EPA NEW ENGLAND

U.S. ENVIRONMENTAL PROTECTION AGENCY

QUALITY MANAGEMENT PLAN

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EPA New England Quality Management Plan

APPROVAL FOR AGENCY

1. NAME: Monica Jones
   TITLE: Director, Quality Staff, Office of Environmental Information

   SIGNATURE: _____ DATE: _____

2. NAME: Renee Wynn
   TITLE: Acting Assistant Administrator, Office of Environmental Information

   SIGNATURE: _____/s/_____ DATE: 7/28/2011_____

EPA New England Quality Management Plan

APPROVAL FOR EPA NEW ENGLAND

1. NAME: Curt Spalding
   TITLE: Regional Administrator

   SIGNATURE: _____DATE: _____

EPA New England Quality Management Plan

CONCURRENCE

1. NAME: Arthur Johnson
   TITLE: Acting Regional Quality Assurance Manager

   SIGNATURE: _____ DATE: _____

2. NAME: Robert Maxfield,
   TITLE: Director, Office of Environmental Measurement & Evaluation

   SIGNATURE: _____ DATE: _____

3. NAME: Susan Studlien
   TITLE: Director, Office of Environmental Stewardship

   SIGNATURE: _____ DATE: _____

4. NAME: Michael Kenyon
   TITLE: Director, Office of Administration & Resource Management

   SIGNATURE: _____ DATE: _____

5. NAME: Ken Moraff
   TITLE: Director, Office of Ecosystem Protection

   SIGNATURE: _____ DATE: _____

6. NAME: James Owens
   TITLE: Director, Office of Site Remediation & Restoration

   SIGNATURE: _____ DATE: _____

EPA New England Quality Management Plan

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INTRODUCTION

EPA New England's Quality Management Plan (QMP) describes the policies, procedures, and management systems within the organization that govern quality assurance and quality control activities in accordance with the CIO 2105.0 (hereafter, the *EPA Data Quality Standard***).** This QMP is applicable to all environmental programs, operations and activities conducted by EPA New England (the Region) that involve the collection, production, and use of environmental data. As defined by the Agency, environmental data refers to "any measurements or information that describe environmental conditions, locations, and processes; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature."

The QMP also describes Regional processes for ensuring the quality of environmental data collected, produced and/or used by other Federal, State, Tribal and local partners under interagency agreements and financial assistance agreements; contractors funded by EPA; regulated entities; and potentially responsible parties.

In addition, this QMP provides both internet and intranet links to allied Regional programs responsible for implementing the Peer Review Policy, Information Quality Guidelines–Pre-dissemination Review, Forum on Environmental Measurement Policies for Assuring Competency, Scientific Integrity Policy and Human Subject Research Policy. EPA intranet links are intended for EPA personnel only.

1.0 MANAGEMENT AND ORGANIZATION

This Section documents the overall policy, scope, applicability, and management responsibilities of the Regional quality system. The EPA New England Regional Administrator, Deputy Regional Administrator, and Senior Leadership Team are fully committed to the implementation of an effective quality system. Senior management ensures understanding and implementation of the Regional quality system by issuing policy statements, allocating resources, performing assessments, developing guidance and providing training. The Region most recently confirmed its commitment to implementing a quality system in the *EPA New England's Commitment to Implementing the Regional Quality System*, May 4, 2005, policy memo. Regional commitment is consistent with the objectives and goals of the *EPA Data Quality Standard.*

1.1 EPA New England Mission Statement

The mission of the U.S. Environmental Protection Agency is to protect human health and the environment -- air, water, and land -- upon which life depends. The EPA New England Regional Office focuses on human health and environmental issues within the six New England States for present and future generations. Additional information about the Region is available at:
http://www2.epa.gov/aboutepa/epa-region-1-new-england

To achieve its mission the Region relies on environmental data to make decisions affecting public health and the environment. Our environmental objectives are to:

- Address climate change;
- Protect New England's diverse populations and ensure healthy communities;
- Improve and protect air and water quality;
- Prevent pollution through source reduction; and
- Clean up contaminated sites.

1.2 EPA New England Quality Assurance Policy

It is Regional policy that environmental data operations will result in the collection, production, and use of environmental data of known and documented quality, suitable for their intended use. This quality policy applies to all environmental data activities performed by and for the Region. To that end, quality assurance (QA) and quality control (QC) requirements, processes, and procedures are integrated into the Region's media programs that administer environmental data operations directly and through grants, cooperative agreements, interagency agreements and contracts.

The Regional Administrator and senior management ensure that adequate resources, including intramural and extramural money, training and travel funds, and personnel are allocated to achieve the Region's quality policy.

1.3 Assignment of Responsibility

In accordance with the *EPA Data Quality Standard*, overall responsibility for the QA program in the Region rests with the Regional Administrator. The Regional Administrator has delegated the responsibility for developing and documenting Regional QA policies, procedures and guidance; overseeing the implementation and assessment of the Regional quality system; and providing QA training to the Regional Quality Assurance Manager (RQAM) in the Office of Environmental Measurement and Evaluation (OEME).

Figure 1 depicts the basic components of the Region's organization and structure in terms of quality assurance reporting and authority. The RQAM reports directly to the OEME Division Director. The dotted line between the RQAM and the Deputy Regional Administrator indicates that the RQAM has recourse to elevate issues to the next higher level of senior management, that is, the Deputy Regional Administrator. Detailed Regional organizational charts are maintained at: *http://www2.epa.gov/aboutepa/organization-chart-epas-region-1-office*.

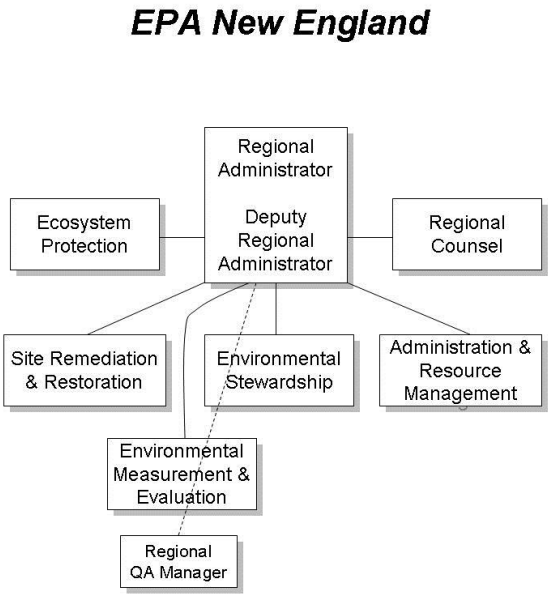

Figure 1: Quality Assurance Reporting and Structure

Roles and responsibilities pertaining to the implementation of allied programs including Peer Review, Information Quality Guidelines-Pre-dissemination Review, and Human Subject Research are detailed in their respective implementation plans. Intranet and Internet links are provided for these program plans in Chapter 2.

Specific quality assurance responsibilities for Regional personnel and partners are described below:

1.3.1 Regional Administrator and Senior Managers

As specified in the *EPA Data Quality Standard* the Regional Administrator (RA) and senior managers are responsible for the Regional quality system, and to that end:

- Designate at least one representative for quality management activities to advise and assist the RA and senior managers in the planning, implementation, documentation, and assessment of the quality management systems for organizations under their responsibility;

- Ensure that all Regional components and programs comply fully with the *EPA Data Quality Standard*, including the preparation of a QMP for the Region, implementation of an effective Regional quality system, and the timely submission of QA Annual Reports and Work Plans (QAARWPs) to Office of Environmental Information (OEI);

- Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in this QMP;

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- Ensure that all environmental programs implemented through extramural agreements comply fully with applicable requirements of the *EPA Data Quality Standard;*

- Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments meet minimal program data quality objectives, are of sufficient quantity and adequate quality for their intended use, and are used consistent with such intentions;

- Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that they may be expected by EPA to perform;

- Ensure that assessments are performed every three to five years (or more frequently where necessary) of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality management system to their approved QMPs and the effectiveness of their implementation;

- Ensure that deficiencies highlighted in the assessments are appropriately addressed;

- Identify QA and QC training needs for all levels of management and staff and provide for this training; and

- Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this QMP.

1.3.2 Regional Quality Assurance Manager (RQAM)

The Regional Administrator has delegated the responsibility and authority to implement the Regional quality system to the RQAM. As shown in Figure 1, the QA Manager position is located within the Office of Environmental Measurement and Evaluation (OEME). The position has a "dotted line" connection to the Deputy Regional Administrator (DRA). The dotted line documents that the QA Manager has independence in all QA matters and has the ability to directly and independently interact and communicate with the DRA. This direct access to the DRA allows the RQAM to independently elevate critical quality-related issues at his/her discretion without challenge. The RQAM does not need approval or pre-notification to initiate such communication.

The RQAM manages the QA Unit located organizationally within OEME. The RQAM utilizes the QA Unit staff to assist in the day-to-day implementation of the Regional quality system. QA staff has access to appropriate levels of management to address all QA matters. They will use commonly accepted practices, such as starting with the lowest possible level of management and escalating to higher levels of management only as necessary, to resolve conflicts. The QA staff is

expected to notify the RQAM whenever any level of management involvement is needed to resolve QA issues. Should the RQAM believe that QA independence is being challenged; the RQAM can initiate communications with the DRA as described above. Specific responsibilities of the RQAM include:

- Facilitating QMP development and approval and preparing updates to the approved QMP;
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- Representing the organization to OEI/Quality Staff and other groups on matters pertaining to the *EPA Data Quality Standard*, general quality management issues, and to QA and QC activities;

- Providing expert assistance to staff in the organization on QA and QC policies, requirements, and procedures applicable to procurement and technical activities;

- Ensuring systematic planning processes are used to determine technical and QA/QC activities for intramural and extramural environmental data operations; that the results of the planning process are documented in planning documents, such as a quality assurance project plan (QAPP) or sampling and analysis plan (SAP); and that technical procedures and practices are documented in standard operating procedures (SOPs);

- Reviewing and approving QMPs, QAPPs, SAPs and other quality documents submitted by intramural programs and by holders of extramural agreements prior to initiation of field activities;

- Delegating approval authority for QA project plans in accordance with Section 7.6;

- Identifying QA and QC training needs for the organization;

- Overseeing QA and QC implementation in the environmental programs conducted by or for the organization;

- Conducting Technical Assessments; identifying non-conformances; documenting findings; requiring documented responses and corrective actions to findings; and monitoring the effectiveness of the implemented corrective actions;

- Conducting Quality System Assessments; identifying non-conformances and program weaknesses; documenting findings; requiring documented responses and corrective actions to findings; and performing follow-up reviews to assess the effectiveness of the implemented corrective actions;

- Preparing Regional QA policies, procedures, and guidance to facilitate implementation of National QA requirements;

- Working with Regional programs to ensure appropriate QA language is developed and incorporated into contracts, financial assistance agreements, memoranda of understanding/agreement, administrative orders, consent decrees, and other agreements which address environmental data operations;

- Providing input to and comment on Agency-wide QA policy by performing peer review of documents and participating in National workgroups;

- Preparing QA Annual Reports and Work Plans (QAARWPs) and submitting to senior management and OEI Quality Staff; and

- Implementing program recording-keeping procedures to ensure tracking and maintenance of quality-related documents and records.

1.3.3 Managers

As primary supervisors of Regional personnel, managers have the ability to directly evaluate the effectiveness of the planning, implementation, and assessment components of the Region's quality system. Managers are responsible for:

- Ensuring that quality management is an identified activity with associated resources adequate to accomplish program quality goals;

- Ensuring that all organizational components and programs for which management is responsible comply fully with the requirements of the *EPA Data Quality Standard;*

- Ensuring that all sampling, analytical and data handling practices are documented in written procedures, i.e., SOPs. SOPs for all Branch/Unit programs are developed as functional, accurate documents that are approved initially and reviewed periodically for continued adequacy;

- Assessing the QA/QC training needs of their staff and arranging for such training with the RQAM;

- Requiring staff to use current guidance and requirement documents from both the OEI Quality Staff and the Regional QA Unit to ensure uniform application of Agency QA policies and procedures;

- Ensuring that a systematic planning process is used to determine project quality objectives for all environmental data operations; and subsequently, ensuring that the results of the planning process are sufficiently documented in approved QA planning documents, i.e., QAPPs and SAPs, prior to the initiation of work;

- Ensuring that QAPPs are implemented as described; that technical assessments are performed as required; and that data are reviewed prior to use;

- Ensuring that corrective actions are monitored for implementation and effectiveness; and

- Implementing program recording-keeping procedures to ensure the maintenance of quality-related documents including QMPs, QAPPs, amendments, technical assessments, corrective action responses, and data review and usability reports.

1.3.4 Project Officers and Project Managers

EPA personnel involved with environmental data operations performed under financial assistance agreements, contracts, and extramural, non-supported measurement (as by industry) are responsible for incorporating QA requirements into grants, contracts, and voluntary, consensual or unilateral enforcement agreements, decrees and orders.

Project Officers, including Grant and Contract Project Officers, and Project Managers (Remedial Project Managers (RPMs), RCRA Facility Managers (RFMs), Contracting Officer's Representatives (CORs), and On-Scene Coordinators (OSCs)) are responsible for:

- Ensuring QA requirements are satisfied in all environmental projects conducted by EPA personnel or through grants, cooperative agreements, interagency agreements and contracts;

- Ensuring QA requirements are incorporated or negotiated into voluntary, consensual or unilateral enforcement agreements, decrees and orders;

- Ensuring that all QA deliverables (QMPs or equivalent quality system documentation, QA Management Reports, QAPPs/SAPs, amendments, addenda, SOPs, QC performance results, data quality reports, etc.) are provided to the Region;

- Providing signature concurrence or approval on QAPPs;

- Ensuring that QAPPs are approved prior to the initiation of data collection and implemented as written for all projects involving environmental data operations;

- Ensuring that appropriate QA documentation, including copies of signed and completed QA Project Plan Approval Forms, QAPP/SAP Title and Approval Pages and/or copies of the Final Approval Letters, are forwarded to the QA Unit prior to the initiation of environmental data operations for programs that have been delegated QAPP approval authority;

- Ensuring that QA Review Forms (QARFs) are completed and provided to the RQAM when required for contracts and work assignments;

- Ensuring that QAPPs are implemented as described; that technical assessments are performed as necessary; corrective actions are implemented when required; and that data are reviewed prior to use;

- Assuring that the results of environmental programs are of sufficient quantity and adequate quality for their intended use; and

- Conforming to record-keeping procedures for QA-related documents.

1.3.4.1 Project Officers/Project Managers for Contracts and Contracting Officer's Representatives (CORs)

Regional Project Officers/Project Managers and CORs involved with preparing acquisition packages, awarding, and overseeing Agency funded contracts and procurements supporting environmental data operations are responsible for ensuring that contractors are fully aware of and compliant with QA requirements.

Project Officers and CORs are responsible for complying with Procurement Policy Notice (PPN) 01-02 and the most current version of the contract and procurement QA Regional policy statements available on the OEME intranet website (http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Quality Assurance Requirements for OSRR Contracts and Procurements*

- *Quality Assurance Requirements for Non-OSRR Contracts and Procurements*

1.3.4.2 Project Officers/Project Managers for Grants, Cooperative Agreements, Interagency Agreements and Grant Specialists

EPA staff including Project Officers and Grant Specialists involved with awarding and overseeing Regionally funded grants, and cooperative and interagency agreements are responsible for ensuring that financial assistance recipients are fully aware of and compliant with QA requirements. The Region's grants management process ensures compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to QA in the award and management of grants, cooperative and interagency agreements.

Project Officers for Grants and Cooperative Agreements and Grant Specialists are responsible for conforming to the most current version of the Regional QA policy available on the OEME intranet website (link http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Grants & Cooperative Agreements*

Similarly, Interagency Agreement Project Officers are responsible for conforming to the most current version of the Regional QA policy available on the OEME intranet website (http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Interagency Agreement Shared Service Centers (IASSC)*

1.3.5 Contracting Officers

EPA personnel involved with preparing acquisition packages, awarding, and overseeing environmental data operations funded by the Region are responsible for ensuring that contractors are fully aware of and compliant with QA requirements. The Region's procurement process ensures compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to QA in the procurement and management of contracts and work assignments. Contracting Officers and authorized CORs are responsible for adhering to Procurement Policy Notice (PPN) 01-02 and the most recent Regional contract QA policies available on the OEME intranet website (http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Quality Assurance Requirements for OSRR Contracts and Procurements*

- *Quality Assurance Requirements for Non-OSRR Contracts and Procurements*

1.3.6 Office QA Contacts

Senior management is committed to providing resources to ensure compliance with QA requirements in the award and management of financial assistance agreements. Specifically, the February 20, 2001 "The EPA New England Grants QA Process" created a new QA function and position within the organizational structure, the "Office QA Contact." Office QA Contacts are senior personnel within each Office who assist staff in complying with the Grants QA Process. Their responsibilities are described in the most current version of the *Grants & Cooperative Agreements* and *Interagency Agreement Shared Service Centers* (IASSC) QA policies described above.

1.3.7 OEME Chemistry Laboratory Quality Assurance Officer (QAO)

The OEME Chemistry Laboratory QAO is responsible for implementing the laboratory quality system as described in the *Quality Manual for US EPA New England Regional Laboratory (NERL), Office of Environmental Measurement and Evaluation* (hereafter the *NERL Quality Manual*). The Environmental Investigations and Analysis (EIA) Section, Quality Assurance Officer (QAO) is the designated quality manager in accordance with ISO/IEC 17025:2005 Standards.

1.3.8 OEME Biology Laboratory Quality Assurance Officer (QAO)

The OEME Biology Laboratory QAO is responsible for implementing the laboratory quality system as described in the *NERL Quality Manual*. The Ecosystem Assessment Unit Biology Laboratory Quality Assurance Officer (QAO) is the designated quality manager in accordance with ISO/IEC 17025:2005 Standards.

1.3.9 Environmental Sampling, Measurement, and Data Acquisition Staff

EPA personnel involved in environmental sampling and direct measurement collection, as well as those involved in acquiring and compiling existing (secondary) data are responsible for:

- Ensuring that work is conducted under approved QA planning documents (e.g., QAPPs, SOPs, and SAPs);
- Following established sampling practices and procedures as described in QA planning documents;
- Following good field measurement techniques, laboratory practices and methodologies as described in QA planning documents;
- Documenting any deviations from established methodologies, SOPs and QC protocols, and reporting the deviations to their supervisor;
- Identifying possible data quality problems and potential areas for quality improvements and reporting these to their supervisor;
- Identifying to management any defective, outdated, or deficient SOPs and suggesting routine operations which are in need of SOPs;
- Developing data selection criteria when existing (secondary) data will be used; and
- Identifying all sources of existing data that will be used.

1.3.9.1 Regional Staff Involved in Environmental Models

EPA personnel involved in developing, evaluating and applying environmental models are responsible for:

- Ensuring that work is conducted under approved QA planning documents and is consistent with the *EPA Data Quality Standard;*

- Following established good modeling practices and procedures as described in QA planning documents;

- Reviewing modeling reports, documenting any deviations from approved QAPPs and reporting deviations to their supervisor;

- Identifying possible data quality problems and potential areas for quality improvements and reporting these to their supervisor;

- Developing data selection criteria in QAPP when planning to use existing (secondary) data; and

- Seeking training on modeling when available and as approved by their supervisor.

1.3.10 Dispute Resolution

When issues regarding quality assurance are in dispute, resolution will be sought at the lowest management level possible. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, and quality system assessments).

All parties will make every effort to resolve disputes through discussion and negotiation. Disagreements will be resolved at the lowest administrative level possible. The Region has trained mediators on staff to help facilitate issue resolution. Should agreement not be reached at this level, the issue will be resolved by senior management. The Regional Administrator and the Deputy Regional Administrator have final dispute authority on all quality issues.

1.4 Environmental Data Programs and Operations

This section identifies the major environmental data programs and operations conducted within the Region that are covered by this QMP.

1.4.1 Office of the Regional Administrator

The Office of the Regional Administrator (ORA) is the central coordinating Office of the Region providing leadership, planning, and oversight of key policy and program initiatives and resource management. While the Regional Administrator is ultimately responsible for the Regional quality system, few environmental data operations are undertaken directly by this Office. However, when ORA does undertake any environmental data operations (e.g., education grants, environmental impact reviews), all Regional quality policies and procedures are followed.

The Agency has appointed a Scientific Integrity Official to champion scientific integrity throughout the Agency. The Scientific Integrity Official chairs a standing committee of Deputy Scientific Integrity Officials representing each EPA Program Office and Region. The EPA New England Scientific Integrity Official is a senior-level employee who provides oversight for the implementation of the Scientific Integrity Policy, acting as liaison for the Region and is available to address any questions or concerns regarding this policy. The Regional Administrator has designated the Director of the Office of Environmental Measurement and Evaluation (OEME) as the Regional Scientific Integrity Official.

1.4.2 Office of Environmental Measurement and Evaluation

The Office of Environmental Measurement and Evaluation (OEME) consists of three Units which provide compliance and ambient monitoring of environmental conditions; design and interpretation of environmental indicators; development and administration of the Regional Quality Management Plan; and development and administration of the OEME Environmental Management System.

In response to the Deputy Administrator's June 14, 2012 memorandum *Establishment of Consistent Field Operations,* OEME is leading a Region 1 workgroup to develop broad options for implementing the requirements of this memorandum. Implementation of a program to achieve compliance will not begin until such time as the Executive Management Council releases an Agency-wide implementation plan in late 2012. As described in Section 1.4.2.2 OEME already has a pilot scale program that implements the Field Operating Guidelines established by the Agency's Regional Science & Technology Directors. Audits conducted under these guidelines provided the basis of the June 14, 2012 memorandum.

1.4.2.1 Quality Assurance Unit

The QA Unit is responsible for managing the Regional quality system; establishing quality policy, guidance, and procedures for all environmental data operations; reviewing and approving intramural and extramural QMPs, QAPPs and other QA documents (e.g., SAPs, Laboratory Quality Assurance Plans/Manuals, workplans, SOPs); conducting Quality System Assessments (QSAs) and Technical Assessments/Audits to ensure conformance with QA requirements; providing guidance in developing project quality objectives, QMPs, QAPPs, SOPs; and providing technical assistance to resolve sampling, analytical and data usability issues.

Members of the QA Unit also provide training in QA/QC concepts, requirements, and practices to the program offices within the Region, Agency contractors, and State, Tribal, and local governments that are involved in environmental data operations.

In addition, the Unit is responsible for coordinating the Regional Peer Review Program; managing the Contract Laboratory Program (CLP) and Environmental Services Assistance Team (ESAT) contracts; coordinating the Information Quality Guidelines-Pre-dissemination Review program; overseeing other analytical service contracts; supporting the FASTAC strategy; providing expert witness testimony; and administering the CERCLA Performance Evaluation Program; managing the Drinking Water Certification Program; performing Alternate Test Method reviews; and supporting the National Environmental Laboratory Accreditation Program (NELAP).

1.4.2.2 Investigations and Analysis Unit

The Investigations and Analysis Unit comprises two teams; Chemistry Team and Investigations Team. The Chemistry Team is responsible for performing chemical analyses of environmental samples, and providing oversight of ESAT and external contract laboratories to support investigations conducted by OEP, OES, OSRR and the Criminal Investigation Division (CID). The Team also provides technical assistance to the Regional media programs, State and local environmental agencies, private industries and independent laboratories in areas such as analytical methods and method development. Members of the Team provide consultation for legal cases and support for laboratory audits.

In accordance with the Draft 1/6/04 Agency Policy Directive *Ensuring the Competency of EPA Laboratories*, the Chemistry Laboratory has documented its quality system in the *NERL Quality Manual* which is maintained in the OEME Lab SOPs Database. The *NERL Quality Manual* describes specific quality system components, and it demonstrates laboratory competency through the use of independent external assessments and participation in inter-laboratory comparison studies and programs. The Draft Directive requires that all EPA laboratories become accredited where appropriate. To this end, NERL most recently applied for and received ISO certification October 12, 2012 for a defined set of chemical parameters. ISO certification is maintained through adherence to ISO requirements.

The Investigations Team is responsible for providing field support, including environmental sampling and regulatory compliance inspections for the Air, Water and Waste Programs. These activities are performed to determine compliance with the applicable provisions of the CAA, RCRA, SWDA, CWA, and TSCA. Environmental sampling is conducted according to generic and project specific QAPPs and sampling and field measurement SOPs and data are reviewed prior to use. The Team also provides field investigation support by conducting CERCLA site investigations and oversight of contractor investigations.

In 2009 the Investigations Team began a pilot scale implementation of the Field Operating Guidelines developed by the Agency's Regional Science & Technology Directors. These

guidelines establish consistent standards for field activities such as field documentation, equipment management, and evidence handling. A review team from other regions assessed this pilot program in March 2011. Based on the findings of this audit, the pilot team developed a set of corrective actions and OEME committed to expanding the scope of our amended FOG program to the entire division. In the fall of 2012 a cross divisional workgroup will begin a division-wide adaptation and implementation of this program.

1.4.2.3 Ecosystems Assessment Unit

The Ecosystems Assessment Unit (ECA) is a field service unit consisting of two teams; Air Monitoring Team and Ecology Monitoring Team. These teams support Regional programs and States and Tribes, as well as nationwide monitoring initiatives. Under the Clean Water Act and Clean Air Act, ECA assists States and Tribes in implementing and ensuring compliance with ambient monitoring programs. The Air Team works with the States to implement National and State ambient air monitoring programs, including special projects and research on priority issues such as mercury. The Air Team oversees the collection and evaluation of air quality data collected by States and other entities in support of Regional and National monitoring. The Team is responsible for reviewing all external air programs' QAPPs for environmental data collection and for approving external air program standard operating procedures (SOPs). The Air Team ensures that air monitoring meets the Agency's required siting and design criteria, data collection techniques, and QA/QC procedures. It ensures that data are accurately reported to the Agency's National data system, AQS, or another appropriate data system. Occasionally, the Air Team collects ambient air data for monitor siting, assessing air pollution impacts, supporting enforcement activities or to assess risks from hazardous waste sites. In addition, the Air Team operates an air monitoring site at OEME, including ozone and particulate matter, and a meteorological station, and enters data into AIRS (under MADEP's QAPP using OEME SOPs). Other Air Team activities involve collecting collocated samples, conducting round robin checks, conducting performance and technical system audits to assess the quality of air data being reported to EPA and preparing reports on ambient air quality. Data are collected by the Air Team according to sampling SOPs, and air analyses are performed in the OEME laboratory in accordance with the Chemistry Laboratory QA Plan and SOPs.

The Ecology Monitoring Team assesses long-term water quality trends, assists State agencies and Tribes, conducts special water quality surveys, coordinates and participates in the Office of Water's National Aquatic Resources Surveys, and assists citizen volunteer monitors. The Team monitors the ecological and biological health of New England's streams, lakes, and estuaries; provides support to Regional program offices; and assists States in regionally significant projects. The Team has a broad range of ecosystem assessment capabilities which are used to provide technical support, high quality environmental data, and expert advice in the areas of aquatic, wetland, and terrestrial biology. The types of field studies in which the Team may be engaged include baseline or ambient water monitoring, non-point and point source monitoring, time-of-travel and dispersion studies, sediment sampling, and biological and habitat assessment. Biology laboratory capabilities include water and sediment toxicity testing, direct mercury analysis, microbiology, Polymerase Chain Reaction (PCR), and chlorophyll a analyses. Data are collected by the Team according to generic

program QAPPs (with associated sampling and analysis plans (SAPs)), project specific QAPPs, and sampling and field measurement SOPs. Data are reviewed prior to use in identifying and characterizing sources of contamination, determining compliance with State water quality standards, developing mathematical models for load allocations, and reporting on the general health of New England's waters.

In fall of 2012 ECA will begin working with EIA on the division-wide implementation of the Agency's Field Operating Guidelines.

In accordance with the Draft 1/6/04 Agency Policy Directive *Ensuring the Competency of EPA Laboratories,* the Biology Laboratory has documented its quality system in the *NERL Quality Manual* which is maintained in the OEME Lab SOP Database. It describes specific quality system components and demonstrates laboratory competency through the use of independent external assessments and participation in inter-laboratory comparison studies and programs. The Draft Directive requires that all EPA laboratories become accredited where appropriate. To this end, NERL applied for and received ISO certification October 12, 2012 for microbiology and aquatic toxicity parameters. ISO certification is maintained through adherence to ISO requirements.

1.4.3 Office of Site Remediation and Restoration

The Office of Site Remediation and Restoration (OSRR) is an integrated office for the management of hazardous waste sites. OSRR implements the Superfund program, including the clean up at National Priorities List (NPL) sites, site assessment, removal actions, emergency responses and counter terrorism activities. OSRR also administers the Region's Brownfields program; the PCB cleanup and disposal under TSCA; conducts oil spill preparedness and prevention activities; and oversees the RCRA "base" program, RCRA Corrective Action, and the Underground Storage Tank (UST)/Leaking Underground Storage Tank (LUST) provisions of the Resource Conservation and Recovery Act (RCRA) in all six of the New England States. OSRR provides various support functions for these specific programs including grants and contracts management, potentially responsible party (PRP) search investigations, the FASTAC strategy, cost recovery, human health and ecological risk assessment, hydrogeologic and geotechnical expertise, and records center, budget and information management. In addition, the current Regional Human Subject Research Officer resides in the Technical and Support Branch of OSRR.

1.4.3.1 Superfund Remediation and Restoration Programs

EPA's Superfund program was established in1980 to locate, investigate, and clean up hazardous waste sites throughout the United States. EPA New England's Superfund program oversees long-term cleanups at National Priorities List (NPL) sites, short-term cleanups ("removal actions") and response to chemical and oil spill emergencies.

During site assessment OSRR, States and their contractors undertake environmental data operations to characterize sites and determine whether sites are eligible for listing on the National Priority List

(NPL), warrant a removal action, other cleanup or no further federal action.

At Fund-lead NPL sites, OSRR, States and their contractors undertake environmental data operations to characterize sites, make site remediation decisions, and monitor remedy implementation and effectiveness. At PRP-lead and Federal Facility NPL sites, Lead agencies and their contractors undertake environmental data operations to characterize sites, develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR and the States oversee activities undertaken at PRP and Federal Facilities sites.

Associated environmental data operations are conducted in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

1.4.3.2 Superfund Emergency Response

During an emergency response including incidents of National significance, OSRR, States and their contractors may undertake environmental data operations to characterize the spill or release, assess the risk to the surrounding population, and determine the appropriate response to contain or minimize the spread of the spill or release. Data collection operations performed by the Emergency Planning and Response Branch (EPRB) are conducted under the *EPRB Generic Program Quality Assurance Plan* developed in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

1.4.3.3 Brownfields Program

EPA NE's Brownfields program provides funds and technical assistance to States, communities, and other stakeholders in economic redevelopment to work together to assess, safely clean up, and sustainably reuse Brownfields. At Brownfield sites, OSRR contractors, States, local communities and their contractors undertake environmental data operations to characterize sites develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR oversees activities undertaken by the States and local communities. Associated environmental data operations are conducted in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

1.4.3.4 Resource Conservation and Recovery Act and Underground Storage Tank Programs

The Resource Conservation and Recovery Act (RCRA) program is permitted and monitored by OSRR and enforced by OES. RCRA was enacted in 1976 and major legislative amendments were adopted in 1984. The primary goals of RCRA are to protect human health and the environment from potential hazards of waste disposal; to conserve energy and natural resources; to reduce the amount of waste generated; and to ensure that wastes are managed in an environmentally sound manner. The responsibility of implementing the RCRA program is assigned to EPA and is accomplished through a compliance, enforcement and permit/closure process. Under the authority of EPA, States can be authorized to implement the RCRA requirements. All six New England

States have been authorized to implement RCRA requirements and EPA maintains oversight responsibility.

In 2009, the Hazardous Waste Unit of the Chemicals Management Branch was renamed the RCRA Waste Management Section and was moved from OEP to the Remediation and Restoration II Branch of OSRR. This Section provides technical input and advice on planning, developing, implementing, and coordinating the RCRA program and the 1984 Hazardous and Solid Waste Amendments (HSWA) in the six New England States in conjunction with EPA HQ's Office of Solid Waste and Emergency Response (OSWER). Authorized aspects of the RCRA and HSWA program are implemented with the Unit's technical and financial support by State agencies authorized to conduct that portion of the RCRA and HSWA program. The Section is the focal point for coordinating with other units in the Regional Office responsible for portions of RCRA, including seeking their involvement as necessary on significant issues, including Performance Partnership Agreements with the States, and other strategic and operational planning processes with the States and OSWER, for all RCRA Program components across the Regional Office. Specifically, the Section is responsible for:

- Issuing State authorizations and approvals;
- Issuing HSWA permit components for HSWA rules for which States have not been authorized providing technical assistance to State agencies in the adoption of "Approved Controls in Place" by Transport, Storage and Disposal Facilities (TSDFs);
- Conducting RCRA public and industry outreach and assistance;
- Providing regulatory interpretations for RCRA Subtitle C for hazardous waste;
- Providing technical assistance for RCRA Subtitle D for Municipal Solid Waste (MSW), and determining adequacy of State MSW Landfill Permitting Programs; and
- Providing technical assistance to Tribal Nations to address specific solid waste issues.

The state program authorization group is responsible for providing assistance to States in the development of regulations and programs that are "equivalent" to the federal program as defined by RCRA and HSWA. This includes RCRA Subtitle C program authorizations and RCRA Subtitle D MSW program approvals. These responsibilities entail providing technical, administrative and procedural guidance to the State agency, regulated community and general public regarding the RCRA and HSWA federal program.

The permits staff is responsible for managing, coordinating, and implementing a program that ensures that all permits for operating facilities and post-closure facilities issued pursuant to Section 3005 of RCRA are in compliance with the appropriate regulations and are consistent with national guidance and policies and have "Approved Controls in Place." The Section provides program and procedural guidance to permit applicants, State programs, other offices within the Region and the

general public concerning the permit requirements pursuant to Section 3005 of RCRA and Section 3004(u) of HSWA. Permitting activities include reviewing and assessing permit applications; reviewing and commenting on proposed permit procedures and permit terms and conditions; taking direct Federal action where necessary to insure that proposed State permits conform with approved State regulations and are enforceable and consistent with National guidance policy. The group also provides assistance to the States to assure that all closure and post-closure activities at facilities in New England are carried out in compliance with the appropriate regulations and consistent with national policies and guidance.

At RCRA corrective action sites, the owner/operator of the RCRA facility undertakes environmental data operations to characterize sites, develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR and the States oversee activities undertaken by the owner/operator of the RCRA facility. Associated environmental data operations are conducted in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

The UST/LUST programs have been delegated to all six New England States, as have the RCRA "base" program and the corrective action provisions of RCRA. OSRR maintains oversight responsibility for the delegated programs in all six New England States.

OSRR also conducts compliance inspections under the UST program and the Spill Prevention Control and Countermeasures/Facility Response Plan programs; however, environmental data operations are not conducted during these compliance inspections.

1.4.3.5 Toxic Substances Control Act PCB Cleanup and Disposal Program

PCBs are mixtures of man-made chemicals that were used in hundreds of industrial and commercial applications. Their characteristics are ideal for use in electrical equipment. PCBs were also used in hydraulic and heat transfer equipment, plasticizers in paints, caulk, plastics and rubber products, dyes, carbonless copy paper and other applications. Before production stopped in 1977, more than 1.5 billion pounds of PCBs were manufactured in the United States.

Since PCBs are toxic and chemically stable in the environment, Congress regulated PCBs in 1976 through the Toxic Substances Control Act (TSCA). TSCA includes, among other things, prohibitions on the manufacture, processing and distribution in commerce of PCBs.

The Federal PCB regulations are found in Part 761. Specifically, Section 761.61 provides the cleanup and disposal options for PCB remediation waste. Under these regulations, OSRR provides technical support, reviews PCB cleanup and disposal projects at a wide variety of sites, and issues approvals for PCB remediation.

1.4.3.6 Technical and Support

The Information and Budget Management Section provides budgetary support and is responsible

for the collection and dissemination of status data for RCRA generators, transporters and facilities in the National RCRA Information System (RCRA Info) and for hazardous waste data in the Biennial Report System (BRS). The group is also responsible for maintaining and improving data collection systems and for providing States with technical assistance in this area.

The Contracts Management Section ensures that contracts and IAs conform to Agency requirements pertaining to quality systems and QAPPs.

1.4.4 Office of Ecosystem Protection and Office of Environmental Stewardship

To adequately address the additional environmental data operations activities for the Region, the Office of Ecosystem Protection (OEP) and the Office of Environmental Stewardship (OES) are described together. The two Offices are linked as they perform different functions for many of the same programs. Organizational charts are maintained on the internet for OEP (*http://www2.epa.gov/aboutepa/organization-chart-epas-region-1-office#eco*) and OES (*http://www2.epa.gov/aboutepa/organization-chart-epas-region-1-office#es*. The OEP is a multi-media, ecosystem-based office that works to establish environmental standards and goals and works with States and communities to achieve these goals. OEP deals with regulatory considerations and issues permits. OES is a multi-media Office that includes enforcement units and an expanded pollution prevention and technical assistance program. OES is the Office responsible for monitoring how well the regulated community is complying with regulations, permit requirements and enforcement orders. In addition, OES provides outreach and technical assistance in order for industry to remain compliant with regulations and permits and in some cases to go beyond compliance.

Programs involved in the collection, production and use of environmental data, including the application or development of models, are described below.

1.4.4.1 Water Programs

OEP has permitting and monitoring responsibilities for the wide range of programs and regulations relating to the Region's water systems, from drinking water to wastewater. OES supports these activities with field inspection and compliance activities as well as enforcement actions. The major data collection activities are divided into different areas pursuant to supporting the Clean Water Act, the Marine Protection, Research and Sanctuaries Act, and the Safe Drinking Water Act. Associated environmental data operations are conducted in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

In addition, OEP is responsible for managing at least 75% of the grant dollars awarded in the Region. This includes, but is not limited to, the Clean Water and Drinking Water State Revolving Fund programs, Performance Partnership Grants (PPGs) with the States, including State and Tribal water program grants combined in PPGs, consolidated grants with Interstate agencies, 104(b)(3) water quality cooperative grants and wetlands grants, and water infrastructure security grants. OEP

is also responsible for managing funds awarded via grants and contracts to support the Total Maximum Daily Load (TMDL) program. All environmental data operations funded by EPA must conform to Agency regulations and Regional quality policies to ensure data are of known and documented quality suitable for their intended use. OEP staff members in conjunction with OEME are responsible for reviewing and approving QAPPs prepared by grantees and contractors working with or gathering environmental data.

1.4.4.1.1 Clean Water Act

OEP water program branches (Surface Water Branch, Water Quality Branch, Wetlands and Information Branch, Industrial NPDES Branch, Municipal NPDES Branch, Drinking Water Branch and Grants, Tribal, Community and Municipal Assistance Branch) are responsible for implementing and monitoring programs which support all aspects of the Clean Water Act (CWA).

OEP staff members in the Industrial and Municipal NPDES Branches implement the National Pollutant Discharge Elimination System (NPDES) permit program either directly or through oversight of a delegated State. For the NPDES and Pretreatment programs, primacy has been delegated to four New England States: Connecticut, Rhode Island, Maine and Vermont. EPA's role is to provide technical assistance and oversight to these state-run programs. This oversight is provided mainly by the Municipal NPDES Branch. For the non-delegated New England States, Massachusetts and New Hampshire, the Industrial and Municipal NPDES Branches and the Grants, Tribal, Municipal Branch implement the NPDES and Pretreatment programs. Wastewater effluent limitations and other appropriate conditions are calculated primarily on the review and analysis of data from applications and discharge monitoring reports (DMR) along with other sources such as special studies, toxicity test reports, etc. Permittees report on the quality and character of their discharge based on the permit's requirements by submitting DMRs to the permitting authority. These data are also used by either OES and/or delegated State staff to assess a facility's compliance with its permit which subsequently may lead to enforcement activity.

OES staff members monitor compliance with Clean Water Act, Safe Drinking Water Act and the Marine Protection, Research and Sanctuaries Act. They also enforce NPDES permits, initiate Federal enforcement actions for non-compliance and oversee State run enforcement programs. Permittee self-monitoring data are entered into the Integrated Compliance Information System (ICIS) and are evaluated by OES and the States to determine compliance with regulations and the need for follow-up enforcement actions. To determine compliance with NPDES permits, the Water Technical Unit of OES as well as the Investigation and Analysis Unit of OEME provide field expertise to conduct inspections of NPDES and pretreatment facilities. These inspections often include evaluation of the permittee's on-site laboratory facilities and procedures. Performance of a permittee's laboratory (either in-house or contract) is monitored through the analysis of Discharge Monitoring Report Study for Quality Assurance (DMRQA) Performance Evaluations samples. The DMRQA program is currently managed by the six New England States and enforcement actions or audits resulting from DMRQA study results are the responsibility of the six New England States. OES personnel take follow-up actions based upon non-response or inadequate response. Adherence to quality control analyses and acceptance criteria specified in required methodologies helps to

ensure the production of valid data by the permittees.

States use water quality data obtained from various sources to develop their CWA Section 303(d) impaired waters list. The OEP staff in the Water Quality Branch reviews and approves these lists which then serve as the basis for the total maximum daily load (TMDL) program. TMDLs are a tool used to identify specific pollutant reduction measures which, when implemented, will result in water quality standards and/or designated use attainment. The States develop most TMDLs based on environmental sampling and analysis and often employ various models simulating differing water quality conditions. TMDLs may also be developed using contract support provided directly by the States, or by OEP's Water Quality Branch with a Regional allocation from the National program, or, for some multi-state issues (such as mercury), through organizations such as the New England Interstate Water Pollution Control Commission. The OEP staff reviews and approves all TMDLs, and, in some special cases (Charles River) develops TMDLs, usually relying on contractor assistance. OEME may also provide support by generating water quality data or developing analytical methodology to support a specific TMDL.

OEP in partnership with the States also operates a myriad of CWA programs. States develop, revise and adopt surface water quality standards for review and approval by OEP's Water Quality Branch. The Surface Water Branch coordinates the Non-point Source program and the National Estuary Program (NEP). EPA provides technical, grant and contract support for various projects and programs that meet specific requirements and environmental objectives. OEP staff members are also responsible for the National Environmental Policy Act (NEPA) compliance activities for NPDES new source performance standard category dischargers using environmental impact and project information submitted by the proponent. Staff members in the Municipal NPDES Branch oversee the 301(h) discharge waiver program as implemented and monitored through NPDES permits. The Wetlands and Information Branch is responsible for the wetlands program. This includes review and assessment of the impact to wetland habitat and resources that specific projects/activities may exert, as well as reviewing CWA section 404 U.S. Corps of Engineers issued permits.

To achieve these goals, the Office is responsible for the technical review and evaluation of environmental impact with regard to the disposal of wastes and dredged materials in marine and/or wetland areas in the Region. Monitoring requirements may be included in permits to identify the nature of the disposed material and its impact on the marine environment. Monitoring is also conducted to support enforcement actions as carried out by the Water Technical Unit of OES with field and analytical support from the Investigation and Analysis Unit of OEME.

Other water programs managed by OEP include the Groundwater Management program, the Clean Lakes program, the Non-point Source program, the Wetland Protection program, and the Marine, Near Coastal and Estuarine Management programs. For all of these programs, the Region works with the State, Tribal, and local governments to set environmental priorities and to develop statewide and place-specific environmental goals and strategies. Assistance to the States, Tribes, and local communities includes the provision of EPA expertise as well as funding through grants for projects that meet Federal, State, and local priorities.

1.4.4.1.2 Marine Protection, Research and Sanctuaries Act

Under the Marine Protection Research and Sanctuaries Act (MPRSA), commonly referred to as the Ocean Dumping Act, EPA through the Oceans and Coastal Protection Unit in OEP is responsible for designating sites for the open water disposal of dredged material. Designation of these sites, located seaward of the territorial baseline, is subject to the Agency's voluntary Environmental Impact Statement (EIS) policy. OEP works closely with the U.S. Corps of Engineers to produce data to support the designation or to dispose of dredged material.

1.4.4.1.3 Safe Drinking Water Act

Safe Drinking Water Act (SDWA) programs are primarily managed by OEP's Drinking Water Quality & Protection Unit of the Drinking Water Branch, as well as the Municipal Assistance Unit of the Grants, Tribal, Community, and Municipal Assistance Branch. SDWA programs include the Public Water Supply Supervision (PWSS) program, the Source Water Assessment and Protection (SWAP) program, the Sole Source Aquifer (SSA) program, and the Underground Injection Control (UIC) Program, all of which are carried out under the Drinking Water Branch. The Drinking Water State Revolving Fund (DWSRF) program and the Drinking Water Operator Certification program are handled by the Municipal Assistance Unit. The DWSRF program is also comprised of a number of set-asides which involve a wide range of drinking water implementation programs. Additional SDWA activities that are handled by Drinking Water Branch include wellhead protection, capacity development, technical assistance focusing on small systems, and Drinking Water Infrastructure security.

All six New England States have been delegated or authorized to enforce the following SDWA programs; PWSS Drinking Water, Wellhead Protection, UIC/Section 1422, and UIC/Section 1425. The Water Technical Unit oversees state enforcement of the SDWA through the Safe Drinking Water Information System (SDWIS), which contains information about public water systems and their violations. OES takes Federal enforcement actions under the SDWA when warranted.

1.4.4.2 Air Programs

OEP works with the New England States to develop State air control requirements necessary to attain the air quality standards set under the Clean Air Act (CAA). Under the Act, the States are required to adopt various stationary source and mobile source programs, as well as permitting for major sources. OES supports these activities with field inspection and compliance activities as well as enforcement actions with support from OEME. OEME is also involved in ambient air monitoring activities for National, State and Local Air Monitoring Stations (NAMS/SLAMS), Photochemical Assessment Monitoring System (PAMS) networks, and particulate matter networks in the Region as previously described for the Ecosystem Assessment Unit of OEME.

Within OEP's Air Programs Branch, the Air Quality Planning Unit and the Air Permits, Toxics and Indoor Environment Programs Unit are responsible for providing technical assistance to the States in planning, development, implementation and evaluation of their program plans and commitments. OEP's air program relies on ambient air quality monitoring data and source emission data collected by the New England States. The States collect ambient air quality monitoring data on air toxics, ground-level ozone, ozone precursors, lead, nitrogen dioxide, carbon monoxide, sulfur dioxide, and particulate matter. All six States have been delegated or authorized to enforce the following CAA programs: Part 60/NSPS, Part/61 NESHAPS, Sect. 52.21/PSD, Title V/Part 70, New Source Review, and Indoor Radon/Section 306. Five of the States (all but Massachusetts) are authorized to enforce Sect. 52.21/PSD. EPA funded programs involving data operations are required to conform to Agency and Regional quality requirements, standards and guidance. OEME works with the States to ensure that quality assurance requirements are met. The States also prepare inventories of emissions from sources. OEP requires the States to have adopted and used proper quality assurance requirements in preparation of these emission inventories.

OES's Air Technical Unit performs inspections and investigations of facilities subject to the Clean Air Act. Where non-compliance with regulations is found, the Unit plans and executes Federal enforcement actions. The Unit also oversees state compliance monitoring and enforcement programs under the Clean Air Act. The Unit enters Federal and some States' compliance and enforcement related data into EPA's Airs Facility Subsystem (AFS) as well as Federal compliance and enforcement data into ICIS. Both systems are monitored for data integrity.

Quality assurance issues are addressed in SIPs which require Agency approval. For Emissions Testing programs, including Stack Testing, pre-test reports are submitted by the regulated community and are reviewed by the Investigation and Analysis Unit of OEME. The tests are then observed to determine conformance with Federal reference methods and the data are evaluated to determine adherence to the pre-test reports.

The Resource Conservation Recovery Act (RCRA), Emergency Planning Community Right-to-Know Act (EPCRA) and Federal Programs Unit is responsible for implementing and enforcing Section 112(r) to the CAA. The purpose of this Section is to prevent accidental or catastrophic releases of toxic or flammable substances from occurring. Section 112(r) contains two key subsections: Section 112(r)(1) and Section (r)(7). Section 112(r)(1), known as the General Duty Clause (GDC), requires owners and operators of stationary sources to anticipate, prevent and minimize the effects of accidental releases. In accordance with Section 112(r)(7), facilities that produce, process, handle, distribute or store greater than a threshold quantity of any listed toxic or flammable extremely hazardous substances are required to develop a Risk Management Program, prepare a Risk Management Plan (RMP), and submit the RMP to EPA. EPA conducts inspections to evaluate a facility's Risk Management Program and its compliance with the GDC and takes enforcement action under the Section 112(r) of the CAA as appropriate. OEME provides sampling support at the request of OES.

1.4.4.3 Resource Conservation and Recovery Act Program

OSRR and OES share responsibilities for permitting, monitoring and enforcement for the Resource Conservation and Recovery Act (RCRA) Program. RCRA was enacted in 1976 and major legislative amendments were adopted in 1984. The primary goals of RCRA are to protect human health and the environment from potential hazards of waste disposal; to conserve energy and natural resources; to reduce the amount of waste generated; and to ensure that wastes are managed in an environmentally sound manner. The responsibility of implementing the RCRA program is assigned to EPA and is accomplished through a compliance, enforcement and permit/closure process. Under the authority of EPA, States can be authorized to implement the RCRA requirements. All six New England States have been authorized to implement RCRA requirements. EPA maintains oversight responsibility for the authorized programs in those States.

1.4.4.3.1 OSRR RCRA Activities ((See QMP Section 1.4.3.4)

1.4.4.3.2 OES RCRA Enforcement/Compliance Activities

To monitor RCRA permit compliance and to enforce compliance, the OES RCRA Technical Unit conducts field inspections. EPA and the States are responsible for conducting Comprehensive Groundwater Monitoring Evaluations (CMEs) and Compliance Evaluation Inspections (CEIs) in order to evaluate the facility's compliance with RCRA. Associated environmental data operations are conducted in accordance with National and Regional quality standards and guidance, and data are reviewed prior to use.

The CME determines the adequacy of the RCRA facility's groundwater monitoring system for complying with the applicable regulations contained in 40 CFR Parts 264, 265 (Subpart F) and 270 established under RCRA.

The CEI evaluates the facility's compliance with RCRA and determines the need for enforcement actions or follow-up inspections/evaluations. Processing and reporting requirements are an essential part of RCRA inspection programs. The RCRA staff, States and contractors are responsible for conducting RCRA lead and oversight inspections as required by the Memorandum of Understanding (MOA) with OECA. The OEME Investigation and Analysis Unit provides sampling support at the request of the OES compliance staff.

1.4.4.4 Office of Chemical Safety and Pollution Prevention

Currently residing within OES, these programs are the principal implementing and enforcement arm of the Agency's Office of Prevention, Pesticides and Toxic Substances (OPTS). The Toxics and Pesticides Programs Unit conducts program activities for the control of agricultural, structural and consumer pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Food Quality Protection Act (FQPA) and toxic substances (principally asbestos, lead (Pb) and polychlorinated biphenyls (PCB's) under the Toxic Substance Control Act (TSCA) within the six New England States.

The Toxics and Pesticide Programs Unit is responsible for providing financial and technical

assistance to States and Tribes in the development and implementation of pesticide regulations and programs to meet FIFRA and FQPA requirements. Similarly, it supports non-regulatory programs of outreach, education and industry assistance to reduce the use of more toxic chemical pesticides and promote the Use of Integrated Pest and Crop Management (IPM, ICM) techniques in agricultural, school and other public buildings, recreational and residential settings, including consumer protection and awareness for the use of home pesticide products. The States are delegated primacy for, and the Unit supports, the enforcement of pesticide use regulations, and the training, certification and licensing of pesticide applicators for both agricultural and structural pest control. In addition, the Unit provides additional technical and financial support for specialized State and Federal programs for the protection from pesticides of Ground Water, Agricultural Workers, and Endangered Species and for the Storage and Disposal of pesticides.

The Toxics and Pesticide Programs Unit is responsible for providing financial and technical assistance to States and Tribes in the development and implementation of toxics regulations and programs focusing on the TSCA requirements for lead (Pb), PCBs and asbestos in schools per the Asbestos Hazards Emergency Response Act (AHERA). The Lead and Asbestos programs focus on accreditation of training providers, certification and licensing of abatement workers, worker protection, hazard disclosure rules and education and outreach to regulated communities, the public, schools and other principal stakeholders on Pb Poisoning Prevention and Management of Asbestos. The PCB program focuses on technical assistance to other EPA programs and the States for enforcement of PCB regulations.

1.4.4.5 Urban Programs

As part of the 2009 reorganization, the Urban Program Unit of the Chemicals Management Branch was moved to the Grants, Tribal, and Community Programs Unit within the OEP Grants, Tribal, Community and Municipal Assistance Branch. The Unit is responsible for the Region's Urban Environmental Program (UEP) which is a multi-media program for targeted inner city neighborhoods focusing on identifying, assessing and addressing in holistic and integrated fashion the environmental problems of greatest concern to local residents based on the principles of Environmental Justice (EJ), Community Based Environmental Protection (CBEP), Pollution Prevention, Smart Growth and Sustainable Economic Development. Innovative public-private partnerships are built across a broad range of stakeholders including non-profit community groups, the private business sector, academia and the medical infrastructure. The long term goal is the establishment and maintenance of sustainable environmental decision-making through coalitions which give communities direct access to the process. Heavy emphasis is placed on building community capacity and leveraging the resources of the community, all levels of government and the private sector. The program manages a multimedia Healthy Communities grant program to identify and fund projects across the Region that reduce environmental risks to protect and improve human health and the quality of life.

1.4.4.6 Assistance and Pollution Prevention

The Assistance and Pollution Prevention (A&P2) Unit of OES develops tools and outreach strategies that lead to improved compliance and sustainable practices. Few direct environmental data operations are undertaken by this Office. If the A&P2 Unit does undertake any environmental data operations (e.g., pollution prevention grants), all Regional quality policies and procedures are followed. A&P2 is engaged in gathering data on environmental management practices of targeted facilities and sectors (e.g., auto body sector), and in assessing the effectiveness of its work through surveys and evaluations. A&P2 also manages a variety of grants including source reduction, pollution prevention, CARE grants, solid waste grants, etc. In managing these grants, A&P2 follows Regional quality policies and procedures including requiring approved QAPPs when required.

A&P2 includes two separate units to accomplish its goals, the Environmental and Compliance Assistance Unit, and the Innovation and Sustainability Unit. The Environmental and Compliance Assistance Unit is primarily focused on promoting compliance and beyond compliance behavior through assistance, while the Innovation and Sustainability Unit is focused on promoting pollution prevention and sustainability. There is extensive overlap between the work of the two Units.

To accomplish the goal of encouraging long-term sustainable practices, A&P2 seeks to support Regional and National priorities and to target its work in priority communities and to support EJ outcomes. Specific work areas include:

- Improving Air Quality: diesel emission reductions, outreach on new source rules, VOC emission reductions, energy efficiency at waste water treatment plants;
- Improving Water Quality: asset management training, significant program specific assistance to municipalities to support compliance with storm water requirements and low impact development practices;
- Encouraging Sustainable Materials Management: the waste reduction/climate change connection, solid waste assistance, municipal composting, and waste wise promotion;
- Promoting Green Economy Outcomes: development of curricula with Department of Labor, "greening" trade curricula, promoting internship programs; and
- Promoting Compliance and Pollution Prevention for Targeted Sectors: auto body shops, the aggregate/ready mix sector, transportation (trucking), healthcare/acute care hospitals, and the hospitality sector. Sequenced enforcement and assistance activities are integrated to provide these sectors with tools and incentives to improve performance.

1.4.5 Office of Administration and Resource Management

The Office of Administration and Resource Management (OARM) is a resource management office responsible for personnel, facilities, and space; financial management, including budgeting;

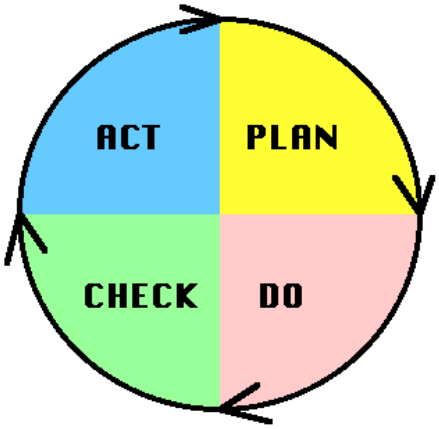
information services; grants, contracts, and procurement; and other support services. No significant environmental data operations are performed directly by this office. Its role in supporting environmental programs is discussed below.

The Contracts and Procurement Office is responsible for ensuring all contracts and procurements incorporate QA requirements in accordance with 48 CFR Part 46, and Regional QA requirements for contracts and procurements.

The Grants Management Office is responsible for ensuring that all statutory and regulatory administrative requirements are addressed prior to the award of all financial assistance agreements. This includes QA requirements specified in 40 CFR Parts 30, 31 and 35 and Regional requirements for implementing QA policies for financial assistance agreements.

The Information Resources Office and the Computing Technology Office are responsible for the storage, management, and retrieval of mainframe data for PCS, CERCLIS, RCRIS, STORET and the AIRS database systems. These Offices are also responsible for the Region's Local Area Network and related IT infrastructure, the purchase and upkeep of computer hardware and software and technical support for the Region's Geographic Information Systems (GIS), providing Web, desktop computing, IT security and local applications development support. Additional information on these functions can be found in Section 6.0 of this QMP.

2.0 QUALITY SYSTEM COMPONENTS



This Section documents how EPA New England manages its data quality system and defines the primary responsibilities for managing and implementing each component of the system. The Regional quality system provides a management structure that ensures the quality of work and services pertaining to environmental data throughout the organization. Specifically, it provides the framework for planning, implementing, documenting, reporting and assessing Regional activities relevant to environmental data operations in keeping with the universally recognized quality cycle.

The scope of this QMP precludes the need for additional QMPs by the organization; hence no approval procedures have been developed for review of QMPs internal to the Region. However, review and approval procedures for QMPs developed for extramural environmental activities are documented in the most recent version of the *EPA New England Standard Operating Procedure for Reviewing Quality Management Plans.*

The Regional data quality management system has evolved since first institutionalized in 1994. It comprises several functional components that have matured into quality system programs, including the:

- Quality Assurance Project Plan Program;
- Performance Evaluation Program;
- Assessment Program;
- Data Review Program; and
- QA Training Program.

The Regional quality system functions in coordination with allied programs, including:

- Peer Review Program;
- Human Subject Research Program; and
- Information Quality Guidelines and Pre-Dissemination Review Program

Quality system programs and components are implemented by policy memoranda and through the use of a variety of quality tools. These tools include National and Regional requirements and guidance documents. The Regional guidance documents may be obtained from the QA Regional Web site: *http://www.epa.gov/region1/lab/qa/qualsys.html* and the Regional Science Council Web site: *http://r1-gis-web.r1.epa.gov:9876/rsc/index.htm* Regional policies are available on the Intranet site: *http://r1-gis-web.r1.epa.gov:9876/oeme/*. Regional policies and SOPs are maintained on the OEME Lotus notes "Lab SOPs" document control database. National documents may be obtained from the Quality Staff Web site: *http://www.epa.gov/quality*.

The following table provides an overview of the Region's quality system programs, components, and available tools. Detailed descriptions of these components including roles and responsibilities for their implementation are provided in Sections 3 – 10 of this QMP.

Table 1. Summary of Regional Quality System Components, Tools and Requirements

Quality System CIO Standard 2106-S-01, *Quality Standard for Environmental Data Collection, Production, and Use By EPA Organizations* (Current Edition)	
Components	**Tools**
Quality System	*EPA New England QMP*
Annual Quality System Review and Planning	QA Annual Report and Workplan
Regional QA Policies	Senior Management Memoranda
Quality Assurance Project Plan Program *EPA New England QAPP Program Guidance* document EPA QA Requirements and Guidance documents *http://www.epa.gov/quality* Tracking Systems for project-related information - OEME Request for Assistance (RFA) Database	
Components	**Tools**
Project Planning	EPA New England Systematic Planning Process
Project QA Documentation	Project-specific QAPPs, Generic Program QAPPs, Combined QMP/QAPPs, and equivalent QA documentation
Project QA Planning Documentation Review and Approval Process	QAPP Review Procedures
Implementation EPA QA Requirements and Guidance Documents *http://www.epa.gov/quality* Tracking Systems - WEB New England Sample Tracking System (WNESTS) - OEME RFA Database - OEME Lotus Notes Lab SOPs Document Control Database	
Components	**Tools**
Representative Sampling	Sampling SOPs
Field Analytics	Field Analytical SOPs
OEME Sampling, Analytical, and QA SOPs	*NERL Quality Manual* OEME SOPs OEME/Lotus Notes Lab SOP Database
Performance Evaluation Samples	*EPA New England Data Review Program Guidance* SPSWEB system

Assessment Program

EPA New England Assessment Program document
Tracking Systems
- Superfund Performance Evaluation Sample Scoring Web (SPSWEB system)
- OEME RFA Database

Components	Tools
Management Assessment	Quality System Assessments *Guidance on Assessing Quality Systems, (QA/G-3)*
Project Assessment	Technical Assessments including : -Field Sampling Technical Systems Audits (TSAs) -Field Analytical TSAs -Field Laboratory TSAs -Fixed Laboratory TSAs -Split Sampling and Analysis Audits -Data Package TSAs -Data Validation TSAs EPA New England Technical Systems Audit SOP Project-Specific Audit Checklists and Audit Reports Performance Evaluation Samples

Data Review Program (Verification, Validation and Usability)

EPA New England Data Review Program Guidance and *Supplement* documents
Tracking Systems
- OEME RFA Database
- WEB New England Sample Tracking System (WNESTS)

Components	Tools
Data Review	*EPA New England Data Review Program Guidance* and *Supplement.*
Data Usability Assessment	*EPA New England Data Review Program Guidance* *EPA Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*

QA Training Program

EPA New England Quality Assurance Training Program Guidance document

Components	Tools
QA Training Program	Types of Training -Classroom - Informal -e-Training -Conferences *EPA New England Standard Operating Procedure for QA Training Documentation*

Quality-related Internet and Intranet Sites

Tracking Systems
- Design/Internet Request Tracking (DIRT) System

Components	Tools
Internet: EPA New England QA Home Page *http://epa.gov/region1/lab/qa/index.html*	Links to: -Training -Services -Quality System Documents
Intranet: EPA New England QA *http://r1-gis-web.r1.epa.gov:9876/oeme/*	Links to: Regional QA Policies
Regional Science Council Home Page *http://r1-gis-web.r1.epa.gov:9876/rsc/index.htm*	Links to: - Human Subjects Research - Peer Review - Information Quality Guidelines- Pre-dissemination Review

Peer Review Program

Program documented in *Science Policy Council Handbook, Peer Review*, 3rd edition, 2006
Tracking Systems
- National Science Inventory Database

Components	Tools
Agency-defined Peer Review Program	Regional Web site: *http://r1-gis-web.r1.epa.gov:9876/rsc/peerreview.htm* Peer Review Call Letters/Memoranda

Information Quality Guidelines

Program documented in *EPA New England Information Quality Guidelines Pre-dissemination Review Final Implementation Plan*, Revision 1, March 26, 2007

Components	Tools
Pre-Dissemination Review Procedures for Agency Information	Intranet EPA NE IQG & PDR Web page Regional Implementation Plan: *http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.htm* IQG-PDR e-Training

3.0 PERSONNEL COMPETENCE

The Region implements procedures to assure all personnel performing work for EPA New England have the competency to effectively accomplish their work. To achieve Regional quality goals and objectives, management and staff performing tasks related to environmental data operations must have the necessary skills and knowledge to effectively accomplish their work.

3.1 Commitment to Training

It is Regional policy to provide and make available to management and staff the training, including QA training, necessary to carry out their work successfully. Senior management takes the lead in ensuring that the necessary levels of technical proficiency and QA knowledge are maintained. In addition, senior management identifies mandatory training required by staff to comply with program requirements.

3.2 Qualifications

Personnel must meet the minimum qualifications defined in the Office of Personnel Management (OPM) Qualification Standards Handbook for their series and grade. The application of sound QA policies and procedures requires that all personnel performing quality-related tasks associated with environmental data operations have an appropriate level of knowledge of QA procedures and principles.

The Human Resources Shared Service Center works with the Regional Human Resources Office to ensure that all EPA positions are properly classified as to job series, title, and grade based on an analysis of the duties of the position, as defined and submitted by the supervisor and manager of record for the position, in compliance with OPM's position classification system. Each classified position defines the principal duties, the knowledge required, the level of supervision, and a variety of other factors used to determine the final grade level of the position. The knowledge, skills, and abilities needed to perform the work of the position are incorporated as part of the qualifications identified to fill the position. Applicants for QA positions must demonstrate that they have the required knowledge, skills, and abilities to meet the qualifications of the position.

It is also essential that the supervisor and manager of record for positions with QA responsibilities ensure that incumbents have performance plans, critical job elements, and performance standards reflecting their QA work each year, in compliance with EPA's performance management system. In this manner, employees with QA responsibility will have identified measurable goals and objectives for each year.

3.3 Professional Development and Training

The Region provides professional development and training, including QA training through the Center for Development and Learning and through external providers. E-training is also provided

through various venues including the HQ Learning Management System. Quality-related training is discussed further in Section 3.5. Needs assessments are conducted periodically to identify training needs for the Region. In-house training is posted on the S.T.A.R.T. database. Registration for training offered by the Center for Development and Learning is accomplished electronically through S.T.A.R.T. The Center for Development and Learning Regional Training Office is responsible for maintaining records of employee training received through the Regional Training Office and training received from sources external to the Region.

3.4 Certifications

Formal certifications are required for various personnel in the Region. Personnel involved in auditing and certifying State SDWA programs are required to successfully complete the SDWA Certification Officer Training. An annual refresher course is provided by the QA Unit.

Personnel involved in managing contracts are required to successfully complete Contracting Officer's Representative (COR) training. An eight hour re-certification training is required every three years. COR training is available at: *http://oamintra.epa.gov/?q=/node/18* and the COR Manual is available at: *http://oamintra.epa.gov/files/OAM/09-01_0.pdf*. On-going certification is maintained by completing 40 hours of contract/job-related training.

Personnel involved in managing grants (Project Officers and Grants Specialists) including, cooperative agreements and interagency agreements are required to successfully complete the Project Officers Basic Grant Certification Training. The Project Officers Refresher Course is required to be taken every three years.

In addition, EPA Offices including OSWER, OAR, OECA, and OW, require program-specific training related to the technical, operational, and administrative aspects of environmental data operations.

Certificates are kept on file by the person certified.

3.5 Regional QA Training

The QA Unit works with the Regional Training Officer, Office Directors and their staff to assess Regional QA training needs. In accordance with the *EPA New England Quality Assurance Training Program Guidance*, the QA Unit provides support in developing general QA awareness training and specific mandatory training.

Also, in conjunction with the Office Directors and program managers, the QA Unit identifies, develops, and provides QA training to EPA contractors, States and other federal financial assistance recipients.

Assessment team members receive appropriate training prior to conducting assessments in

accordance with Section 9.3 of this QMP.

QA training is based on prioritized needs and implemented as resources permit. QA training provided by the QA Unit of EPA and non-EPA personnel is tracked in the OEME RFA database. Training information is compiled and presented in the QA Annual Report and Work Plan.

3.5.2 QA Training Needs Assessment

The Region uses a multi-pronged approach to identify Regional QA training and re-training needs.

1. Employee training needs are identified and documented during annual PARS reviews.
2. Training needs are identified through internal and external audits and management systems reviews.
3. Training is developed when new National and Regional quality-related policies are issued.

3.5.2 QA Unit Staff Training

The RQAM evaluates the training needs of the QA Unit staff members during the PARS process. In general, training for QA Unit staff includes attendance at one or more job-related training courses, workshops, or professional meetings each year.

3.5.3 Financial Assistance Agreement Recipients and Contractors

The competency and training of personnel performing environmental data operations funded by the Region under federal financial assistance agreements and contracts are evaluated through quality system assessments, technical system audits, performance evaluation sample analysis, and pre-award reviews of QA documentation (e.g., QMPs, QAPPs, SOPs) and accreditations, as applicable. In addition, States participating in the EPA NE/State QA Roundtable identify their QA training needs. The Region provides QA training based on prioritized programmatic needs as resources permit.

3.5.4 Regional QA Training Program and Outreach

3.5.4.1 Training Program

The Regional QA training program is described in the *EPA New England Quality Assurance Training Program Guidance* available through the OEME "Lab SOPs" document control database.

3.5.4.2 Mandatory QA Training

Regional management determines which training is mandatory and for whom, and the frequency of the training. Currently the following Regional QA training is mandatory:

- Quality System Awareness Training is required for all EPA New England personnel;
- Project Officer Quality Assurance Awareness Training is required for EPA Project Officers, Grants Specialists and supervisors;
- QAPP training and/or QAPP Review Training is required for all Superfund RPMs, and RCRA Corrective Action RFMs; and
- Laboratory Annual Ethics and Data Integrity Training is required for OEME technical staffs, managers and contractors.

3.5.4.3 QA Training Web Site and Outreach

A separate Regional QA Training Web page *http://epa.gov/region1/lab/qa/training.html* provides Web-based training courses and information on Regional, and National QA Training Conferences.

3.5.5 QA Training Records Maintenance - QA Training Provided by EPA New England

Procedures for maintaining records of training provided by the QA Unit are described in the most current version of the *Quality Assurance Unit Quality Assurance Training Documentation Standard Operating Procedure* (OEME "Lab SOPs" document control database: EQASOPQATrainDoc)

3.5.6 QA Training Records - QA Training Provided by other Sources

QA training provided by sources external to the Region is tracked by the Center for Development and Learning Regional Training Office.

4.0 ACQUISITIONS AND ASSISTANCE AGREEMENTS

Regional procedures for funding and purchasing items and services that directly affect the quality of environmental programs are documented. It is the Region's policy to specify the designated quality assurance and quality control requirements when acquiring items and/or services that relate to environmental data operations. Regional policy also requires that environmental data acquired through extramural agreements will be reviewed prior to use and dissemination.

Regional procurement functions are conducted in accordance with Federal Acquisition Regulations and related Agency policies, directives, and guidance. Contractors, suppliers, and financial assistance recipients are responsible for the quality of work performed directly for EPA and for items and services provided by their subcontractors/sub-awardees and suppliers.

A graded approach to implementing QA/QC requirements is a key tenet of the Regional quality system. The RQAM has the authority to establish "equivalent" quality requirements. All deviations from the requirements set forth below must be documented in the program/project/ contract file.

4.1 Contracts

All procurements and contracts originating in the Region must meet established administrative and QA requirements in the Federal Acquisition Regulations (FAR 46.202-4 and 52.246-11), *Acquisition Handbook*, and the *Contracts Management Manual*, Chapter 46. The most recent Regional procurement policies are outlined in the following memoranda and available on the OEME intranet website (*http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm*) under **Quality Assurance (QA) Requirements, Guidance and Tools**:

- *Quality Assurance Requirements for Non-OSRR Contract Actions*
- *Quality Assurance Requirements for OSRR Contract Actions*

These policy memoranda outline policies, procedures, and responsibilities. In procurements and contracts where higher level quality requirements apply, appropriate contract clauses must be used.

For all new contracts or procurements, the Contracting Officer's Representative (COR) must complete the *Contracts Management Manual* (CMM) QA Review Form (QARF) prior to forwarding a request for procurement/contract placement.

After contract award, when requesting services either through the issuance of work assignments or task orders, the "Region 1 QARF" must be completed and provided to the QA Office by the COR.

4.1.1 OEME Procurement and Tracking of Chemicals

Chemicals are procured and checked in accordance with the *Chemical Inventory and MSDS Management* Standard Operating Procedure maintained in the OEME "Lab SOPs" document control database. Purchase orders are maintained by OEME facilities staff to compare against incoming orders. Facilities personnel route materials to the requestor as they are received. As described in the *NERL Quality Manual*, chemicals are entered into the OEME Chemical Inventory System as they are received. In addition, the quality of supplies used for environmental data collection and testing is assured in accordance with the procedures detailed in the *NERL Quality Manual*.

4.1.2 Contracted OEME Analytical Services

OEME manages contracted analytical services to provide additional analytical support for programs. Requests for OEME analytical services are planned using an "Analytical Request Form". All requested analyses must be conducted under a QAPP. Contract laboratory oversight and monitoring is accomplished through evaluation of data deliverables, periodic on-site assessments, and review of SOPs, as appropriate.

4.2 Financial Assistance Agreements

Financial assistance recipients are required to conform to applicable QA requirements as specified in:

- 40 CFR Part 30, "Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-profit Organizations"
- 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments"
- 40 CFR Part 35, "State and Local Assistance"

Specifically, organizations funded by the Region to conduct environmental data programs, operations and activities are required to submit QMPs (or equivalent quality system documentation) and QAPPs to EPA for review and approval. These programs include (but are not limited to) "direct measurements or data generation, environmental modeling, compilation of data from literature or electronic media, and data supporting the design, construction, and operation of environmental technology".

4.2.1 Grants and Cooperative Agreements

The Region's process for ensuring that financial assistance recipients meet QA requirements was revised in 2000 to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the award and management of grants, cooperative and interagency agreements. This grants management process was initiated through the January 25, 2001 policy statement *Revised Quality Assurance Requirements for Grants*.

In addition to the responsibilities outlined in the 1/25/2001 memo, Grant Project Officers and Grant Specialists were required to conform to Regional policy issued February 20, 2001, *Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements*. This policy explained the new requirements and responsibilities for Project Officers, Grants Specialists, and the QA Unit in implementing new regional QA policies and procedures for all financial assistance agreements. It outlined the new long-term Regional Grant QA Process and implemented training and technical support to ensure consistent implementation of these new requirements.

This policy memo is reissued annually to update procedural changes and to remind Project Officers of their roles and responsibilities. The most current version of the Regional Grants QA policy is available on the OEME intranet website (*http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm*) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Grants & Cooperative Agreements*

The Integrated Grants Management System (IGMS) handles the award and tracking of financial assistance agreements electronically; the general process for ensuring QA has remained the same since 2001. For continuing program grants that involve environmental data operations, QMPs (or equivalent quality system documentation as approved by the RQAM) and QAPPs are required. For one-time grants that involve environmental data operations, only QAPPs are required. The RQAM ensures that QAPPs for one-time grants contain sufficient information to describe consistent application of QA at the organizational level.

The policy memo describes the following process;

> The Grant Project Officer determines if a QAPP is needed and the decision is documented on the Funding Recommendation. If a QAPP is not needed, the appropriate Office QA Contact must concur with that decision on the Funding Recommendation. If a QAPP is needed, the Grant Specialist incorporates the appropriate special grant condition(s) into the grant award. Any modifications to the special grant condition language must be reviewed and approved by the RQAM. Once the grant is awarded, the Grant Project Officer works pro-actively with the grantee to ensure that the QAPP is developed, completed and submitted to the RQAM for review and approval. Grant Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements. Attachment 3 of the policy memo identifies those organizations required to have a QMP.

QMPs and QAPPs will be prepared, reviewed and approved in accordance with the specifications provided in Section 7.0 of this QMP. All QMPs and QAPPs are reviewed and approved by the RQAM as received from the Grant Project Officer or directly from the financial assistance recipient. The only exception to the required RQAM approval is when QAPP approval authority has been delegated as discussed in Section 7.6.

4.2.2 Interagency Agreements

Interagency agreements funded by EPA New England are subject to the requirements described in the most recent policy memo available on the OEME intranet website (*http://r1-gis-web.r1.epa.gov:9876/oeme/index.htm*) under **Quality Assurance (QA) Requirements, Guidance and Tools.**

- *Interagency Agreement Shared Service Centers (IASSC)*

These requirements are incorporated into individual agreements by IA Project Officers/Project Managers. This policy memo is reissued periodically to describe any procedural changes and to remind personnel of their roles and responsibilities.

5.0 DOCUMENTS AND RECORDS

The Region implements appropriate controls for quality-related documents and records determined important to the mission of the organization. The Federal Records Act of 1950, as amended, requires all Federal agencies to make and preserve records containing adequate and proper documentation of their organization, function, policies, decisions, procedures, and essential transactions. These records are public property and must be managed according to applicable laws and regulations.

All records and documents used in administering this QMP and conducting environmental data operations must be managed according to current Federal laws and regulations and EPA policy and guidance specified in Section 5.4.

Records will be managed as an Agency asset throughout their life cycle, which consists of three basic stages: creation, active maintenance and use, and disposition. The records life cycle is initiated by the creation, collection, or receipt of records in the form of data or documents in the course of carrying out EPA's administrative and programmatic responsibilities. The life cycle continues through the processing and active use of the information in the record until the record is determined to be inactive. The final step in the life cycle is disposition which frequently includes transfer to inactive storage, followed by transfer to the National Archives or destruction.

Maintenance of documents and records (both printed and electronic) associated with the mission of a given program or project is the responsibility of the Office which has primary responsibility for that program or project. Each Office is responsible for establishing and implementing procedures for identifying and managing records throughout their life cycle and ensuring that procedures conform to established records retention schedules.

This Section of the QMP describes roles and responsibilities for ensuring records and documents used to administer this Quality Management Plan are properly managed. Understanding roles and responsibilities is essential because official Agency records are public assets and belong to the government not to programs, by virtue of their possession, or to individuals, by virtue of their position as Agency officials. Penalties for the willful and unlawful destruction, removal from files and private uses of official records are found in 18 U.S.C. 2071.

5.1 Records and Documents Pertaining to the Quality Management Plan

In accordance with the *EPA Data Quality Standard*, the EPA NE QMP must be revised every 5 years and resubmitted to OEI for review and signature approval by the AA of OEI. Also, the QMP must be reviewed annually and changes/revisions must be reported in the QAARWP. Minor changes to the QMP, as determined by the Quality Staff, do not require OEI signature approval.

The most recent version of EPA New England QMP is available to the public at: *http://epa.gov/region1/lab/qa/qualsys.html*. It is maintained in the OEME "Lab SOPs" document

control database in accordance with the *OEME Document Control Standard Operating Procedure*. Superseded versions are archived in the database for reference. All QMP citations must include the document control number and date of revision.

The QA Unit has been delegated the authority to and is responsible for developing Regional guidance and procedures relevant to QA-related documents and records. The QA Unit identifies and provides guidance for preparing quality-related records and documents in the following:

- *EPA New England QA Project Plan Program Guidance;*
- *EPA New England Assessment Program;*
- *EPA New England Data Review Program Guidance;* and
- *OEME Document Control Standard Operating Procedure.*

The QA Unit assesses conformance to Regional requirements through its Assessment Program.

5.1.1 Records and Documents Pertaining to Environmental Data Operations

Each Office is the custodian of quality-related documents and records pertaining to environmental data operations that it conducts and manages. As provided for in this QMP, the QA Unit has a role in the review and approval of project-specific documents; however, each Office must ensure the management of documents and records according to laws, statutes, policy and program-specific guidance. Each Office is responsible for managing its QA-related ***documents*** (both printed and electronic), including but not limited to:

- Project-specific QA planning documents (e.g., QAPPs, SAPs, FSPs, QAPP addenda and amendments);
- Generic Program QAPPs and site-specific addenda and amendments;
- Written procedures and other SOPs;
- Data Review and Usability Reports; and
- Technical System Audit Reports and Corrective Action Responses.

In addition, each Office is responsible for managing project-related QA/QC ***records*** (both printed and electronic), including but not limited to:

- Chain of Custody Records;
- Field Sampling and Measurement Logs;
- Deviations from approved QAPPs and SOPs;
- Sample Results and Supporting Data; and
- Communication Records (e-mail are managed in accordance with the Enterprise Content Management System (ECMS)).

5.1.2 Document Control Requirements

Identifying documents and records (both printed and electronic) associated with the mission of a given program or project is the responsibility of the Office which has primary responsibility for that program or project. Each Office is responsible for establishing and implementing procedures for preparing, distributing, filing, storing, protecting, accessing, and archiving documents and records. The Manager is responsible for ensuring that proper procedures are implemented.

In addition, programs involved in environmental data operations follow Regional requirements for quality-related records and documents. At a minimum, the approved QAPP and its addenda and amendments, SOPs, technical assessments, corrective action responses, data usability determinations, and final project/site reports are to be filed together according to the Office's file structure guidance. The specific file system used by each program is the responsibility of the individual Managers.

For those programs delegated QAPP approval authority (refer to Section 7.6.1), the authorized program representative must maintain the original copy of the completed Title and Approval Page with approval signatures (or other record of approval) and forward a copy to the QA Unit for each project-specific QAPP. The QA Unit maintains these copies on file.

5.1.2.1 OEME Document Control Procedures

OEME describes an electronic process for maintaining Office documents in the *OEME Document Control Standard Operating Procedure*. The SOP applies to controlled documents across all OEME Units including the QA Unit. Controlled documents include manuals, plans, policies, guidance, SOPs, forms and other documents used to implement management systems. The electronic document control system is a Lotus Notes database entitled "Lab SOPs" and is available through the OEME intranet page. Controlled documents are accessible to all OEME personnel as portable document format (PDF) files. Only the electronic document viewed on-line is a controlled document. Printed copies are not considered controlled copies, and a caveat stating this is included with each SOP.

Archived versions are maintained in order to permit reconstruction of historical practices. Write access for entering, editing, and archiving controlled documents is limited to designated Document Control Contacts. Documents which are still current, but were developed prior to the implementation of the electronic system, are maintained as hard copies in the appropriate OEME Unit.

5.1.2.2 QA Unit Documents and Records

All QA Unit work is logged into the Request for Assistance (RFA) Database. Each assignment is automatically assigned a sequential RFA number and tracked in accordance with the RFA Manual. The RFA Manual is accessible through the RFA Database "Help" tab.

Hard copy documents and records are maintained in the QA Unit file room by RFA number for 5 years in accordance with the *OEME QA Unit File System SOP*. After which, records are disposed of in accordance with program records retention regulations, policies and Regional procedures.

5.2 Process for Ensuring Documents and Records Accurately Reflect Completed Work

Each Office is responsible for establishing and implementing procedures for ensuring the consistency and technical accuracy of its work products. In accordance with the *EPA New England Information Quality Guidelines – Pre-dissemination Review Implementation Plan* (, http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.htm each Office will use established review procedures to ensure that disseminated information products are of adequate quality for their intended use. Specifically, all Regional information products must be reviewed prior to their dissemination to ensure these products meet established quality guidelines for objectivity, utility and integrity.

5.3 Process for Establishing and Implementing Chain of Custody and Confidentiality Procedures

Each Office is responsible for establishing and implementing chain of custody and confidentiality procedures, including confidential business information (CBI). It is the Manager's responsibility to ensure that required procedures and security are implemented and comply with current EPA policies.

5.4 Regulations, Policies, and Guidance Pertaining to Documents and Records

The Region adheres to all Federal regulations, statutes and laws pertaining to documents and records as specified at: *http://www.epa.gov/records/laws/index.htm*. It also conforms to policy and guidance available at: *http://www.epa.gov/records/policy/index.htm* and to Agency Records Disposition Schedules at: *http://www.epa.gov/records/policy/schedule/index.htm*. These include, but are not limited to:

- 44 U.S.C. Chapter 31, Records Management by Federal Agencies;
- 44 U.S.C. Chapter 33, Disposal of Records;
- 18 U.S.C. Chapter 101, Records and Reports; and
- *Records Management Manual* *http://www.epa.gov/records/policy/manual/index.htm*.

5.5 EPA New England Office of Site Remediation and Restoration (OSRR) Records and Information Center

The OSRR Records and Information Center supports the Superfund Document Management System for the Region and maintains the EPA NE Superfund Enterprise Management System Portal

https://sems.epa.gov/sems/welcome.do?region=01.

Guidance, Site File Structure procedures, Document Coding forms, training and contact information are provided through the Intranet site.

6.0 INFORMATION TECHNOLOGY SUPPORT AND USE

EPA's ability to fulfill its mission is dependent upon a strong information technology infrastructure and reliable electronic information products. The Office of Environmental Information (OEI) is responsible for managing the Agency's information functions, including information collection, technology infrastructure, access and security. In that role, OEI establishes information technology (IT) policies, standards and procedures to ensure that information technology components integrate properly into the overall IT infrastructure and that Agency-owned environmental databases provide accurate data. OEI has also developed information product standards to ensure that information deliverables can be readily integrated and used for a varied range of uses.

The Region conforms to OEI's IT policies, standards, and procedures specified at: *http://www.epa.gov/irmpoli8/policies/*. In addition, Service Bulletins are periodically issued by OARM to address Information Management issues including e-mail, data retention, data back-up, data storage, etc. Service Bulletins are available at*:* *http://r1-gis-web.r1.epa.gov:9876/oarm/hr/SBulletins.html*
. Consistent with the Region's IQG-PDR procedures (http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.htm), the Region expects that all information and environmental data acquired from IT methods and sources to be evaluated prior to use.

6.1 Roles and Responsibilities

The designated Senior Information Officer (SIO) for EPA New England, as part of the SIO network supporting the CIO, is responsible for ensuring consistent Agency-wide management of information technology, information management and the integrity of electronic data.

6.1.1 Hardware and Software

The Information Resources Office and Computing Technology Office within the Office of Administration and Resource Management (OARM) are responsible for the following computer hardware and software support activities:

- Installing, configuring, testing, and troubleshooting network operating system and LAN based application software;
- Troubleshooting and solving problems for the LAN server, data switches and routers, and any related gateways and communications equipment;
- Supporting personal computer (PC) hardware and software procurement, system configuration, testing and installation of PC and peripheral equipment;

- Coordinating system software and hardware changes for PC equipment;
- Troubleshooting and fixing software and hardware problems reported by users;
- Overseeing PC and LAN security;
- Ensuring security software, system patches, system controls procedures and policies are implemented to prevent introduction of malicious software and computer viruses as well as to prevent unauthorized system/network access by hackers via the Internet; and
- Reviewing security practices to ensure that appropriate levels of information security are maintained. This includes review and implementation of policies and practices such as those that apply to user IDs and passwords, remote access, Internet, server system/data backup and recovery, physical access to Regional data center and communication closets.

6.1.2 Computer Models

Project Managers and Project Officers are responsible for ensuring all activities involving the development, modification, evaluation and/or application of mathematical or computerized models of environmental processes and conditions are conducted under an approved QAPP.

6.2 Regional Information Management Systems

All information management system development, improvements, and updates will comply with *Information Resources Management Policy Manual* CIO 2100 and will include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers prior to the design and installation of the system.

It is Regional policy to work closely with information system customers, as well as OEI and National Program Offices, as appropriate, on all phases of system development, improvements, and updates, including contractor-developed systems and those developed by other entities. During all life cycle phases of information management systems, the Region will comply with requirements within the *Information Resources Management Policy Manual*, the *System Life Cycle Management Policy*, and the *System Life Cycle Management Procedure*.

6.3 Hardware and Software Requirements

The Region conforms to OEI policies, standards and guidance pertaining to hardware and software specified at: *http://www.epa.gov/irmpoli8/policies/* and the Enterprise Architecture Policy CIO 2122.0. Through its procurement procedures, the Region ensures that purchased hardware and software meet user requirements and conform to OEI's technology and procurement guidelines.

6.4 Data Standards

It is Regional policy to comply with all applicable Federal regulations, guidance, executive orders, and internal policy documents concerning data standards specified at: *http://www.epa.gov/irmpoli8/* and Data Standards CIO 2133.0. These include EPA's core information data standards: the

Locational Data Accuracy Standard, the Facility Identification Standard, the Groundwater Data Element Standard, the Chemical Abstract Number Standard, and the Electronic Transmission of Lab Measurements Standard. It is the responsibility of individual Offices within the Region to be aware of the current standards and regulations.

Other relevant data product standards include standards for Web product development contained in the EPA Web Guide (http://www2.epa.gov/webguide) and two related EPA Orders: 2190.1 Cookies and other User Tracking Methods and 2190.2 Children's Privacy and Copyright Issues.

The EPA Data Standards Program is established and documented in the *Information Resources Management Policy Manual*. Within EPA, adherence to data standards policy is accomplished through the direction of OEI and the Senior Information Officer (SIO) network. EPA's information product-related policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems and products for the Region.

6.5 EPA New England Internet Web Site

The Regional Web Content Coordinator is responsible for information products posted on the Regional Web site. EPA New England Web Site Policy is available at:
http://www2.epa.gov/webguide/policies-and-procedures
The EPA New England Communication Group maintains the Regional Internet Web site. This requires a three-pronged approach focused on the following issues: 1) content creation and maintenance; 2) navigation through the Web site; and 3) maintaining and incorporating new Web technology. The Communications Group comprises Communication Coordinators from the various Offices, staff from the Regional Administrator's Office and Web technical staff.

All Web site requests are treated as information products used by EPA to represent or support Agency positions and policies. Therefore, in accordance with the Information Quality Guidelines (*http://www.epa.gov/quality/informationguidelines/*) all Web site requests are reviewed and approved prior to dissemination through the EPA New England Web site. Requests for Web site dissemination of information, reviews, and managerial concurrence are managed through the Design/Internet Request Tracking (DIRT) system.

6.6 New England Intranet Site

It is Regional policy to conform to EPA Intranet Publishing Guidelines available at:
http://intranet.epa.gov/oneepa/workplace/intranet/guide.html

7.0 PLANNING

Regional policy requires the use systematic processes to plan all aspects of environmental work, including strategic goal setting, quality management planning at the organizational level, and technical and QA/QC planning at the project level.

7.1 Regional QA Annual Work Plan

The *EPA Data Quality Standard* requires EPA organizations to submit a Quality Assurance Annual Report and Work Plan (QAARWP) to the Quality Staff of the Office of Environmental Information (OEI). The Region prepares a yearly work plan that addresses QA activities for all environmental data programs, including the oversight of delegated activities, and those specific to the QA Unit.

7.2 QA Unit Planning

The QA Unit uses a management tool to plan, track, and report requests for technical assistance from its internal and external clients. This Request for Assistance (RFA) tool serves to expedite client requests, allocate workloads, meet work schedules, and ensure that QMPs, QAPPs and other planning documents are reviewed and approved in a timely manner.

7.3 Quality Management Plans (QMPs)

In accordance with the *EPA Data Quality Standard*, EPA organizations and extramural organizations funded by EPA that conduct environmental data operations are required to operate under quality systems that conform to ANSI/ASQC E-4 specifications and to document those quality systems in QMPs.

Therefore, the Regional quality system is planned, developed, and documented in this QMP in accordance with the *EPA Data Quality Standard.* The QMP is reviewed by the Quality Staff of OEI and approved by the Assistant Administrator of OEI (also, Chief Information Officer). Implementing the QMP is a shared responsibility of all Regional personnel; the RQAM is responsible for overseeing the implementation of the quality system. To that end, the RQAM maintains a current QMP, resubmits the QMP to HQ whenever revisions are necessary or at a minimum of every five years, and performs annual reviews of the quality system.

For organizations funded by EPA NE, a quality system must be planned, developed, and documented in accordance with applicable Federal Regulations for Acquisition and Financial Assistance Agreements. QMPs, or equivalent organizational quality system documents, are required by the Region. Equivalent documentation of a quality system is determined on a case-by-case basis by the RQAM and may include a combined QMP/QAPP (Section 7.3.1). All extramural QMPs and other organizational quality system documentation are reviewed and approved by the RQAM or designated QA Unit member. The QA Unit reviews and approves QMPs in accordance with the *EPA New England Standard Operating Procedure for Reviewing Quality Management*

Plans (OEME "Lab SOPs" document control database).

Federally funded organizations are responsible for keeping their QMPs (or equivalent documentation) current, performing annual reviews of their quality systems, and resubmitting their QMPs whenever revisions are necessary, when so directed by EPA NE, or at a minimum of every five years. The QA Unit maintains a tracking database that provides the status of State, Tribal and Interstate organization QMPs, and the status of contractor QA documents that have been reviewed and approved.

In conjunction with members of the EPA New England/State QA Roundtable, the Annual Quality System Status Report Template (*http://epa.gov/region1/lab/qa/pdfs/EQAGUI-QSReportTemplate0.pdf*) was developed as guidance for organizations required to report annually on the status of their quality systems. Areas of reporting include assessments, training needs and notable QA issues/activities of the year.

7.3.1 Combined QMP/QAPP

For some external agreements, the Region may elect to require a combined QMP and QAPP. A combined QMP/QAPP incorporates some elements of the QMP and some elements of the QAPP. The specific elements to be addressed are determined on a case-by-case basis by the RQAM. The combined QMP/QAPP is subject to the same review and approval process as any other QMP and QAPP.

7.4 Systematic Planning Process

The Region requires that all environmental data operations conducted by or funded by the Agency be planned using a systematic process based on the scientific method.

The Region has adopted a systematic planning process to ensure that all environmental data operations performed by and for the Region will collect, produce, and use data that are of the type, quality and quantity that will support environmental-decision making.

The Regional systematic planning process is outlined in the *EPA New England QA Project Plan Program Guidance (http://epa.gov/region1/lab/qa/pdfs/QAPPProgram.pdf)* and includes the following steps:

- Identify Project Manager, Lead organization (sponsoring organization) and responsible official, technical personnel, stakeholders, data generators and suppliers and data users and decision-makers. Involve relevant personnel in planning;
- Convene planning meeting with identified project personnel to determine client needs, project goals, quality objectives, project boundaries, and environmental questions that must be addressed;
- Develop a project schedule that takes into account resources, budget, milestones and any

applicable requirements;

- Determine the type and quantity of data needed;
- Specify performance criteria for measuring quality and selecting QA activities and QC samples to assess the quality;
- Decide of how, when, and where the data will be collected; consider the constraints and limitations on data collection;
- Determine the process for obtaining and evaluating secondary data; consider the constraints and limitations on the use of secondary data;
- Identify environmental models that will be developed/modified or applied;
- Select assessment and oversight activities that will be conducted to ensure project activities will be conducted as planned; and
- Determine how data will be analyzed, evaluated, reviewed, and assessed against their intended use and the quality performance criteria.

The *EPA New England QAPP Program Guidance* serves to implement Agency requirements for systematic project planning and the preparation of QAPPs as required in the *EPA Data Quality Standard*. The QA Unit provides several general and program-specific QAPP development tools on its Quality Systems Documents Internet page *http://www.epa.gov/region1/lab/qa/qualsys.html* . This site provides examples of various project QAPPs, in addition to the following specific QAPP tools:

- Brownfields
  http://www.epa.gov/region1/lab/qa/pdfs/PlanDocBrownfields.pdf
- Environmental modeling
  http://epa.gov/region1/lab/qa/qamodeling.html
- Water quality monitoring
  http://epa.gov/region1/lab/qa/qaprojectplandevtool.html
- Secondary/Existing data projects
  http://www.epa.gov/region1/lab/qa/pdfs/EPANESecondaryDataGuidance.pdf

For media programs, many of the National Program Offices have developed programmatic data quality objectives and model QAPPs. In these cases, the Region may use the National guidance and model QAPPs.

The Region adopts a graded approach, based on program-specific guidance, for planning, documenting, and assessing environmental projects. QAPP elements are addressed using the systematic planning process and are commensurate with the intended use of the data.

The RQAM and QA Unit staff members are available for technical assistance in planning projects and developing project quality objectives. However, the ultimate project and data quality decisions lay with the program. It is the program's responsibility to properly plan the project to ensure the collection of data that are the right type, quantity, and quality needed to support decision making. To that end, Project Managers and Project Officers are required to use a systematic planning

process when planning environmental projects.

7.5 Quality Assurance Project Plans (QAPPs)

The Regional QAPP Program requires that the results of the systematic planning process be documented in a QAPP (or in an equivalent QA planning document). Equivalent documentation is determined on a case-by-case basis by the RQAM and is based upon the project quality objectives and the intended use of the data.

Approved QAPPs are required for all environmental data operations. Project Managers and Project Officers are responsible for ensuring that the results of the systematic planning process are documented in an approved QAPP prior to the start of work.

The Region has adopted a graded approach to project activities, including the preparation and review of QAPPs. However, to be approved, a QAPP must include sufficient information to document a transparent process that supports the achievement of project objectives.

7.5.1 Types of QAPPs

The Region supports the use of two types of QAPPs, as defined in the *EPA New England QAPP Program Guidance;* project-specific QAPPs and generic program QAPPs.

The Region encourages the use of generic program QAPPs whenever practicable. The QA Unit is available to provide technical assistance to the States, Tribes and local governments for developing them. Approved generic program QAPPs are supported by site-specific or project-specific addenda or SAPs which address the issues unique to each site or project. The generic program QAPP will specify the preparation, review, and approval of site-specific or project-specific addenda. EPA may authorize the Lead organization to approve site-specific and project-specific addenda. This authorization is contingent upon a review and approval process that is fully documented in the generic program QAPP.

7.6 QAPP Approval Authority

All environmental data operations conducted by EPA or funded by EPA must have an approved QAPP in place prior to the initiation of data collection. The RQAM has the authority and responsibility to approve all extramural and intramural environmental data operation QAPPs, unless delegated as described in the Regional QMP (refer to 7.6.1 and 7.6.2). In addition, Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements.

7.6.1 Authorizing EPA New England Program Personnel to Approve QAPPs

In accordance with the *EPA Data Quality Standard*, the RQAM may authorize a representative, as

defined in the approved QMP, to review and approve QAPPs. Delegation of QAPP approval authority does not preclude review by the QA Unit. Regional QA staff is available for technical and QA assistance upon request.

In EPA NE, the RQAM has authorized Project Managers in the Superfund and RCRA Corrective Action programs to review and approve QAPPs prepared for EPA by contractors, other Federal agencies, States, and those QAPPs submitted by the regulated community under voluntary and consensual or unilateral enforcement agreements, decrees and orders. Superfund and RCRA Corrective Action Project Managers are required to forward a completed copy of the QA Project Plan Approval Form (*http://www.epa.gov/region1/lab/qa/qmp/interagencyagreementpo.html*) to the QA Unit after they review and approve the QAPP.

Delegation of authority is contingent upon Project Managers attending QAPP training, conforming to this QMP, and providing the required QA approval documentation to the RQAM.

Records of current and expired authorizations of QAPP approval authority are maintained by the QA Unit on the OEME S/Quality Assurance directory.

7.6.2 Authorizing State Agencies to Approve QAPPs

The RQAM may authorize a State agency or one of its environmental programs to approve its own QAPPs. For example, QAPP approval authority could be delegated to an entire Department of Environmental Protection, or the approval authority could be limited to just the Water Quality program. Delegation of QAPP approval authority does not preclude review by the QA Unit. Regional QA staff is available for technical and QA assistance upon request.

Delegation of this approval authority is contingent upon concurrence by the environmental program manager within EPA New England. In addition, the organization must:

- Document and implement an effective quality system;
- Use a systematic process to plan projects, identify clients, determine project quality objectives, and select technical activities and QA/QC activities for the project;
- Document results of systematic planning processes in QA planning documents, i.e., QAPPs;
- Document and implement procedures for reviewing and approving QAPPs prior to the initiation of work; and
- Document and implement assessment and oversight programs that will ensure project activities are conducted as planned and non-conformances will be corrected.

Records of current and expired delegations of QAPP approval authority are maintained by the QA Unit on the OEME S/Quality Assurance directory.

7.7 Regional QAPP Review and Approval Process

The Regional review procedures for QAPPs are detailed in the *EPA New England Standard Operating Procedure for Reviewing Quality Assurance Project Plans* available from the OEME "Lab SOPs" document control database.

7.7.1 Time Frame for Reviewing and Approving QAPPs

The time required to review and approve a QAPP is dependent upon whether or not the initial submission of the QAPP provides sufficient and appropriate project information. In order to allow for comment and response, organizations are requested to submit an approvable QAPP to the QA Unit a minimum of 30 calendar days before the initiation of work. An approvable QAPP is one that is complete and contains adequate information to describe project activities and quality objectives. The information must be sufficiently transparent to allow a recreation of the data collection activity.

7.8 Implementing and Revising QAPPs

Approved QAPPs must be implemented as prescribed; however, a QAPP may be modified and amended at any time. Modifications may be necessary to address changing site/project conditions and to ensure project objectives are met. Modifications must be documented in an amendment and undergo a proper approval process similar to that of the original QAPP.

QAPPs are generally approved for a fixed period of time specific to the environmental data operation. They must be kept current and revised whenever necessary and when so directed by the Region or National Program Office. The QAPP must be reviewed annually, and this annual review must be documented and submitted to the original approval authority (i.e., EPA QA Unit and/or Superfund RPM, State authority).

8.0 IMPLEMENTATION OF WORK PROCESSES

Work processes must be implemented appropriately to ensure that environmental data collected and used by and for the Region are of the needed and expected quality for their intended purposes. To that end, the Region documents technical and administrative procedures for the collection and use of environmental data in all environmental programs including monitoring, regulatory enforcement, and permitting.

It is the policy of the Region to implement data collection operations as described in the approved QAPP. QAPPs are required to include written descriptions of all technical and QA/QC activities that will be performed. These descriptions may either be provided in the text of the QAPP document or as attachments of standard operating procedure (SOP) documents.

8.1 Regional Procedures

Regional procedures are documented to ensure consistency in the collection and use of environmental data and data products. Documented procedures are used to ensure continuity of operations, serve as a basis for auditing and to assist in training and succession planning.

8.2 Standard Operating Procedures (SOPs)

For routine activities such as field sampling, analytical methods, and data handling procedures, the Region develops and uses SOPs. These written protocols serve to ensure a standardized and consistent approach for work conducted on individual projects within one environmental program.

Standardization of sampling, analytical and review procedures provides a basis for generating data that are representative and comparable. Deviations from approved SOPs are documented and maintained with other project records. In addition, SOPs describe quality control acceptance limits that are used to support the collection of data that will achieve quality performance criteria determined for the project. Documented protocols also serve as a basis for performing technical assessments.

8.3 Responsibility for Regional Procedures and SOPs

The responsibility for identifying operations that need written procedures/SOPs, and for preparing, updating, approving, withdrawing, and archiving procedures, rests with the Manager responsible for the routine use of the specific procedure in conducting day-to-day activities. However, it is incumbent upon all staff to identify operations needing written procedures/SOPs and revisions to existing written procedures.

Managers are responsible for ensuring that Office procedures are implemented appropriately. Managers can use a variety of mechanisms to accomplish this, including direct oversight of work being performed, comparability of work products between staff, and results of assessments. Written procedures/SOPs are to be clearly and concisely written so that a person with the appropriate technical background can follow the procedure without interpretation or assumption.

Written procedures are initially prepared by staff and revised when necessary. Managers are responsible for the initial review, approval, and subsequent periodic review and revision of Office procedures. Office procedures must be current and readily available to all personnel. Managers are responsible for ensuring that the most recent version of an Office procedure/SOP is followed. Modifications to current procedures must be documented and have supervisory concurrence. Outdated procedures are withdrawn from work areas and archived when no longer relevant. Archived procedures/SOPs should be maintained to allow for reconstruction of historic practices. In addition, Managers are responsible for implementing other record keeping procedures specific to their Office and program.

8.4 QA Training on Technical SOPs

To assist the Region in implementing its work procedures appropriately, the QA Unit offers training modules (QAB-Training Module #96 and 96a) on SOPs. These training modules deal specifically with the components of an SOP and how to review an SOP to ensure that a project activity, as described, will achieve data quality objectives. SOP training emphasizes the following:

- Activities that need SOPs;
- Difference between published methods and organizational procedures;
- Difference between vendor manuals and organizational procedures;
- Information to include in an SOP, including QA/QC procedures and criteria;
- How to review an SOP for procedural inaccuracies and inconsistencies;
- SOP approval process; and
- SOPs as controlled documents (relevance of SOP revision numbers, and modification process).

The RQAM also identifies the need for standardized procedures through quality system assessments and technical system audits. When this occurs, the QA Unit recommends developing SOPs as a corrective action.

8.5 OEME SOPs

OEME maintains controlled copies of all SOPs in the OEME Lotus Notes database entitled "Lab SOPs" in accordance with the *OEME Document Control Standard Operating Procedure*. EPA staff and contractors are required to read and attest to all SOPs relevant to their work. The "reading and attesting to" SOPs by personnel is monitored electronically and reported to Managers.

Controlled documents are accessible to all OEME personnel as portable document format (PDF) files. Only the electronic document viewed on-line is a controlled document. Printed copies are not considered controlled copies, and a caveat stating this is included with each SOP.

Archived SOPs are maintained in order to permit reconstruction of historical practices. Write access for entering, editing, and archiving controlled documents is limited to designated Document Control Contacts.

8.5.1 QA Unit SOPs

QA Unit staff develops SOPs in accordance with *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents* (EPA QA/G-6). QA Unit SOPs are internally reviewed and are approved by the RQAM or designee.

All QA Unit SOPs written or revised after February 18, 2004 are maintained in the OEME "Lab SOPs" Lotus Notes database in accordance with the most recent version of the *U.S. EPA New*

England, Office of Environmental Measurement and Evaluation Document Control Standard Operating Procedure.

All QA Unit SOPs written prior to February 18, 2004 are maintained within the QA Unit. During the transition period to an all electronic database SOP format these SOPs will be retained as approved/signed hardcopies with the Regional quality system documents. Once these SOPs are revised they too will be maintained in the OEME "Lab SOPs" document control database. Outdated copies of approved SOPs are archived in accordance with the Unit's archival procedures.

8.6 Inspection and Oversight of Work-Related Processes

Program Managers and Project Officers are responsible for program oversight. They monitor work conducted by and for the Agency at the project level. Regional processes described in Section 9 of this QMP are used to ensure that approved QAPPs, technical procedures, and SOPs are implemented as written. Data review and evaluation procedures are used to monitor project deliverables, ensuring data usability and that project objectives are met. Corrective actions resulting from performance monitoring are resolved, confirmed and documented.

Managers oversee the work products of their staff and are responsible for reviewing data and information products prior to their dissemination.

8.7 Tracking and Reporting QA Unit Work

The QA Unit tracks all work projects in its Request for Assistance (RFA) database. In accordance with RFA procedures, relevant project information (acceptance and due dates, requestor, service requested, etc.) are entered by QA Unit staff.

The RQAM uses the reporting features of the RFA database to compile monthly reports to management. Cumulative tracking information is reported in the annual QAARWP.

9.0 ASSESSMENT, OVERSIGHT AND RESPONSE

EPA New England documents processes and procedures to determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs to which the quality system applies.

The Regional quality system comprises four basic components: 1) planning, 2) implementation, 3) documentation, and 4) assessment. Assessment, the final component, is the evaluation process used to measure the performance or effectiveness of a system and its elements. Assessment is a learning process intended to increase understanding of the program or system being assessed, and to provide a basis for improving such program or system. Assessments identify problems, reveal areas of strength and weakness, and allow management to evaluate the organization's processes and performance.

To measure the effectiveness and performance of the Regional quality system, the QA Unit coordinates an assessment program for Regional environmental programs. This assessment program is described in the *EPA New England Assessment Program* document.

9.1 Quality System Assessment

The Regional quality system is assessed annually and the assessment documented in the QAARWP for the Region. Each October the QA Unit requests, compiles, and reviews information regarding Regional quality resources and activities including 1) quality management resources, 2) QA/QC training, 3) quality system-related accomplishments, and 4) assessments of quality systems. For any area found to need improvement, an action plan is developed and incorporated in the QA Annual Work Plan as a QA activity for the coming year.

9.2 Conducting Assessments

Two types of assessments are conducted under the EPA New England Assessment Program, quality system and technical. The results of routine technical assessments should feed into quality system assessments.

1) **Quality System Assessments:** Qualitative assessments that systematically measure the adequacy and effectiveness of the organization's quality system (as documented in the QMP), and its impact on Regional work products.

2) **Technical Assessments**: Focused assessments that measure the performance of the work itself, with respect to the established technical guidelines, SOPs, and project requirements as defined in QAPPs or other project planning documents.

The process used by the QA Unit for planning, implementing and documenting assessments and reporting results to management is described in the *Assessment Program* document. Specific procedures are detailed in the QA Unit SOPs for quality system assessments and technical systems audits.

Assessment Tools - Selection of the appropriate assessment tool depends upon whether a quality system or technical system is being assessed. Technical system assessment tool selection also depends on the stage of the project during which the assessment is conducted. The appropriate tool types for quality system assessments and various technical assessments based on project stages are outlined in the tables below.

Quality System Assessments

Level	Appropriate Tool Type	Comments and Examples
Assessment of Quality System	Quality System Assessment (QSA) (This encompasses the former MSR.)	Assesses conformance to a documented quality system through collection of information and documented evidence of implementation

Technical (Project) Assessments

Project Stage	Appropriate Tool Types	Examples
Planning	QA Project Plan Review Site Scoping Visit	QAPP Review
Sampling	Technical Systems Audit (TSA)	Field Sampling TSA (Low Flow Ground Water TSA)
Analysis	Technical Systems Audit; Performance Evaluation Sample (PES)	Field Analysis TSA Field Lab TSA Fixed Lab TSA Proficiency Testing
Data evaluation and reporting	Data Audits	Data Verification Data Package TSA Data Validation - 3 Tiers
Usability	Data Usability Assessment	Data Quality Assessment (DQA) – statistical Usability – report review Peer Review

Specific tools utilized by the Region are described in tabular form in the *Assessment Program* for both quality system and technical assessments along with frequency requirements and recommendations. Organizational applicability, sources of assessment criteria and guidance references are also included in the tools' tables.

9.2.1 Internal Assessments - Frequency

The Regional quality system is reviewed annually as described in Section 9.1. Additional Quality System assessments and major technical assessments to be conducted by QA personnel are outlined each year in the QA Work Plan.

9.2.1.1 OEME Management Reviews

As part of OEME's quality system, the OEME management team (Office Director, Deputy, EIA Unit Manager, ECA Unit Manager and EQA Unit Manager), meets annually to conduct a review of the laboratory's biology and chemistry quality systems and environmental testing activities to ensure their continuing suitability and effectiveness, consistency between laboratories, and to identify necessary changes or improvements on an Office-wide basis. The meetings review and take into account the following items:

- Suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- Results of proficiency tests;
- Changes in volume and type of work;
- Client feedback and complaints; and
- Other relevant factors, such as QA activities, resources and staff training.

The results of this annual review are documented in the Office Director's files. Any corrective actions identified by this review are tracked as part of the Office-wide problem tracking system to ensure appropriate action is taken according to an acceptable time schedule.

9.2.1.2 Technical Assessments

Project assessments are stipulated in individual QA project plans. The Region's strategy is to conduct technical assessments as early as practicable in the course of a data collection activity to identify potential problems and prevent the generation of data that do not meet the needs of the project. Data audits may be useful in the early stages of a project, while data usability assessments may be conducted at the end of a project to evaluate overall usability (i.e., were the project objectives achieved?). Performance evaluation samples are specified for every sample delivery group, for each matrix, analytical parameter and concentration level, unless none exist.

9.2.2 External Assessments - Frequency

9.2.2.1 Air Monitoring Programs

a. New England States – comprehensive technical systems audit including evaluation of program quality system scheduled every three years

b. New England Tribes with air programs – TSA scheduled every three years in same year as State where Tribe resides

9.2.2.2 State Certification Programs for Drinking Water Laboratories

a. New England States – evaluation (QSA) of drinking water laboratory certification

program scheduled every three years

9.2.2.3 State Principal Laboratories Analyzing Drinking Water

a. Connecticut, Massachusetts, Rhode Island – evaluation performed by Region under Agency's laboratory certification program every three years

b. Maine, New Hampshire, Vermont – assessment performed under NELAC Standards by NH Environmental Laboratory Accreditation Program with on-site support from Regional Office every two years (Effective July 1, 2011, laboratories will be assessed to The NELAC Institute (TNI) Standards, adopted September 2009.)

9.2.2.4 Environmental Agencies/Organizations

a. New England States – quality system assessments conducted every three to five years

b. New England Interstate Organizations – quality system assessments conducted every three to five years

9.2.3 Internal and External Assessments – Summary Documentation

The quality system and technical assessments conducted by Regional QA personnel each year are summarized in the Request for Assistance system database. A print out from the database is included in the Regional QAARWP.

9.3 Assessor Qualifications, Responsibilities and Authority

Qualifications - Within the QA Unit, all assessment team members receive appropriate training prior to conducting assessments. Most QA Unit members have attended Quality System Training Conferences or Workshops presented by the Agency's Quality Staff and received training for management system reviews, quality system assessments and/or data quality assessment. This training is recommended for new QA Unit assessors as available. All OEME team members participating in assessments of the State drinking water programs must have successfully completed a laboratory certification course offered by the OGWDW Technical Support Center, Cincinnati and must be familiar with quality assurance and quality control practices necessary to support data integrity, usability and defensibility. Annual refresher training (Training Module 97.00) is conducted for drinking water program assessors prior to the first on-site evaluation of that year. Personnel conducting laboratory assessments under NELAC or the new TNI Standards are required to have the appropriate assessor training. Similarly, teams evaluating NELAP Accreditation Bodies are required to have evaluator training.

Quality system assessors need to have direct experience with the implementation of quality systems before conducting assessments. Similarly, personnel leading technical systems audits should have experience or familiarity with the technical procedures they are auditing. Assessors in the QA Unit have been cross-trained (e.g., both field sampling and laboratory analysis) so that in addition to their own areas of technical expertise, they are familiar with other areas as well. When resources are available, a minimum of two assessors is preferred for conducting each assessment. In addition

to increasing the degree of experience, this practice increases the level of competence and helps to prevent disputes over findings. The Assessment Team Leader and the RQAM review assessment plans to ensure that the designated assessors have no direct involvement or responsibility for the work being assessed, and that there are no real or perceived conflicts of interest. In the case of peer review, assessment personnel (reviewers) are required to respond to a Conflict of Interest Inquiry to avoid any potential conflicts.

Responsibilities - Assessors are responsible for the actual planning, conduct, evaluation, reporting, and documentation of assessments. They are also responsible for follow up to the assessments and evaluation of the response actions. Assessors' roles and responsibilities are described in the *Assessment Program* document.

Authority - The authority to assess is derived from the CIO 2106-S-01.0 *Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations.* Assessment authority is confirmed in the planning stage for each assessment. The purpose, scope and time frame for the assessment are documented in an assessment plan. For quality system assessments, the Lead Assessor and the organization's point of contact for quality assurance concur on the assessment's purpose, scope and time frame. For technical systems audits, the Lead Assessor and the Project Manager concur on the assessment's purpose, scope and time frame. These may be documented in a letter or in the final report for an assessment requested on short notice. Confirming the authority to assess in the planning stage of an assessment allows access to programs, managers, documents and records, and provides the organizational freedom to identify both problems and noteworthy practices, propose recommendations, and verify implementation and effectiveness of corrective actions.

9.4 Reporting and Response

Assessments conducted under the Assessment Program must, by definition, produce a written report which summarizes the assessment, states the findings, and, for certain types of assessments, provides recommendations for response actions. Without documentation in a final report, a site visit, evaluation, or other review is not considered an assessment.

The objective of the report is to communicate assessment results to the responsible level of management. Efficient communication of results allows management to implement timely, effective response actions so that the quality objectives can be met. Quality system assessments are typically reported to senior managers of the organization responsible for the work. Assessments of project activities are reported to the EPA Project Manager. Copies of reports for internal assessments of project activities conducted by Lead Organizations also are sent to the EPA Project Manager. The EPA Project Manager may request a review of an audit report by the QA Unit. The process for reporting results of project assessments to EPA managers is described in Section 5.0, Key Components - Reporting, of the *Assessment Program*.

Senior managers of the assessed organization are responsible for ensuring that any deficiencies

found in quality system assessments are appropriately addressed. Project Officers and Project Managers are responsible for ensuring that findings from assessments of project activities are appropriately addressed.

9.5 Corrective Actions

The process for corrective action in response to the findings of an assessment is described under Response Actions/Corrective Actions (Section 6.0) in the *Assessment Program*. Essentially, the principal responsibility for the implementation of response/corrective action is that of the assessed organization. A written response is provided by the assessed organization for all assessment findings with objective evidence of the effectiveness of the correction, and with specified time frames for those actions in progress or planned for the future. For project activities, copies of all corrective action response letters and corrective action forms should be included as attachments to the QA Management Reports and included in the Final Project Report.

The authority and responsibility for verifying the timeliness and effectiveness of corrective action resides with the senior management ultimately responsible for the work that was assessed. The responsible senior manager may request the assessors who conducted the assessment to verify the effective implementation of corrective actions. Assessment follow up is documented and reported using the same process as the original assessment.

9.6 Dispute Resolution

If disputes are encountered as a result of assessments and related responses, then the dispute resolution process outlined in Section 1.3.10 of this QMP will apply.

9.7 Documentation and Tracking

The content requirements and recommended format for documenting and tracking assessments are presented in Section 7.0 of the *Assessment Program* document. Assessment documentation includes:

- Assessment planning information including the criteria for the assessment;
- Checklist, questionnaire or other instrument for collecting and recording evidence;
- Assessment report;
- Follow up documentation verifying effective implementation of corrective action; and
- Assessment file containing the response from the assessed organization, relevant communications and the documentation listed above.

The Regional assessment activities are tracked in the Request for Assistance system, a database that captures the following information for each assessment:

1) Project Name

2) Program
3) Type of Assessment
4) Subject of Assessment
5) Requester
6) Request for Assistance (RFA) Number
7) Assessment Team Leader
8) Assessment Plan, where applicable
9) Date Assessed (On-Site Visit)
10) Final Report Date
11) Final Report (attached electronic file, if available)
12) Corrective Action Recommendation
13) Corrective Action Completion Date (Documentation Received)
14) Comments

9.8 Roles, Responsibilities, and Authorities

The roles, responsibilities and authorities for assessment and response in the Region are described in the *Assessment Program* document in Section 3.0 specifically and throughout the document. Among those defined are the roles, responsibilities and authorities for the following:

- Assessors;
- Case Team;
- QA Unit;
- Lead Organization;
- Quality Managers; and
- Senior Managers.

10.0 QUALITY IMPROVEMENT

EPA New England continuously evaluates and improves its quality system. The Region's senior management is fully committed to quality improvement as a process by which to proactively address vulnerabilities and to enhance efficiency. Quality improvement is incorporated as a core organizational element of the Region's quality culture and philosophy and looks to correct systemic problems, improve consistency, streamline processes, re-engineer ineffective work procedures, and customize quality tools. Management and staff are encouraged to establish communications among themselves and with customers and suppliers to explore areas for improved service. EPA personnel are expected to identify areas for process improvement and to actively participate in problem solving.

10.1 Annual Reporting

Under the *EPA Data Quality Standard*, the Region must report annually to the AA of OEI on the state of the Regional quality system. This QA Annual Report provides an opportunity for the

Region to identify areas of performance as well as components of the quality system that require correction or improvement. The QAARWP serves to communicate major quality issues to senior management to assist them in prioritizing workloads and allocating resources to support quality needs.

10.2 Organizational Improvement Based on Assessments

As discussed in Sections 8 and 9, the RQAM uses both external and internal assessment findings to initiate quality improvement. The RQAM identifies root causes of deficiencies; makes recommendations for improvement; works with Regional management, staff and external partners to implement corrective actions; and subsequently, evaluates the effectiveness of corrective actions in an overall effort to improve the quality and consistency of data products.

10.2.1 External Quality System Assessments

The Quality Staff of the OEI is responsible for conducting an assessment of the Regional data quality system every three to five years. In addition, National Program Offices may perform assessments of Regional programs including HSR, IQG-PDR, and Peer Review. These assessments serve to periodically evaluate the effectiveness of the quality system and quality-related procedures for Regional environmental programs; ensure consistency across the ten Regions; and to identify Agency data quality system issues.

The results of Regional data quality system assessments are communicated to the Regional Administrator and RQAM. The RQAM works directly with senior management to plan and implement corrective actions and to modify the quality system when and where appropriate. In addition, the RQAM may assist Offices within the Region in responding to National assessments of their environmental programs.

10.2.2 Internal Quality System Assessments

In accordance with the Regional Assessment Program, at least one internal quality system assessment is planned annually. The RQAM communicates the findings and results of internal assessments to the affected program managers. As a follow-up to internal and external quality system assessments, the RQAM monitors the effectiveness of corrective actions and evaluates improvements that have been made to the quality system.

10.3 Responsibility for Quality Improvement

All Regional personnel are responsible for preventing quality problems whenever possible; identifying systemic problems in the quality system; and reporting opportunities for improvement. Roles and responsibilities for identifying, planning, implementing and evaluating the effectiveness of quality improvement activities are interwoven throughout the fabric of the organization and have been discussed throughout this QMP. Regional policy requires the resolution of all issues that

could potentially impact the quality of work and, ultimately, the environmental decision-making process. Problems/issues with immediate solutions should be resolved in an appropriate and timely fashion by program staff. All problems and corrective actions must be documented and approved by the direct supervisor.

Problems/issues that require additional investigation to identify their cause may be referred to the QA Unit for evaluation. The QA Unit will evaluate the problem and determine if it is:

- An isolated non-conformance with Regional policies, requirements or procedures;
- A recurring systemic problem requiring "re-engineering" of the quality system component, work processes and procedures, and/or training to prevent reoccurrence of system failures and deficiencies; and/or
- A result of inconsistent implementation of work procedures and/or quality system processes.

In all cases, the QA Unit provides written reports that identify the quality issues and makes recommendations for planning corrective actions, revising procedures and training. All corrections and/or modifications made to work processes and procedures are documented in new or revised standardized written procedures. It is management's responsibility to communicate to their staff identified problems and their resolution.

Enhancements to components of the quality system are documented in revisions and amendments to the QMP. The QMP is reviewed annually to ensure that all information is relevant and up-to-date. Any necessary QMP revisions will be made, and revisions submitted to OEI's Quality Staff Every five years the RQAM will review the document and submit a revised QMP to OEI Quality Staff for review and approval.

The approved Regional QMP will be posted on the EPA New England QA Web page (*http://www.epa.gov/region1/lab/qa/qualsys.html).* Quality system components and tools, including guidance documents and standard operating procedures, will also be posted on Regional Internet and Intranet sites.

Section 11. Data Review, Validation and Verification, and Data Usability Reporting

Among other requirements, Agency quality policies and standards require that results obtained from products or services involving environmental data shall be reviewed, verified, validated and qualified according, and prior, to their intended use. Specific data review procedures, roles and responsibilities are described in applicable planning documents including quality assurance project plans (QAPPs) or other equivalent documents.

The regional implementation document, the *EPA New England Environmental Data Review Program Guidance:*

- outlines regional processes to ensure measurement data are adequately reviewed prior to use;
- incorporates program-specific and general data review guidance;
- ensures that "existing" data collected for purposes other than that of the current project (e.g., modeling applications, total maximum daily load (TMDL) determinations, survey reports) will also be technically reviewed prior to use;
- describes the roles and responsibilities of project management and personnel; and
- is intended to be used in conjunction with the *EPA New England Environmental Data Review Supplement* to ensure region-specific technical criteria are applied to sample results based on field duplicates, performance evaluation samples, etc.

The *EPA New England Environmental Data Review Supplement* specifically:

- Provides region-specific guidance for reviewing and reporting sample results generated for data collection activities (Note: review of previously collected or existing data is addressed in the *EPA New England Environmental Data Review Program Guidance*);
- Describes Superfund data review including:
  - adoption of the National Functional Guidelines criteria;
  - use of automated procedures;
  - incorporation of the *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*; and
  - use of a 2-Tiered data review approach dependent on project objectives
  - in instructions for using the regional Performance Evaluation Sample Program.

12.0 REFERNCES

1. American National Standards Institute (ANSI)/American Society for Quality (ASQ) E4-2004: Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use, 2004, ASQ, Milwaukee, WI, 2004

2. EPA Records Management Manual 2160, EPA National Records Management Program, February 2007, Washington, D.C.

3. Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4 (PDF) (121 pp 1.61 MB) (EPA/240/B-06/001) February 2006, OEI, Washington, D.C.

4. Data Quality Assessment: A Reviewers Guide, EPA QA/G-9R (PDF) (61 pp, 258 KB) (EPA/240/B-06/002) February 2006, OEI, Washington, D.C.

5. Data Quality Assessment: Statistical Tools for Practitioners, EPA QA/G-9S (PDF) (198 pp, 2.37 MB) (EPA/240/B-06/003) February 2006, OEI, Washington, D.C.

6. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated the Environmental Protection Agency, (EPA/260R-02-008) October 2002, OEI, Washington, D.C.

7. EPA Directive for Assuring the Competency of Environmental Protection Agency Laboratories (PDF) (4 pp, 183 KB), EPA, February 2004, Science Policy Council (SPC), Washington D.C.

8. Guidance for Geospatial Data Quality Assurance Project Plans, EPA QA/G-5G (PDF) (106 pp, 1.42 MB) (EPA/240/R-03/003) March 2003, OEI, Washington, D.C.

9. Guidance on Choosing a Sampling Design for Environmental Data Collection, EPA QA/G-5S (PDF) (178 pp, 1.02 MB) (EPA /240/R-02/005) December 2002, OEI, Washington, D.C.

10. EPA Directive 2100, http://www.epa.gov/irmpoli8/policies/index.html EPA Order 2104.1 Software Management and Piracy Policy (PDF) (5 pp, 60 KB)

11. Uniform Federal Policy for Quality Assurance Project Plans, Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs (PDF) (177 pp, 1.8 MB)

12. ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.