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: Reggie Cheatham
   TITLE: Director, Quality Staff, Office of Environmental Information

   SIGNATURE: _____ DATE: _____

2. NAME: Molly O'Neill
   TITLE: Assistant Administrator, Office of Environmental Information

   SIGNATURE: _____ DATE: _____

EPA New England Quality Management Plan

APPROVAL FOR EPA NEW ENGLAND

1. NAME: Robert W. Varney
   TITLE: Regional Administrator

   SIGNATURE: _____ DATE: _____

2. NAME: Ira W. Leighton
   TITLE: Deputy Regional Administrator

   SIGNATURE: _____ DATE: _____

EPA New England Quality Management Plan

CONCURRENCE

1. NAME: Gerard A. Sotolongo
   TITLE: Regional Quality Assurance Manager

   SIGNATURE: _Gerard Sotolongo _/s/_____ DATE: 1/9/08

2. NAME: Michael Kenyon
   TITLE: Director, Office of Environmental Measurement & Evaluation

   SIGNATURE: _____ DATE: _____

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

   SIGNATURE: _____ DATE: _____

4. NAME: Linda M. Murphy
   TITLE: Director, Office of Administration & Resource Management

   SIGNATURE: _____ DATE: _____

5. NAME: Stephen Perkins
   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

Table of Contents

LIST OF APPENDICES

Appendix

1. EPA New England's Commitment to Implementing the Regional Quality System, 5/4/05

2. Organizational Chart

3. a. Quality Assurance Requirements for OSRR Contract Actions, rev. 3/14/2007
   b. Quality Assurance Requirements for Non-OSRR Contract Actions, rev. 3/14/2007

4. Policy Statement Describing Revised Quality Assurance Requirements for Grants, 1/25/01

5. Policy Statement Describing Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements, 2/20/01

6. FY08 Requirements for Implementing Quality Assurance Policies for Financial Assistance Agreements Including Grants and Cooperative Agreements, rev. 10/17/07

7. FY08 Requirements for Implementing New Quality Assurance Policies for Interagency Agreements, rev. 11/30/07

8. EPA New England Quality Assurance Project Plan Policy, rev. 2/3/05

9. Development of EPA NE Quality Assurance Training Modules, 11/21/95

10. Amended Delegation of QA Approval Authorities to OSRR, 12/23/04

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 EPA Order 5360.1 A2. This QMP is applicable to all environmental programs managed by EPA New England (the Region) and encompasses all environmental data operations and environmental technology activities performed directly by the Region. It also applies to 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 describes Regional implementation of the Peer Review Policy, Information Quality Guidelines–Pre-dissemination Review, Environmental Management System (EMS) Policy, and Human Subject Research Policy.

The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The term "environmental data" includes measurements or information that describe environmental conditions, locations, and processes; ecological or health effects and consequences; and the performance of environmental technology. Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature. Environmental technology includes the design, construction, and operation of systems and components that prevent or remediate environmental contamination, and prevent, remove or monitor pollutants from process discharges.

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, 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 memorandum (Appendix 1). Regional commitment is consistent with the objectives and goals of EPA Order 5360.1 A2, May 2000, and is documented in accordance with the *EPA Quality Manual for Environmental Programs, (Quality Manual)* 5360 A1, May 2000.

1.1 EPA NE 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.
http://www.epa.gov/region1/about/index.html

The Region articulates its vision for the environment and Regional plan for achieving the Agency's ten environmental goals in the *EPA New England FY 2003-2008 Strategic Plan* http://www.epa.gov/region1/about/pdfs/stratplan2004.pdf.

1.2 EPA New England Quality Assurance Policy

Quality assurance (QA) requirements are integrated into the Region's media programs that administer environmental data operations and environmental technology activities. It is the Region's policy that environmental data operations will result in the collection of environmental data of known and documented quality, suitable for its intended use, and that environmental technology activities will perform as specified. This quality policy applies to all data collected and environmental technology activities performed by and for the Region.

The Regional Administrator, Senior Leadership Team and managers 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 EPA Order 5360.1 A2, overall responsibility for the QA program in the Region rests with the Regional Administrator. However, 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 has been delegated to the Regional Quality Assurance Manager (RQAM) in the Office of Environmental Measurement and Evaluation (OEME).

The Regional organizational chart is presented in Appendix 2. This chart identifies the components of the Region's organization and reporting structure. 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.

Specific roles and responsibilities pertaining to the implementation of other quality-related programs including Peer Review, Information Quality Guidelines-Pre-dissemination Review, EMS, 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 are described below:

1.3.1 Regional Administrator

As specified in EPA Order 5360.1 A2 (QA Order), the Regional Administrator has overall responsibility for the Regional quality system, including the following:

1. Ensuring that all Regional components and programs comply fully with the requirements of the QA Order and the specifications of the *Quality Manual, 5360 A1*, 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).

2. Ensuring that quality management is an identified activity with associated resources adequate to accomplish its program goals.

3. Ensuring that all applicable environmental programs delegated to state, tribal, and local governments, and performed by organizations outside EPA pursuant to EPA regulations and requirements, comply fully with the requirements of the QA Order.

4. Ensuring that quality management and QA/QC training are provided to Regional management and staff.

5. Ensuring that federal agencies and state, tribal and local governments performing environmental data operations and environmental technology activities under financial assistance agreements with EPA have sufficient quality management and QA/QC training in order to perform the work successfully.

6. Ensuring that periodic management assessments of Regional organizational units performing environmental programs are conducted to evaluate the implementation of this QMP.

7. Ensuring that periodic management assessments of state, tribal and local organizations funded by EPA are conducted to determine the effectiveness of their required quality systems.

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 Appendix B, the QA Manager position is located within the Office of Environmental Measurement and Evaluation. The position has a "dotted line" connection to the Deputy Regional Administrator. 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 Deputy Regional Administrator (DRA). This direct access to the DRA allows the Regional QA Manager to independently elevate critical quality-related issues at his/her discretion without challenge. The QA Manager does not need approval or pre-notification to initiate such communication.

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 to resolve issues and escalating to higher levels of management only as necessary, to resolve conflicts. The QA staff is expected to notify the QA Manager whenever any level of management involvement is needed to resolve QA issues. Should the QA Manager believe that QA independence is being challenged; the QA Manager can initiate communications with the Deputy Regional Administrator as described above. The RQAM utilizes the Quality Assurance Unit staff to assist in the day-to-day implementation of the Regional quality system. Specific responsibilities of the RQAM include the following:

1. Facilitating the development and approval of the Regional QMP, conducting annual reviews and subsequent updates, as necessary, to the QMP within the five-year approval period.

2. Acting as official contact for the Region in all QA matters and communications with OEI Quality Staff, as well as with other regions and environmental programs within the Agency.

3. Providing expert assistance to Regional personnel on QA/QC policies, requirements, and procedures applicable to the implementation of the Region's QMP.

4. Assessing QA/QC training needs and providing training for Regional programs and financial assistance recipients, including states, tribes, and interstate organizations.

5. Preparing Regional QA policies, procedures, and guidance to facilitate implementation of national QA requirements.

6. Ensuring that organizations receiving federal funds from the Region have approved QMPs in place and operate effective quality systems.

7. Ensuring that a systematic planning process is used to determine technical and QA/QC

activities for intramural and extramural environmental data operations and environmental technology activities; that the results of the planning process are documented in planning documents, such as a QAPP or SAP; and that technical procedures and practices are documented in standard operating procedures (SOPs).

8. Reviewing and approving QA planning documents, including QMPs, QAPPs, and SAPs, for intramural and extramural environmental data operations and environmental technology activities prior to initiation of field activities, and delegating approval authority for QA project plans in accordance with Section 7.6.

9. 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.

10. 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.

11. 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 and environmental technology activities.

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

13. Preparing QA Annual Reports and Work Plans (QAARWPs) and submitting to Senior Management and OEI Quality Staff.

Requests for QA services and support are tracked through the OEME Request for Assistance (OEME RFA) Process. The OEME RFA process and tracking system are described in the *EPA New England, OEME Request for Assistance (RFA) Tracking System Manual.*

1.3.3 Office Directors

As part of the Senior Leadership Team, Office Directors are responsible for:

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

2. Ensuring that all staff members are familiar with the Regional QMP.

3. Ensuring that data of the type, quantity and quality necessary to support environmental decisions are obtained and used for both intramural and extramural programs.

4. Ensuring that all projects involving environmental data operations and environmental technology activities conducted by and for the Region are supported by a documented organizational quality system and are conducted in accordance with an approved QAPP.

5. Ensuring that approved QAPPs are reviewed annually and updated as necessary for continued adequacy.

6. Ensuring that sufficient assessments are performed to determine compliance with QA/QC project QAPPs, and that appropriate qualified personnel perform the assessments.

7. Ensuring that deficiencies identified during assessments are corrected expeditiously.

8. Identifying program-specific QA training needs and obtaining the required QA training.

1.3.4 Managers

As primary supervisors of Agency 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:

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

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

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

4. Requiring staff 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.

5. Ensuring that a systematic planning process is used to determine project quality objectives for each environmental data operation and environmental technology activity conducted;

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.

6. Ensuring that the QAPP is implemented as described; that technical assessments are performed as required; and that data are reviewed prior to use.

7. Ensuring that corrective actions are monitored for implementation and effectiveness.

1.3.5 Project Officers and Project Managers

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

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

1. Ensuring QA requirements are satisfied in all applicable acquisitions management activities.

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

3. Providing signature concurrence or approval on QAPPs.

4. Ensuring that QAPPs are approved prior to the initiation of data collection and implemented as written for all projects involving environmental data operations and environmental technology activities.

5. Ensuring that appropriate QA documentation, including copies of signed and completed 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 and environmental technology activities for programs that have been delegated QAPP approval authority.

6. Ensuring that the QAPP has been implemented as described; that technical assessments are

performed as necessary; and that data are reviewed prior to use.

1.3.5.1 Contract Project Officers

EPA staff involved with preparing acquisition packages, awarding, and overseeing environmental data operations and environmental technology activities funded by the Region are responsible for ensuring that contractors are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI Quality Staff, the Region's procurement process was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the procurement and management of contracts and work assignments.

Contract Project Officers are responsible for adhering to Procurement Policy Notice (PPN) 01-02 and the most recent contract QA Regional policy statements included as Appendices 3a and 3b.

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

1.3.5.2 Grant Project Officers and Grant Specialists

EPA staff involved with awarding and overseeing environmental data operations and environmental technology activities funded by the Region are responsible for ensuring that financial assistance recipients are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI Quality Staff, the Region's process for ensuring that QA requirements of financial assistance recipients were met was revised 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 new grants management process was initiated through the January 25, 2001 policy statement *Revised Quality Assurance Requirements for Grants* (Appendix 4), which states that:

> "A new grants process for the Region is being implemented to insure that the Region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA New England Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team."

In addition to the responsibilities outlined above, Grant Project Officers and Grant Specialists are responsible for conforming to the February 20, 2001 policy statement *Requirements for*

Implementing New Quality Assurance Policies for Financial Assistance Agreements (Appendix 5). This policy statement explains the requirements and responsibilities for Project Officers and Grants Specialists in implementing the QA policies and procedures for all financial assistance agreements. It outlines the long-term Regional Grant QA Process and implements training and technical support to ensure consistent implementation of these requirements. This policy memo is updated and reissued annually as a reminder.

1.3.6 Contracting Officers

EPA staff involved with preparing acquisition packages, awarding, and overseeing environmental data operations and environmental technology activities funded by the Region are responsible for ensuring that contractors are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI Quality Staff, the Region's procurement process was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the procurement and management of contracts and work assignments. Contracting Officers and authorized Contracting Officer Representatives are responsible for adhering to Procurement Policy Notice (PPN) 01-02 and the most recent contract QA Regional policy statements included as Appendices 3a and 3b.

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

1.3.7 Office QA Contacts

In response to the 2000 Quality System Audit of this Region by OEI Quality Staff, Senior Management 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; "Office QA Contact." Office QA Contacts are senior personnel within each Office who assist staff in complying with the new Grants QA Process. Their responsibilities are detailed in Appendix 5.

1.3.8 OEME Chemistry Laboratory Quality Assurance Officer (QAO)

The OEME Chemistry Laboratory QAO is responsible for implementing the laboratory quality system as described in the OEME Chemistry QA Plan. The QAO is the designated quality manager in accordance with NELAC standards.

1.3.9 OEME Biology Laboratory Quality Assurance Officer (QAO)

The OEME Biology Laboratory QAO is responsible for implementing the laboratory quality system as described in the OEME Biology QA Plan. The Biology Laboratory QAO is the designated quality manager in accordance with NELAC standards.

1.3.10 Environmental Data Collection and Technology Staff

Environmental data collection and technology staff are responsible for:

1. Ensuring that work is conducted under approved QA planning documents.

2. Following established sampling practices and procedures as described in QA planning documents.

3. Following good laboratory practices and methodologies as described in QA planning documents.

4. Documenting any deviations from established methodologies, SOPs and QC protocols, and reporting the deviations to their supervisor.

5. Identifying possible data quality problems and potential areas for quality improvements and reporting these to their supervisor.

6. Identifying to management any defective, outdated, or deficient SOPs and suggesting routine operations which are in need of SOPs.

1.3.11 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 Operations and Environmental Technology Activities

This section identifies the major environmental data operations and environmental technology activities covered by the Quality Management Plan.

1.4.1 Regional Administrator's Office

The Regional Administrator's (RA's) Office is the central coordinating office of the Region that provides leadership, planning, oversight of key policy and program initiatives and resource management. While the Regional Administrator is ultimately responsible for the Regional quality system, few direct environmental data operations or environmental technology activities are undertaken by this office. Therefore, its functions are not discussed in detail. However, if the RA's Office does undertake any environmental data operations or environmental technology activities (e.g., education grants, environmental impact reviews), all Regional quality policies and procedures are followed.

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.

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 and environmental technology activities; reviewing and approving intramural and extramural Quality Management Plans (QMPs), Quality Assurance Project Plans (QAPPs) and other QA documents (e.g, Sampling and Analysis Plans (SAPs), Laboratory Quality Assurance Plans/Manuals, workplans, standard operating procedures (SOPs), etc); conducting Quality System Assessments (QSAs) and Technical Assessments 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 various program offices within the Region, Agency contractors, and state, tribal, and local governments, that are involved in environmental data operations and environmental technology activities.

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 CERCLA analytical service contracts; supporting the FASTAC strategy; providing expert witness testimony; administering the CERCLA Performance Evaluation Program and the Discharge Monitoring Report for Quality Assurance (DMRQA) Studies for the National Pollutant Discharge Elimination System (NPDES) Program; managing the Drinking Water Certification Program; performing Alternate Test Method reviews; and supporting NELAP.

1.4.2.2 Investigations and Analysis Unit

The Investigations and Analysis Unit is comprised of two teams; Chemistry Team and Investigations Team. The Chemistry Team is responsible for performing chemical analyses of environmental samples, and 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, support for laboratory audits, screening for problem assessment and follow-up confirmatory analysis projects for the protection of ground water and drinking water supplies.

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 *EPA New England Chemistry Quality Assurance Plan* (Lotus Notes Lab SOPs Database). This QA plan 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, the Chemistry Laboratory applied for and received NELAC accreditation July 2004 for potable and non-potable water.

The Investigations Team is responsible for providing field support, including 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, SARA, EPCRA, SWDA, CWA, and TSCA. The Team also provides field investigation support by conducting CERCLA site investigations and oversight of contractor investigations.

1.4.2.3 Ecosystem Assessment Unit

The Ecosystems Assessment Unit (ECA) is a field service unit consisting of two teams; Air Monitoring Team and Ecology Monitoring Team. They 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. ECA also develops environmental indicators and environmental assessment reports.

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 supervises the collection and evaluation of air quality data collected by states and other entities in support of Regional and national monitoring, State Implementation Plan (SIP) planning and enforcement programs. 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 this 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, AIRS, 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 PM, 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 QA Plan.

The Ecology Monitoring Team assesses long-term water quality trends, assists state agencies, conducts special water quality 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, microbiology, and Polymerase Chain Reaction (PCR) analyses. Data are collected by the Team according to project specific QAPPs and sampling SOPs. Data may be used for problem identification, 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 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 *EPA New England Ecosystem Assessment Unit (ECA) Biology Team Quality Assurance Plan.* The plan 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, the Biology laboratory applied for and received NELAC accreditation July 2004 for microbiology and aquatic toxicity.

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, conducts oil spill preparedness and prevention activities, and oversees the Underground Storage Tanks (UST)/Leaking Underground Storage Tanks (LUST) programs and Corrective Action provisions of the Resource Conservation and Recovery Act (RCRA). 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 Support Branch of OSRR.

During site assessment, OSRR, states and their contractors undertake environmental data operations and environmental technology activities to characterize sites, determine whether sites are eligible for listing on the National Priority List (NPL) and/or warrant a removal action.

At Fund-lead NPL sites, OSRR, states and their contractors undertake environmental data operations and environmental technology activities to characterize sites, make site remediation decisions, and monitor remedy implementation and effectiveness. At PRP-lead and federal facility NPL sites, PRPs, federal facilities and their contractors undertake environmental data operations and environmental technology activities to characterize sites, develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR and the states oversee activities undertaken by PRPs and federal facilities.

At Brownfield sites, OSRR contractors, states, local communities and their contractors undertake environmental data operations and environmental technology activities to characterize sites develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR oversees activities undertaken by the states and local communities.

At RCRA corrective action sites, the owner/operator of the RCRA facility undertakes environmental data operations and environmental technology activities 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.

Currently, the UST/LUST programs and the corrective action provisions of RCRA are the only programs administered by OSRR that can be delegated to the states. The UST/LUST programs have been delegated to all six New England States and the corrective action provisions of RCRA have been delegated to the states of Connecticut, Maine, New Hampshire and Vermont. OSRR maintains oversight responsibility for the delegated programs in those states and directly implements the corrective action provisions of RCRA in the states of Rhode Island and the Commonwealth of Massachusetts.

During an emergency response, OSRR, states and their contractors may undertake environmental data operations and environmental technology activities 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. All data collection operations performed by the Emergency Planning and Response Branch (EPRB) are conducted under the *EPRB Generic Program Quality Assurance Plan.*

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

1.4.4 Office of Ecosystem Protection and Office of Environmental Stewardship

To adequately address the additional environmental data operations and environmental technology 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. The OEP is a multi-media, ecosystem-based office that is in the process of establishing environmental standards and goals and works with states and communities to achieve these goals. The OEP deals with regulatory considerations and issues permits. The OES is a multi-media office which includes a flexible, enforcement unit 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; and providing outreach and technical assistance in order for industry to remain compliant with regulations and permits regulatory requirements and in some cases to go beyond compliance.

Programs with significant environmental data operations and environmental technology activities are described below.

1.4.4.1 Water Programs

The 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. The 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.

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 our 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.

1.4.4.1.1 Clean Water Act

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

OEP staff in the Industrial and Municipal NPDES Branches implements the National Pollutant Discharge Elimination System (NPDES) permit program either directly or through oversight of a delegated State. For the National Pollutant Discharge Elimination System (NPDES) and Pretreatment programs, primacy has been delegated to four New England states, Connecticut, Rhode Island, Maine and Vermont. The EPA role is to provide technical assistance and oversight to the 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. This data also is used by either OES and/or delegated State staff to assess a facility's compliance with its permit which may lead to subsequent enforcement activity.

OES staff monitors compliance with NPDES permits, initiates federal enforcement actions for non-compliance and oversees state run enforcement programs. Permittee self-monitoring data are entered into the Permits Compliance System (PCS) 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 which often evaluate the permittee's on-site laboratory facilities and procedures. The performance of the permittee's laboratory (either in-house or contract) is monitored the analysis of Discharge Monitoring Report Study for Quality Assurance (DMRQA) Performance Evaluations samples. Enforcement actions or audits resulting from study results are performed by the six New England States. The QA Unit DMR-QA coordinator helps permit holders complete appropriate paperwork and directs them to appropriate State coordinators for technical assistance. OES staff takes follow-up actions based upon non-response or inadequate response. Adherence to the quality control analyses and acceptance criteria specified in the 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. OEP staff in the Water Quality Branch review and approve 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 sampling and analysis and often employ various models simulating differing water quality conditions. Some TMDLs utilize contract support provided directly by the states or through organizations such as the New England Interstate Water Pollution Control Commission. OEP staff prepares TMDLs and usually relies on contractor assistance, with occasional OEME and state staff support, to generate the necessary water quality data or to develop the 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 Watershed and Non-point Source Branch also operates the non-point source program and the Surface Water Branch (Oceans and Coastal Protection Unit) implements 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 is also responsible for the National Environmental Policy Act (NEPA) compliance activities for NPDES new source performance standard category dischargers utilizing environmental impact and project information submitted by the proponent. Staff in the Municipal NPDES Branch oversees 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 programs managed by the OEP Water Program 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 included 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 – OEP

Safe Drinking Water Act (SDWA) Programs are primarily managed by OEP's Drinking Water Quality & Protection Unit of the Drinking Water Branch (CDW), as well as the Municipal Assistance Unit (CMU) of the Grants, Tribal and Municipal Branch. The 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 CDW. The Drinking Water State Revolving Fund (DWSRF) Program and the Drinking Water Operator Certification Program are handled by CMU. 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 CDW 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.

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, the Air Quality Planning Office and Air Permits, Toxics and Indoor Environment Programs Office 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 date 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. 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.

For those instances which require enforcement and compliance action, the Air Technical Unit of OES plans and executes federal enforcement actions. They also oversee state initiated enforcement programs under the Clean Air Act. Compliance data and emissions inventory data are entered into the AIRS database system which is monitored to ensure the integrity of the data.

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.

1.4.4.3 Resource Conservation and Recovery Act Program

The Resource Conservation and Recovery Act (RCRA) Program, with the exception of the RCRA Corrective Action program (OSRR), is permitted and monitored by OEP 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. EPA maintains oversight responsibility for the authorized programs in those states.

The Hazardous Waste Unit of the Chemicals Management Branch (OEP) 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 an HSWA program. The Unit 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 Unit 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).
- Gathering and disseminating data regarding hazardous waste.
- Maintaining the national RCRA Information System (RCRA Info) and the Biennial Report System (BRS) for the Region.
- 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.
- Providing technical assistance to Tribal Nations to address specific solid waste issues.
- Responding to Freedom of Information Act (FOIA) requests.

The State Program Authorizations and Approvals 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 Data Management group 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 Permits group 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 group 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 or 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.

1.4.4.3.1 OES RCRA Enforcement/Compliance Activities

To monitor RCRA permit compliance and to enforce compliance, the RCRA Technical Unit of OES 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.

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 Pesticides, Toxics and Urban Programs

The Pesticides, Toxics, and Urban Programs Unit of the Chemicals Management Branch (OEP) is one of the principal implementing arms of the Office of Prevention, Pesticides and Toxic Substances (OPTS) at EPA-Headquarters, incorporating 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 Unit is also responsible for the Region's Urban Environmental Program (UEP) which addresses a variety of issues that cross various HQ Office responsibilities.

The Urban Environmental Program (UEP) 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.

The Pesticides Program 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, as well as non-regulatory programs of outreach, education and industry assistance to reduce the use o 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 Program 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 Pb 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 PCB clean-ups and enforcement of PCB regulations, and issues TSCA permits for the storage and disposal of PCB contaminated material and TSCA approvals for PCB clean-ups.

The Chief of the Chemicals Management Branch serves as the Regional policy contact for all matters related to Decommissioning of Nuclear Power Plants within the Region, arranges technical assistance, coordinates EPA programs (both Regional and HQ offices, especially the Office of Radiation) involved with the dismantlement and clean-up of nuclear power plants and surrounding areas, and represents EPA in dialogues with the Utilities, NRC, State Agencies and Public Stakeholders.

1.4.4.5 Assistance and Pollution Prevention

The Assistance and Pollution Prevention (A&P2) Unit of OES uses the alternative approaches described below to encourage environmental compliance and beyond compliance changes. Few direct environmental data operations or environmental technology activities are undertaken by this office. If the A&P2 Unit does undertake any environmental data operations or environmental technology activities (e.g., pollution prevention grants, etc.), all Regional quality policies and procedures are followed. A&P2 is engaged in gathering data on environmental management practices of targeted facilities and sectors, and in assessing the effectiveness of its work through surveys and evaluations.

Sector Specific Assistance

A large part of A&P2's assistance work is focused on targeted sectors, including colleges and universities, secondary schools, and hospitals and marinas. The goal of this work is to work with these sectors in a way that integrates enforcement and assistance, providing them with tools and incentives to improve performance. A&P2 also provides program specific assistance in areas such as storm water regulation and small sources of drinking water.

Innovation

A&P2 is also focused on regulatory innovation and works with states, other regional Offices, and HQ to promote the assessment and use of innovative practices in core programs such as the, RCRA, TMDL and NPDES programs. A&P2 also promotes innovative approaches to improve performance through the Performance Track leadership program, Greening the Supply Chain efforts, and the use of Environmental Management Systems.

Sustainable Practices/Waste Reduction

A third area of A&P2 work is promotion of sustainable practices and over reduction in non-

hazardous waste. Specific activities are in the area of Green Buildings, proper management of electronic waste, and reduction in municipal waste, and in particular food waste.

Center for Industry and Technology (CEIT)

The mission of CEIT is to be a window to resources, people and programs for the environmental technology industry in New England, and to promote the acceptance of innovative environmental technologies to solve the most significant environmental problems in New England. The Center offers services to address three specific problem areas that impede technology development and acceptance: 1) the access to information on government programs, 2) the access to information on new technologies for the regulated and non-regulated communities and 3) regulatory and institutional barriers. These services include a web site; trade shows; Small Business Innovation Research (SBIR) program workshops; newsletters; and efforts to match technology developers with some of New England's priority environmental problems.

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 or environmental technology activities 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 quality assurance requirements in accordance with 48 CFR Part 46, PPN 01-02, Contracts Management Manual, and Regional quality requirements for contracts and procurements (Appendix 3a and b). The Grants Management Office is responsible for ensuring that all statutory and regulatory administrative requirements are addressed prior to the award of any grant, cooperative agreement, or interagency agreement. This includes the quality assurance requirements of 40 CFR and the Regional requirements for implementing quality assurance policies for financial assistance agreements (Appendices 4, 5, 6 and 7).

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, the purchase and upkeep of computer hardware and software and technical support for the Region's Geographic Information Systems (GIS) implementation. 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 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 throughout the organization. Specifically, it provides the framework for planning, implementing, documenting and assessing Regional activities relevant to environmental data operations and environmental technology activities and for carrying out required QA and QC activities for the entire organization. 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 5360.1 A2 data quality system has evolved since first institutionalized in 1994. It is comprised of several functional components that have matured into quality system programs, including the following:

- Quality Assurance Project Plan Program
- Performance Evaluation Program
- Assessment Program
- Data Validation Program
- QA Training Program

Our regional quality system also incorporates other quality-related regional programs, including:

- Peer Review Program
- Human Subject Research Program R Program
- Information Quality Guidelines and Pre-Dissemination Review Program
- Environmental Management System

The 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. Many of the Regional guidance documents may be obtained from the QA Regional Web site: http://www.epa.gov/ne/lab/qa/qualsys.html and the Regional Science Council Web site: http://r1-gis-web.r1.epa.gov:9876/rsc/index.htm. The 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, available tools, and the primary responsibilities for those programs. A detailed description of these components, and roles and responsibilities for their implementation, is provided in Sections 3 – 10 of this QMP.

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

Quality System
EPA New England's Commitment to Implementing the Regional Quality System, 5/4/05

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Quality System	EPA New England QMP	*EPA Quality Manual 5360 A1*	RQAM/QA Unit
Regional Planning	EPA New England FY 2003-2008 Strategic Plan	*Government Performance and Results Act (GPRA)*	Strategic Planning Team
Annual Quality System Review and Planning	QA Annual Report and Workplan	*EPA Quality Manual 5360 A1*	RQAM/QA Unit
QA Policies	Senior Management Memoranda	*EPA Quality Manual 5360 A1*	Senior Management; RQAM/QA Unit

Quality Assurance Project Plan Program

- *EPA New England Quality Assurance Project Plan Policy*, Rev. 2/3/05
- Program documented in *EPA New England QAPP Program Guidance*, Rev. 4/05 under revision
- Tracking Systems for project related information
  - OEME Request for Assistance (RFA) Database
  - New England Sample Tracking System (NESTS)
  - QMP Tracking Database
  - IGMS

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Project Planning	The EPA New England Systematic Planning Process	*EPA New England QAPP Program Guidance*	Managers; Project Personnel
Project QA Documentation	QAPPs	*EPA New England QAPP Program Guidance*	Managers; Project Personnel
Project QA Planning Documentation Review and Approval Process	QAPP Review Procedures	*EPA New England SOP for Reviewing QAPPs*	RQAM/QA Unit

Implementation

- Tracking Systems
  - New England Sample Tracking System (NESTS)
  - OEME RFA Database
  - OEME Lotus Notes Lab SOPs Database

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Representative Sampling	Sampling SOPs	http://www.epa.gov/quality EPA QA Requirements and Guidance documents	Project Personnel
Field Analytics	Field Analytical SOPs	http://www.epa.gov/quality EPA QA Requirements and Guidance Documents	RQAM/QA Unit
OEME Sampling, Analytical, QA etc. SOPs	OEME Chemistry and Biology Laboratory QA Plans OEME SOPs	OEME/Lotus Notes Lab SOP Database	OEME
Performance Evaluation Samples	SPSWEB system	*EPA Region 1 Performance Evaluation Program Guidance*	RQAM/QA Unit

Assessment Program

- Program documented in *EPA New England Assessment Program*, 2/2002 under revision
- Tracking Systems
  - Superfund Performance Evaluation Sample Scoring Web (SPSWEB system)
  - Assessment Tracking System (ATRACK)
  - OEME RFA Database

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Management Assessment	Quality System Assessments	*EPA New England Assessment Program* *Guidance on Assessing Quality Systems, (QA/G-3)*	RQAM/QA Unit; Managers
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 Assessment Program* *EPA New England Technical Systems Audit SOP* Project-Specific Audit Checklists and Audit Reports	RQAM/QA Unit; Managers; Project Personnel
	Performance Evaluation Samples	*EPA New England Performance Evaluation Program Guidance*, 7/96	RQAM/QA Unit; Project Personnel

Data Validation Program

- Program documented in *EPA New England Data Validation Functional Guidelines for Evaluating Environmental Analyses*, 12/96 under revision
- Tracking Systems
  - OEME RFA Database
  - New England Sample Tracking System (NESTS)
  - Government Inspection Activities Database (GIAD)

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Data Review	Data Verification and Validation Criteria and Procedures	*EPA New England Data Validation Functional Guidelines for Evaluating Environmental Analyses*, 12/96 with Attachments A-Q	RQAM/QA Unit; Managers; Project Personnel
Data Usability Assessment	Data Usability Assessment Procedures	*EPA Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*	RQAM/QA Unit; Managers; Project Personnel

QA Training Program

- Program documented in "Development of EPA New England QA Training Modules," Implementation memo 11/21/95
- Tracking System:
  - QA Training Tracking Database

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
QA Training Program	QA Unit Training Modules	*EPA Guidance for Developing a Training Program for Quality Systems (QA/G-10)* *Standard Operating Procedure for the EPA New England QA Training Tracking System*	QA Training Coordinator/RQAM/ Managers

Quality-related Internet and Intranet Sites

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

Components	Available Tools	National and/or Regional Requirements and Guidance	Responsibility
EPA New England QA Home Page http://epa.gov/ne/lab/qa/index.html	Links to: -Training -Services -Quality System Documents	*EPA New England Web Site Policy*	QA Unit; EPA New England Communication Group
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 - EMS	National Program Regulations, Policies and Guidance	Senior Management

Peer Review Program

- Program documented in *Science Policy Council Handbook, Peer Review*, 3rd edition, 2006

Tracking Systems
- National Science Inventory Database

Components	Available Tools	National/Regional Requirements and Guidance	Responsibility
Agency-defined Peer Review procedures	Regional Web page: http://r1-gis-web.r1.epa.gov:9876/rsc/peerreview.htm Peer Review Call Letters/Memoranda	*Science Policy Council Handbook, Peer Review, 3rd edition,* Regional Processes for Identifying Candidates for Peer Review	Peer Review Coordinator; Office Peer Review Contacts; Peer Review Product Coordinator; Peer Review Leaders; Managers

Information Quality Guidelines

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

Components	Available Tools	National and/or Regional Requirements and Guidance	Responsibility
Pre-Dissemination Review Procedures for Agency Information	R1 IQG & PDR Web page http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.html IQG-PDR Web-based Training	**National** EPA IQGs http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf EPA Pre-Dissemination Review Guidelines http://intranet.epa.gov/quality/informationguidelines/pdf/pdr-guidelines.pdf **Regional** Regional IQG-PDR Implementation Plan http://r1-gis-web.r1.epa.gov:9876/oeme/EPANE_IQGPDR_IP.pdf	Office Directors; Managers; IQG Officer; IQG Office Contact; Product Authors
Region 1 Publishing Management System SOP	Procedure under revision to incorporate IQG requirements	Database currently being modified to address IQG issues	IQG Coordinator; Office Directors

Human Subjects Research

- Program documented in *EPA New England Human Subjects Research Implementation Plan,* Rev. 1.1, 5/23/07

Components	Available Tools	National and/or Regional Requirements and Guidance	Responsibility
Public Health Practices "Common Rule" ethical practices	Region 1 HSR Web page http://r1-gis-web.r1.epa.gov:9876/rsc/hsr.htm - Implementation Plan - Training	**National** 40 CFR Part 26 Protection of Human Subjects http://www.access.gpo.gov/nara/cfr/waisidx_00/40cfr26_00.html **Regional** -Implementation Plan http://r1-gis-web.r1.epa.gov:9876/rsc/data/Regional_HSR_Plan.pdf	Regional HSR Coordinator Office Directors

Environmental Management System (EMS)

- Program documented in

Components	Available Tools	National and/or Regional Requirements and Guidance	Responsibility
Boston Facility Chelmsford Facility	Region 1EMS Web pages http://www.epa.gov/region1/ems/index.html and http://r1-gis-web.r1.epa.gov:9876/ora/green/EMS.htm - EMS Plans - Training -Audits	**National** EMS Policy **Regional** Boston Office EMS Policy Chelmsford Office EMS Policy	Boston: Jean Holbrook Chelmsford: Scott Pellerin

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

This Section documents the procedures for assuring that all personnel performing work for EPA New England have the necessary skills to effectively accomplish their work. To achieve Regional quality goals and objectives, management and staff performing tasks related to environmental data operations and environmental technology activities must have the necessary skills and knowledge to effectively accomplish their work.

3.1 Commitment to Training

It is the policy of the Region 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.

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 staff performing quality-related tasks associated with environmental data operations and technology activities have an appropriate level of knowledge of QA procedures and principles.

The EPA New England Human Resources Office has responsibility for ensuring 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 of those positions 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. 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 START database. Registration for training offered by the Center for Development and Learning is accomplished electronically through START. 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. For those personnel involved in auditing and certifying state SDWA programs, special training is required and certificates are received upon successful completion of the training course. Certificates are kept on file by the person certified.

For those personnel involved in managing financial assistance agreements and contracts, including Grant Project Officers and Contract Project Officers, successful completion of the Contract Officer Representative Training is required for certification and an 8 hour re-certification training is required every three years. On-going certification is maintained by completing 40 hours of contract/job-related training.

3.5 Training for Quality

The QA Unit works with the Regional Training Officer, Office Directors and their staff to assess Regional QA training needs. 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.

QA training is based on prioritized needs and implemented as resources permit. The QA Training Coordinator uses the QA Training Database to track EPA and non-EPA attendees of QA Unit training courses. Training information is compiled and presented in the QA Annual Report and Workplan.

3.5.1 QA Training Needs Assessment

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

1. Employee training needs are identified and documented during annual PARS reviews.

The PARS process identifies training and developmental needs to enhance or improve an employee's current performance, or it may specify remedial training needed to correct deficiencies in performance or educational preparation. Training may include technical, quality assurance, operational, non-technical, and managerial topics.

2. **Training needs are identified through internal and external audits and management systems reviews.** For example, the January 2000 Quality Staff Audit performed by the Quality Staff of the OEI identified noncompliance with quality system documentation pertaining to federal assistance agreement regulations. In response to this finding, a "Grants QA Workgroup" was convened. This workgroup developed and presented mandatory "QA Awareness Training" to all Regional grants specialists, project officers and their supervisors.

3. **Training is developed when new National and Regional quality-related policies are issued.** For example, in 2006 EPA New England developed a web-based training course on the EPA Information Quality Guidelines that described Pre-dissemination review procedures and personnel responsibilities as documented in the regional Pre-dissemination Implementation Plan. In addition, a Web-based training course on Human Subjects Research was developed and presented to technical staff in response to National priorities on HSR.

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 qualifications and training of personnel performing environmental data operations and environmental technology activities funded by the Region under federal financial assistance agreements and contracts are evaluated through quality system assessments, technical system audits, and pre-award reviews, as applicable. The Region provides QA training based on prioritized programmatic needs as resources permit. For example, in response to the needs of regional grantees, the QA Unit developed a Web-based introductory QAPP course.

3.5.4 Regional QA Training Program and Outreach

3.5.4.1 Modular Training Program

The Regional Training Program was instituted on November 21, 1995 in a memorandum titled

Development of EPA New England Quality Assurance Training Modules (Appendix 9). The Regional QA training program is based on a modular approach. Modules may be presented as stand-alone training sessions, combined with other modules, and/or integrated with training courses developed by OEI Quality Staff. Regional training modules are designed and tailored to meet identified Regional needs. A current list of training modules is maintained on the OEME share directory, and available upon request.

3.5.4.2 Mandatory QA Training

In 2005, EPA New England instituted mandatory Quality System Awareness Training for all EPA New England personnel. Also, 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.

Management determines which training is mandatory and for whom; the EMS, IQG-PDR and HSR Web-based trainings are mandatory for selected employee groups and tracked accordingly. Peer Review training is also mandatory for selected employees.

3.5.4.3 QA Training Web Site and Outreach

A separate Regional QA Training Web page http://epa.gov/ne/lab/qa/training.html provides Web-based training courses and information on Regional and National QA Training Conferences. Currently, the QA Training Web page offers the following Web-based training: "Beginner's Guide to Preparing Quality Assurance Project Plans." Additional Web-based training courses will be developed as resources allow.

The QA Unit in conjunction with the State/Tribal QA Roundtable initiated a QuickPlace Lotus Web-based shared workspace to enhance real time collaboration among the geographically dispersed Roundtable participants.

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

The QA Training Tracking System (QA-TTS) supports the Regional QA training program by tracking the QA training provided by the QA Unit to Regional personnel and stakeholders. The QA-TTS is comprised of:

- QA Training Files
- QA Training Tracking Database
- QA-TTS Standard Operating Procedure

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 PROCUREMENT OF ITEMS AND SERVICES (ACQUISITIONS AND ASSISTANCE)

This Section documents the procedures for purchasing items and services that directly affect the quality of environmental programs. 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 and environmental technology activities. Within the Region, 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 and items and services provided by their subcontractors and suppliers.

A graded approach to implementation of quality assurance and quality control requirements is a key tenet of the Region quality system. The RQAM has the authority to establish "equivalent" quality requirements. Any 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 quality assurance requirements in the latest editions of the Federal Acquisition Regulations, *Acquisition Handbook*, and *Contracts Management Manual.*

Regional procurement policy has been revised to conform with the new Federal Acquisition Regulations (FAR) 46.202-4 and 52.246-11, as well as Procurement Policy Notice (PPN) No. 01-02, the interim guidelines for EPA's quality requirements for use in acquisitions. Regional procurement policies are outlined in two memoranda included in Appendix 3:

- *Quality Assurance Requirements for Non-OSRR Contract Actions, 3/14/07*
- *Quality Assurance Requirements for OSRR Contract Actions, 3/14/07*

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

In summary, for all new contracts or procurements, the Contracting Officer Representative (COR) must complete the Contracts Management Manual (CMM) QA Review form prior to forwarding a request for procurement/contract placement.

After contract award, when requesting services either through the issuance of a work assignment or task order, the Region 1 QAR form 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 (ESHSOP-MSDSMANA3) maintained in the Lab SOPs database. Purchase orders are maintained by OEME facilities staff to compare against incoming orders. Facilities staff route materials to the requestor as they are received. As described in the Chemistry QA Plan, chemicals are entered into the OEME Chemical Inventory System as they are received.

The quality of supplies used for environmental data collection and testing is assured in accordance with the procedures detailed in the OEME Chemistry and Biology QA Plans.

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.

The Office of Grants and Debarment document, *Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance*, http://www.epa.gov/ogd/grants/assurance.htm is used by the Region during "Project Officer QA Awareness Training" to educate management and staff on QA requirements as they pertain to grants and cooperative agreements. Specifically, organizations funded by the Region to conduct environmental programs that include "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" are required to submit QMPs (or equivalent quality system documentation) and QAPPs to EPA for review and approval.

4.2.1 Grants and Cooperative Agreements

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff, the Region's process for ensuring that financial assistance recipients meet QA requirements was revised 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* (Appendix 4), which

states that:

> "A new grants process for the Region is being implemented to ensure that the Region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA New England Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team."

In addition to the responsibilities outlined above, 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 statement explained the new requirements and responsibilities for Project Officers, Grants Specialists, and the QA Unit in implementing the 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.

Reissued annually, the policy memorandum describes any procedural changes and serves to remind project officers of their roles and responsibilities. The most recent revision of the memorandum *Requirements for Implementing Quality Assurance Policies for Financial Assistance Agreements Including Grants and Cooperative Agreements* is provided in Appendix 6. Recent updates detail new procedures associated with the implementation of the Agency IGMS tracking system. Although the 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 and environmental technology activities, QMPs (or equivalent quality system documentation as approved by the RQAM) and QAPPs are required. For one-time grants that involve environmental data operations and environmental technology activities, just 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 memorandum 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 memorandum

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 revision of *Requirements for Implementing New Quality Assurance Policies for Interagency Agreements* (Appendix 7). These requirements are incorporated into individual agreements by Project Officers or Project Managers. This policy memorandum will be reissued periodically to describe any procedural changes and to remind project officers of their roles and responsibilities.

5.0 DOCUMENTS AND RECORDS

This Section documents 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 Quality Management Plan and conducting environmental data operations and environmental technologies must be managed according to federal laws and regulations and EPA policy and guidance (refer to Section 5.5).

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 that adhere to established records retention schedules.

This Section of the QMP also addresses the roles and responsibilities for ensuring that records and documents that are 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.

Furthermore, understanding roles and responsibilities provides for an efficient workflow which minimizes duplicative steps and saves agency resources in the storing and retrieval of these information assets.

5.1 Records and Documents Pertaining to the Quality Management Plan

The processes for identifying, preparing, reviewing, approving, issuing, using, and revising quality-related documents and records are described herein. The QA Unit is responsible for and has been delegated the authority to develop Regional guidance and procedures relevant to QA-related documents and records. The QA Unit assesses the conformance to Regional requirements through its Assessment Program.

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 Validation Functional Guidelines for Evaluating Environmental Analyses*
- *EPA Region 1 CSF Completeness Evidence Audit Program*
- *EPA Region 1 Performance Evaluation Program Guidelines*
- *The Regional Sample Control Center Guidance for the Contract Laboratory Program and Delivery of Analytical Services Program for EPA New England*
- *OEME Document Control Standard Operating Procedure*

In accordance with the EPA QA Manual 5360 A1, the 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 in the QMP do not require OEI signature approval.

The most recent revision of EPA New England QMP is available at: http://epa.gov/ne/lab/qa/qualsys.html. It is maintained in accordance with the *OEME Document Control Standard Operating Procedure*. All references to the QMP should include the document control number and date of revision.

5.1.1 Records and Documents Pertaining to Environmental Data Operations and Environmental Technologies

Each Office is the custodian of quality-related documents and records pertaining to environmental data operations and environmental technology projects. 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 guidance. Each Office is responsible for managing the QA-related documents, including but not limited to:

- Project-specific QA planning documents (e.g., QAPPs, SAPs, FSPs)

- Generic Program Quality Assurance Project Plans
- Standard Operating Procedures
- Data Review and Usability Reports
- Technical System Audit Reports and Corrective Action Responses

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

- Chain of Custody Records
- Field Sampling Notes
- Test Results and Supporting Data
- Communication Records

5.1.2 Document Control Procedures

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 and environmental technology follow Regional requirements for quality-related records and documents. At a minimum, the QAPP and the final project/site report 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. In addition, for those programs delegated QAPP approval authority, the authorized program representative must forward a copy of the completed Title and Approval Page with approval signatures to the QA Unit, for each project-specific QAPP.

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, OEME QAPPs, SOPs, forms and other documents used to implement management systems. The electronic document control system is a Lotus Notes database entitled "Lab SOPs." Controlled documents are accessible to all OEME personnel as portable document format (PDF) files. 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.

5.2 Process for Ensuring Documents and Records Accurately Reflect Completed Work

Each Office is responsible for establishing and implementing procedures for ensuring consistency and technical accuracy of its work products. In accordance with the *EPA New England Information Quality Guidelines – Pre-dissemination Review Implementation Plan*, March 26, 2007 http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.html , each Office will use established procedures to ensure that disseminated information products are of adequate quality for their intended use.

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. It is the Manager's responsibility to ensure that required procedures are implemented and comply with EPA Order 2160 and EPA Directive 2100, (Draft Records Management Manual (http://intranet.epa.gov/records/drafts/2160/index.htm) and EPA Directive 2100, (U.S. EPA Information Management Resources Policy Manual (IRM) Policy Manual) Chapter 10 (Chapter 10 - Records Management).

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

The Region adheres to the most current version of the following regulations, guidance, and policies pertaining to documents and records as they pertain to program requirements:

- 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
- Paperwork Reduction Act of 1995
- OMB Circular A-130, Management of Federal Information Resources
- 36 CFR Chapter XII, Subchapter B
- *Records Management Manual*, EPA Order 2160
- *Information Resources Management Manual*, EPA Directive 2100, Chapter 10, Records Management
- Agency Records Disposition Schedules http://intranet.epa.gov/records/schedule/index.htm
- Best Practices and Model Documents, National Records Management Program http://intranet.epa.gov/records/best/index.htm
- *A Guide to Conducting a Records Management Baseline Assessment*
- *Using the Federal Records Center: A Guide for Headquarters Staff*

For CERCLA, the following regulations, guidance and policies pertaining to documents and records are also followed:

- 40 CFR Part 300, National Contingency Plan
- *U.S. EPA New England Region Records Management Program Manual*
- *File Structure Guidance for Region I Superfund NPL Site Files, Superfund Removal Site Files, and Federal Facility Site Files* (Rev. September 1997)
- *Plan/Classification for EPA New England Region OSRR* (OSRR Standard Operations Manual)

6.0 COMPUTER HARDWARE, SOFTWARE AND INFORMATION PRODUCTS

This Section documents how the organization ensures that computer hardware and software support the Region's data operations and environmental technology activities. EPA's ability to fulfill its mission is dependent upon a strong information technology infrastructure and reliable electronic information products. These must be able to support a broad range of mission objectives; all of which require information integration and dynamic communication among EPA offices and its partners.

OEI is responsible for managing the Agency's information functions, including information collection, technology infrastructure, and access. In that role, OEI has established information technology (IT) standards to ensure that information technology components integrate properly into the overall IT infrastructure. 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 standards.

6.1 Roles and Responsibilities

The Information Resources Office and Computing Technology Office within 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.
- 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.

6.2 Regional Information Management Systems

All information management system development, improvements, and updates will comply with EPA Directive 2100, *Information Resources Management Policy Manual* 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 Regional 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 and other entity developed systems. During all life cycle phases of information management systems, the Region will comply with requirements within EPA Directive 2100, *Information Resources Management Policy Manual*, the *Interim Agency System Life Cycle Management Policy* http://epawww.epa.gov/rmpolicy/ads/orders/2100_4.pdf and *Interim Agency System Life Cycle Management Procedures* http://intranet.epa.gov/rmpolicy/im/sys-life-cyc-mgmt-procedures.pdf Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are developed, installed, and tested prior to use, to guarantee they perform as expected, are well documented, and meet user requirements.

6.3 Hardware and Software Requirements

The Region conforms to the *System Design and Development Guidance and Operations and Maintenance Manual* and the *Delegation of Procurement Authority Guide*. This ensures that purchased hardware and software will meet user requirements and will conform to OEI's technology and procurement guidelines. Other pertinent hardware and software standards utilized by the Region include: EPA's Network Security guidelines, Energy Star and Section 508 guidelines, and EPA's Hardware and Software Standards Roadmap http://basin.rtpnc.epa.gov:9876/etsd/itaroadmap.nsf . The EPA New England General Support Security Plan, Land Security Plan and Recovery Plan is currently under revision and will be finalized in the later half of 2005.

6.4 Data Standards

All federal agencies are required to adhere to federally mandated data standards and regulations. It is the policy of the Region to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. 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. These standards and polices can be

found at http://www.epa.gov/irmpoli8/

Other relevant data product standards include: standards for web product development contained in the EPA Web Guide 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 EPA Directive 2100 *Information Resources Management Policy Manual.* Within EPA, adherence to data standards policy is accomplished through the direction of OEI. 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. A comprehensive list of both final standards and those under development is provided at: http://oaspub.epa.gov/edr/epastd$.startup#1

6.5 EPA New England Web Site

The EPA New England Web Site Policy is detailed on the following Regional Intranet subsite: http://r1-gis-web.r1.epa.gov:9876/oarm/info_res/webpub/webpolicy1204.pdf . In summary, the EPA New England Communication Group is responsible for maintaining the quality of the EPA Region 1 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 is comprised of 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.

7.0 PLANNING

This Section documents how the Region uses systematic processes to plan all aspects of environmental work, including strategic goal setting, quality management planning at the organizational level, and project planning.

7.1 Regional Strategic Plan

The Region has initiated a Strategic Planning Process which sets the direction and priorities for the Region. This ongoing planning process integrates the activities of the Region, assigns resources to areas that support its mission, and moves EPA New England closer to achieving its goals. The most recent 5 year strategic plan is available at http://www.epa.gov/region1/about/pdfs/stratplan2004.pdf

At the Office level, OEME implemented a unified management tool to plan and track requests for technical assistance from its three units, EIA, ECA, and EQA. This "Request For Assistance" (RFA) system is available on the EPA New England intranet to all internal customers. It serves to expedite client requests, allocate work loads, meet work schedules, and ensure that QAPPs are prepared and approved prior to data collection activities.

7.2 QA Annual Work Plan

EPA Order 5360.1 A2 requires EPA organizations to submit a Quality Assurance Annual Report and Work Plan (QAARWP) to the Quality Staff of the Office of Environmental Information. The Region prepares a yearly work plan that addresses both the QA activities of line management and those of the QA Unit, including the oversight of delegated activities.

7.3 Quality Management Plans

In accordance with EPA Order 5360.1 A2, EPA organizations and extramural organizations funded by EPA that conduct environmental data operations and environmental technology activities are required to operate under quality systems that conform to ANSI/ASQC E-4 (E-4) specifications. EPA implements those specifications through the *EPA Quality Manual for Environmental Programs*, 5360 A1, and *EPA Requirements for Quality Management Plans,* (EPA QA/R-2), as described below.

For all EPA organizational units governed by 5360.1 A2, the *EPA Quality Manual for Environmental Programs*, 5360 A1, provides program requirements for implementing the mandatory quality system as defined by the Order. Therefore, our Regional quality system is planned, developed, and documented in this QMP in accordance with the *EPA Quality Manual for Environmental Programs*. The QMP is reviewed by the Quality Staff of OEI and approved by the

Assistant Administrator of OEI . The implementation of the QMP is a shared responsibility of all Regional personnel and is overseen by the RQAM. The RQAM is responsible for keeping the QMP current, performing annual reviews of the quality system, and resubmitting the QMP whenever revisions are necessary or at a minimum of every five years.

For organizations funded by EPA NE, a quality system must be planned, developed, and documented in accordance with *EPA Requirements for Quality Management Plans,* (EPA QA/R-2), or in an equivalent document as specified by the Region. Equivalent documentation of a quality system is determined on a case-by-case basis by the RQAM. 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 Lotus Notes "Lab SOPs" 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 a status of state, tribal and interstate organization QMPs and a status of contractor QA documents that have been reviewed. In conjunction with members of the EPA New England/State QA Roundtable, the Annual Quality System Status Report Template http://epa.gov/ne/lab/qa/qualsys.html was developed as guidance for organizations required to annual report the status of their quality systems.

7.4 Systematic Planning Process

The Region requires that all environmental data operations and environmental technology activities 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, generate, and use data or information that are of the type, quality and quantity that will support environmental-decision making. A systematic planning process is also used to plan environmental technology activities to ensure that performance needs are met.

The Regional systematic planning process is outlined in the *EPA New England QA Project Plan Program Guidance* http://epa.gov/ne/lab/qa/qualsys.html and includes the following steps:

- Identify and involve the project manager, lead organization (sponsoring organization) and responsible official, project personnel, stakeholders, data generators and suppliers and data users and decision-makers.

- Determine project goals, quality objectives, 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.
- Select assessment and oversight activities that will be conducted to ensure project activities will be conducted as planned.
- Determine how data will be analyzed, evaluated, reviewed, and assessed against its intended use and the quality performance criteria.

The *EPA New England QAPP Program Guidance* serves to implement national QA requirements for systematic project planning and the preparation of QAPPs as described in the *EPA Quality Manual*, 5360 A1 (for EPA organizations) and in the *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5 (for contractors and financial assistance recipients).

For many routine monitoring programs, the National Program Offices in EPA Headquarters have developed programmatic data quality objectives and model QAPPs. In these cases, the Region uses the national guidance and model QAPPs. These program-specific guidance documents form the basis of the graded approach adopted by the Region 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 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 should ensure that a systematic planning process is used to plan projects.

7.5 QA Project Plans

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.

QAPPs are required for all environmental data operations and environmental technology activities. 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 support 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, and the QA Unit provides 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 (such as Sampling and Analysis Plans) 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 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 and environmental technology activities conducted by EPA or funded by EPA must have an approved QAPP in place prior to the initiation of work. The RQAM has the responsibility and authority to approve all extramural and intramural environmental data operation and environmental technology QAPPs, unless delegated as part of the Regional QMP (see 7.6.1 and 7.6.2 below). In addition, Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements (Appendices 4 and 5).

7.6.1 Authorizing EPA New England Program Personnel to Approve QAPPs

In accordance with EPA Order 5360.1 A2, the RQAM may authorize a representative, as defined in the approved QMP, to review and approve QAPPs. In EPA NE, the RQAM has authorized Project Managers in the Superfund and RCRA Corrective Action programs to review and approve QAPPs prepared for the EPA by contractors, other federal agencies, states, and those submitted by the regulated community under voluntary and consentual or unilateral enforcement agreements, decrees and orders. Superfund and RCRA Corrective Action Project Managers are required to provide a copy of the signed "Title and Approval Page" to the QA Unit after they review and approve the QAPP (Appendix 12).

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 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, determine project quality objectives, and select technical activities and QA/QC activities for the project.
- Document results of the systematic planning process in a QA planning document, e.g., QAPP.
- Document and implement procedures for reviewing and approving QAPPs prior to the initiation of work.
- Document and implement an assessment and oversight programs that will ensure project activities are conducted as planned and non-conformances will be corrected.

NHDES was delegated QAPP approval authority for QAPPs developed for Section 319 projects that involve the generation of load reduction estimates. The Memorandum of Agreement is effective for a period of five years from the date of signature, 1/7/2006.

MEDEP was delegated QAPP approval authority for water program QAPPs excluding generic program QAPPs and those project QAPPs involving modeling. The Memorandum of Understanding was effective on 7/10/06. Under the MOU, the QA Unit may periodically access implementation.

7.7 Regional QAPP Review and Approval Process

The Regional review procedures for QAPPs are detailed in the *U.S. EPA, EPA New England Standard Operating Procedure for Reviewing Quality Assurance Project Plans.* The most recent revision is available in the OEME Lotus Notes "Lab SOPs" 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 sufficient information to describe project activities and quality objectives.

7.8 Implementing and Revising QAPPs

The approved QAPPs must be implemented as prescribed; however, the 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 the proper approval process. QAPPs are 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 should be documented.

8.0 IMPLEMENTATION OF WORK PROCESSES

This Section documents how work processes will be implemented within the Region to ensure that data or information collected are of the needed and expected quality for their desired use. The policy of the Region is to implement data collection operations and environmental technology activities as described in the approved QAPP. Among other things, QAPPs are required to include written descriptions of all technical activities and QA/QC that will be performed. These descriptions may either be provided in the text of the QAPP document or as attachments of standard operating procedure documents.

8.1 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 and analytical procedures provides a basis for generating representative data and comparable data. In addition, SOPs include documented quality control provisions that are used to support the collection of data that will meet the quality performance criteria for the project. Documented protocols also serve as a basis for performing technical assessments.

8.2 QA Training on 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 the 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 approvals
- SOPs as controlled documents (relevance of SOP revision numbers, and modification process)

8.3 Responsibility for SOPs

The responsibility for identifying operations that need SOPs, and for preparing, updating, approving, withdrawing, and archiving SOPs, 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 SOPs or revisions to existing SOPs.

Managers are responsible for ensuring that SOPs 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. 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.

SOPs are initially prepared by staff and revised when necessary. Managers are responsible for the initial review, approval, and subsequent periodic review and revision of SOPs. Current SOPs must be readily available to all personnel. Managers are responsible for ensuring that current SOPs are followed. Modifications to current procedures must be documented and have supervisory concurrence. Outdated SOPs are withdrawn from work areas and archived when no longer relevant.

The RQAM also identifies the need for standardized procedures through quality system assessments and technical system audits, which identify areas of inconsistency that would benefit from standardized procedures. When this occurs, the QA Unit recommends the development of SOPs as a corrective action.

8.3.1 Responsibility for Quality-Related SOPs

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

All QA Unit SOPs written or revised since February 18, 2004 are maintained in the OEME "Lab SOPs" Lotus Notes database in accordance with the latest revision 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" database. Outdated copies of approved SOPs are archived in accordance with the Unit's archival procedures.

8.4 Inspection and Oversight of Facilities and Work-Related Processes

Program managers are responsible for program oversight while project officers oversee work conducted at the project level. Regional processes described in the Assessment Program and described in Section 9 of this QMP are used to ensure that approved QAPPs, technical procedures, and SOPs are implemented as written.

8.4.1 OEME Environmental Management System (EMS) Related Procedures

In accordance with Executive Order 13148, the Chelmsford Facility implemented its Environmental Policy on August 19, 2004. Procedures and operational controls are documented on the intranet at http://r1-gis-web.r1.epa.gov:9876/ora/green/EMS.htm and describe safe and environmentally sound waste management and techniques that are used to reduce the facility's impact on the environment. The *EPA New England Regional Laboratory Environmental Management System Manual* is available from the Lab SOPs Database.

8.4.2 EPA Boston EMS Related Procedures

In accordance with Executive Order 13148, the Boston Facility implemented its Environmental Policy on August, 29, 2004. Procedures and operational controls are documented on the intranet at http://r1-gis-web.r1.epa.gov:9876/ora/green/EMS.htm and describe techniques that are in place to reduce the facility's impact on the environment. The *EPA New England Boston Office Environmental Management System Manual* is posted at http://r1-gis-web.r1.epa.gov:9876/ora/green/EMS%20manual.pdf

9.0 ASSESSMENT AND RESPONSE

This Section documents how EPA New England will 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. Assessments are a learning process intended to increase understanding of the program or system being assessed, and to provide a basis for improving such programs or systems. 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.*

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 our *Assessment Program* document. Specific

procedures are detailed in the QA Unit standard operating procedures for quality system assessments and technical systems audits, which are contained in Attachment A of the *Assessment Program.*

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 identification of necessary changes or improvements on an Office-wide basis. The meetings will review and take into account the following items:

- Suitability of policies and procedures
- Reports from managerial and supervisory personnel
- Outcome of recent internal audits
- Corrective actions and preventative programs
- Independent external assessments
- Results of inter-laboratory comparisons or proficiency test
- Changes in the volume or type of work
- Customer feedback
- Complaints
- Other relevant factors, such as quality control activities, resources and staff training

The result of this annual review will be documented in the Office Director's files. Any corrective actions identified by this review will be 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, Vermont – evaluation performed by Region under Agency's laboratory certification program every three years

b. Maine, New Hampshire – assessment performed under NELAC Standards by NH Environmental Laboratory Accreditation Program with on-site support from Regional Office every two years

9.2.2.4 Environmental Agencies/Organizations

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

b. New England Interstate Organizations – quality system assessments conducted every three 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 Assessment Tracking System, ATRACK, which 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 NERL-CI 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 assessments under NELAC are required to have the appropriate NELAC training (accreditation authority evaluator or laboratory assessor).

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 EPA Order 5360.1 A2. Assessment authority is confirmed in the planning stage for each assessment. For quality system assessments performed by the QA Unit, the RQAM obtains concurrence of the senior management of the organization being assessed. The purpose, scope and time frame for the assessment are documented in an assessment plan. 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, and states the findings and recommendations for response

actions. Without documentation in a final report, a review or evaluation 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 1.3.11 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*. 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.
- Assessment file containing the response from the assessed organization, relevant communications and the documentation listed above.

The Regional assessment activities are tracked in ATRACK, a tracking system 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 Receipt Date
7) Assessment Team Members
8) Date Assessed (On-Site Visit)
9) Final Report Date
10) Corrective Action Recommendation
11) Corrective Action Completion Date (Documentation Received)
12) 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*** 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
- Senior Managers

10.0 QUALITY IMPROVEMENT

This Section documents how EPA New England will continuously evaluate and improve its quality system. The Region's senior management is fully committed to quality improvement as a continuing process by which the organization actively seeks opportunities to improve the overall quality system. Quality improvement looks to correct systemic problems, improve consistency, enhance individual system components, re-engineer ineffective work processes and procedures, and customize quality tools. Quality improvement is incorporated as a core organizational element of the Region's quality culture and philosophy. 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.

As a critical component of the Regional quality system, quality improvement provides an effective baseline for current and future Regional involvement in environmental data operations and environmental technology activities.

10.1 Annual Reporting

Under EPA Order 5360.1 A2, 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 the Region management. Based upon this report, senior management prioritizes workloads and allocates resources, as necessary, to address quality needs.

Specific reporting requirements pertaining to other quality-related programs including Peer Review, Information Quality Guidelines-Pre-dissemination Review, Environmental Management System, and Human Subjects Research are detailed in their respective implementation plans. Intranet and Internet links are provided for these program plans in Chapter 2.

10.2 Organizational Improvement Based on Assessments

As discussed in Sections 8 and 9, the RQAM will use both external and internal assessment findings to initiate quality improvement. The RQAM will identify root causes of deficiencies; make recommendations for improvement; work with Regional management and staff to implement corrective actions; and subsequently evaluate the effectiveness of corrective actions in an overall effort to improve quality.

10.2.1 External Quality System Assessments

The Quality Staff of the OEI is responsible for conducting an assessment of the Regional 5360.1 A2 data quality system every three years. In addition, national program offices may perform assessments of Regional programs including HSR, IQG-PDR, EMS and Peer Review. These assessments serve to periodically evaluate the effectiveness of the quality system and quality-related procedures for Regional environmental programs, to help ensure consistency across the ten regions, and to identify areas of needed improvement.

The results of Regional 5360.1 A2 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 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.

- 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 standard operating 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. Five years from the date of approval of this QMP, 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/ne/lab/qa/qualsys.html. Quality system components and tools, including guidance documents and standard operating procedures, will also be posted on Regional Inter and Intranet sites.

Appendix 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: May 4, 2005

SUBJ.: EPA New England's Commitment to Implementing the Regional Quality System

FROM: Robert W. Varney, Regional Administrator
Ira W. Leighton, Deputy Regional Administrator

TO: EPA New England Employees

The success of our regional mission to protect human health and the environment depends upon the consistent application of sound science and the collection of credible data of the type and quality necessary to make critical program decisions. In support of this mission, we are reaffirming EPA New England's commitment to:

1. Consistent and complete implementation of the regional quality system across all regional programs, as documented in the approved *EPA New England Quality Management Plan.*
2. Conformance with Agency quality policies as defined by EPA Order 5360.1 A2.
3. Compliance with federal extramural agreement regulations pertaining to quality.
4. Region-wide quality system (QS) awareness training.

Scheduled Regional Quality System Assessment and Required QS Awareness Training

EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System,* directs all Agency organizations to develop and implement a quality system that conforms to the requirements in the Order and in applicable extramural agreement regulations.

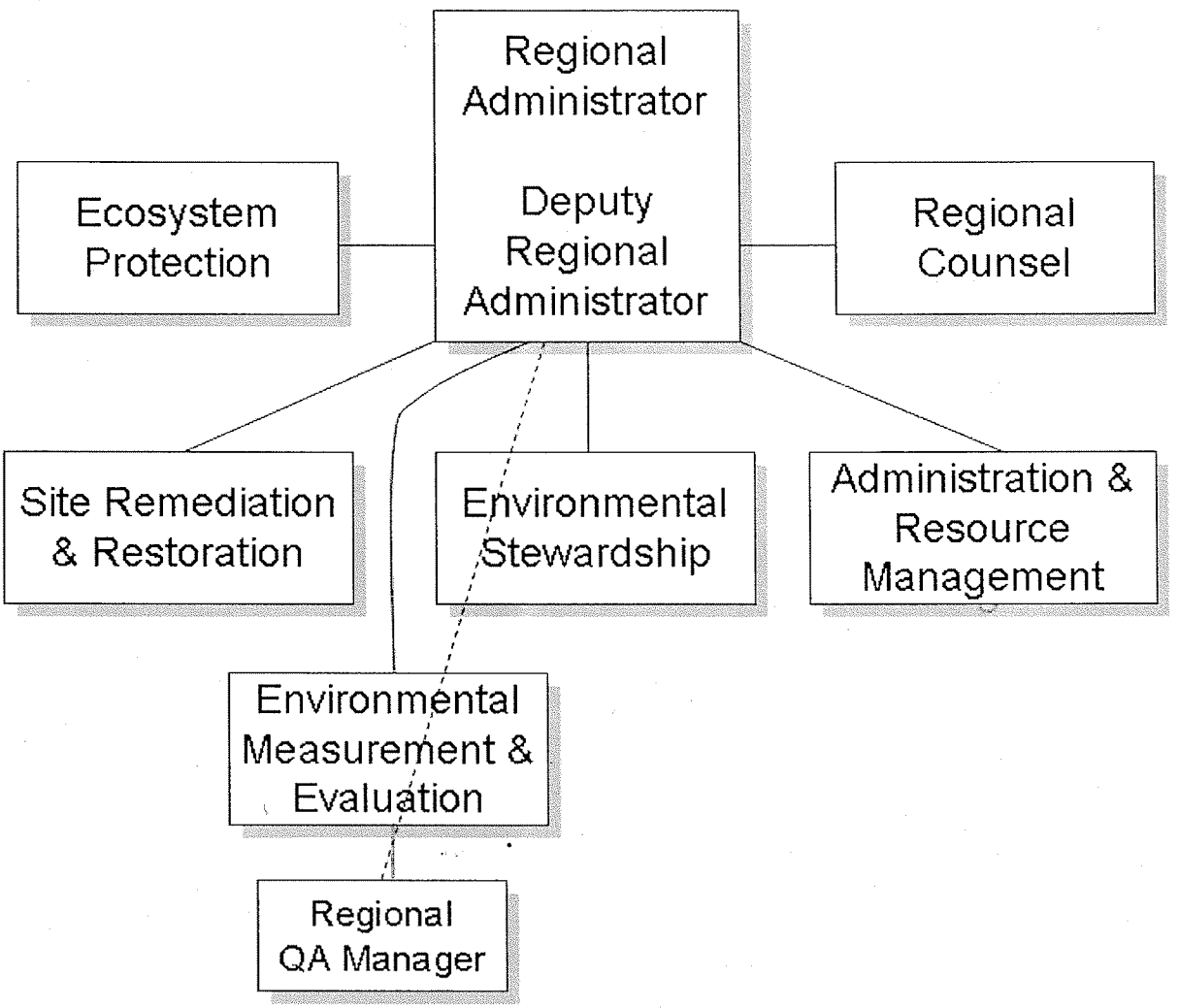
As part of the Agency's overall quality system, Quality Staff from the Office of Environmental Information conduct periodic assessments of all Agency organizations that collect, generate, and use environmental data, or design, construct, and operate environmental technology. An assessment of our region's quality system is scheduled for June 6 to June 10, 2005.

To ensure effective implementation and awareness of our quality system, QA representatives from each Office have developed a Web-based training course. We are asking all regional personnel to take this "Quality System Awareness Training" to ensure consistent regional knowledge and application of system processes. Details for the training will be provided in an upcoming e-mail.

If you would like further information on the regional quality system, you can access the EPA New England QA home page at http://epa.gov/ne/lab/qa/index.html or contact any member of QA Unit.

Appendix 2

EPA New England



Appendix 3a

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND REGION

MEMORANDUM

DATE: March 14, 2007

SUBJ: Quality Assurance Requirements for OSRR Contract Actions

FROM: Gerry Sotolongo, Regional Quality Assurance Manager /s/

TO: OSRR Project Officers for Contracts and Contracting Officer Representatives

This memorandum outlines the EPA New England procedures related to Quality Assurance requirements for contract actions including those done via Simplified Acquisition Procedures or orders against GSA Schedule contracts, and your responsibilities to implement these procedures.

The EPA Contracts Management Manual (CMM), Chapter 46, requires that all requests to contracting officers for placement of: 1) a new contract or a modification to a contract (including those using simplified acquisition procedures (SAPs)); 2) an order (task order, work assignment, delivery order) under an existing contract or a modification to an existing task order, work assignment, or delivery order which involves a significant change to the Statement of Work (SOW) or Performance Work Statement (PWS); or 3) non-regional contract actions, include a Quality Assurance (QA) Review Form (QARF), completed by the project officer or other authorized contracting officer representative (COR). The QARF documents that a review has been conducted to assure that appropriate QA requirements are met for products or services ordered.

Examples of environmental data collection/information activities can be found at the following URL: http://www.epa.gov/quality/examples/html or see Attachment A.

For assistance, contact Vicki Maynard of the Quality Assurance Unit at 8-8614.

1. New Contracts, or Modifications to a Contract

The CMM QA Review Form (QARF) must be initiated by the COR prior to forwarding a request for placement of a new contract. An electronic copy of the QARF (CMM Appendix 46.1D) is located at the following URL: http://epawww.epa.gov/oamintra/policy/cmm.pdf, and provided as Attachment B.

- If "Yes" is the response on the QA Review Form for any of the situations specified in Section II. Scope of Work, question "a.", all sections of the form must be completed. A copy of the completed form must be provided to the Region 1 QA Manager for signature, and the signed form must be included with the procurement package.

- If "No" is the response to all questions in "a." under Section II. Scope of Work, the COR should skip Section III, sign the form in Section IV, and send a copy to the Region 1 QA Manager for signature and include the signed form with the procurement package.
- For new contracts done via simplified acquisition procedures or orders against GSA Schedule contracts, for which the response is "No", the COR may use Attachment C in lieu of the CMM QARF. The COR must provide a copy of the completed Attachment C, "Region 1 Alternate Form to the CMM QARF, When QA Is Not Required," to the Region 1 QA Manager.

For modifications to existing contracts done via simplified acquisition procedures or orders against GSA Schedule contracts, the COR must use the CMM QARF unless the response is "No", in which case the COR must use Attachment C and submit a copy to the Region 1 QA Manager.

2. Ordering/Modifying an Order Under Existing Regional Contracts (with significant change to the Statement of Work (SOW) or Performance Work Statement (PWS))

When ordering services under an existing contract by task order, work assignment or delivery order, the COR must complete and sign the Region 1 QA Review Form for OSRR (Attachment D). This form must be completed, signed by the COR, signed by the COR's Section Chief and the original sent to the PO with a copy to the Region 1 QA Manager.

When modifying a task order, work assignment, or delivery order, under an existing regional contract with a significant change to the Statement of Work (SOW) or Performance Work Statement (PWS), the COR must complete the Region 1 QARF for OSRR (Attachment D). This form must be completed, signed by the COR, signed by the COR's Section Chief and the original sent to the PO with a copy to the Region 1 QA Manager.

3. Non-Regional Contract Actions

You should be aware that if work is obtained through a Headquarters contract or another Region's contract, QA requirements still apply. In such cases, you should contact the appropriate Headquarters or other Region's contracting officer or COR to identify their established QA requirements under that contract. Additionally, the Region 1 QA Review Form for OSRR must be completed.

- Complete Sections I-IV if the answer to Section II: Work Information, question 1. is "Yes." The COR and the COR's Section Chief must sign the form and provide a copy to the Region 1 QA Manager.
- Complete Sections I, II and IV if the answer to question 1 is "No." The COR and the COR's Section Chief must sign the form and submit a copy to the Region 1 QA Manager.

Headquarters or another Regional office should be contacted to ensure that appropriate overall contract quality assurance requirements have been established. It is recommended to obtain a summary of the QA requirements for the site file and provide a copy to the Region 1 QA Manager.

Attachment A - Example Activities
Attachment B- U.S. EPA Quality Assurance Review Form for Contract Actions
Attachment C - Region 1 Alternate Form to CMM QARF When QA Is Not Required
Attachment D - Region 1 Quality Assurance Review Form - OSRR

cc: Supervisors
Regional Contracting Officers
Program Analysts
Sharlene Begley, Manager, Contracts & Procuremen

Attachment A

Example Activities

Environmental data are any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include both primary data (i.e., information collected directly from measurements) and secondary/existing data (i.e., data that were collected for other purposes or obtained from other sources, including literature, industry surveys, models, data bases, and information systems). Example activities covered by the EPA Quality System that involve environmental data include, but are not limited to:

- Characterize and/or evaluate the states and/or conditions of environmental or ecological systems and the health of human populations;

- Characterize and/or evaluate chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;

- Establish the ambient conditions in air, water, sediments, soil, etc. in terms of physical, chemical, radiological, or biological characteristics;

- Determine and/or categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;

- Quantify and/or monitor the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);

- Develop and/or evaluate environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control and the use of the technology to generate and/or collect data (e.g., treatability and pilot studies);

- Map environmental processes and conditions, and/or human health risk data, etc. (e.g., geographic information system);

- Support enforcement and/or compliance monitoring efforts;

- Develop or evaluate methods for use in the collection, analysis, and use of environmental data;

- Develop and/or evaluate models of environmental processes and conditions and use models to characterize environmental processes or conditions;

- Develop, revise, or use information technology and management system operations that impact the quality of the results of environmental programs (e.g., electronic databases with environmental information including data entry, handling, transmission and analysis and laboratory information management systems); and

- Monitor or address concerns over the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

Attachment B

APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM FOR CONTRACT ACTIONS

I. General Information

a. Vehicle Type:

[ ] Solicitation/Sole Source (RFP #: _____)

[ ] Delivery Order/Work Assignment /Task Order
(SOW #: _____ and Contract #: _____)

b. Descriptive Title: _____
_____

c. Sponsoring Organization *(e.g., Branch, Division, Office, etc.)*: _____

d. Project Duration: _____

e. Is this a new [ ] or continuation of an existing [ ] project?

II. Scope of Work

[For example activities, see www.epa.gov/quality/examples.html]

a. Does the work involve:	Yes	No
• the collection, generation, use and/or reporting of environmental data? (Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)	[ ]	[ ]
• design, construction, and/or operation of environmental technologies?	[ ]	[ ]
• development and/or use of models?	[ ]	[ ]
• other activities that need quality assurance or quality control requirements as identified in your organization's Quality Management Plan? If yes, list: _____	[ ]	[ ]

If all answers are No, skip Section III and complete Section IV.

b. Estimate of percentage of costs or level-of-effort allocated to the activities identified above: _____%.

III. Quality-Related Requirements

[Where applicable, reference a specific section of the Statement of Work.]

a. **For Solicitations Only** *[complete (b) - (f) below, as well]*

1. Insert the percentage of technical evaluation points assigned to offeror's quality system documentation, or P/F if the evaluation is pass/fail: _____

2. List any quality standards (from your organization's Quality Management Plan) that you will use in lieu of, or in addition to, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4)*. These standards are

Title: _____
Numbering: _____
Date: _____
Requirements (Tailoring): _____
_____

b. **QA Documentation Options:** *[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in your organization's Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For items checked under #2, there must be adequate information in the SOW for the offeror to develop this documentation.]*

Before Award Documentation[1]

1. ___ Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____
___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other: _____

2. ___ Programmatic QA Project Plan: Either developed in accordance with R5 or ☐ Other: _____

[1]QMP refers to a Quality Management Plan. Programmatic QA Project Plan refers to a QA Project Plan that would cover multiple projects with similar activities. R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01) - copies of these documents are available at www.epa.gov/quality.

___ Application of QA and QC activities to the single project covered by contract: Either ☐ QA Project Plan developed in accordance with R-5 or ☐ Other: _____

___ Not applicable.

After Award Documentation[1]

3. ___ Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____

___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other: _____

___ Not applicable.

4. ___ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with ☐ R-5; ☐ A supplement to the following Programmatic QA Project Plan _____; or ☐ Other: _____

___ Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with: _____

___ Existing documentation of the application of QA and QC activities will be used: Either ☐ Documentation developed pre-award; ☐ Documentation will be identified in individual Statements of Work or ☐ Documentation identified in Section _____ of the Statement of Work.

c. **Reports**: Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? [ ] Yes [ ] No

If yes, identify the required reports and the time frame for submission: _____

d. **Assessments**: Select all quality assessments that will be performed either pre-award or post-award:

	Pre-Award	Post-Award
On-site evaluation of offeror's/contractor's facility		
Assessments of the offeror's/contractor's Quality System (e.g., quality system audits, management system reviews, etc.)		

Project-specific assessments (e.g., technical systems audits, surveillance, performance evaluations, data quality assessments, peer reviews, readiness reviews)		

For each assessment, specify type, date to perform, and who will perform it (if known):

_____

e. **Procedures to Update Documentation:** Identify any procedures/requirements for updating EPA-approved quality-related documentation: _____

_____

f. **Other Requirements:** Identify any other pertinent quality-related requirements (as identified in your organization's Quality Management Plan): _____

_____

IV. **The signatures below verify that the Statement of Work has been reviewed to ascertain if quality assurance or quality control activities are needed and that the appropriate quality requirements have been established.**

Contracting Officer's Representative	**Date**	**Quality Assurance Manager**	**Date**

Attachment C
Region 1 Alternate Form to CMM QARF
When QA Is Not Required

Please include the following question with response. Attach it to the Procurement Request/Order,EPA Form 1900-B and send a copy of this Form and PR to the Regional QA Manager:

Does this PR require activities that involve environmentally related measurements?
(Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)

NO____ **YES** _____ *(if Yes, you must complete and attach the* U.S. EPA Quality Assurance Review Form for Contract Actions)

_____ _____
Project Officer Signature Date

Attachment D

REGION I QUALITY ASSURANCE REVIEW FORM - OSRR
For Work Assignments and Task Orders

SECTION I: GENERAL INFORMATION

COR	Name	Telephone	Mail Code
Contract	Name	Contractor	Number
WA/TO	Name	Number	Amendment Number

SECTION II: WORK INFORMATION

1. Does the Work involve the collection, use, and/or reporting of environmental data? *(Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)*	Yes	No
2. Does the Work involve other activities (i.e. modeling, surveys) that need quality assurance or quality control requirements?	Yes	No
3. If the answer to 2 is "Yes," then list these activities here:		

NOTE: If all answers to these questions are "No," then only complete Section IV below.

SECTION III: QUALITY-RELATED REQUIREMENTS

1. For the work requiring quality assurance or quality control, will the contractor **prepare** a QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
2. For the work requiring quality assurance or quality control, will the contractor **revise** a QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
3. For the work requiring quality assurance or quality control, will the contractor **utilize an already approved** QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
4. If any answer to 2 and/or 3 is "Yes," then provide the following information and attach a copy:	QAPP Title	QAPP Approval Date	QAPP Approving Official	
5. Are WA/TO-specific assessments (e.g., field audits, laboratory audits, data quality assessments) currently planned?			Yes	No
6. If the answer to 5 is "Yes," then provide the following information:	Type of quality assessment	Anticipated date of assessment	Name of person(s) to perform assessment	

SECTION IV: VERIFICATION OF REVIEW

The signatures below verify (1) that the Work has been reviewed to ascertain if quality assurance or quality control activities are needed; (2) that a determination of the QA requirements has been made, and (3) that the QA requirements have been established and agreed to as specified in Section III above.	
COR	Date
COR Section Chief	Date

Original to Project Officer
Copy to QA Manager/OEME
QARF- OSRR 3/05

Appendix 3b

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND REGION

MEMORANDUM

DATE: March 14, 2007

SUBJ: Quality Assurance Requirements for Non-OSRR Contract Actions

FROM: Gerry Sotolongo, Regional Quality Assurance Manager /s/

TO: Non-OSRR Project Officers for Contracts and Contracting Officer Representatives

This memorandum outlines the EPA New England procedures related to Quality Assurance requirements for contract actions including those done via Simplified Acquisition Procedures or orders against GSA Schedule contracts, and your responsibilities to implement these procedures.

The EPA Contracts Management Manual (CMM), Chapter 46, requires that all requests to contracting officers for placement of: 1) a new contract or modifications to a contract (including those using simplified acquisition procedures (SAPs); 2) an order (task order, work assignment, delivery order) under an existing contract or a modification to an existing task order, work assignment, or delivery order which involves a significant change to the Statement of Work (SOW) or Performance Work Statement (PWS); or 3) non-regional contract actions, include a Quality Assurance (QA) Review Form (QARF), completed by the project officer or other authorized contracting officer representative (COR). The QARF documents that a review has been conducted to assure that appropriate QA requirements are met for products or services ordered.

Examples of environmental data collection/information activities can be found at the following URL: http://www.epa.gov/quality/examples/html or see Attachment A.

For assistance, contact Vicki Maynard of the Quality Assurance Unit at 8-8614.

1. New Contracts, or Modifications to a Contract

The CMM QA Review Form (QARF) must be initiated by the COR prior to forwarding a request for placement of a new contract or procurement. An electronic copy of the QARF (CMM Appendix 46.1D) is located at the following URL: http://epa.gov/oamintra/policy/cmm.pdf, and provided as Attachment B.

- If "Yes" is the response on the QA Review Form for any of the situations specified in Section II. Scope of Work, question "a.", all sections of the form must be completed. A copy of the completed form must be provided to the Region 1 QA Manager for signature and the signed form must be included with the procurement package.

- If "No" is the response to all questions under Section II. Scope of Work, question "a.", the COR should skip Section III, sign the form in Section IV and send it to the Region 1 QA Manager for signature and include the signed form with the procurement package.
- For new contracts done via simplified acquisition procedures or orders against GSA Schedule contracts for which the response is "No", the COR may use Attachment C in lieu of the CMM QARF. The COR must provide a copy of the completed Attachment C, "Region 1 Alternate Form to the CMM QARF, When QA Is Not Required," to the Region 1 QA Manager.

For modifications to existing contracts done via simplified acquisition procedures or orders against GSA Schedule contracts, the COR must use the CMM QARF unless the response is "No", in which case the COR must use Attachment C and submit a copy to the Region 1 QA Manager.

2. Ordering/Modifying an Order Under Existing Regional Contracts (with significant change to the Statement of Work (SOW) or Performance Work Statement (PWS))

When ordering services under an existing contract by task order, work assignment, or delivery order, the COR must complete and sign the Region 1 QA Review Form for Non-OSRR (Attachment D) and send it to the Region 1 QA Manager for signature. The signed form must be included with the ordering request documentation.

When modifying a task order, work assignment, or delivery order, under an existing regional contract with a significant change to the Statement of Work (SOW) or Performance Work Statement (PWS), the COR must complete a Region 1 QARF, (Attachment D). Once it is complete, the COT must submit the form to the Region 1 QA Manager for signature. The signed form must be included with the ordering request documentation.

3. Non-Regional Contract Actions

You should be aware that if work is obtained through a Headquarters contract or another Region's contract, QA requirements still apply. In such cases, you should contact the appropriate Headquarters or other Region's contracting officer or COR to identify their established QA requirements under that contract. Additionally, the Region 1 QA Review Form for non-OSRR must be completed.

- Complete Sections I-IV if the answer to Section II: Work Information, question 1. is "Yes." The COR must sign the form and submit the form to the Region 1 QA Manager for signature.
- Complete Sections I, II and IV if the answer to question 1 is "No." The COR must sign the form and submit the form to the Region 1 QA Manager for signature.

Headquarters or another Regional office should be contacted to ensure that appropriate overall contract quality assurance requirements have been established. It is recommended to obtain a summary of the QA requirements for the site file and provide a copy to the Region 1 QA Manager.

Attachment A – Example Activities
Attachment B – U.S. EPA Quality Assurance Review Form for Contract Actions
Attachment C – Region 1 Alternate Form to CMM QARF When QA Is Not Required
Attachment D - Region 1 Quality Assurance Review Form - Non-OSRR

cc: Supervisors
Regional Contracting Officers
Program Analysts
Sharlene Begley, Chief, Contracts & Procurement

Attachment A

Example Activities

Environmental data are any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include both primary data (i.e., information collected directly from measurements) and secondary/existing data (i.e., data that were collected for other purposes or obtained from other sources, including literature, industry surveys, models, data bases, and information systems). Example activities covered by the EPA Quality System that involve environmental data include, but are not limited to:

- Characterize and/or evaluate the states and/or conditions of environmental or ecological systems and the health of human populations;

- Characterize and/or evaluate chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;

- Establish the ambient conditions in air, water, sediments, soil, etc. in terms of physical, chemical, radiological, or biological characteristics;

- Determine and/or categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;

- Quantify and/or monitor the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);

- Develop and/or evaluate environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control and the use of the technology to generate and/or collect data (e.g., treatability and pilot studies);

- Map environmental processes and conditions, and/or human health risk data, etc. (e.g., geographic information system);

- Support enforcement and/or compliance monitoring efforts;

- Develop or evaluate methods for use in the collection, analysis, and use of environmental data;

- Develop and/or evaluate models of environmental processes and conditions and use models to characterize environmental processes or conditions;

- Develop, revise, or use information technology and management system operations that impact the quality of the results of environmental programs (e.g., electronic databases with environmental information including data entry, handling, transmission and analysis and laboratory information management systems); and

- Monitor or address concerns over the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

Attachment B

APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM FOR CONTRACT ACTIONS

I. General Information

a. Vehicle Type:

[ ] Solicitation/Sole Source (RFP #: _____)

[ ] Delivery Order/Work Assignment /Task Order
(SOW #: _____ and Contract #: _____)

b. Descriptive Title: _____
_____

c. Sponsoring Organization *(e.g., Branch, Division, Office, etc.)*: _____

d. Project Duration: _____

e. Is this a new [ ] or continuation of an existing [ ] project?

II. Scope of Work

[For example activities, see www.epa.gov/quality/examples.html.]

a. Does the work involve:	Yes	No
• the collection, generation, use and/or reporting of environmental data? (Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)	[ ]	[ ]
• design, construction, and/or operation of environmental technologies?	[ ]	[ ]
• development and/or use of models?	[ ]	[ ]
• other activities that need quality assurance or quality control requirements as identified in your organization's Quality Management Plan? If yes, list: _____	[ ]	[ ]

If all answers are No, skip Section III and complete Section IV.

b. Estimate of percentage of costs or level-of-effort allocated to the activities identified above: _____%.

III. **Quality-Related Requirements**

[Where applicable, reference a specific section of the Statement of Work.]

a. **For Solicitations Only** *[complete (b) - (f) below, as well]*

1. Insert the percentage of technical evaluation points assigned to offeror's quality system documentation, or P/F if the evaluation is pass/fail: _____

2. List any quality standards (from your organization's Quality Management Plan) that you will use in lieu of, or in addition to, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4)*. These standards are

Title: _____
Numbering: _____
Date: _____
Requirements (Tailoring): _____
_____

b. **QA Documentation Options:** *[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in your organization's Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For items checked under #2, there must be adequate information in the SOW for the offeror to develop this documentation.]*

Before Award Documentation[1]

1. ___ Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____
___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other:
_____

2. ___ Programmatic QA Project Plan: Either developed in accordance with R5 or ☐ Other:
_____

[1]QMP refers to a Quality Management Plan. Programmatic QA Project Plan refers to a QA Project Plan that would cover multiple projects with similar activities. R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01) - copies of these documents are available at www.epa.gov/quality.

___ Application of QA and QC activities to the single project covered by contract: Either ☐ QA Project Plan developed in accordance with R-5 or ☐ Other: _____

___ Not applicable.

After Award Documentation[1]

3. ___ Documentation of an organization's Quality System: Either ☐ QMP developed in accordance with R-2 or ☐ Other: _____

___ Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Either developed in accordance with ☐ R-2 and R-5 or ☐ Other: _____

___ Not applicable.

4. ___ Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with ☐ R-5; ☐ A supplement to the following Programmatic QA Project Plan _____; or ☐ Other: _____

___ Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with: _____

___ Existing documentation of the application of QA and QC activities will be used: Either ☐ Documentation developed pre-award; ☐ Documentation will be identified in individual Statements of Work or ☐ Documentation identified in Section ____ of the Statement of Work.

c. **Reports:** Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? [ ] **Yes** [ ] **No**

If yes, identify the required reports and the time frame for submission: _____

d. **Assessments:** Select all quality assessments that will be performed either pre-award or post-award:

	Pre-Award	Post-Award
On-site evaluation of offeror's/contractor's facility		
Assessments of the offeror's/contractor's Quality System (e.g., quality system audits, management system reviews, etc.)		

Project-specific assessments (e.g., technical systems audits, surveillance, performance evaluations, data quality assessments, peer reviews, readiness reviews)		

For each assessment, specify type, date to perform, and who will perform it (if known):
_____

e. **Procedures to Update Documentation:** Identify any procedures/requirements for updating EPA-approved quality-related documentation: _____
_____

f. **Other Requirements:** Identify any other pertinent quality-related requirements (as identified in your organization's Quality Management Plan): _____
_____

IV. **The signatures below verify that the Statement of Work has been reviewed to ascertain if quality assurance or quality control activities are needed and that the appropriate quality requirements have been established.**

_____ _____
Contracting Officer's Representative Date **Quality Assurance Manager Date**

Attachment C

Region 1 Alternate Form to CMM QARF
When QA Is Not Required

Please include the following question with response. Attach it to the Procurement Request/Order,EPA Form 1900-B and send a copy of this Form and PR to the Regional QA Manager:

Does this PR require activities that involve environmentally related measurements?
(Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)

NO____ YES _____ ***(if Yes, you must complete and attach the*** U.S. EPA Quality Assurance Review Form for Contract Actions)

_____ _____

Project Officer Signature Date

Attachment D

REGION I QUALITY ASSURANCE REVIEW FORM - Non-OSRR Work Assignments and Task Orders				
SECTION I: GENERAL INFORMATION				
COR	Name	Telephone	Mail Code	
Contract	Name	Contractor	Number	
WA/TO	Name	Number	Amendment Number	
SECTION II: WORK INFORMATION				
1. Does the Work involve the collection, use, and/or reporting of environmental data? *(Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.)*			Yes	No
2. Does the Work involve other activities (i.e. modeling, surveys) that need quality assurance or quality control requirements?			Yes	No
3. If the answer to 2 is "Yes," then list these activities here:				
NOTE: If all answers to these questions are "No," then only complete Section IV below.				
SECTION III: QUALITY-RELATED REQUIREMENTS				
1. For the work requiring quality assurance or quality control, will the contractor **prepare** a QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
2. For the work requiring quality assurance or quality control, will the contractor **revise** a QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
3. For the work requiring quality assurance or quality control, will the contractor **utilize an already approved** QA Project Plan (QAPP) or other equivalent project specific documentation?			Yes	No
4. If any answer to 2 and/or 3 is "Yes," then provide the following information and attach a copy:	QAPP Title	QAPP Approval Date	QAPP Approving Official	
5. Are WA/TO-specific assessments (e.g., field audits, laboratory audits, data quality assessments) currently planned?			Yes	No

6. If the answer to 5 is "Yes," then provide the following information:	Type of quality assessment	Anticipated date of assessment	Name of person(s) to perform assessment

SECTION IV: VERIFICATION OF REVIEW	
The signatures below verify (1) that the Work has been reviewed to ascertain if quality assurance or quality control activities are needed; (2) that a determination of the QA requirements has been made, and (3) that the QA requirements have been established and agreed to as specified in Section III above.	
COR	Date
Quality Assurance Manager	Date

Original to Project Officer
Copy to QA Manager/OEME
QARF(non-OSRR) 3/05

Appendix 4

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: January 25, 2001

SUBJ.: Revised Quality Assurance Requirements for Grants

FROM: Ira Leighton, Acting Regional Administrator

TO: Project Officers and Supervisors

A new grants process for the region is being implemented to insure that the region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent The EPA NE Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team.

The long-term process is currently being rolled out and includes 1) the development of training programs, 2) the delivery of training to insure that everybody knows their roles and has the technical knowledge to implement their responsibilities, and 3) a tracking system to document compliance with these requirements. A more detailed memo is being drafted and will be sent to the project officers shortly outlining their specific duties and responsibilities.

The project officers should continue to use the request for award memo to identify when QA is required. A set of standard grant conditions has been developed that the project officers, in consultation with the grants specialist, should utilize for all awards where quality assurance plans are required. Each office will have a QA representative, who, together with the Quality Assurance Office, will be available to provide advice and assistance to the project officer and the grants specialist in making the QA determination.

I would like to thank you in advance for your cooperation in implementing these procedures and in creating a culture that supports "continual quality improvement" within the region.

If you would like further information on the Agency's quality system or need help in implementing this process, please contact Carol Wood at (781) 860-4316 or 8-4316. You can access fact sheets for frequently asked questions at www.epa.gov/quality1/qual_sys.html

cc: Carol Wood, Acting RQAM
Office Directors and Deputy Office Directors

Appendix 5

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

Memorandum

Date: February 20, 2001
Subject: Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements
From: Carol Wood, Quality Assurance Manager (QAM) and Pam Ringhoff, Grants Manager
To: Project Officers

The purpose of this memo is to explain new requirements for Project Officers' (PO) in implementing the new Quality Assurance (QA) policies and procedures for all financial assistance agreements (See Ira Leighton's memo of January 25, 2001, Attachment 1). An outline of the recently developed long-term Region 1 Grant QA Process is also attached (Attachment 2) for your reference. Training and technical support from the Office QA contacts (listed herein) and the QA Office will be available to assist PO's in implementing these new requirements.

The following are the key steps PO's are responsible for in order to insure compliance with these procedures.

Step 1 – Project Officer determines if a Quality Assurance Project Plan (QAPP) is needed. A "yes" or "no" decision must be made and then indicated on the "Assistance Agreement Request for Award/Action" memo. Your Office QA contact listed below must concur on all "no" decisions. The QA Office is also available for consultation and assistance as you make this decision.

ORA – Kristen Conroy
OES – Gerry Sotolongo
OSRR – Stan Chin
OEP - Robert Goetzl, Tony DePalma, Paul Bryan
OEME – Carol Wood
OARM – Pam Ringhoff

Note: EPA Order 5360.1 (May 2000, http://www.epa.gov/quality/qa_docs.html) outlines the Quality Assurance requirements for the agency and is applicable to the collection, evaluation, and use of environmental data by or for EPA and the design, construction, and operation of environmental technology by EPA. A more detail discussion and training on what is included by this order will be given at a upcoming QA Awareness training within the next several months.

Step 2 – The Grants Specialist, based on the PO's QA determination listed on the Assistance Agreement Request for Award/Action, will incorporate the appropriate special grant condition(s) into the grant award. The special grant conditions are attached (Attachment 3). Although these conditions should address the majority of grants, a case by case review should be done by the

Project Officer to insure that they are applicable to the specific grant. Any modifications to the special grant condition language must be reviewed and approved by the QAM.

Step 3 – Once the grant is awarded, the PO should work proactively with the grantee to insure that the QAPP is developed, completed and submitted to the QA Office for review and approval. The QA Office is available to help the PO discuss QA requirements with the grantee during development of the plan. In particular, for complex monitoring projects, a scoping meeting between the grantee, PO and QA representative is strongly recommended. Since the QAPP must be approved prior to the initiation of any monitoring activities, the QAPP must be submitted at least 30 days prior to the projected sampling date. Otherwise, work may be delayed pending the review and approval of the QAPP.

Additional Future Requirements

The Grants Quality Assurance Workgroup is in the process of developing additional items necessary to fully implement the attached long-term process. These items include the development of a system to track the grants QA requirements region wide and the development of a pre-application insert for the grants kits.

Your QA responsibilities as Project Officers will be discussed in more detail during the upcoming QA Awareness and QA Project Plan Program training courses. We welcome your comments and suggestions on this process and request that you send any specific questions that you would like to see addressed at the training course to Carol Wood. You may also direct any questions to your Office QA contact.

cc: Grants Specialist

Attachment 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM
DATE: January 25, 2001
SUBJ.: Revised Quality Assurance Requirements for Grants
FROM: Ira Leighton, Acting Regional Administrator
TO: Project Officers and Supervisors

A new grants process for the region is being implemented to insure that the region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA New England Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team.

The long-term process is currently being rolled out and includes 1) the development of training programs, 2) the delivery of training to insure that everybody knows their roles and has the technical knowledge to implement their responsibilities, and 3) a tracking system to document compliance with these requirements. A more detailed memo is being drafted and will be sent to the project officers shortly outlining their specific duties and responsibilities.

The project officers should continue to use the request for award memo to identify when QA is required. A set of standard grant conditions has been developed that the project officers, in consultation with the grants specialist, should utilize for all awards where quality assurance plans are required. Each office will have a QA representative, who, together with the Quality Assurance Office, will be available to provide advice and assistance to the project officer and the grants specialist in making the QA determination.

I would like to thank you in advance for your cooperation in implementing these procedures and in creating a culture that supports "continual quality improvement" within the region.

If you would like further information on the Agency's quality system or need help in implementing this process, please contact Carol Wood at (781) 860-4316 or 8-4316. You can access fact sheets for frequently asked questions at www.epa.gov/quality1/qual_sys.html

cc: Carol Wood, Acting RQAM
Office Directors and Deputy Office Directors

Attachment 2

Region 1 Long Term Grant QA Process - 2/12/01

QAPP Requirement Determination

- Project Officer (PO) determines if a QAPP is needed.
  - If yes, indicate requirement on the Assistance Agreement Request for Award/Action.
  - If no, obtain concurrence of Office QA contact.
- QA Office is available for consultation for above determination.
  - QA Office will review a random sample of approximately 10% of the negative determinations and report the findings to management.
  - The QAPP requirement is documented on the funding recommendation form. The Project Officer will determine the appropriate special grant condition(s) and the Grants Specialist will incorporate into the grant award.

QAPP Preparation

- The PO will be proactive and provide on-going information and support to grantee(s) with assistance from QA Office.
- The PO will work with the grantee to understand the project and inform the grantee of QA requirements. The QAPP requirements will be commensurate with the complexity and intended use of the data.
- The Grants Office, based on the PO's QA determination listed on the Assistance Agreement Request for Award/Action, will send a post-award kit to the grantee that describes QAPP requirements and includes key EPA QA contacts (PO and QA Unit).
- For large or significant grants it is encouraged to hold a scoping meeting or conference call to: determine data quality objectives, QA requirements to meet objectives, and content of QAPP. The PO determines if this is necessary and will coordinate the effort. Participants will include grantee, the PO, QA Office staff, and other participants identified by the PO or QA Office.

QAPP Approval

- Compliance with QAPP requirements is a shared responsibility between the PO and QA Office.
- PO has the lead to ensure QAPPs are submitted. The PO or designee can be delegated the completeness (Level 1) review responsibility as appropriate after QA training.
- QA Office conducts the technical (Level 2) review and approves the QAPP with the PO concurrence.

QA Tracking

- A QA tracking system will be developed to track and allow monitoring of requirements.
- Data maintenance will be a shared responsibility between Grants, the PO, and QA Office.

Note: If a QAPP is required and the grant is a continuing program grant, a Quality Assurance Management Plan (QMP) is also required. The QA Office will be responsible for approval of the QMP. The long-term strategy is to delegate QAPP approval to the states based on an approved QMP and documentation of capacity and capability to carry out this responsibility.

Attachment 3
Quality Assurance Grant Conditions for FY2001 - 2/12/01

A. If a grant is to be made to a State Environmental Agency with a PPA/PPG
[These are the organizations notified of QMP requirements by the RA's letter of 6/5/00]

[x] The State has developed its Quality Management Plan (QMP) and made a timely submittal of the QMP to EPA for review and approval. The State has submitted a schedule for development/revision of applicable Quality Assurance Project Plans (QAPPs). The grantee shall provide timely responses to written comments from EPA concerning its QMP and QAPP submittal. This award of financial assistance and any further assistance during the budget period is contingent upon adequate progress toward achieving approval of the QMP and implementation of the QAPP schedule as agreed to by the State and EPA. In addition, the grantee shall modify and update the QMP and QAPPs as necessary to assure consistency with the regulatory requirements and changes in protocols and/or procedures. Each submittal should be sent to:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

B.1. If a Pesticides Program Grant is to be made to a State Agency with an approved QMP [CT, ME, MA, NH, VT]

INCLUDE BOTH CONDITIONS
[x] The State will review the existing Quality Management Plan (QMP) and provide a letter to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and documenting the review and accuracy of the QMP or submit a revised QMP within 1 year of the date of the existing QMP's approval.
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

[x] The State will develop a Quality Assurance Project Plan [QAPP] to support environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* (QA/R-5, 11/99) and/or the EPA New England Compendium Of Quality Assurance Project Plan Requirements and Guidance, 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The State will submit, by no later than 6/30/01, a Quality Assurance Project Plan (QAPP) to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency

60 Westview Street
Lexington, MA 02421

B.2. If a Pesticides Program Grant is to be made to a State Agency without an approved QMP [RI]

INCLUDE BOTH CONDITIONS

[x] The State will submit the revised Quality Management Plan (QMP) within 30 days of the effective date of this assistance agreement to the following
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421.

[x] The State will develop a Quality Assurance Project Plan [QAPP] to support environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* (QA/R-5, 11/99) and/or the EPA New England Compendium Of Quality Assurance Project Plan Requirements and Guidance, 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The State will submit, by no later than 6/30/01, a Quality Assurance Project Plan (QAPP) to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

C. For other Continuing Program Grants not covered by A or B above:

[this includes State Agencies not covered in A, interstate organizations, and Tribal Governments. A special letter from EPA to these organizations will lay out QMP requirements]

INCLUDE BOTH CONDITIONS

[x] The recipient will develop and implement an ongoing quality system. The recipient will document this quality system in a Quality Management Plan (QMP) in accordance with "EPA Requirements for Quality Management Plans" (QA/R-2,11/99) and submit it to EPA for approval. Within 30 days of the effective date of this assistance agreement, the recipient will submit a schedule for the development of a QMP; the date for the submittal of the QMP will be no later than 9/30/01. Each submittal should be sent to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

[x] The recipient will develop Quality Assurance Project Plans [QAPPs] to support all environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* QA/R-5, 11/99 and/or the *EPA New England Compendium Of Quality Assurance Project Plan Requirements and Guidance,* 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. Within 30 days of the effective date of this assistance agreement, the recipient will submit a schedule for the development of all QAPPs. The recipient will submit the schedule for QAPP development to the following:

- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

1.1 **For All Project Grants not included in A, B or C above:**

[x] The recipient will develop a Quality Assurance Project Plan [QAPP] to support all environmental data operations in accordance with "*EPA Requirements for Quality Assurance Project Plans*" (QA/R-5, 11/99) and/or the EPA New England Compendium Of Quality Assurance Project Plan Requirements and Guidance, 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The Quality Assurance Project Plan must be approved by EPA before any data collection and/or generation activities begin. Within 30 days prior to the scheduled commencement of data collection and/or data generation activities, the recipient will submit a Quality Assurance Project Plan to the following:

- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

Appendix 6

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: October 17, 2007

SUBJECT: Revised FY08 Requirements for Implementing Quality Assurance Policies for Financial Assistance Agreements Including Grants and Cooperative Agreements

FROM: Gerry Sotolongo, Quality Assurance Manager
Pam Ringhoff, Grants Manager

TO: Project Officers

This memo updates the requirements for Project Officers (POs) in implementing the Quality Assurance (QA) policies and procedures for grants and cooperative agreements. For the purposes of this memo, a PO is anyone who manages or has primary oversight responsibilities for grants and cooperative agreements (interagency agreements are covered in a separate memo). An outline of the EPA New England financial assistance QA Process is attached (Attachment 1) for your reference. Also attached are instructions on how to obtain concurrence from your office QA contact using the Integrated Grants Management System (IGMS) (Attachment 2), and the FY08 special financial assistance agreement conditions related to QA (Attachment 3). Technical support from the Office QA contacts (listed below) and the QA Office (Attachment 4) will be available to assist POs in implementing these requirements.

Please note,

- ❑ Attachment 3 includes a table that identifies the appropriate grant condition for many organizations. *The QMP status of some of these organizations may have changed. Please refer to this table for assistance in selecting the proper grant condition.*
- ❑ Condition C has been modified to allow for the use of equivalent quality system document instead of a formal QMP. Those organizations permitted to use equivalent documents to describe their quality systems are noted in Attachment 3.

The following are the key steps POs are responsible for in order to ensure compliance with regulatory requirements.

Step 1 – Project Officer determines if a Quality Assurance Project Plan (QAPP) is needed. Attachment 5 (QA "Cheat Sheet" to Help Identify Projects that Require QAPPs) provides examples of key words that may be helpful to make the QAPP determination. A "yes" or "no" decision must be made and then indicated on the Funding Recommendation in the Integrated Grants Management System (IGMS). If a QAPP is needed but not prepared yet, the PO must include a term and condition in the programmatic conditions of the funding recommendation.

The QA Office is available for consultation and assistance as you make this decision. **Your Office QA contact listed below must concur on all "no" decisions.**

ORA - Doug Gutro
OES – Lucy Casella
OSRR – Stan Chin, Maggie Leshen, Lynne Jennings
OEP – Lois Adams, Tony DePalma, Paul Bryan
OARM – Pam Ringhoff
OEME – Gerry Sotolongo

To obtain concurrence on a "no" decision, add the Office QA contact to your list of Approvers of the Funding Recommendation (Attachment 2). You may want to amend or add to the standard notification message to notify the contact that you are requesting review of the quality assurance requirement. When the Approver takes action (or concurs) on your request for approval, you will receive an e-mail notification message that the Approver has approved your document. If you forward the Funding Recommendation to the grants specialist without obtaining the proper concurrence from your office's QA contact on a "no" decision, the grants specialist will notify you by e-mail or by phone that you need to correct the Funding Recommendation and resubmit it with the proper concurrence.

Step 2 – The Grant Specialist, based on the PO's QA determination will incorporate the appropriate special financial agreement condition(s) into the award (Attachment 3). *Attachment 3 also includes a list of major grantees and cooperative agreement recipients and a preliminary indication of which condition applies.* Although these conditions should address the majority of financial agreements, a case-by-case review should be done by the Project Officer to insure that they are applicable to the specific financial agreement. *Any modifications to the special financial agreement condition language must be reviewed and approved by the QAM.*

Step 3 – Once the financial agreement is awarded, the PO should work proactively with the recipient to ensure that the QAPP is developed, completed, and submitted to EPA for review and approval. **Review and approval of QAPPs is a shared responsibility of the Project Officer and the QA Office** (the sole exception is the Superfund program which has been delegated QAPP approval authority). **Both the Project Officer and QA must sign the QAPP approval page**. The project officer is responsible for maintaining a copy of the signed QAPP with the project file. The QA Unit only retains a copy of the signed QAPP title/signature page(s).

The QA Office is available to help the PO discuss QA requirements with the recipient during development of the plan. In particular, for complex monitoring projects, a scoping meeting between the recipient, PO, and QA representative is strongly recommended. Since the QAPP must be approved prior to the initiation of any monitoring activities, the QAPP must be submitted at least 30 days prior to the projected sampling date. Otherwise, work may be delayed pending the review and approval of the QAPP.

We welcome your comments and suggestions on this process and request that you send any specific questions that you have to Gerry Sotolongo or a QA Unit State Coordinator (Attachment 4). You may also direct any questions to your Office QA contact.

Note: EPA Order 5360.1 (May 2000) http://www.epa.gov/quality/qs-docs/5360-1.pdf outlines the Quality Assurance requirements for the agency and is applicable to the collection, evaluation, and use of environmental data by or for EPA and the design, construction, and operation of environmental technology by EPA.

cc: Grant Specialists
Office QA Contacts
QA State Coordinators

Attachment 1 - Region 1 Financial Assistance QA Process

QAPP Requirement Determination

- Project Officer (PO) determines if a QAPP is needed.
  If yes, indicate requirement in IGMS.
  If no, obtain concurrence of Office QA contact.
- QA Office is available for consultation for above determination.
- QA Office may review a random sample of the negative determinations and report the findings to management.
- The Project Officer will determine the appropriate special financial agreement condition(s) and the Grants Specialist will incorporate into the financial agreement award.

QAPP Preparation

- The PO will be proactive and provide on-going information and support to recipient(s) with assistance from QA Office.
- The PO will work with the recipient to understand the project and inform the recipient of QA requirements. The QAPP requirements will be commensurate with the complexity and intended use of the data.
- The Grants Office, based on the PO's QA determination will send a post-award kit to the recipient that describes QAPP requirements and includes key EPA QA contacts (PO and QA Office).
- For large or significant projects it is recommended that a scoping meeting or conference call be held to determine data quality objectives, QA requirements to meet objectives, and content of QAPP. The PO determines if this is necessary and will coordinate the effort. Participants will include the recipient, the PO, QA Office staff, and other participants identified by the PO or QA Office.

QAPP Approval

- Compliance with QAPP requirements is a shared responsibility between the PO and QA Office.
- PO has the lead to ensure QAPPs are submitted.
- QA Office conducts the technical review and approves the QAPP (the sole exception is the Superfund program which has been delegated QAPP approval authority) with the PO co-signing the QAPP approval page.
- The project officer is responsible for maintaining a copy of the signed QAPP with the project file. The QA Unit only retains a copy of the signed QAPP title/signature page(s).

Note: If a QAPP is required and the financial agreement is a continuing agreement (for example a program grant), a Quality Assurance Management Plan (QMP) is also required. The QA Office will be responsible for approval of the QMP (including for Superfund). The long-term strategy is to delegate QAPP approval to the states based on an approved QMP and documentation of capacity and capability to carry out this responsibility.

Attachment 2 - IGMS Process

KEY STEPS IN NAMING APPROVERS AND OBTAINING CONCURRENCE FROM APPROVERS WHEN CREATING A FUNDING RECOMMENDATION IN THE INTEGRATED GRANTS MANAGEMENT SYSTEM

Assign and Notify Approvers

Open the document in Edit mode.

At the Approvers field, use the pick list to select the name or names of Approvers.

At the Due Date field, enter a date by which the Approver should respond.

Click the Workflow action button.

Click the Approvers action button.

At the Approval Notifications dialog box, verify/modify the recipient and message and click the OK button.

When the Approver takes action on the Funding Recommendation, you will receive an e-mail notification message that the approver has approved your document. The Approver action creates an Approver Response document which becomes associated with the Funding Recommendation. The Approver Response document will include any comments made by the Approver.

When all Approvers have approved your Funding Recommendation, you will obtain the signature of the Approval Official. If you find that you must correct your Funding Recommendation after it is signed by the Approval Official because you did not obtain the concurrence of your Office QA contact, you will have to go through the signature process again.

Correction After Obtaining Approval Official Signature

Open the Funding Recommendation.

Click the "Edit" button.

Click the "Correction" button. You will get a warning message advising that corrections to the document will erase all signature information and put the document back into the Draft Phase. (*NOTE: Erasure of all signature information does not include concurrence by Approvers.*)

Click the "OK" button.

The Funding Recommendation will close and change from the "Final" phase back to the "Draft" phase.

Open it again, click the "Edit" button, add the Approver (see above), and then repeat the process to obtain the concurrence of the Approver and the signature of the Approval Official. When you request the Approval Official's signature again, you should edit the e-mail notification message to explain why you are requesting his/her signature again.

Attachment 3 - Quality Assurance Conditions for Grants and Cooperative Agreements

A. For all continuing program grants, project grants, and cooperative agreements to recipients with approved QMPs, or grants (for example one-time grants) that do not require QMPs:

The recipient will develop Quality Assurance Project Plans [QAPP] to support all environmental data operations in accordance with *"The EPA New England Quality Assurance Project Plan Program Guidance,"* 2005. The term "environmental data operations" refers to any measurement or information that describe environmental processes, conditions, or location; ecological or health effects; produced from models or surveys; compiled from other sources such as data bases and literature; or the performance of environmental technology. The Quality Assurance Project Plan must be approved by EPA before any data collection and/or generation activities begin. Unless an alternate schedule was previously agreed upon, no later than 30 days prior to the scheduled commencement of data collection and/or data generation activities, the recipient will submit a Quality Assurance Project Plan to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
11 Technology Drive
North Chelmsford, MA 01863

For organizations having EPA-approved Quality Management Plans, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (fives years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager; or on another mutually agreeable schedule.

B. For all grants and cooperative agreements in which the QMP is under review:

The recipient has developed its Quality Management Plan (QMP) and submitted the QMP to EPA for review and approval. The recipient shall provide responses, consistent with a mutually agreeable schedule, to written comments from EPA concerning its QMP. This award of financial assistance and any further assistance during the budget period is contingent upon adequate progress toward achieving approval of the QMP. The response to comments should be sent to:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
11 Technology Drive
North Chelmsford, MA 01863

The recipient will develop Quality Assurance Project Plans [QAPP] to support all environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"*

(QA/R-5, 3/01) and/or the "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. The term "environmental data operations" refers to any measurement or information that describe environmental processes, conditions, or location; ecological or health effects; produced from models or surveys; compiled from other sources such as data bases and literature; or the performance of environmental technology. The Quality Assurance Project Plan must be approved by EPA before any data collection and/or generation activities begin. Unless an alternate schedule was previously agreed upon, no later than 30 days prior to the scheduled commencement of data collection and/or data generation activities, the recipient will submit a Quality Assurance Project Plan to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
11 Technology Drive
North Chelmsford, MA 01863

After the Quality Management Plan has been approved by EPA, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (fives years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager; or on another mutually agreeable schedule.

3. For continuing program grants, project grants, and cooperative agreements to recipients when QMPs are required, but have not been received, or when the QMP was approved 5 or more years ago:

The recipient will develop and implement an ongoing quality system. The recipient will document this quality system in a Quality Management Plan (QMP) in accordance with "EPA Requirements for Quality Management Plans" (QA/R-2, 3/01) and submit it to EPA for approval. Alternatively, with pre-approval by the RQAM, certain financial assistance recipients may be permitted to document their quality systems in an equivalent quality document such as a streamlined QMP or an expanded QAPP. Within 30 days of the effective date of this assistance agreement, the recipient will submit a schedule for the submission of a QMP; the date for the submittal of the QMP or equivalent document will be no later than 180 days from the effective date of this assistance agreement. Each submittal should be sent to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
11 Technology Drive
North Chelmsford, MA 01863

The recipient will develop Quality Assurance Project Plans [QAPP] to support all environmental data operations in accordance with "*EPA Requirements for Quality Assurance Project Plans*" (QA/R-5, 3/01) and/or the "*The EPA New England Quality Assurance Project Plan Program*

Guidance," 2005. The term "environmental data operations" refers to any measurement or information that describe environmental processes, conditions, or location; ecological or health effects; produced from models or surveys; compiled from other sources such as data bases and literature; or the performance of environmental technology. The Quality Assurance Project Plan must be approved by EPA before any data collection and/or generation activities begin. Unless an alternate schedule was previously agreed upon, no later than 30 days prior to the scheduled commencement of data collection and/or data generation activities, the recipient will submit a Quality Assurance Project Plan to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
11 Technology Drive
North Chelmsford, MA 01863

After the Quality Management Plan or equivalent document has been reviewed and approved by EPA, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (fives years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager; or on another mutually agreeable schedule.

FY08 Grant and Cooperative Agreement Condition for Select Regional Recipients

DEPs:

MA, ME, NH, RI, VT – Condition A
CT – Condition C

Pesticide Programs:

CT – Condition C
MA – Condition A
ME – Condition A
NH – Condition A
RI – Pesticide program is covered by the RI DEM's QMP
VT – Condition A

Public Health Agencies:

CT DPH (Drinking Water Program.) – Condition A
CT DPH (Radon, Asbestos and Lead Programs) – Condition A
MA DPH – Condition C (equivalent quality system documentation allowed)
ME DHHS (Drinking Water) Condition A; (Radon Programs) Condition B **(possibly customized) for radon grant**
RI DOH – Condition A
VT DOH (Radon Program) – Condition B (equivalent quality system documentation allowed); (Lead and Asbestos QMPs not required)

Interstate Organizations:

NEIWPCC – Condition A
NESCAUM – Condition A
NEWMOA – Condition A

Cities:

Brownfield Program – Condition A

Tribes:

Houlton Band of Maliseets – Condition A
Narragansett – Condition B
Passamaquoddy (Indian Township) – Condition A
Passamaquoddy (Pleasant Point) – Condition A
Penobscot – Condition A
Wampanoag (Aquinnah) – Condition A
Aroostook Band of Micmacs – Condition B

Federal Agencies:

Army Corps of Engineers – Condition A
USGS Water Resources, Northeastern Division – Condition A

Attachment 4 - Quality Assurance Unit State, Interstate, and Tribal Coordinators

Tribes	Steve DiMattei (QAPPs and project issues) Pat Svetaka (QMP and quality system matters)
Maine	Art Clark
New Hampshire	Moira Lataille
Vermont	Ann Jefferies
Massachusetts	John Smaldone
Connecticut	Pat Svetaka
Rhode Island	Steve DiMattei
NEIWPCC	Art Clark
NEWMOA	Charles Porfert
NESCAUM	Dick Siscanaw

Attachment 5 – QA "Cheat Sheet" to Help Identify Projects that Require QAPPs

QAPP Action Verbs

Collect
Gather
Generate
Monitor
Evaluate
Use
Quantify
Compile
Analyze
Model
Implement
Measure

QAPP Action Verbs used with:

Environmental data
Sample
Measurements
Information
Research
Computerized and mathematical models
Survey/compliance/enforcement data
Conditions of environmental systems or processes
Ambient conditions in air, water, soil, sediments
Environmental technology – remediation, treatability, pilot studies, innovative methods
Secondary data – existing data from literature, data bases, previous studies
Human/ecological health

Projects/activities that do not require QAPPs

Symposiums/conferences
Guidance documents
Videos
Outreach programs
Education

Appendix 7

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: November 30, 2007

SUBJECT: Requirements for Implementing New Quality Assurance Policies for Interagency Agreements

FROM: Gerry Sotolongo, Quality Assurance Manager
Pam Ringhoff, Grants Manager

TO: Interagency Agreement Project Officers
Superfund RPMs and OSCs
Grant Specialists

This memo updates the requirements for Project Officers (POs) in implementing the Quality Assurance (QA) policies and procedures for Interagency Agreements with other Federal Agencies. Specifically, requirements for Quality Management Plans (QMP) and Quality Assurance Project Plans (QAPP) are presented. For the purposes of this memo, a PO is anyone who manages or has primary oversight responsibilities for Interagency Agreements. The following are attached to help you to process IAGs: An outline of the EPA New England Interagency Agreement QA Process (Attachment 1); the Special Interagency Agreement conditions related to QA (Attachment 2); and, the Interagency Agreement Quality Assurance Review Memorandum (Attachment 3). Technical support from the Office QA contacts (listed below) and the QA Office will be available to assist POs in implementing these requirements.

The following are the key steps POs are responsible for in order to ensure compliance with these procedures.

Step 1 – Project Officer (RPM or OSC for Superfund site specific work) determines if a Quality Assurance Project Plan (QAPP) is needed. A "yes" or "no" decision must be made and then indicated on the Interagency Agreement Quality Assurance Review Memorandum (Attachment 3). The Grants Specialist will then make the appropriate entry in the Integrated Grants Management System (IGMS). The QA Office is available for consultation and assistance as you make this decision. **Your Office QA contact listed below must concur on all "no" decisions.**

ORA - Doug Gutro
OES – Lucy Casella
OSRR - Stanley Chin, Margaret Leshen, Lynne Jennings
OEP – Lois Adams, Tony DePalma, Paul Bryan
OEME - Gerry Sotolongo
OARM - Pam Ringhoff

Step 2 – The Grants Specialist, based on the PO's QA determination will incorporate the appropriate special condition into the interagency agreement (Attachment 2). Although these conditions should address the majority of interagency agreements, a case-by- case review should be done by the Project Officer to insure that they are applicable to the specific agency. *Any modifications to the interagency agreement condition language must be reviewed and approved by the QAM.*

Step 3 – Once the interagency agreement is accepted, the PO should work proactively with the other federal agency to insure that the QAPP is developed, completed, and submitted to the QA Office for review and approval. The sole exception is the Superfund program which has been delegated QAPP approval authority. Non-Superfund POs must also co-sign the QAPP. The QA Office is available to help the PO discuss QA requirements with the other federal agency during development of the plan. In particular, for complex monitoring projects, a scoping meeting between the other federal agency, PO, and QA representative is strongly recommended. Since the QAPP must be approved prior to the initiation of any monitoring activities, the QAPP must be submitted at least 30 days prior to the projected sampling date. Otherwise, work may be delayed pending the review and approval of the QAPP. The project officer is responsible for maintaining a copy of the signed QAPP with the project file. The QA Unit only retains a copy of the signed QAPP title/signature page(s)

We welcome your comments and suggestions on this process and request that you send any specific questions that you have to Nora Conlon. You may also direct any questions to your Office QA contact.

Note: EPA Order 5360.1 (May 2000) http://www.epa.gov/quality/qs-docs/5360-1.pdf outlines the Quality Assurance requirements for the agency and is applicable to the collection, evaluation, and use of environmental data by or for EPA and the design, construction, and operation of environmental technology by EPA.

cc: Grants Specialist
Office QA Contacts
QA Staff

Attachment 1 - Region 1 Interagency Agreement QA Process

QAPP Requirement Determination

- Project Officer (PO) determines if a QAPP is needed.
  If yes, indicate requirement on the IAG QA Review Memorandum.
  If no, obtain concurrence of Office QA contact.
- QA Office is available for consultation for above determination.
- QA Office may review a random sample of the negative determinations and report the findings to management.
- The Project Officer will determine the appropriate special condition(s) and the Grants Specialist will incorporate the condition(s) into the interagency agreement.

QAPP Preparation

- The PO will be proactive and provide on-going information and support to recipient(s) with assistance from QA Office.
- The PO will work with the other federal agency to understand the project and inform the other federal agency of QA requirements. The QAPP requirements will be commensurate with the complexity and intended use of the data.
- For large or significant projects it is recommended that a scoping meeting or conference call be held to determine data quality objectives, QA requirements to meet objectives, and content of QAPP. The PO determines if this is necessary and will coordinate the effort. Participants will include the recipient, the PO, QA Office staff, and other participants identified by the PO or QA Office.

QAPP Approval

- Compliance with QAPP requirements is a shared responsibility between the PO and QA Office.
- PO has the lead to ensure QAPPs are submitted.
- QA Office conducts the technical review and approves the QAPP (the sole exception is the Superfund program which has been delegated QAPP approval authority) with the PO concurrence. Non-Superfund POs must also co-sign the QAPP.
- The project officer is responsible for maintaining a copy of the signed QAPP with the project file. The QA Unit only retains a copy of the signed QAPP title/signature page(s)

Note: If a QAPP is required, a Quality Assurance Management Plan (QMP) is usually required. The QA Office will be responsible for approval of the QMP (including for Superfund).

Attachment 2 - IAG QA Conditions

4. For non-Superfund Interagency Agreements to recipients with approved QMPs, or do not require QMPs, but QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

Quality Assurance Project Plan. Recipient is entering into an agreement with EPA New England to conduct environmental data operations and therefore must develop a quality assurance project plan (QAPP). The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. Depending on the program, other planning documents such as field sampling plans (FSPs), or sampling and analysis plans (SAPs) may be developed. The QAPP, or other planning document, must be approved by EPA before any data collection and/or generation activities begin. The QAPP or other planning document, must be sent to the following no later than 30 days prior to the scheduled commencement of data collection and/or data generation activities:

- EPA Project Officer (see page 1 of the IAG for name and address) and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. Alternatively, QAPPs developed by DOD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2005).

For organizations having EPA-approved Quality Management Plans, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (five years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager.

[Additional QA/QC requirements should be negotiated into the Interagency Agreement based upon

project objectives whenever necessary and should be specified here.]

B. For non-Superfund Interagency Agreements in which the Quality Management Plan is under review, and QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

The recipient has developed its Quality Management Plan (QMP) and submitted the QMP to EPA for review and approval. The recipient shall provide responses, consistent with a mutually agreeable schedule, to written comments from EPA concerning its QMP. This award of financial assistance and any further assistance during the budget period is contingent upon adequate progress toward achieving approval of the QMP. The response to comments should be sent to:

- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  11 Technology Drive
  North Chelmsford, MA 01863

After the Quality Management Plans has been approved by EPA, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (five years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager.

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- EPA Project Officer (see page 1 of the IAG for name and address) and
- Regional Quality Assurance Manager

US. EPA New England
11 Technology Drive
North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. Alternatively, QAPPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2004).

[Additional QA/QC requirements should be negotiated into the Interagency Agreement based upon project objectives whenever necessary and should be specified here.]

C. For non-Superfund Interagency Agreements to recipients when QMPs are required, but have not been received, and QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

Quality system documentation is required by the ANSI/ASQC E-4 standard in two forms: 1) the **Quality Management Plan** (QMP), which documents the organizational quality system; and 2) the **Quality Assurance Project Plan** (QAPP), which documents the application of quality assurance and quality control activities at the project level. To demonstrate conformance, the EPA requires the submission of both QMPs and QAPPs (or equivalent documents).

Quality Management Plan. Recipient is entering into an agreement with EPA New England to conduct environmental data operations and must therefore develop and implement an ongoing quality system. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The quality system must be documented in a QMP (or equivalent document) and submitted to EPA New England for review and approval within 90 days of the effective date of this agreement. A copy of the QMP must be sent to each of the following:

- EPA Project Officer (see page 1 of the IAG for name and address) and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

Quality Systems must comply with specifications outlined in ANSI/ASQC E-4, Part A, and be documented in QMPs prepared in accordance with EPA QA/R-2, *EPA Requirements for Quality Management Plans* (EPA/240/B-01/002 March 2001). Alternatively, QMPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy for Implementing Environmental Quality Systems* (Final Version 2, March 2005).

After the Quality Management Plans has been reviewed and approved by EPA, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (five years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the

approval of the QMP by the Regional QA Manager.

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- EPA Project Officer (see page 1 of the IAG for name and address) and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. Alternatively, QAPPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2004).

[Additional QA/QC requirements should be negotiated into the Interagency Agreement based upon project objectives whenever necessary and should be specified here.]

D. For Superfund Interagency Agreements to recipients with approved QMPs, or do not require QMPs, but QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

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- Superfund Remedial Project Manager and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the *"The EPA New England Quality Assurance Project Plan Program Guidance,"* 2005. Alternatively, QAPPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2004).

When conducting work for EPA New England, parties entering into agreements must provide documentation which demonstrates the QA/QC procedures for the following activities:

- Obtaining laboratories for analytical services.
- Oversight of laboratories providing analytical support.
- Review of the data generated by the laboratories.
- Summarizing and reporting data to EPA New England.

To meet these requirements the following documents, or their equivalent, must be used:
- Region 1, EPA New England Data Validation Functional Guidelines for Evaluating

Environmental Analyses, December, 1996.
- Region 1, Tiered Organic and Inorganic Data Validation Guidelines, July, 1993.
- EPA Region 1 Performance Evaluation Program Guidance, July, 1996.
- Region 1 Laboratory Pre-Qualification Standard Operating Procedure, 15 March 1994.
- Region 1 Laboratory Audit Standard Operating Procedure, 15 March 1994.
- Region 1 DAS Tracking Standard Operating Procedure, January 1994.

For organizations having EPA-approved Quality Management Plans, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (five years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager.

E. For Superfund Interagency Agreements in which the Quality Management Plan is under review, and QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

The recipient has developed its Quality Management Plan (QMP) and submitted the QMP to EPA for review and approval. The recipient shall provide responses, consistent with a mutually agreeable schedule, to written comments from EPA concerning its QMP. This award of financial assistance and any further assistance during the budget period is contingent upon adequate progress toward achieving approval of the QMP. The response to comments should be sent to:

- Superfund Remedial Project Manager and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  11 Technology Drive
  North Chelmsford, MA 01863

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- Superfund Remedial Project Manager and
- Regional Quality Assurance Manager
  US. EPA New England

11 Technology Drive
North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. Alternatively, QAPPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2004).

When conducting work for EPA New England, parties entering into agreements must provide documentation which demonstrates the QA/QC procedures for the following activities:

- Obtaining laboratories for analytical services.
- Oversight of laboratories providing analytical support.
- Review of the data generated by the laboratories.
- Summarizing and reporting data to EPA New England.

To meet these requirements the following documents, or their equivalent, must be used:

- Region 1, EPA New England Data Validation Functional Guidelines for Evaluating Environmental Analyses, December, 1996.
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F. For Superfund Interagency Agreements to recipients when QMPs are required, but have not been received, and QAPPs are required.

EPA's Quality Order (Order 5360.1 A2, May 2000) and Information Quality Guidelines (October 2002) require that EPA base decisions on scientifically sound information of known and documented quality. EPA has selected ANSI/ASQC E-4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis to fulfill its environmental quality requirements. Additionally, EPA, Department of Defense (DoD) and Department of Energy (DOE) have adopted the *Intergovernmental Data Quality Task Force, Uniform Federal Policy (UFP) for Implementing Environmental Quality Systems*, Final Version 2, March 2005. The *UFP*, based on ANSI/ASQC E-4, ensures consistent implementation of quality systems on joint projects.

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- Superfund Remedial Project Manager and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

Quality Systems must comply with specifications outlined in ANSI/ASQC E-4, Part A, and be documented in QMPs prepared in accordance with EPA QA/R-2, *EPA Requirements for Quality Management Plans* (EPA/240/B-01/002 March 2001). Alternatively, QMPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy for Implementing Environmental Quality Systems* (Final Version 2, March 2005).

After the Quality Management Plans has been reviewed and approved by EPA, the recipient will submit an annual update letter to EPA documenting progress over the year and any changes to the Quality Management Plan. Annual update letters will be sent every year for four years until the expiration of the QMP (five years from initial EPA approval). Annual QA update letters will be sent to the EPA Project Officer and Regional Quality Assurance Manager on the anniversary of the approval of the QMP by the Regional QA Manager.

Quality Assurance Project Plan. Recipient is entering into an agreement with EPA New England to conduct environmental data operations and therefore must develop a quality assurance project plan (QAPP). The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. Depending on the program, other planning documents such as field sampling plans (FSPs), or sampling and analysis plans (SAPs) may be developed. The QAPP, or other planning document, must be approved by EPA before any data collection and/or generation activities begin. The QAPP or other planning document, must be sent to the following no later than 30 days prior to the scheduled commencement of data collection and/or data generation activities:

- Superfund Remedial Project Manager and
- Regional Quality Assurance Manager
  US. EPA New England
  11 Technology Drive
  North Chelmsford, MA 01863

QAPPs must comply with specifications outlined in ANSI/ASQC E-4 Part B and be prepared in accordance with EPA QA/R5,. *EPA Requirements for QA project Plans* (EPA240/B-01/003 March 2001) and the *"The EPA New England Quality Assurance Project Plan Program Guidance,"* 2005. Alternatively, QAPPs developed by DoD and DOE should be prepared in accordance with the *Uniform Federal Policy Guidance for Quality Assurance Project Plans* (Final July 2004).

When conducting work for EPA New England, parties entering into agreements must provide documentation which demonstrates the QA/QC procedures for the following activities:

- Obtaining laboratories for analytical services.
- Oversight of laboratories providing analytical support.
- Review of the data generated by the laboratories.
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To meet these requirements the following documents, or their equivalent, must be used:

- Region 1, EPA New England Data Validation Functional Guidelines for Evaluating Environmental Analyses, December, 1996.
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- EPA Region 1 Performance Evaluation Program Guidance, July, 1996.
- Region 1 Laboratory Pre-Qualification Standard Operating Procedure, 15 March 1994.
- Region 1 Laboratory Audit Standard Operating Procedure, 15 March 1994.
- Region 1 DAS Tracking Standard Operating Procedure, January 1994.

Attachment 3 - MEMORANDUM Interagency Agreement (IAG) Quality Assurance Review

Memorandum

DATE:

TO: _____, Grants Specialist
Grants Management Office (MGM)

FROM:_____, Project Officer (RPM or OSC for Superfund Site Specific Work)

SUBJ: Interagency Agreement (IAG)Quality Assurance Review

PROGRAM: _____Federal Agency IAG to be Given:_____

SUMMARY DESCRIPTION OF PROGRAM/PROJECT:

Quality Assurance: Does this project involve the collection, use, and/or reporting of environmental data? *Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; 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 data bases or the literature.*

YES___ NO____

If no, Please have your QA Office Representative Sign:

Signature, QA Office. Rep.

If yes, does the recipient/federal agency have an approved Quality Management Plan (QMP)?

YES____ NO___

Does recipient have a Quality Assurance Project Plan (QAPP) approved by the EPA Quality Assurance Office or delegate in OSRR? YES ____ NO _____
If no, recipient (other federal Agency) or their contractor must prepare and have approved prior to beginning work.

Specify appropriate QA conditions to be included in IAG: Superfund_____
QMP required to be submitted_____
QAPP required to be submitted_____

Questions: Call Nora Conlon 8-8325 of the Quality Assurance Unit in Chelmsford.

Appendix 8

Background

The EPA New England Quality Assurance Unit implements the Regional Quality Assurance (QA) Program in accordance with EPA Order 5360.1 A2, May 2000 (QA Order). One key requirement of the QA Order is the development, review, and approval of Quality Assurance Project Plans (QAPPs) for all environmental data operations conducted by or on behalf of EPA.

Planning is a critical component for successful projects. The QAPP describes the results of the planning process used to identify all technical and quality aspects for the life-cycle of the project including planning, implementation, documentation, and assessment. In particular, the QAPP documents the type, quantity, and quality of data needed to support environmental decision-making.

EPA New England's systematic implementation approach for QAPPs is described in "*The EPA New England Quality Assurance Project Plan Program Guidance*," 2005. The guidance provides region-specific implementation information and program-specific guidance.

Applicability

QAPP requirements are specified in "*EPA Requirements for Quality Assurance Project Plans,*" EPA QA/R5, March 2001, or latest revision, and the "*EPA Quality Manual for Environmental Programs, 5360 A1.*" **The requirements described in EPA QA/R5 apply to all environmental data operations (as defined in the QA Order) performed by, on behalf of, or funded by, EPA New England.** The requirements specifically apply to:

1. EPA contractors and organizations under contract to EPA.

2. States, tribes, and local governments under financial assistance agreements, including grants and cooperative agreements.

3. Other federal agencies under interagency agreements and memoranda of understanding with EPA-NE.

4. Non-profit organizations under financial assistance agreements.

In addition, these QAPP requirements apply to the regulated community and shall be included in voluntary, consentual, or unilateral enforcement agreements, decrees, and orders.

This policy rescinds and supercedes the EPA-NE Quality Assurance Project Plan Policy dated October 1, 1999 and is effective immediately.

Appendix 9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
60 WESTVIEW STREET, LEXINGTON, MA 02173

MEMORANDUM

DATE: November 21, 1995

SUBJ: Development of EPA-NE Quality Assurance Training Modules

FROM: Moira M. Lataille, CLP-TPO Region I

TO: Nancy Barmakian, Quality Assurance Officer

In accordance with the QA Annual Report for FY'95, the QA office is continuing to develop its QA Training and Outreach programs for FY'96. Training materials will be developed that enable the QA office to train other EPA personnel and State, Local and Tribal partners. The training will complement the QA guidance that is now in effect and that which is currently being written.

Training modules will be developed for a number of QA related topics. Each training module will be assigned a two digit number, the first digit will identify the general QA subject while the second digit will be assigned in sequence of module development. The Region I modules may be stand alone training units or they may integrate the Quality Assurance Division (QAD) training modules that currently exist, i.e., DQO process-QAD Course Number 140 etc., or they may integrate training courses developed by commercial vendors, e.g. Immuno Assay Technology Transfers. I envision that most of the training will consist of several modules linked together.

The following numbers will identify specific training modules:

I. EPA-NE QUALITY ASSURANCE PROCESSES

10 EPA-NE QA Unit
- o Organizational Structure and Goals
- o Written Guidance
- o Affiliation with Quality Assurance Division (QAD)
- o Technical Assistance in field and method applications
- o QAPjP Reviews
- o Technical Systems Audits-Field Sampling, Fixed and field laboratory audits
- o Data Reviews
- o PE Sample Program
- o Management Systems Reviews (MSRs)
- o Self-Assessment Programs
- o Corrective Actions or Closing the QA Loop
- o QA Resources and References

o Contract Administration of QA Support Contractors and Contract Laboratory Program

II. PLANNING

20 Scoping/Planning/DQOs
- o QAD DQO Course Numbers: 140,141,142, 143,241,242,243,244,245, 246,247,248,341,342,347 (including some environmental statistics that encompass both quantitative and qualitative approaches)

30 Quality Assurance Project Plans
- o QAD Course Numbers: 151, 251 and 252

40 EPA-NE Quality Assurance Plan

41 Removal Quality Assurance Program Plan

III. IMPLEMENTATION

50 Sampling
- o QAD Course Number: 445

51 Standard Operating Procedures
52 CLP Sampling Procedures
- o Preservation and Packing (TRs, etc.)

53 Sampling Scheduling under CLP and REAP

60 Analytical Methods
- o Choosing an analytical method

61 Detection Limits
62 Screening Methods
63 Innovative Technologies-new Methods

70 General Field and Laboratory QA
- o Field QC samples
- o Laboratory QC samples
- o PARCC parameters

IV. ASSESSMENT

80 Data Validation

81 Introduction to the new "EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses"

- Description of new Document-Parts 1-IV
- Overview and Purpose of Data Validation
- Tiered Validation approach
  - Comparison to old Functional Guidelines Guidance

82 Data Validation training for the experienced validator (in depth training with discussion of comparison of old and new FG guidance)

83 Data Validation training for the beginner (in depth training-no comparison discussion needed)

84 Performance Evaluation Sample Evaluation
- Availability and applicability of PES materials

85 Data Validation Training for the non-chemist

90 Data Quality Assessment (QAD Course Numbers: 191,291,391)

91 Interpretation of Data (QAD Course Number: 192)

92 Preparing for litigation (Utilizing course materials from the Expert Witness Training recently put on by the Air group)

Developing the Quality Assurance Training Modular Program will be a cooperative team effort. Each member of our Quality Assurance Team will be able to provide added value to the evolution of specific modules. Over the next few months we should be able to develop the outline for many of these modules and begin training.

If you have any questions or would like to discuss this training plan, please feel free to contact me at (617) 860-4635.

ATRAIN.11M

Appendix 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND REGIONAL LABORATORY
11 TECHNOLOGY DRIVE, CHELMSFORD, MA 01863

DATE: December 23, 2004

SUBJECT: Amended Delegation of QA Approval Authorities to OSRR

FROM: Gerard Sotolongo /s/
Regional QA Manager

TO: Susan Studlien, Director, OSRR
Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs), RCRA Facility Managers (RFMs), Site Assessment Managers (SAMs) in OSRR

This memorandum amends and supercedes the September 25, 2002 memorandum relating to delegation of Quality Assurance (QA) approval authorities to OSRR. Specifically, it deletes the requirement to forward copies of the DQO summary forms to the QA office.

Continuing delegation of QA authorities is contingent upon successful implementation of OSRR's quality processes including training requirements, administrative procedures, and documentation requirements.

Quality Assurance Project Plan (QAPP) Approvals
OSRR RPMs, OSCs, RFMs, and SAMs are delegated QAPP approval authority in lieu of the Regional QA Manager (RQAM), or QA staff, subject to the following requirements:

1) All OSRR personnel with QAPP approval authority must have appropriate QA training. For existing employees they must have attended either the regional 2-day "QAPP Writing" course, or the half-day "QAPP review" course. New RPMs, OSCs, RFMs or SAMs please check with the QA Manager to fulfill the training requirement.

2) After review and approval, OSRR personnel with QAPP approval authority must forward a copy of the signed QAPP Title and Approval page(s) to the QA Manager, Gerard Sotolongo, Mail Code EQA.

Quality Assurance Review Form (QARF) for Work Under Existing OSRR Contracts that Use Work Assignments or Task Orders (i.e. RACs, ROC, ERRS, REPA)
OSRR Contracting Officer Representatives (CORs) must complete and sign the QARF and send it to their managers for QA concurrence. OSRR managers are delegated QA signature authority for the QARF in lieu of the RQAM. QA signature authority may not be further delegated. The COR must sent the completed original QARF to the Regional Project Officer and a photocopy to the QA manager, Gerard Sotolongo. The QARF helps to ensure that QA requirements for contract work assignments and task orders are met and, thus, fulfills the Contracts Management Manual documentation requirements.

cc: OSRR Managers