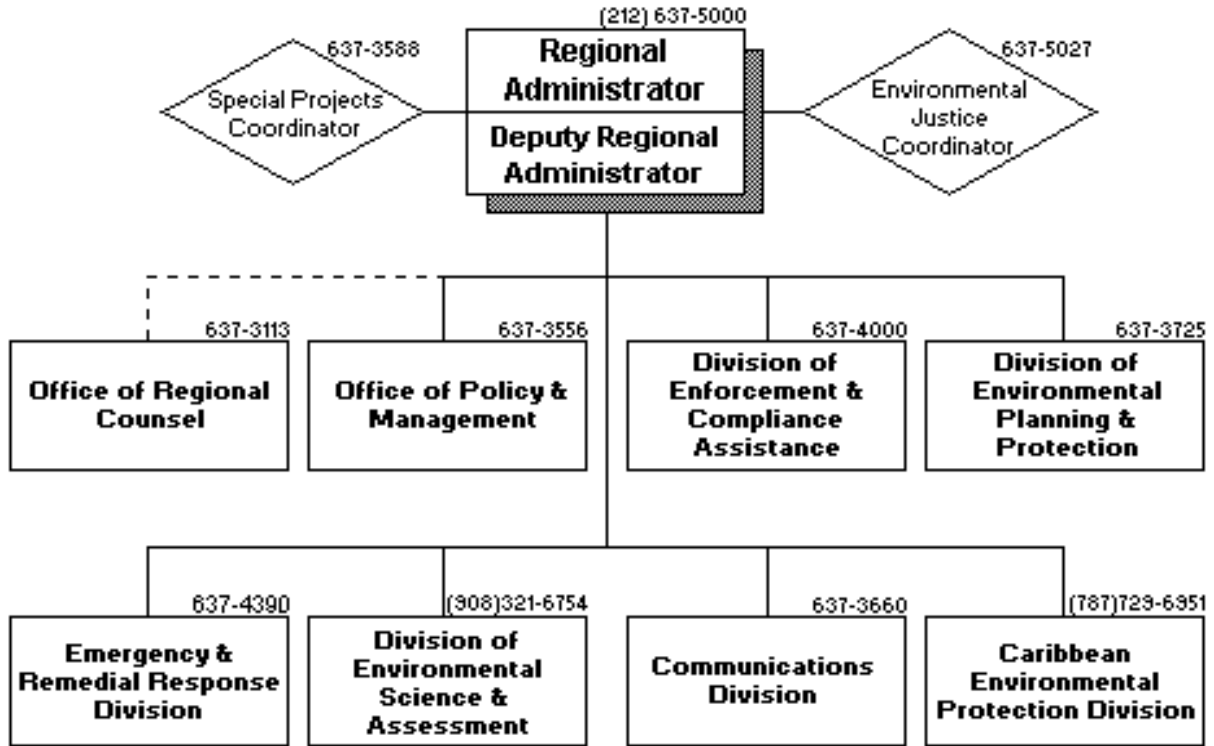
10.3 Creating an Environment for Facilitating and Promoting Quality Improvement

It is the responsibility of POs to request project reviews and/or audits and to identify where improvements can be made. This process is started during the scoping meeting initiating the Systematic Planning Process and is finalized during the assessment of data quality in the project final report. All corrective actions and deviations required during the life cycle of the project are to be filed in or with the final report. QAOs are encouraged to attend project meetings and conference calls and to conduct technical audits.

Appendix A

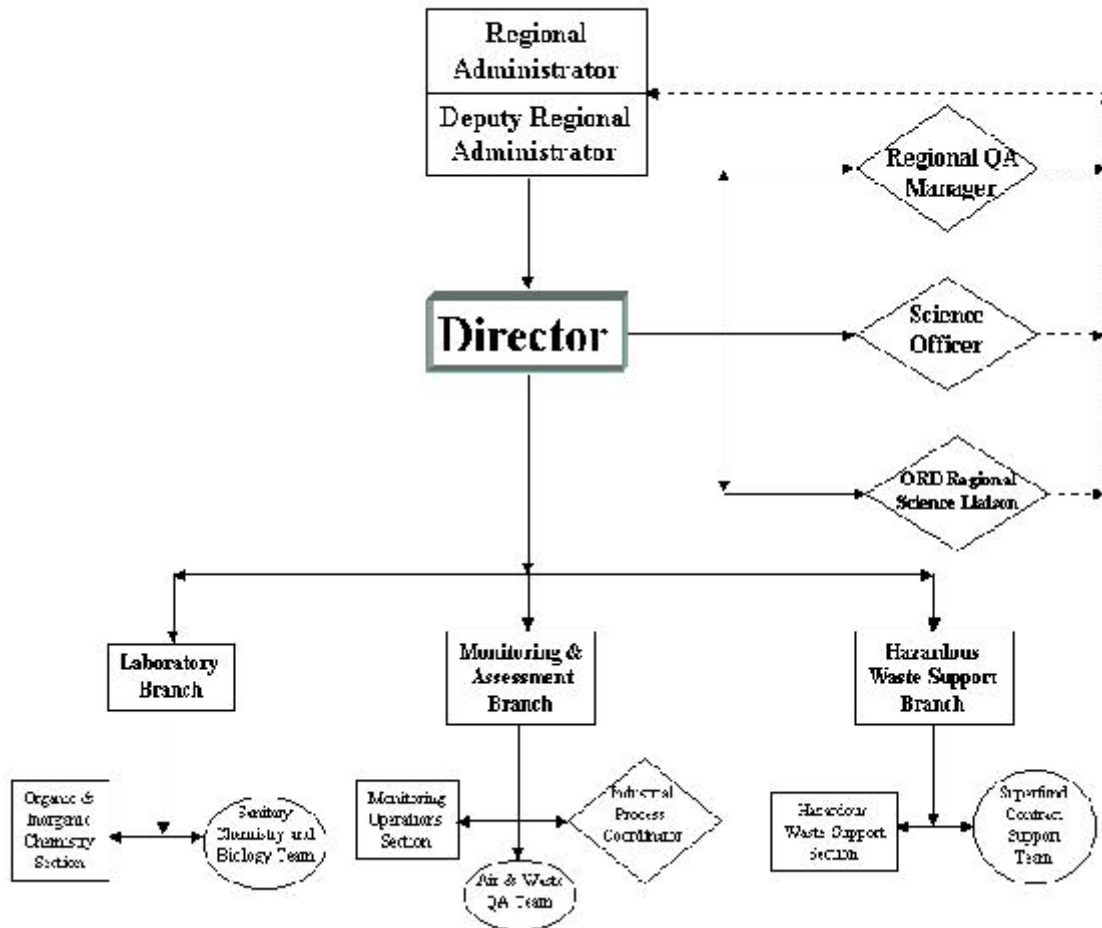
Region 2 Organizational Charts

U.S. Environmental Protection Agency - Region 2



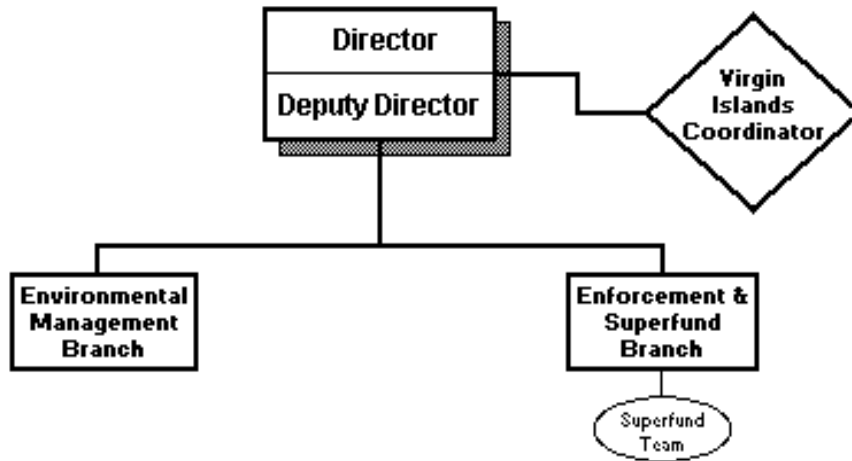
Region 2 Organizational Charts

Division of Environmental Science and Assessment



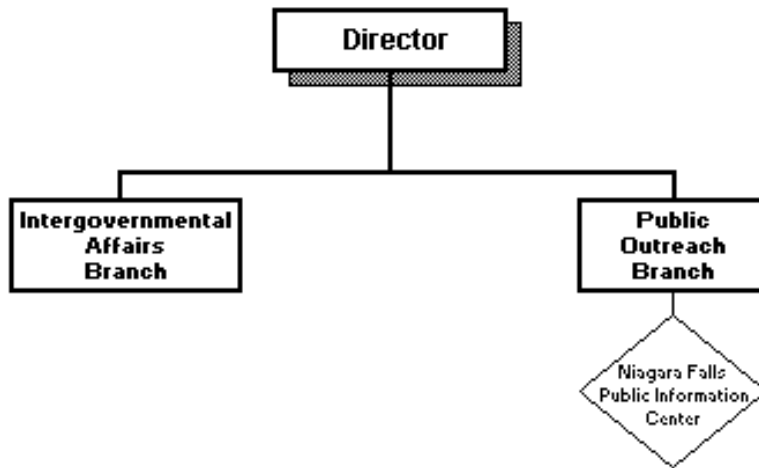
Region 2 Organizational Charts

Caribbean Environmental Protection Division



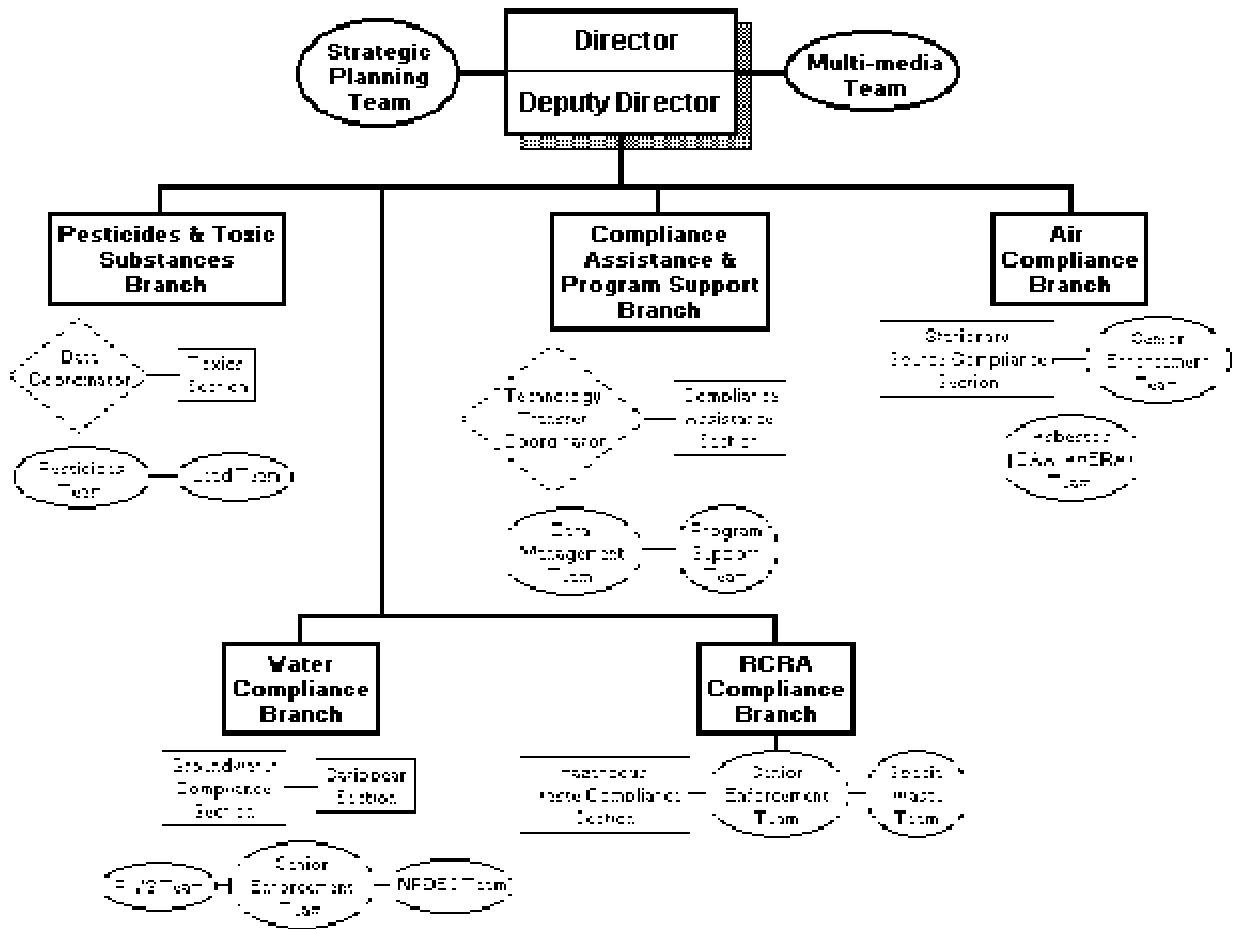
Region 2 Organizational Charts

Communications Division



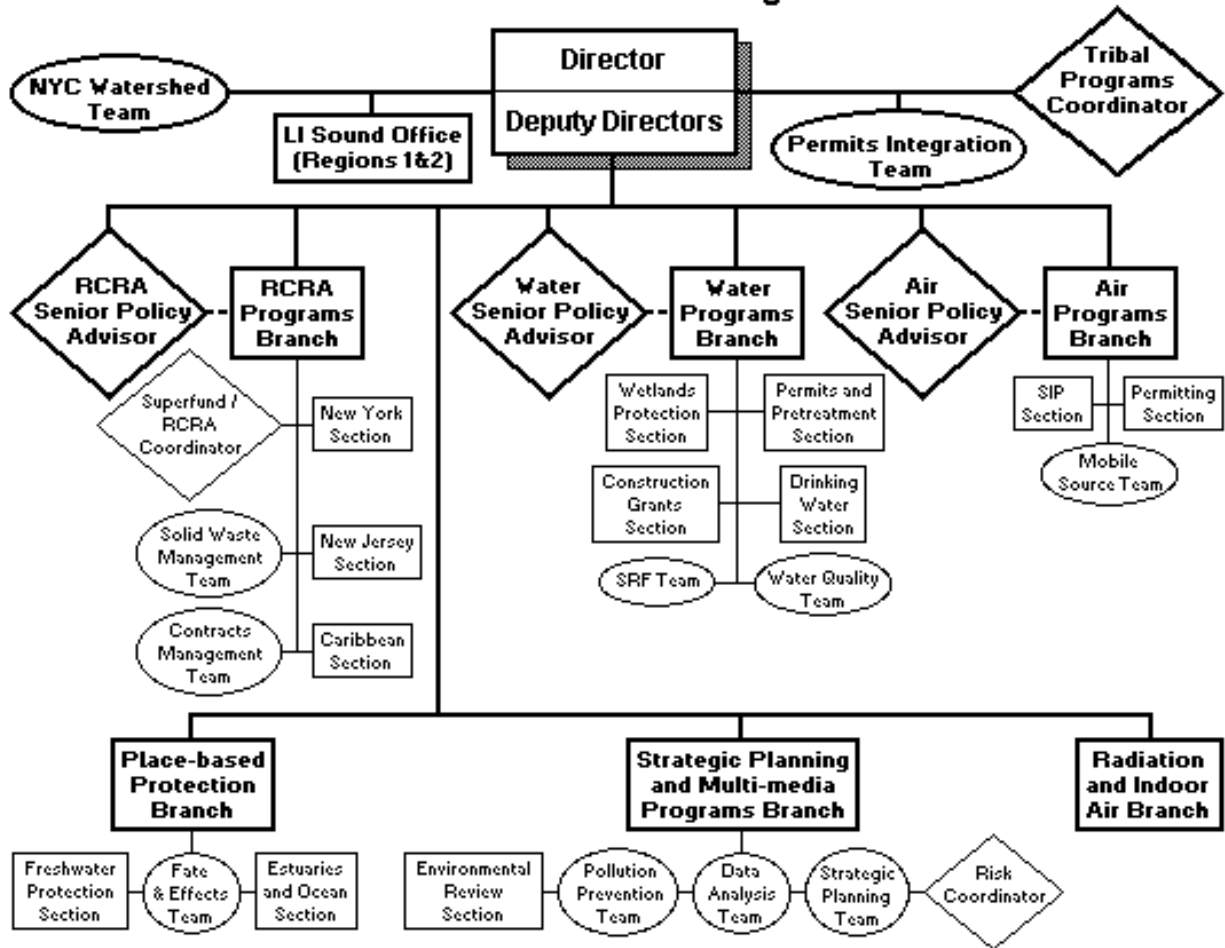
Region 2 Organizational Charts

Division of Enforcement and Compliance Assistance



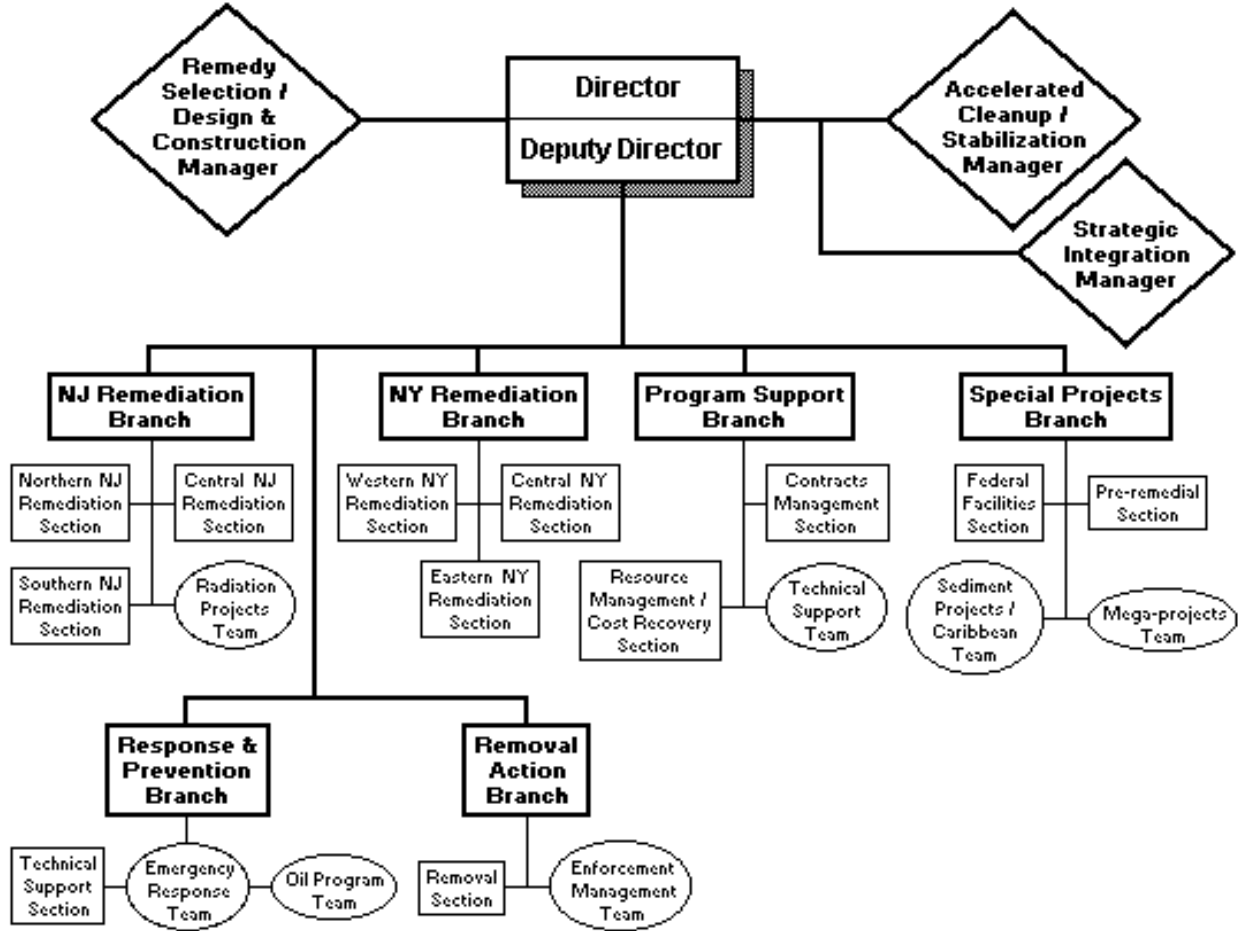
Region 2 Organizational Charts

Division of Environmental Planning & Protection



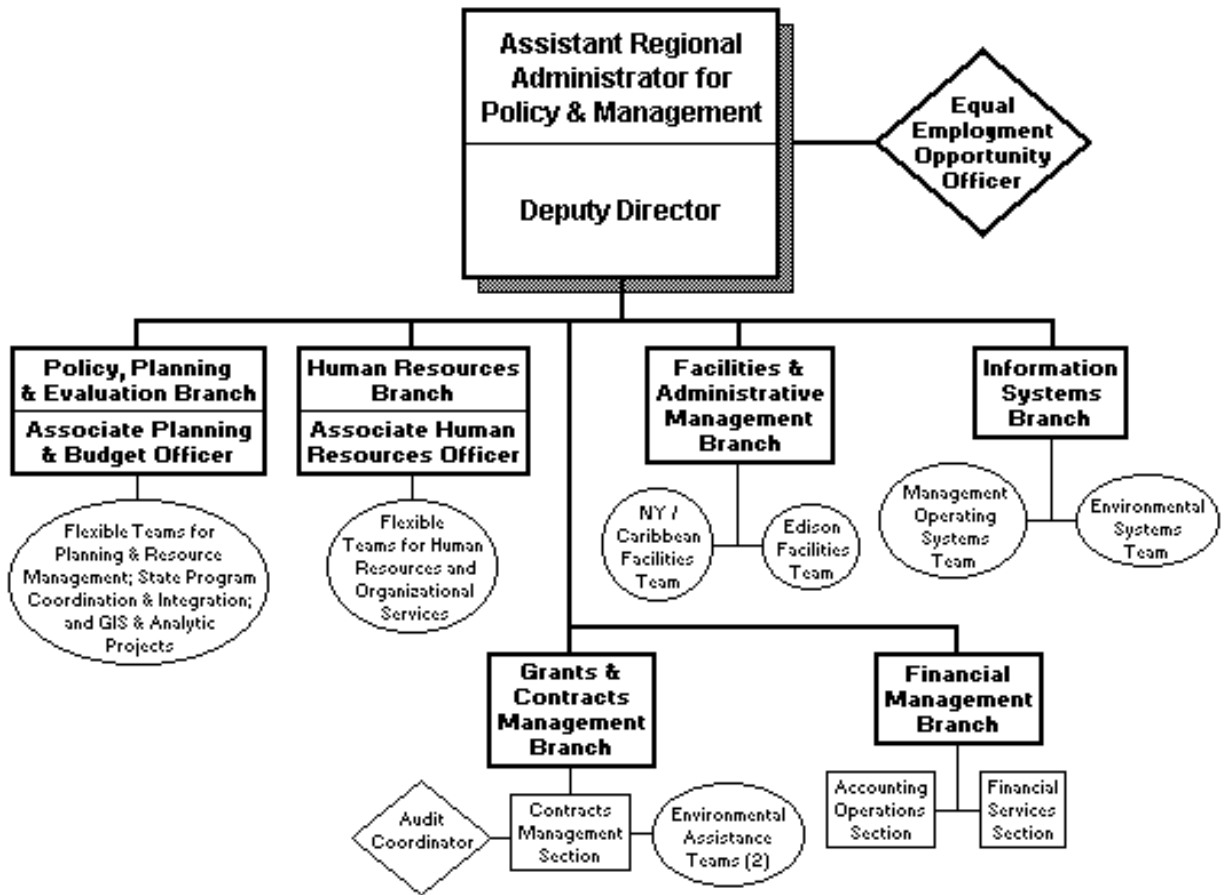
Region 2 Organizational Charts

Emergency & Remedial Response Division



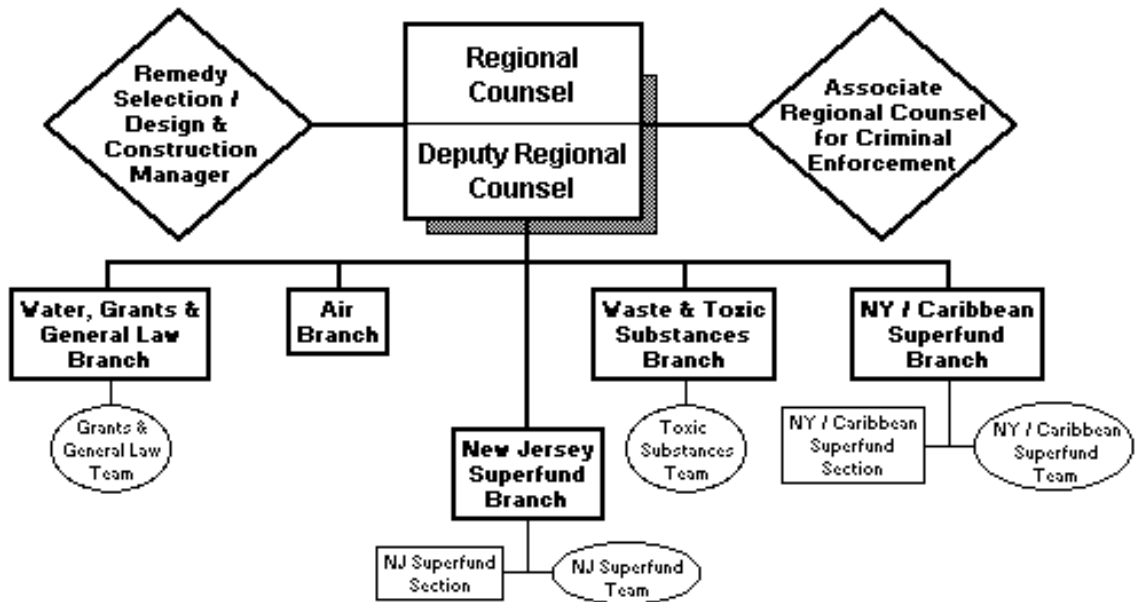
Region 2 Organizational Charts

Office of Policy and Management



Region 2 Organizational Charts

Office of Regional Council



Appendix B

List of Region 2 Quality Assurance Staff

Regional Quality Assurance Manager (RQAM)

Kevin Kubik

Hazardous Waste Support Section Chief

Shari Stevens

Organic and Inorganic Section Chief

John Bourbon

Air and Water QA Team Leader

Marcus Kantz

Superfund Contract Support Team Leader

Joseph Hudek

Quality Assurance Officers

CERCLA/RCRA

Russ Arnone

Jennifer Feranda

Amelia Jackson

George Karras

Ray Klimcsak

Sergio Lopez-Luna

Adly Michael

Muhammad Sheikh

Patricia Sheridan

William Sy

Air/Water

Ann Marie Carlton

Carol Lynes

Linda Mael

Dennis McChesney

Mustafa Mustafa

Donna Ringel

Kai Tang

Avraham Teitz

Mark Winter

Donald Wright

Ann Zownir

Laboratory

Elaine Vikara

Appendix C

Acronyms

ADP	Automatic Data Processing
ADQ	Audit of Data Quality
AHERA	Asbestos Hazard Emergency Response Act
CAA	Clean Air Act
CD	Communications Division
CEM	Continuous Emission Monitor
CEPD	Caribbean Environmental Protection Division
CERCLA	Comprehensive Environmental Response, Compensation & Liability Act
CLP	Contract Laboratory Program
CWA	Clean Water Act
DD	Division Director
DECA	Division of Enforcement & Compliance Assistance
DEPP	Division of Environmental Planning & Protection
DESA	Division of Environmental Science & Assessment
DMR	Discharge Monitoring Report
DQA	Data Quality Assessment
DQO	Data Quality Objective
EMP	Environmental Monitoring Project
EPCRA	Emergency Planning & Community Right-To-Know Act
ERRD	Emergency & Remedial Response Division
FFCA	Federal Facility Compliance Act
FIFRA	Federal Insecticide, Fungicide & Rodenticide Act
GCMB	Grant & Contracts Management Branch
GIS	Geographic Information System
HSWA	Hazardous and Solid Waste Amendments
IRM	Information Resource Management
LAN	Local Area Network
LUST	Leaking Underground Storage Tank
MPRSA	Marine Protection, Research and Sanctuaries Act
MSR	Management Systems Review
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NPDES	National Pollution Discharge Elimination System
NSPS	New Source Performance Standards
OPA	Oil Pollution Act
ORC	Office of Regional Counsel
ORD	Office of Research and Development
PE	Performance Evaluation
PO	Project Officer
PWS	Public Water System
QA	Quality Assurance
QAARWP	Quality Assurance Annual Report and Work Plan
QAM	Quality Assurance Manager
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QAR	Quality Assurance Report
QC	Quality Control
QMP	Quality Management Plan
OPM	Office of Policy & Management
ORD	Office of Research & Development
RA	Regional Administrator
RCRA	Resource Conservation Recovery Act
RQAM	Regional Quality Assurance Manager
SARA	Superfund Amendments and Reauthorization Act
SIP	State Implementation Plan

SWDA Solid Waste Disposal Act
SDWA Safe Drinking Water Act

Appendix C (continued)

SOP Standard Operating Procedure
TAT Technical Assistance Team
TSCA Toxic Substances Control Act
TSA Technical Systems Audit
UIC Underground Injection Control
UST Underground Storage Tank
WAM Work Assignment Manager

Appendix D

Glossary of QA Terms

Accuracy: the degree of agreement between an observed value and an accepted reference value; a data quality indicator.

Audit: a systematic evaluation to determine the conformance to quantitative specifications of some operational function or activity. Also known as an assessment.

Audit of Data Quality: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Bias: the systematic or persistent distortion of a measurement process; a data quality indicator.

Certification: the process of testing and evaluation against specifications designed to document, verify and recognize the competence of a person, organization or other entity to perform a function or service usually for a specified time.

Comparability: the degree to which different methods, data sets and/or decisions agree or can be represented as similar; a data quality indicator.

Completeness: the amount of valid data obtained compared to the planned amount, and usually expressed as a percentage; a data quality indicator.

Corrective Action: measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Criteria: a standard on which a judgement is based.

Data: facts or figures from which conclusions can be inferred.

Data Base: collection of integrated data that can be used for a variety of applications.

Data of Known Quality: data are of known quality when the qualitative and quantitative components associated with their derivation are documented appropriately for their intended use and such documentation is verifiable and defensible.

Data Quality Assessment: the evaluation of environmental data to determine if they meet the quality criteria required for a specific application.

Data Quality Indicators: qualitative statistics and quantitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy, comparability, completeness, and representativeness.

Data Quality Objectives: qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Data Validation: the process of determining that the data satisfies the requirements as defined by the data user.

Defensible: the ability to withstand any reasonable challenge related to the veracity of integrity of laboratory documents and derived data.

Deficiency: an unauthorized deviation from acceptable procedures or practices, or a defect in an item.

Environmental Monitoring: the process of measuring or collecting environmental data.

Environmental Sample: a sample of any material that is collected from an environmental source.

False Negative: estimation that an analyte is not present when it actually is present.

Appendix D (continued)

False Positive: estimation that an analyte is present when it is actually not present.

Hardware: physical equipment such as the computer and its related peripheral devices, tape drives, disk drives, printer, etc.

Internal Audit: a systematic evaluation, conducted by QA and technical staff from within an organizational unit, to determine the conformance to quantitative specifications of some operational function or activity.

Management Systems Review: the qualitative assessment of a data collection operation and/or organization to establish whether the prevailing quality management structure, practices and procedures are adequate for ensuring that the type and quality of data needed and expected are obtained.

Peer Review: a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty that is conducted by qualified individuals or organizations who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e. peers) to those who performed the original work.

Performance Evaluation Audit: a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with data of known quality to evaluate the proficiency of an analyst or laboratory.

Performance Evaluation Sample: a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits.

Precision: the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator.

Quality: the sum of features and properties/characteristics of a product or service that bear on its ability to satisfy stated or implied needs. The consistent conformance of a product or service to a given set of standards or expectations.

Quality Assessment: the evaluation of environmental data to determine if they meet the quality criteria required for a specific application.

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

Quality Assurance Manager: individual responsible for coordinating all QA activities, including development and revision of the Quality Assurance Management Plan and development of QA policies and procedures. Serves as the liaison between the Regional and the Quality Assurance Division. Also known as the Regional Quality Assurance Manager.

Quality Assurance Officer: individual responsible for oversight of all aspects of QA activities within their assigned area, as designated by the RQAM.

Quality Assurance Project Plan: a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable and economic.

Quality Improvement: a management program for improving the quality of operations.

Quality Management Plan: a formal document describing the management policies, objectives, principles, organization authority, responsibilities, accountability and implementation plan of an agency, organization or laboratory for ensuring quality in its products and utility to its users.

Appendix D (continued)

Representativeness: the degree to which data accurately and precisely represent the frequency distribution of a specific variable in the population; a data quality indicator.

Software: computer programs, procedures, rules and associated documentation pertaining to the operation of a computer system.

Standard Operating Procedure: a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

Technical Systems Audit: a thorough, systematic on-site qualitative review of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management and reporting aspects.

Appendix E

List of Referenced Documents

USEPA OEI/QS Documents:

Policy and Program Requirements for the Mandatory Agency-wide Quality System, EPA Order 5360.1 A2, May 2000.

EPA Quality Manual for Environmental Programs, EPA Manual 5360 A1, May 2000.

EPA Requirements for QA Project Plans (QA/R-5), EPA/240/B-01/003, March 2001.

EPA Requirements for Quality Management Plans (QA/R-2), EPA/240/B-01/002, March 2001.

Guidance for the Data Quality Objectives Process (G-4), EPA/600/R-96/055, August 2000.

Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW), EPA/600/R-00/007, January 2000.

Guidance on Quality Assurance Project Plans (G-5), EPA/600/R-98/018, February, 1998.

Guidance for the Preparation of Standard Operating Procedures (G-6), EPA/240/B-01/004, March 2001.

Guidance on Technical Audits and related Assessments (G-7), EPA/600/R-99/080, January, 2000

USEPA Region 2 Documents:

Review of Quality Management Plans, USEPA Region 2 DESA SOP # MCCG2, Rev # 3.0, May 1, 1999.

Guidance for Management System Review (MSR) of State, Interstate, Commonwealth, Territory, and Indian Programs, USEPA Region 2 DESA SOP # MACG2, Rev # 2.0, May 17, 1999.

Guidance for the Development of Quality Assurance Project Plans for Environmental Monitoring Projects, USEPA Region 2 DESA SOP # MCCG3, Rev # 99/12, May 1, 1999.

Guidance for Review of Quality Assurance Project Plans (QAPPs), USEPA Region 2 DESA SOP # MACG3, Rev # 1.0, October 17, 1994.

Guidance for Development of Standard Operating Procedures (SOPs), USEPA Region 2 DESA SOP # MCCG1, Rev # 4.0, May 1, 1999.

Guidance for Technical System Audits for Field, Laboratory, and Data Assessment Activities, USEPA Region 2 DESA SOP # MACG1, Rev # 2.0, May 17, 1999.

Technical Systems Audit of a Non-potable Water Microbiology Laboratory - Analysis of Total and Fecal Coliform Bacteria, USEPA Region 2 DESA SOP # MAW01, Rev # 3.0, May 1, 1999.

Technical Systems Audit of Toxicity Testing Laboratories for The Ocean Dredge Disposal Program, USEPA Region 2 DESA SOP # MAW02, Rev #: 2.0, May 1, 1999.

Other Documents

Guidelines for Stack Testing Protocol Development and Submittal, December 1987 or later revision.

Quality Assurance Guidelines for Modeling Development and Application Projects, a Policy Statement, Environmental Research Laboratory, Duluth, Michigan. November 1991.

USEPA Region 2 CERCLA Quality Assurance Manual, October 1989.

National Data Processing Division Guidance on Hardware and Software Standards (draft). U.S. Office of Information and Resources Management. November 1993.

