U.S. ENVIRONMENTAL PROTECTION AGENCY

REGION 1

QUALITY MANAGEMENT PLAN

Revision 1.0
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EPA Region 1 Quality Management Plan

APPROVAL FOR AGENCY

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EPA Region 1 Quality Management Plan

APPROVAL FOR EPA REGION 1

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INTRODUCTION

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. EPA Region 1 focuses on human health and environmental issues within the six New England States for present and future generations.

The EPA Region 1 mission framework is documented in the EPA Region 1 Quality Management Plan (QMP) which defines the Quality System (QS). The QMP describes the policies, procedures, and management systems within the organization that govern quality assurance (QA) and quality control (QC) practices applied to environmental programs involving environmental information and technology[1]. The QS was developed in accordance with the EPA Order CIO 2105.0. EPA's policy it to ensure that all environmental programs performed by EPA, or directly for EPA through EPA-funded extramural agreements, shall be supported by individual quality systems that comply with the American National Standard ASQ/ANSI E4:2014, *Quality management systems for environmental information and technology programs – Requirements with guidance for use*, prepared as an American National Standard by: ASQ Energy and Environmental Division and ASQ Standards Committee.

The QMP also incorporates, by reference, the QA allied Regional policies and/or programs including the: Peer Review Policy; Information Quality Guidelines–Pre-dissemination Review[2]; Policies for Assuring Competency, Scientific Integrity Policy, Human Subject Research Policy and the Quality Assurance Field Activities Procedure (QAFAP).

1.0 MANAGEMENT AND ORGANIZATION

This Section documents the Regional quality system overall policy, scope, applicability, and management responsibilities. The EPA Region 1 Administrator, Deputy Regional Administrator, and senior management are fully committed to implementing an effective quality system. Senior management ensures understanding and implementation of the Regional quality system by issuing policy statements, allocating resources, performing assessments, developing guidance and providing training. Regional commitment is consistent with the objectives and goals EPA Order CIO 2105.0.

[1] ASQ/ANSI E4:2014, environmental information – any data, measurements, or calculations that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology.
Note 1 – Environmental information includes data collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.
Note 2 – Environmental information also includes data derived from samples collected from the environment, the results of other analytical testing (e.g., geophysical, hydrological) of environmental conditions, and process data of physical parameters collected from the operation of environmental technologies.

[2] Please note that not all hyperlinks are available to all users. If you need access to a site that you are restricted from please contact the RQAM.

1.1 EPA Region 1 Mission Statement

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

1.2 EPA Region 1 Quality Assurance Policy

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

The Regional Administrator and senior management ensure that adequate resources, including; intramural, extramural, training and travel funds, and personnel are available and allocated to achieve the Region's quality mission. All Region 1 employees have a responsibility to implement the quality system elements, as appropriate, to ensure the quality of decisions made.

1.3 Assignment of Responsibility

In accordance with EPA Order CIO 2105.0, the Regional Administrator has overall responsibility for the QA program. Through the approved QMP, the Regional Administrator has delegated authority to the Regional Quality Assurance Manager (RQAM) for: developing and documenting Regional QA policies, procedures and guidance; overseeing the implementation and assessment of the Regional quality system; and providing QA training. The RQAM is located within the Laboratory Services and Applied Science Division (LSASD).

Figure 1 depicts the basic components of the Region's organization and structure for quality assurance authority and reporting. The RQAM reports directly to the LSASD Division Director. The dashed line between the RQAM and the Deputy Regional Administrator indicates that the RQAM can elevate issues to the next higher level of senior management, that is, the Deputy Regional Administrator. Further detail can be found in the Region 1 organizational charts.

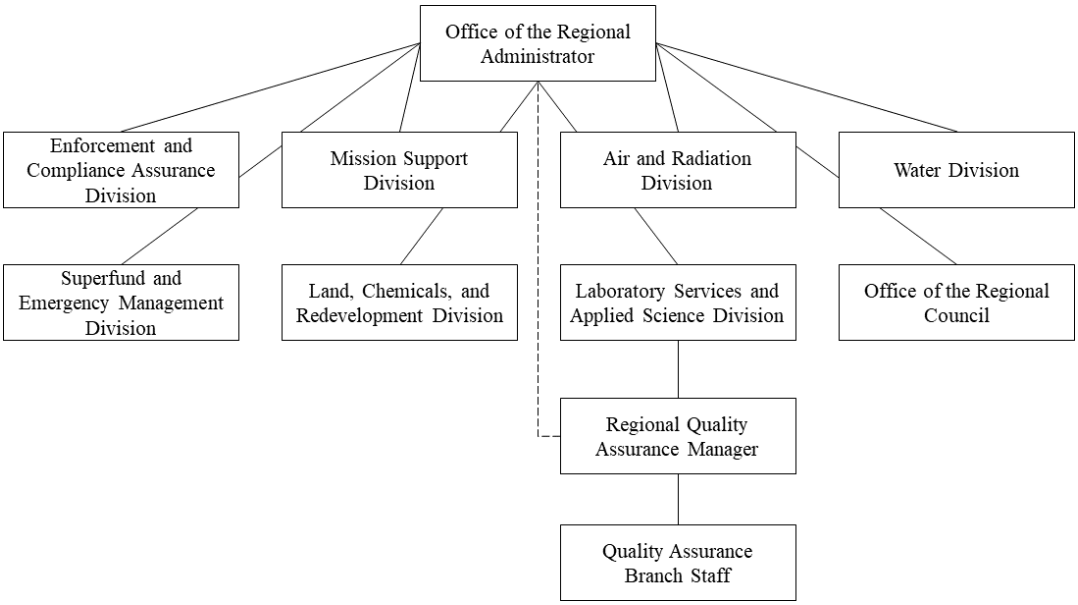


Figure 1 Quality Assurance Reporting and Structure

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

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

1.3.1 Regional & Deputy Regional Administrator, Division Directors/Deputy Directors, and Branch/Section Chiefs

As specified in EPA Order CIO 2105.0 the Regional Administrator (RA) and Deputy Regional Administrator (DRA), Division Directors (DD), Deputy Division Directors (DDD), Branch Chiefs, and Section Chiefs are responsible for the Regional quality system, and to that end they:

- Designate one representative from each division and/or branch for quality management activities, to advise and assist the implementation of the Quality System (QS) through planning, documentation, implementation, assessment, and quality improvement within their purview (see 1.3.6);
- Ensure that all Regional components and programs comply fully with the EPA Order CIO 2105.0, including the preparation of the Region 1 QMP, implementation of an

effective Regional quality system (QS), and effective communication and support to the HQs, Office of Mission Support (OMS);

- Ensure that quality management activities are identified, and resources are adequate to support the Quality System (QS) components, and that the QS is implemented as prescribed in this QMP;
- Ensure that all environmental programs implemented through extramural agreements are compliant with the EPA Order CIO 2105.0*;*
- Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments meet program data quality objectives, including sufficient quantity and adequate quality for their intended use;
- Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA. Training specific to the fundamental concepts and practices of quality management, and QA/QC activities which ensure the quality of outcomes or products;
- Ensure that assessments of Regional environmental programs, internal and external programs, are performed at a frequency appropriate to the program, and that assessments are performed against approved QMPs to determine the effective implementation of the Quality System;
- Ensure that deficiencies identified through assessments are addressed appropriately;
- Identify QA and QC training needs for all levels of management and staff and support the training; and
- Ensure that performance plans for all Region 1 personnel are commensurate with the quality management responsibilities designated by this QMP.

1.3.2 Regional Quality Assurance Manager (RQAM)

The Regional Administrator has delegated the responsibility and authority to implement the Regional quality system to the RQAM. As shown in Figure 1, the Regional QA Manager position is located within the Laboratory Services and Applied Science Division (LSASD). The dashed line connection to the Deputy Regional Administrator (DRA), indicates that the QA Manager can directly and independently interact and communicate with the DRA. This signifies independence in all QA matters. The RQAM can independently elevate quality-related issues to the DRA at his/her discretion without challenge. The RQAM does not need approval or pre-notification to initiate such communication.

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

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

- Facilitating the EPA Region 1 QMP development, approval, and maintenance;
- Collaborating with EQMD OMS, EPA programs and partners regarding the implementation of EPA Order CIO 2105.0;
- Providing expert assistance to staff in the organization regarding QA/QC policies, requirements, and procedures applicable to procurement and technical activities;
- Ensuring the implementation of Quality System (QS) policies and procedures, and tools for EPA Region 1;
- Identifying and providing or making provisions for QS, QA, and/or QC training needs for the organization,
- Collaborate with the Mission Support Division (MSD) to ensure the implementation of QS financial agreements and contract QS requirements.

1.3.3 Managers

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

- Ensuring that quality management is an identified activity with associated resources adequate to accomplish program quality goals;
- Ensuring that all organizational components and programs for which management is responsible comply fully with the requirements of the EPA Order CIO 2105.0*;*
- Ensuring that all sampling, analytical and data handling practices are documented in written procedures, i.e., SOPs. SOPs for all Branch programs are developed as functional, accurate documents that are approved initially and reviewed routinely for continued adequacy;
- Assessing the QA/QC training needs of their staff and arranging for such training with the RQAM;
- Requiring staff to use current guidance and requirement documents from both OMS and the Regional QAB to ensure uniform application of Agency QA policies and procedures;
- Ensuring that a systematic planning process is used to determine project quality objectives for all environmental data operations; and subsequently, ensuring that the results of the planning process are sufficiently documented in approved QA planning documents, i.e., QAPPs and SAPs, prior to the initiation of work;
- Ensuring that QAPPs are implemented as described; that technical assessments are

performed as required; and that data are reviewed prior to use;

- Ensuring that corrective actions are monitored for implementation and effectiveness; and
- Implementing program recording-keeping procedures to ensure the maintenance of quality-related documents including QMPs, QAPPs, amendments, technical assessments, corrective action responses, and data review and usability reports.

1.3.4 Contracting Officer's Representatives, Project Officers and Project Managers

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

Project Officers, including Grant and Interagency Agreement; Contracting Officer Representatives, and Project Managers (Remedial Project Managers (RPMs), Site Assessment Mangers (SAMs), RCRA Facility Managers (RFMs), and On-Scene Coordinators (OSCs)) are responsible for:

- Ensuring EPA Order CIO 2105.0 and Regional requirements are satisfied in all environmental projects conducted by EPA personnel or through grants, cooperative agreements, interagency agreements and contracts;
- Ensuring QA requirements are incorporated or negotiated into voluntary, consensual or unilateral enforcement agreements, decrees and orders;
- Ensuring that all QA deliverables (QMPs or equivalent quality system documentation, QA Management Reports, QAPPs/SAPs, amendments, addenda, SOPs, QC performance results, data quality reports, etc.) are provided to the Region;
- Providing signature concurrence or approval on QAPPs;
- Ensuring that QAPPs are approved prior to the initiation of data collection and implemented as written for all projects involving environmental data operations;
- Ensuring that appropriate QA documentation, including copies of signed and completed QA Project Plan Approval Forms, QAPP/SAP Title and Approval Pages and/or copies of the final approval letters or documentation, are provided to the QAB prior to the initiation of environmental data operations for programs that have been delegated QAPP approval authority;
- Ensuring that QA Review Forms (QARFs) are completed and provided to the RQAM when required for contracts, work assignments, delivery orders and task orders;

- Ensuring that QAPPs are implemented as described; that technical assessments are performed as necessary; corrective actions are implemented when required; and that data are reviewed prior to use;
- Assuring that the results of environmental programs are of sufficient quantity and adequate quality for their intended use; and
- Conforming to program record-keeping procedures and QA-related documents.

1.3.4.1 Contract Officers, Contracting Officer's Representatives (CORs)

Regional Contract Officers and Contracting Officer's Representatives (CORs) preparing acquisition packages, awarding, and overseeing Agency funded contracts and procurements supporting environmental information and technologies are responsible for ensuring that contracts and associated documents include current QA requirements from National and Regional policies and programs.

The Region's procurement process ensures compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to QA in the procurement and management of contracts, work assignments, delivery orders and task orders. Contracting Officers and authorized CORs are responsible for adhering to the EPA Acquisition Guide, Chapter 46 Quality Assurance, Section 46.2 Contract Quality Requirements and the most current version of the Contract and Procurement QA Requirements Statements.

- *Quality Assurance Review Forms (QARF) for SEMD Contracts and Procurements*
- *Quality Assurance Review Forms (QARF) for Non-SEMD Contracts and Procurements*

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

EPA staff including Project Officers and Grant Specialists that award and oversee Regionally funded grants, cooperative agreements and interagency agreements are responsible for ensuring that financial assistance agreements include current National and Regional QA policies and procedures. The Region's grants management process was established to ensure compliance with and participation by all Regional programs with applicable QA policies and regulations pertaining to the award and management of grants, cooperative and interagency agreements.

Project Officers for Grants and Cooperative Agreements and Grant Specialists are responsible for the procedures in the most current version of the Region 1 QA Policy Memo for Grants. **See Appendices.**

Similarly, Interagency Agreement (IA) Project Officers are responsible for the procedures in the most current version of the Region 1 QA Policy Memo for IAs. **See Appendices.**

1.3.5 Office QA Contacts

Senior management is committed to providing resources to ensure compliance with QA requirements in the award and management of financial assistance agreements. In each

Division/Office an individual has been identified as a QA Contact. The office QA contacts assist staff in complying with QA policies and procedures specific to the Division/Office functions. QA Division/Office contacts responsibilities are described in the memos referenced above.

1.3.6 LSASD Laboratory Quality Assurance Officer (QAO)

The LSASD Laboratory QAO, is a member of the QAB, and is responsible for implementing the laboratory quality system as described in the *Quality Manual for US EPA New England Regional Laboratory (NERL), Laboratory Services and Applied Science Division* (hereafter the *NERL Quality Manual*). The QAO reports to the RQAM and keeps the LSASD Management team apprised on the status of the lab qualtiy system. The QAO works together with QAB staff to conduct audits and other necessary checks on the quality system.

1.3.7 Field Sampling/Measurements, Existing Data, and Environmental Modeling

1.3.7.1 Field Sampling and Field Measurements

For EPA personnel performing field sampling and/or collecting field measurements, QA activities include:

- Ensuring that the procedures comply with CIO 2105-P-02.0, EPA QA Field Activities Procedure (EPA QAFAP), which include QA documents; QAPPs, SAPs, FSPs, SOPs, etc.;
- Documenting any deviations from established methodologies, SOPs and QC protocols, in the report or final documents as appropriate, and communicating the deviations to the project team, including the data users;
- Identifying possible data quality problems and potential areas for quality improvement and reporting these to the project team, including the data users in a timely manner;

1.3.7.2 Regional Staff Acquiring, Using, and Compiling Existing Data

EPA personnel acquiring, using, and compiling existing data are responsible for:

- Ensuring that existing data activities are performed according to an approved QAPP or equivalent document. Specifically, data selection and rejection criteria must be documented in the QAPP and all data sources of existing data must be documented;
- Documenting any deviations from established methodologies, SOPs and QC protocols, and reporting the deviations to their project team and data users as appropriate;

1.3.7.3 Regional Staff and Environmental Models

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

- Ensuring that work is conducted under approved QA planning documents and is consistent with the most EPA Order CIO 2105.0. Data selection and rejection criteria must be documented in the planning document and necessary training for the subject model must be procured prior to generating data;

- Following established appropriate and applicable modeling practices/procedures as described in QA planning documents;
- Reviewing modeling reports, documenting any deviations from approved QAPPs and reporting deviations to the project team and end users;
- Identifying possible data quality problems and potential areas for quality improvements and reporting them to the project team and end users;
- Ensuring that the model performs as anticipated and meets the objectives and documenting the procedures for the mechanism of assurance.

1.3.8 Dispute Resolution

When quality assurance issues are disputed, 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 dispute resolution. Should agreement not be reached at a lower level of management, the issue will be resolved by senior management. The Regional Administrator and the Deputy Regional Administrator have final dispute authority for all quality issues.

1.4 Environmental Program and Operations

1.4.1 Office of Regional Administrator

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

The Agency has appointed a Scientific Integrity Official to champion scientific integrity throughout the Agency. The Scientific Integrity Official chairs a standing committee of Deputy Scientific Integrity Officials representing each EPA Program Office and Region. The EPA Region 1 Scientific Integrity Official is a senior-level employee who provides oversight for the implementation of the Scientific Integrity Policy, acting as liaison for the Region and is available to address any questions or concerns regarding this policy. The Regional Administrator has designated the Director of the Laboratory Services and Applied Science Division (LSASD) as the Regional Scientific Integrity Official.

1.4.2 Laboratory Services and Applied Science Division

The Laboratory Services and Applied Science Division (LSASD) is organized into the following Branches:

- Quality Assurance Branch
- Field Services Branch
- Lab Services Branch

LSASD administers the following programs:

- Quality management
- Scientific integrity
- Field sampling
- Lab services

In accordance with the Agency Policy Directive *Ensuring the Competency of EPA Laboratories,* the FSB and LSB have documented their quality system in the *NERL Quality Manual* which is maintained in the LSASD Document Control System. 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 Directive requires that all EPA laboratories become accredited where appropriate. To this end, NERL maintains ISO 17025 certification for biology, chemistry and field sampling parameters. ISO certification is maintained through adherence to ISO requirements.

1.4.2.1 Quality Assurance Branch

The QAB is responsible for managing the Regional quality system; establishing quality policy, guidance, and procedures for all environmental data operations as appropriate; reviewing and approving intramural and extramural QMPs and QAPPs; and reviewing various QA documents (e.g., SAPs, workplans, SOPs); conducting Quality System Assessments (QSAs) and Technical Assessments/Audits to ensure conformance with QA requirements; providing guidance for developing project quality objectives, QMPs, QAPPs, SOPs; and providing technical assistance to resolve sampling, analytical, and data usability issues. Members of the QAB also provide training for QA/QC concepts and QA requirements, for the program offices within the Region, Agency contractors, and State, Tribal, and local governments that are involved in environmental data operations.

In addition, the Branch is responsible for coordinating the Regional Peer Review Program; providing analytical services through the Contract Laboratory Program (CLP), providing various support through the Environmental Services Assistance Team (ESAT) contract; coordinating the Information Quality Guidelines-Pre-dissemination Review program; supporting the FASTAC strategy; providing quality assurance assistance to the Superfund Program by administering the Performance Evaluation Sample Program; managing the Drinking Water Certification Program; performing Alternate Test Method reviews; and supporting the National Environmental

Laboratory Accreditation Program (NELAP).

1.4.2.2 Lab Services Branch

The Lab Services Branch (LSB) is responsible for performing chemical and biological analyses of environmental samples, and providing oversight of ESAT, and external contract laboratories to support investigations conducted by the EPA Region 1. The Team also provides technical assistance to the Regional media programs, State and local environmental agencies, private industries and independent laboratories in areas such as analytical methods and method development. Members of the Team provide consultation for legal cases and supporting various laboratory audits.

1.4.2.3 Field Services Branch

The Field Services Branch (FSB) supports Regional programs, States and Tribes, as well as nationwide monitoring initiatives. Under the Clean Water Act and Clean Air Act, FSB assists States and Tribes implementing and ensuring compliance with ambient monitoring programs.

FSB works with the States to implement National and State ambient air monitoring programs, including special projects and research on priority issues such as mercury. FSB oversees the collection and evaluation of air quality data collected by States and other entities in support of Regional and National monitoring. FSB has delegated QAPP approval authority and is responsible for reviewing all external air programs' QAPPs for environmental data collection and for approving external air program standard operating procedures (SOPs). FSB ensures that air monitoring meets the Agency's required siting and design criteria, data collection techniques, and QA/QC procedures. It ensures that data are accurately reported to the Agency's National data system, AQS, or another appropriate data system.

The FSB is also responsible for providing field support, including environmental sampling and regulatory compliance inspections for the Air, Water and Waste Programs. These activities are performed to determine compliance with the applicable provisions of the CAA, RCRA, SDWA, CWA, and TSCA. Environmental sampling is conducted according to generic and project specific QAPPs, sampling and field measurement SOPs, and data are reviewed prior to decision making.

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

1.4.3 Superfund and Emergency Management Division

The Superfund and Emergency Management Division (SEMD) is an integrated office for the management of hazardous waste sites and emergency response activities. SEMD is organized into the following branches:

- Emergency Planning and Response Branch

- Remediation Branch I
- Remediation Branch II

SEMD Administers the following programs:

- Superfund site assessment and cleanup
- Emergency response
- Oil spill prevention and planning

1.4.3.1 Remediation and Restoration Programs

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

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

1.4.3.2 Superfund Emergency Planning and Response

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

1.4.4 Land, Chemicals, and Redevelopment Division

The Land, Chemicals, and Redevelopment Division (LCRD) is organized into the following sections:

- Brownfields and Sustainable Materials Management Section
- RCRA Waste Management, UST and Pesticides Section
- RCRA Corrective Action and TSCA Section

LCRD administers the following programs:

- RCRA Hazardous waste management
- RCRA facility corrective action
- Underground storage tanks/Leaking underground storage tanks

- Brownfields
- Toxic Substances Control Act (TSCA)
    - PCB program and
    - Lead-based paint program
- Asbestos demolition/renovation
- Pesticides
- Pollution prevention

1.4.4.1 LCRD Programs

The Resource Conservation and Recovery Act (RCRA) program is overseen and monitored by LCRD and enforced by ECAD. All six New England States have been authorized to implement RCRA requirements and EPA maintains oversight responsibility.

The UST/LUST programs have been delegated to all six New England States. LCRD maintains oversight responsibility for the delegated programs in all six New England States.

1.4.5 Water Division

WD is a multi-program, ecosystem-based office that works to establish environmental standards and goals and works with States and communities to achieve these goals. The WD manages regulatory considerations and issues permits.

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

The Water Division is organized into the following Branches and Sections:

- Drinking Water and Municipal Assistance Branch
- Surface Water Protection Branch
- Water Permits Branch

The Water Division administers the following programs:

- Coastal and ocean resources
- Drinking water
- Groundwater protection
- Water infrastructure
- National Estuary Program
- Lake Champlain Basin Program

- Southeast New England Program
- Non-point source pollution
- NPDES permits
- Ocean disposal and dredging
- Clean Water State Revolving Fund (CWSRF)
- Drinking Water State Revolving Fund (DWSRF)
- Water quality standards
- Total Maximum Daily Loads (TMDLs)
- Wastewater and stormwater permitting
- Watershed restoration
- Wetlands

1.4.5.1 Water Programs

The WD 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. ECAD 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.

WD staff members in conjunction with LSASD are responsible for reviewing and approving QAPPs prepared by grantees and contractors working with or gathering environmental data.

1.4.5.1.1 Clean Water Act

The WD's water program branches (Surface Water Branch, Water Permits Branch, Drinking Water and Municipal Assistance Branch) are responsible for implementing and monitoring programs which support all aspects of the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA).

WD staff members in the Water Permits Branch implement the National Pollutant Discharge Elimination System (NPDES) permit program either directly or through oversight of a delegated State. For the NPDES and Pretreatment programs, primacy has been delegated to four New England States: Connecticut, Rhode Island, Maine and Vermont.

1.4.5.1.2 Safe Drinking Water Act

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

1.4.6 Enforcement and Compliance Assurance Division

The Enforcement and Compliance Assurance Division (ECAD) is responsible for developing and implementing Regions 1's enforcement and compliance assurance programs and statutes that EPA administers in the geographic boundaries of the region. ECAD is organized into the following Sections:

- Water Compliance Section
- Air Compliance Section
- Waste and Chemical Compliance Section
- Toxics, Pesticides and Drinking Water Compliance Section
- Multi-Media Assistance and Support Section

ECAD administers the following programs:

- Enforcement of broad range of environmental statutes, including the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Toxics Substance Control Act (TSCA), Emergency Planning and Right- To- Know Act (EPCRA), Marine protection, Research, and Sanctuaries Act (MPRSA
- Inspections and compliance monitoring programs, including targeting, on- and off-site compliance monitoring activities, credentialing, and inspection reports Developing enforcement cases, preparing and issuing administrative actions, assessing penalties, developing judicial enforcement actions, and negotiating Tracking and resolution of tips and complaints
- Implementing compliance assistance activities

1.4.7 Mission Support Division

The Mission Support Division is a resource management office responsible for personnel, facilities, and space; financial management, including budgeting; information services; grants, contracts, and procurement; and other support services. No significant environmental data operations are performed directly by this office. Its role in supporting environmental programs is discussed below.

MSD is organized into the following Branches and Sections:

- Information Services Branch
- Customer Service and Facilities Branch
- Comptroller Branch
- Human Resources Branch
- Contracts and Procurement Branch

- Grants Management Branch

MSD administers the following programs:

- Strategic planning and process improvement
- Budget
- Finance
- Financial aspects of cost recovery
- Management Control and Financial Integrity Federal Managers Financial Integrity Act (FMFIA)
- Facilities and security
- Health and safety
- Human resources
- Information technology and information management (including geographic information systems)
- Customer service support
- Management of grants and interagency agreements
- Contracts and acquisitions

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

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

The Information Services Branch is responsible for the storage, management, and retrieval of mainframe data for PCS, STORET and the AIRS database systems. This Office is also responsible for the Region's IT infrastructure, the purchase and upkeep of computer hardware and software and technical support for the Region's Geographic Information Systems (GIS), providing Web, desktop computing, IT security and local applications development support. Additional information on these functions can be found in Section 6.0 of this QMP.

1.4.8 Air and Radiation Division

The Air and Radiation Division (ARD) implements the programmatic aspects of the Clean Air Act (CAA) within the geographic boundaries of Region 1, except for inspections and enforcement, which are principally managed by the ECAD. Additionally, LSASD principally implements regional and federal regulations and guideline associated with the collection of air quality data. Under the CAA and in accordance with implementing regulations and agency guidelines, the Division conducts activities to reduce emissions so that air pollution does not constitute a threat to public health, safety, well-being and the environment. To carry out its mission, the Division works with other federal agencies, state and local agencies, tribal governments, the public, and the private sector. The Division coordinates with the Office of Air and Radiation to ensure national consistency and strives to meet legal deadlines imposed by the CAA.

ARD is organized into the following Branches:

- Air Quality Branch
- Energy and Resilience Branch
- Air Permits, Toxics and Indoor Programs Branch
- Grants and Program Support Branch

ARD administers the following programs:

- State, Tribal, and Federal Implementation Plans (SIPs/TIPs/FIPs)
- National Ambient Air Quality Standards (NAAQS) designations
- Air permits
- Air toxics
- New Source Performance Standards (NSPS)
- National Emission Standards for Hazardous Air Pollutants (NESHAP)
- Maximum Attainable Control Technology (MACT)
- Diesel Emissions Reduction Act (DERA)
- Air grants
- Tribal Air
- Radon
- Indoor air
- Voluntary programs consultation, technical assistance and outreach (Energy Star, radon, asthma, etc.)
- Programmatic grant support, including state, tribal, air, and water grants

1.4.8.1 Clean Air Act

ARD's air program relies on ambient air quality monitoring data and source emission data collected by the New England States. The States collect ambient air quality monitoring data on air toxics, ground-level ozone, ozone precursors, lead, nitrogen dioxide, carbon monoxide, sulfur dioxide, and particulate matter. All six States have been delegated or authorized to enforce in part or in full the following CAA programs: Part 60/NSPS, Part/61 and 63 NESHAPS, Sect. Prevention of Significant Deterioration permitting, Title V/Part 70 permitting , Nonattainment New Source Review (NSR) permitting, minor NSR permitting, and Indoor Radon/Section 306.

EPA funded programs involving data operations are required to conform to Agency and Regional quality requirements, standards and guidance. LSASD works with the States to ensure that quality assurance requirements are met. The States also prepare inventories of emissions from sources. ARD requires the States to have adopted and used proper quality assurance requirements in preparation of these emission inventories.

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 Field Service Branch of LSASD. 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.

1.4.9 Office of Regional Council

The Office of Regional Counsel (ORC) Counseling Branch provides legal advice to Region 1 programs on the implementation of all environmental statutes and on the general legal requirements applicable to the operations of the Region. This Branch also represents the Region in any defensive litigation that arises from the Agency's actions in Region 1, either directly before administrative bodies such as the Environmental Appeals Board or the Equal Opportunity Employment Commission or in coordination with the Department of Justice when a case is in federal court.

The ORC Legal Enforcement Branch provides legal advice and representation of the agency in connection with enforcement and compliance assurance programs and statutes EPA administers in the geographic boundaries of the region. The Legal Enforcement Branch Chief works closely with the other Region 1 divisions, OECA, and Department of Justice (DOJ) to deliver a comprehensive enforcement and compliance assurance program utilizing the entire spectrum of compliance assurance tools available to the region.

ORC is organized into the following Branches and Sections:

- Counseling Branch
- Legal Enforcement Branch
    - Superfund and Site Remediation Legal Enforcement Section
    - Regulatory Legal Enforcement Section

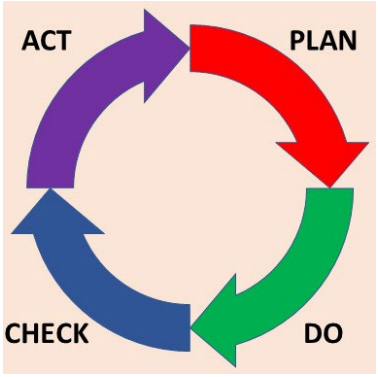
ORC administers the following programs:

- Legal counsel
- Litigation
- Ethics
- Regional Hearing Clerk

Freedom of Information Act (FOIA)

2.0 QUALITY SYSTEM COMPONENTS

This Section documents how EPA Region 1 quality system is managed and defines the primary responsibilities for managing and implementing each component of the system. The Regional quality system provides a management structure that ensures the quality of work and services pertaining to environmental data throughout the organization. Specifically, it provides the framework for planning, implementing, documenting, reporting and assessing Regional activities relevant to environmental data operations in keeping with the universally recognized quality cycle. See also Section 1.1 Mission Statement.



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

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

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

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

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

Quality system programs and components are implemented by policy memoranda and using a variety of quality tools. These tools include National and Regional requirements and guidance documents. The Regional guidance documents may be obtained from the QA Regional Web site, and the Regional Science Council SharePoint site. Regional policies are available on the Intranet site. Regional policies and SOPs are maintained on the LSASD Document Control System. National documents may be obtained from the Enterprise Quality Management Web site.

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

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

Quality System CIO Standard 2105-P-01-0, (formerly 5360 A1) EPA *Quality Manual for Environmental Programs*	
Components	**Tools**
Quality System	*EPA Region 1 QMP*
Annual Quality System Review and Planning	QA Annual Report
Regional QA Policies	Management Memoranda
Quality Assurance Project Plan Program *EPA New England QAPP Program Guidance* document EPA QA Requirements and Guidance documents Tracking Systems for project-related information - LSASD Request for Assistance (RFA) Database	
Components	**Tools**
Project Planning	EPA Region 1 Systematic Planning Process
Project QA Documentation	Project-specific QAPPs, Generic QAPPs, Program QAPPs, Combined QMP/QAPPs, and equivalent QA documentation
Project QA Planning Documentation Review and Approval Process	QAPP Review Procedures
Implementation EPA QA Requirements and Guidance Documents - New England Sample Tracking System (NESTS) - LSASD RFA Database - Region 1 Document Control System - QAFAP Standard Operating Procedures	
Components	**Tools**
Representative Sampling	Sampling SOPs
Field Analytics	Field Analytical SOPs

LSASD Sampling, Analytical, and QA SOPs	*NERL Quality Manual* LSASD SOPs LSASD Document Control System
Performance Evaluation Samples	*EPA New England Data Review Program Guidance* SPSWEB system
Assessment Program *Quality Assurance Branch SOP for Quality System Assessments and Technical Systems Audits* Tracking Systems - Superfund Performance Evaluation Sample Scoring Web (SPSWEB system) - LSASD RFA Database	
Components	**Tools**
Management Assessment	Quality System Assessments *Guidance on Assessing Quality Systems, (QA/G-3)*
Project Assessment	Technical Assessments including: -Field Sampling Technical Systems Audits (TSAs) -Field Analytical TSAs -Field Laboratory TSAs -Fixed Laboratory TSAs -Split Sampling and Analysis Audits -Data Package TSAs -Data Validation TSAs -Drinking Water Program Audits EPA Region 1 Technical Systems Audit SOP Project-Specific Audit Checklists and Audit Reports Performance Evaluation Samples
Data Review Program (Verification, Validation and Usability) *EPA New England Data Review Program Guidance* and *Supplement* documents Tracking Systems - LSASD RFA Database - WEB New England Sample Tracking System (WNESTS)	
Components	**Tools**
Data Review	*EPA New England Data Review Program Guidance* and *Supplement.*
Data Usability Assessment	*EPA New England Data Review Program Guidance* *EPA Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*
QA Training Program	
Components	**Tools**

QA Training Program	Types of Training -Classroom - Informal -e-Training -Conferences *EPA New England Standard Operating Procedure for QA Training Documentation*
Quality-related Internet and Intranet Sites	
Components	**Tools**
Internet: EPA Region 1 QA Home Page	Links to: -Training -Services -Quality System Documents
Intranet: EPA Region 1 QA	Links to: Regional QA Policies
Regional Science Council SharePoint Site	Links to: - Human Subjects Research - Peer Review - Information Quality Guidelines - Pre-dissemination Review
Peer Review Program Program documented in *Science Policy Council Handbook, Peer Review*, 4rd edition, 2015 Tracking Systems - National Science Inventory Database	
Components	**Tools**
Agency-defined Peer Review Program	Regional Web site Peer Review Call Letters/Memoranda
Information Quality Guidelines	
Components	**Tools**
Pre-Dissemination Review Procedures for Agency Information	Intranet EPA NE IQG & PDR Web page Regional Implementation Plan IQG-PDR e-Training

3.0 PERSONNEL QUALIFICATIONS, TRAINING AND COMPETENCE

The Region implements procedures to assure all personnel performing work for EPA Region 1 have the competency to effectively accomplish their work. To achieve Regional quality goals and objectives, management and staff performing tasks related to environmental data operations must have the necessary skills and knowledge to effectively accomplish their work.

3.1 Commitment to Training

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

3.2 Qualifications

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

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

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

3.3 Professional Development and Training

The Region provides professional development and training, including QA training and field measurement training (or use environmental data operations) through the Center for Development and Learning, through external providers, and other means. E-training is also provided through various venues including the EPA eLearning FedTalent training system. Quality-related training is discussed further in Section 3.5. Needs assessments are conducted periodically to identify training needs for the Region, such as training for Project Officers and new hires. In-house training is also posted on the FedTalent training system. Registration for training is accomplished electronically through FedTalent. The Human Resources Office is responsible for maintaining records of employee training received through FedTalent and received from sources external to the Region.

3.4 Certifications

Formal certifications are required for various personnel in the Region. Personnel involved in auditing and certifying State SDWA programs are required to successfully complete the SDWA Certification Officer Training. A refresher training course is provided by the QAB prior to each state laboratory audit.

Personnel involved in managing contracts are required to successfully complete Contracting Officer's Representative (COR) training. The following are links for COR Certification and recertification training requirements.

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

Personnel in positions that require EPA-issued credentials must complete all initial and refresher training required by EPA order 3500.1 (which also includes Health and Safety training required by EPA order 1440.2). In addition, EPA Offices including OLEM, OAR, OECA, and OW, require program-specific training related to the technical, operational, and administrative aspects of environmental data operations.

Certificates are kept on file by the person certified.

3.5 Regional QA Training

The QAB works with the Regional Training Officer, Office Directors and their staff to assess Regional QA training needs. The QAB provides support in developing general QA awareness training and specific mandatory training.

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

Assessment team members receive appropriate training prior to conducting assessments in accordance with Section 9.3 of this QMP.

QA training is based on prioritized needs and implemented as resources permit. QA training provided by the QAB of EPA and non-EPA personnel is tracked in the LSASD RFA database.

3.5.1 QA Training Needs Assessment

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

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

2. Training needs are identified through internal and external audits and management systems reviews.
3. Training is developed when new National and Regional quality-related policies are issued.

3.5.2 QAB Staff Training

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

3.5.3 Financial Assistance Agreement Recipients and Contractors

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

3.5.4 Regional QA Training Program and Outreach

3.5.4.1 Training

The Regional QA training is described in the *EPA New England Quality Assurance Training Documentation SOP* available through the LSASD Document Control System.

3.5.4.2 Mandatory QA Training

Regional management determines which training is mandatory and for whom, and the frequency of the training. Managers are responsible for ensuring that staff complete their required trainings. Currently the following Regional QA training is mandatory:

- Quality System Awareness Training is required for all EPA Region 1 personnel;
- Project Officer Quality Assurance Awareness Training is required for EPA Project Officers, Grants Specialists and supervisors;
- QAPP training and/or QAPP Review Training is required for all Superfund RPMs, Site Assessment Managers (SAMs), and RCRA Corrective Action RFMs; and
- Laboratory Annual Ethics and Data Integrity Training is required for LSASD technical staffs, managers and contractors.

3.5.5 QA Training Records Maintenance - QA Training Provided by EPA Region 1

Procedures for maintaining records of training provided by the QAB are described in the most current version of the *Quality Assurance Unit Quality Assurance Training Documentation Standard Operating Procedure* (LSASD Document Control System.: EQASOPQATrainDoc).

All trainings conducted by the QAB are logged in the QAB tracking database. Each entry includes a copy of the training materials as appropriate and an attendance sheet.

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 Regional Training Office.

4.0 PROCUREMENT OF ITEMS AND SERVICES

Regional procedures for acquiring items and services that directly affect the quality of environmental programs are documented. It is the Region's policy to specify the designated quality assurance and quality control requirements when acquiring items and/or services that relate to environmental data operations and environmental technologies. Regional policy also requires that environmental data acquired, regardless of the mechanism, must be reviewed prior to use and dissemination. Regional procurement functions and financial assistance agreements are conducted in accordance with Federal Acquisition Regulations and related Agency policies, directives, and guidance. Contractors, suppliers, and financial assistance recipients are responsible for the quality of work performed directly for EPA and for items and services provided by their subcontractors/sub-awardees and suppliers.

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

4.1 Contracts

All procurements and contracts originating in the Region must meet established administrative and QA requirements in the Federal Acquisition Regulations (FAR 46.202-4 and 52.246-11), the EPA Acquisition Guide (EPAAG), Chapter 46 Quality Assurance, Section 46.2.1 Contract Quality Requirements. The most recent Regional procurement policies regarding Quality Assurance Review Forms (QARFs) are in the following memoranda and available on the LSASD intranet website under **Quality Assurance (QA) Requirements, Guidance and Tools. See also the Appendices.**

- *Quality Assurance Requirements for Non-SEMD Contract Actions (QARFs)*
- *Quality Assurance Requirements for SEMD Contract Actions*

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

For all new contracts or procurements, the Contracting Officer's Representative (COR) must complete the EPAAG QA Review Form (QARF) in Appendix 46.2.1-D prior to forwarding a request for procurement/contract placement.

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

4.2 Financial Assistance Agreements

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

- 1 CFR1500.11, "Quality Assurance"
- 40 CFR Part 30, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations"
- 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments"
- 40 CFR Part 35, "State and Local Assistance"

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

4.2.1 Grants and Cooperative Agreements

The current Regional process for ensuring that financial assistance recipients meet QA requirements was developed in 2000 and is revised annually 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 regional grants management process was initiated through the January 25, 2001 policy statement *Revised Quality Assurance Requirements for Grants.*

This policy memo is reissued periodically to update procedural changes and to remind Project Officers of their roles and responsibilities. The most current version of the Regional Grants QA policy is available on the LSASD intranet website under **Quality Assurance (QA) Requirements, Guidance and Tools. See also the Appendices.**

- *Grants & Cooperative Agreements*

For continuing program grants that involve environmental data operations, QMPs (or equivalent quality system documentation as approved by the RQAM) and QAPPs are required. There may be situations where a QMP may not be appropriate such as one-time grants where only a QAPP

would be required. The RQAM ensures that QAPPs for one-time grants or similar situations contain sufficient information to describe consistent application of QA at the organizational level.

The QA requirements memo describes the following process;

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

QMPs and QAPPs will be prepared, reviewed and approved in accordance with the specifications provided in Section 7.0 of this QMP. All QMPs and QAPPs are reviewed and approved by the RQAM, or designated QAB staff, 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 7.4.

4.2.2 Interagency Agreements

Interagency agreements funded by EPA Region 1 are subject to the requirements described in the most recent policy memo available on the LSASD intranet website under **Quality Assurance (QA) Requirements, Guidance and Tools. See also the Appendices.**

- *Quality Assurance Review Forms (QARFs) Interagency Agreement Shared Service Centers (IASSC)*

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

5.0 DOCUMENTS AND RECORDS

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

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

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

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

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

5.1 Records and Documents Pertaining to the Quality Management Plan

In accordance with the most current EPA Order CIO 2105.0, the EPA Region 1 QMP must be revised every 5 years and resubmitted to EQMD for review and signature approval by EPA's Chief Information Officer (CIO). Also, the QMP must be reviewed annually and changes/revisions must be reported in the QA Annual Report. Minor changes to the QMP do not require EQMD signature approval.

The QMP is maintained in the LSASD Document Control System in accordance with the *LSASD Document Control User Manual*. Superseded versions are archived in the database for reference. All QMP citations must include the document control number and date of revision.

The QAB has been delegated the authority to and is responsible for developing Regional guidance and procedures relevant to QA-related documents and records. The QAB 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 Data Review Program Guidance;* and

The QAB assesses conformance to Regional requirements through assessments.

5.1.1 Records and Documents Pertaining to Environmental Data Operations

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

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

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

- Chain of Custody Records;
- Field Sampling and Measurement Logs;
- Deviations from approved QAPPs and SOPs;
- Sample Results and Supporting Data; and
- Communication Records

5.1.2 Document Control Requirements

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

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

For those programs delegated QAPP approval authority (refer to Section 7.6.1), the authorized program representative must maintain the official copy of the completed Title and Approval Page with approval signatures (or other record of approval) and provide a copy to the QAB for each project specific QAPP.

5.1.2.1 LSASD Document Control Procedures

The handling of LSASD controlled documents is described in the *NERL Quality Manual*, *QAB Document Control SOP*, and the *SOP for the Management of Standard Operating Procedures*. Controlled documents include manuals, plans, policies, guidance, SOPs, forms and other documents used to implement management systems. The electronic document control system is available through the LSASD intranet page. Controlled documents are accessible to all LSASD personnel as portable document format (PDF) files. Only the electronic document viewed on-line is a controlled document. Printed copies are not considered controlled copies, and a caveat stating this is included with each SOP.

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

5.1.2.2 QAB Documents and Records

All QAB work is logged into the Request for Assistance (RFA) Database. Each assignment is automatically assigned a sequential RFA number and tracked in accordance with the RFA Manual. In March of 2012, the database was upgraded to accommodate digital storage of documents.

Hard copies of documents and records may also be maintained in the QAB file room by RFA number for 5 years in accordance with the *LSASD QAB File System SOP*. After five years, records are disposed of in accordance with program records retention regulations, policies and Regional procedures.

5.2 Ensuring Documents and Records Accurately Reflect Completed Work

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

5.3 Establishing and Implementing Chain of Custody and Confidentiality

Procedures

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

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

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

- 44 U.S.C. Chapter 31, Records Management by Federal Agencies;
- 44 U.S.C. Chapter 33, Disposal of Records; and
- 18 U.S.C. Chapter 101, Records and Reports;

The EPA Region 1 SEMS Records and Information Center (SEMS RIC) supports the Superfund Enterprise Management System – Records Management (SEMS-RM) and maintains the EPA NE SEMS Portal.

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

6.0 COMPUTER HARDWARE AND SOFTWARE

EPA's ability to fulfill its mission is dependent upon a strong information technology infrastructure and reliable electronic information products. The Environmental Information Program is responsible for managing the Agency's information functions, including information collection, technology infrastructure, access and security. Within the Environmental Information Program, the Office of Information Management (OIM) establishes information technology (IT) policies, standards and procedures to ensure that information technology components integrate properly into the overall IT infrastructure and that Agency-owned environmental databases provide accurate data. OIM 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 OIM's IT policies, standards, and procedures. In addition, Service Bulletins are periodically issued by the Mission Support Division (MSD) to address Information Management issues including e-mail, data retention, data back-up, data storage, etc. Consistent with the Region's IQG-PDR procedures, the Region expects that all information and environmental data acquired from IT methods and sources are evaluated prior to use using systematic planning procedures described in Section 7.0 Planning.

6.1 Roles and Responsibilities

The designated Senior Information Officer (SIO) for EPA Region 1, as part of the SIO network supporting the CIO, is responsible for ensuring consistent Agency-wide management of information technology, information management and the integrity of electronic data.

6.1.1 Hardware and Software

The Information Services Branch within the Office of Mission Support (OMS) is responsible for the following computer hardware and software support activities:

- Installing, configuring, testing, and troubleshooting network operating system and LAN based application software;
- Troubleshooting and solving problems for the LAN server, data switches and routers, and any related gateways and communications equipment;
- Supporting personal computer (PC) hardware and software procurement, system configuration, testing and installation of PC and peripheral equipment;
- Coordinating system software and hardware changes for PC equipment;
- Troubleshooting and fixing software and hardware problems reported by users;
- Overseeing PC and LAN security;
- Ensuring security software, system patches, system controls procedures and policies are implemented to prevent introduction of malicious software and computer viruses as well as to prevent unauthorized system/network access by hackers via the Internet; and
- Reviewing security practices to ensure that appropriate levels of information security are maintained. This includes review and implementation of policies and practices such as those that apply to user IDs and passwords, remote access, Internet, server system/data backup and recovery, physical access to Regional data center and communication closets.

6.1.2 Computer Models

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

6.2 Regional Information Management Systems

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

It is Regional policy to work closely with information system customers, as well as OMS and National Program Offices, as appropriate, on all phases of system development, improvements,

and updates, including contractor-developed systems and those developed by other entities. During all life cycle phases of information management systems, the Region will comply with requirements within the *Information Resources Management Policy Manual*, the *System Life Cycle Management Policy,* and the *System Life Cycle Management Procedure.*

6.3 Hardware and Software Requirements

The Region conforms to OMS policies, standards and guidance pertaining to hardware and software, and the Enterprise Architecture Policy CIO 2122.0. Through its procurement procedures, the Region ensures that purchased hardware and software meet user requirements and conform to OMS's technology and procurement guidelines.

6.4 Data Standards

It is Regional policy to comply with all applicable Federal regulations, guidance, executive orders, and internal policy documents concerning data standards, and Data Standards CIO 2133.0. These include EPA's core information data standards: The Locational Data Accuracy Standard, the Facility Identification Standard, the Groundwater Data Element Standard, the Chemical Abstract Number Standard, and the Electronic Transmission of Lab Measurements Standard. It is the responsibility of individual Offices within the Region to be aware of the current standards and regulations.

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

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

6.5 EPA Region 1 Internet and Intranet Site Responsibilities and Procedures

The Regional Web Content Coordinator is responsible for information products posted on the Regional Web site. The EPA Region 1 Communication Group maintains the Regional Internet Web site. This requires a three-pronged approach focused on the following issues: 1) content creation and maintenance; 2) navigation through the Web site; and 3) maintaining and incorporating new Web technology. The Communications Group comprises Communication Coordinators from the various Offices, staff from the Regional Administrator's Office and Web technical staff.

All Web site requests are treated as information products used by EPA to represent or support

Agency positions and policies. Therefore, requests are managed in accordance with the Information Quality Guidelines through the EPA Region 1 Web site. Requests for Web site dissemination of information, reviews, and managerial concurrence are managed through the Video/Internet/Design Information (VIDI) system.

It is Regional policy to conform to the EPA Intranet Publishing Guidelines.

7.0 PLANNING

Regional policy requires the use of systematic planning according to the *Guidance of Systematic Planning Using the Data Quality Objectives, EPA QA/G-4,* and the Region 1 Systematic Planning Process (Table 1) to ensure that all data, including existing data, and information are of the needed and expected quality for the desired use.

The G-4 planning process elements include: Organization, Project Goal, Schedule, Data Needs, Criteria, Data Collection, Quality Assurance, and Analysis.

7.1 Region 1 QAB Planning Procedures

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

The QAB provides several general and program specific QAPP development tools on the R1 Quality Systems Documents Internet page. This site provides examples of various project QAPPs, in addition to the following specific QAPP tools:

- Brownfields
- Environmental modeling
- Water quality monitoring
- Secondary/Existing data projects

For media programs, many of the National Program Offices have developed programmatic data quality objectives and model QAPPs, the Region typically uses the National guidance and/or model QAPPs. The Region adopts a graded approach for the development of a QAPP, based on program-specific guidance, for planning, documenting, and assessing environmental projects. QAPP elements are addressed using the systematic planning process and are commensurate with the objectives and intended use of the data.

The RQAM and QAB staff, as project team members, provide QA recommendations and technical assistance when planning projects and developing project quality objectives. However, the ultimate project and data quality decisions are made by the program. It is the program's responsibility to properly plan the project to ensure that the collection or use of data/information

are the right type, quantity, and quality needed to support the objectives.

7.2 Quality Management Plans (QMPs)

In accordance with EPA Order CIO 2105.0, EPA organizations and extramural organizations funded by EPA that conduct environmental data operations are required to operate under quality systems that conform to ANSI/ASQ E-4 specifications and are documented in a Quality Management Plan (QMP).

Therefore, the Regional quality system is planned, developed, and documented in this QMP in accordance with the most current EPA Order CIO 2105.0. This QMP is reviewed and approved by EQMD. Implementing the QMP is a shared responsibility among all Regional personnel; the RQAM is responsible for overseeing the implementation of the quality system. To that end, the RQAM maintains a current QMP, resubmits the QMP to EQMD whenever major revisions are necessary or at a minimum of every five years, and performs annual reviews of the quality system.

For organizations funded by EPA Region 1, a quality system must be planned, developed, and documented in accordance with applicable Federal Regulations for Acquisition and Financial Assistance Agreements. QMPs, or equivalent organizational quality system documents, are required by the Region. Equivalent documentation of a quality system is determined on a case-by-case basis by the RQAM (Section 4.2.1). All extramural QMPs and other organizational quality system documentation is reviewed and approved by the RQAM or designated QAB staff. The QAB reviews and approves QMPs in accordance with the *EPA New England Standard Operating Procedure for Reviewing Quality Management Plans* (LSASD Document Control System). QMPs are not required for all grants, for example one-time grants.

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 major revisions are necessary, when so directed by EPA NE, or at a minimum of every five years. The QAB maintains a tracking database that provides the status of State, Tribal and Interstate organization QMPs, and the status of contractor QA documents that have been reviewed and approved.

In conjunction with members of the EPA Region 1/State QA Roundtable, the Annual Quality System Status Report Template was developed as guidance for organizations required to report annually on the status of their quality systems. Areas of reporting include assessments, training needs, notable QA issues/activities for the year, and current QAPPs.

7.3 Quality Assurance Project Plans (QAPPs)

The Regional QAPP Program requires that the results of the systematic planning process are 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 QAB staff and is based upon the project quality objectives and the intended use of the data.

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

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

7.3.1 Types of QAPPs

The Region supports the use of project specific QAPPs, Generic QAPPs and Program QAPPs as defined in the *EPA New England QAPP Program Guidance.*

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

7.3.2 QAPP Review/Approval Process and Turnaround Time

The Regional review procedures for QAPPs are detailed in the *EPA New England Standard Operating Procedure for Reviewing Quality Assurance Project Plans* in the LSASD Document Control System.

The time required to review and approve a QAPP is dependent on whether the initial submission of the QAPP provides appropriate and sufficient project information. In order to allow for comment and response, organizations are requested to submit an approvable QAPP to the QAB a minimum of 60 calendar days before the initiation of work. An approvable QAPP is one that is complete, includes adequate information to describe project activities and the quality objectives are well defined. The information must be sufficiently transparent to allow a re-creation of the data collection or use activity.

7.3.3 Implementing and Revising QAPPs

Approved QAPPs must be implemented as written, however, a QAPP may be modified and amended to be current and accurate. 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 approval process, which is similar to the new QAPP approval process.

QAPPs are generally approved for a fixed time period specific to the environmental

data/information operation. They must be kept current and revised whenever necessary and when so directed by the Region or National Program Office. The QAPP should be reviewed annually, and this annual review should be documented and submitted to the original approval authority (i.e., EPA QAB and/or Superfund RPM, State authority).

7.4 QAPP Approval Authority

All environmental data operations conducted by EPA or funded by EPA must have an approved QAPP in place prior to the initiation of data collection. The RQAM has the authority and responsibility to approve all extramural and intramural environmental data operation QAPPs, unless delegated as described in the Regional QMP (refer to 7.4.1 and 7.4.2). In addition, Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements.

7.4.1 Delegation of QAPP Approval Authority

7.4.1.1 EPA Region 1 Delegation

In accordance with EPA Order CIO 2105.0, the RQAM may authorize a representative, as defined in the approved QMP, to review and approve QAPPs. Delegation of QAPP approval authority does not preclude review by the QAB. Regional QA staff are available for technical and QA assistance upon request.

In EPA Region 1, the RQAM has authorized Project Managers in the Superfund and RCRA Corrective Action programs to review and approve QAPPs prepared for EPA by contractors, other Federal agencies, States, and those QAPPs submitted by the regulated community under voluntary and consensual or unilateral enforcement agreements, decrees and orders. Superfund and RCRA Corrective Action Project Managers are required to provide a completed copy of the approval documentation to the QAB after they review and approve the QAPP.

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

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

7.4.1.2 State Agency or Environmental Program Delegation

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

Delegation of approval authority is contingent upon concurrence by the environmental program manager within EPA Region 1. In addition, the organization must:

- Document and implement an effective quality system;

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

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

8.0 IMPLEMENTATION OF WORK PROCESSES

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

It is the policy of the Region to implement data and information collection activities according to an approved QAPP, by reference Standard Operating Procedures (SOPs) and all other associated documents and/or regulations. QAPPs are required to include written descriptions of all technical and QA/QC activities that will be performed.

8.1 Regional Procedures

Regional procedures are documented to ensure consistency in the collection and use of environmental information and data products. Documented procedures are used to ensure consistency, continuity of operations, serve as a basis for auditing, assist in training, and succession planning. LSASD SOPs are maintained in the LSASD Document Control System (DCS). EPA Region 1 uses EPA QA Field Activities Procedures (QAFAP) for field investigations. QA refresher training reinforces the importance of planning and documenting environmental activities.

8.2 Standard Operating Procedures (SOPs)

For routine activities, the Region uses Standard Operating Procedures (SOPs) for documenting procedures and a consistent application of processes. Some activities with SOPs include; QAFAP field investigations, inspections, analytical methods, data handling procedures, and QAPP review, etc. These written protocols serve to ensure a standardized and consistent approach for work processes.

Standardization of sampling, analytical, and review procedures provides a basis for generating information that is useful for determining whether objectives were achieved. Deviations from approved SOPs are documented and maintained with project records for usability determination. Documented protocols also serve as a basis for technical assessments.

8.3 Responsibility for Regional Procedures and SOPs

The responsibility for identifying operations that need written procedures/SOPs, and for preparing, updating, approving, withdrawing, and archiving procedures, ultimately lies with the Manager. The determination for when an SOP is or is not necessary, is through collaboration between staff performing the work and management. However, it is incumbent upon all staff to identify operations which need SOPs and/or revisions to remain current.

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

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

For compliance with CIO 2105-P-02.0 (EPA QA Field Activities Procedure) Region 1 established several regional standard operating procedures including an Oracle-based Document Control System to house all controlled documents related to field activities. It is available through the Region 1 intranet page. All Region 1 QAFAP SOPs can be accessed here.

8.4 LSASD SOPs

LSASD manages the SOP process with the LSASD *SOP for the Management of Standard Operating Procedures* and copies of all LSASD SOPs and the QAFAP SOPs, are maintained in the LSASD Document Control System (DCS) in accordance with the *LSASD Document Control System User Guide.* The LSASD Quality Assurance Officer, QAO, is responsible for the *SOP for the Management of Standard Operating Procedures*. EPA staff and contractors are required to read and attest to all SOPs relevant to their work. The "reading and attesting to" SOPs by personnel is managed electronically for management and staff to oversee the process.

Controlled documents are accessible to all LSASD personnel as portable document format (PDF)

files. Only the electronic document viewed/maintained on-line is a controlled document. Printed copies are not considered controlled copies, and a caveat stating this is included with each SOP.

Archived SOPs are maintained in the DCS which allows for the reconstruction of historical practices, as necessary. DCS access for uploading and maintaining controlled documents is limited to management and SOP/document custodians.

8.5 Inspection and Oversight of Work-Related Processes

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

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

8.6 Tracking and Reporting QAB Activities

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

The RQAM uses the reporting features of the RFA and SOP Document Control System (DCS) to generate reports for management and reporting purposes. Cumulative tracking information is generated and reported as necessary.

9.0 ASSESSMENT AND RESPONSE

EPA Region 1 documents processes and procedures to determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs.

To measure the effectiveness and performance of the Regional quality system, the QAB coordinates an assessment program for Regional environmental programs such as states, tribal nations and interstate organizations. The assessment process is described in the *EPA New England SOPs for Quality System Assessments* and *Technical System Audits.*

9.1 Region 1 Quality System Assessment

The Regional quality system is assessed annually and may include responding to an OMS request for a QA Annual Report. The QA Annual Report may be requested by OMS, EQMD and the reporting elements may vary from year-to-year. Annually the QAB requests, compiles, and reviews information regarding Regional quality resources and activities that may include 1) quality management resources, 2) QA/QC training – provided and received, 3) quality system-

related accomplishments, and 4) assessments performed and received.

The process used by the QAB for planning, implementing and documenting assessments and reporting results to management is described in the LSASD QAB SOPs for Quality System Assessments and Technical System Audits.

9.1.1 Assessment Tools

Selection of the appropriate assessment tool depends on whether a quality or technical system will be performed. Technical system assessment tool selection may also depend on the stage of the project during which the assessment is conducted. Tool types for quality system assessments and various technical assessments are in the tables below.

Quality System & Technical Assessment Tools

Quality System	Appropriate Tool Type	Comments and Examples
Quality System	Quality System Assessment (QSA); Management System Review	Assesses conformance to a documented quality system through the collection of information and documented evidence of the system implementation.

Technical Assessments	Appropriate Tool Types	Examples
Planning	Site Scoping Meeting; Site Visit; QA Project Plan Review	Site Scoping; Site Visit; QAPP Review
Sampling	Technical Systems Audit (TSA)	Field Sampling TSA (example, Low Flow Ground Water TSA)
Analysis	Technical System Audit; Performance Evaluation Sample (PES)	Field Analysis TSA
		Field Lab TSA
		Fixed Lab TSA
		PES Analysis/Scoring
Data Evaluation and Reporting	Data Review, Validation and/or Audit	See Section 9.9 - Data Review, Validation and Verification, and Data Usability Reporting

Data Usability	Data Usability Assessment	See Section 9.9 - Data Review, Validation and Verification, and Data Usability Reporting

Specific tools utilized by the Region are described in QA SOPs and/or other appropriate documents.

9.1.2 Data & Information Review, Verification, Validation, and Usability Reporting

Another assessment tool, among other requirements Agency quality policies and standards, is that results obtained from products or services involving environmental data and information shall be reviewed, verified, validated and qualified, prior to decision making, or data/information usage. Specific data and information review procedures, roles and responsibilities are described in applicable guidance and planning documents, including QAPPs or other equivalent documents.

The regional implementation documents include, the *EPA New England Environmental Data Review Program Guidance* and *EPA New England Environmental Data Review Supplement.*

9.1.3 Assessor Qualifications, Responsibilities and Authority

Qualifications - QAB members that lead assessments have apprenticed under senior members of the Branch prior to and during an assessment.

All LSASD team members participating in Chemistry, Microbiology and Cryptosporidium assessments of the State drinking water programs must have successfully completed a laboratory certification course offered by the OGWDW Technical Support Center, Cincinnati and must be familiar with quality assurance and quality control practices necessary to support data integrity, usability and defensibility. Radiochemistry assessments are performed by an EPA contractor as there currently is no Certification Officer training for radiochemistry. The QAB leads refresher training for drinking water program assessors prior to the first on-site evaluation of the assessment year. Personnel conducting laboratory assessments under NELAC or the new TNI Standards are required to have the appropriate assessor training. Similarly, teams evaluating NELAP Accreditation Bodies are required to have evaluator training.

As described above, quality system assessors need to have direct experience with the implementation of quality systems before conducting these assessments. Similarly, personnel leading technical systems audits should have experience or familiarity with the technical procedures they are auditing, including reviewing Quality Management Plans, Quality Assurance Project Plans and Standard Operating Procedures, as appropriate. When resources are available, a minimum of two assessors is preferred for conducting assessments. In addition to increasing

the degree of experience, this practice increases the level of competence and helps to prevent disputes over findings. The Assessment Lead 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.

9.1.3.1 Responsibilities

Assessors are responsible for planning, conducting, evaluating, documenting and reporting assessments. They are also responsible for follow-up to the assessment and evaluation of the response actions. Assessors' roles and responsibilities are described in the *Assessment SOPs*.

9.1.3.2 Authority

The authority to assess is derived from the most current version of EPA Order CIO 2105.0. Assessment authority is confirmed in the planning stage for each assessment. The purpose, scope and time frame for the assessment are documented in an assessment plan. For quality system assessments, the Lead Assessor and the organization's point of contact for quality assurance concur on the assessment's purpose, scope and time frame. For technical systems audits, the Lead Assessor and the Project Manager concur on the assessment's purpose, scope and time frame. Confirming the authority to assess in the planning stage of an assessment allows access to programs, managers, documents/records, and provides the organizational freedom to identify both problems and noteworthy practices, propose recommendations, and verify implementation and effectiveness of corrective actions.

9.2 Internal Assessments

9.2.1 Region 1 Quality System Assessment Procedures

EPA Order CIO 2105.0 requires EPA organizations to perform an annual review of their Quality System (QS), and when requested, submit a Quality Assurance Annual Report to the Office of Mission Support (OMS), Environmental Quality Management Division (EQMD). When an Annual Report is requested, the Region prepares the report which addresses QA activities for all environmental data and information programs, including the oversight of delegated activities, and those specific to the QAB. The OMS request includes the reporting elements and format.

When the annual report is not requested by EQMD, the RQAM generates internal reports to assess the Region 1 Quality System.

Internal assessments include; a) As part of requested reporting to OMS/EQMD, the Regional quality system is reviewed as described in Section 9.1. b) LSASD, LSB assessments are performed annually. c) TSAs, Data Evaluation and Reporting, Data Usability, and various other assessments are performed on an ongoing basis. d) As appropriate, QAB assessments of internal programs.

When necessary the RQAM assists with reviewing plans for internal audits, corrective action plans and follow-up, for EPA Region 1 field sampling and measurement activities, for compliance with CIO2015-P-02.0 EPA QA Field Activities Procedure.

Annually Peer Review activities are compiled, documented, and reported according to Peer Review Guidance or current procedures.

9.2.2 LSASD Management Reviews

As part of LSASD's quality system, the LSASD management team (Division and Deputy Directors, LSB, FSB, and QAB Branch Chiefs) and QAO, meet annually to conduct a review of the laboratory's Laboratory Services, Field Services, and Quality Assurance Branch activities to ensure services are suitable, appropriate, effective, and consistent. The management team meeting also is a time to identify necessary Division wide changes or improvements. The meeting is an opportunity to evaluate the following items:

- Suitability of policies and procedures,
- Reports from managerial personnel,
- Recent internal & external audit/assessment results,
- Corrective and preventive actions,
- Results of proficiency tests,
- Changes in volume and type of work,
- Client feedback and complaints, and
- Other relevant factors, such as QA activities, resources and staff training.

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

9.2.3 Technical Assessments

Technical Assessments are identified through project planning procedures including; the Quality Assurance Review Form (QARF), Project Manager's requests, Scoping Meetings, Quality Assurance Project Plans or comparable documents, etc. The Region's strategy is to conduct technical assessments as early as practicable in a data/information collection activity to identify potential problems and prevent the generation of data/information that do not meet the project objectives. 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 to determine if the project objectives were achieved. In the Superfund program, performance evaluation samples PES) are included with each sample delivery group (SDG) of samples, for each matrix, analytical parameter, and concentration level, as available. The PESs are considered an assessment for a specific time period.

9.3 External Assessments Performed

9.3.1 Air Monitoring Programs

a. New England States – comprehensive Technical Systems Audits (TSA) including evaluation of program quality system scheduled every three years. Performance Audits, NPAP TTP and PEP Program Audits complement the TSAs.
b. New England Tribes with air programs – TSA scheduled every three years in same year as State where Tribe resides.

9.3.2 State Certification Programs for Drinking Water Laboratories

a. Connecticut, Maine, Massachusetts and Rhode Island – Evaluation performed by the Region under the Agency's laboratory certification program every three years.
b. New Hampshire and Vermont – Assessment performed under NELAC Standards by NH Environmental Laboratory Accreditation Program with observation by Regional Office every two years (Effective July 1, 2011, laboratories are assessed to The NELAC Institute (TNI) Standards, adopted September 2009.)

9.3.3 State Principal Laboratories Analyzing Drinking Water

a. Connecticut, Maine, Massachusetts and Rhode Island – Assessment performed by the Region under the Agency's laboratory certification program every three years.
b. New Hampshire and Vermont – Assessment performed under NELAC Standards by NH Environmental Laboratory Accreditation Program with observation by the Regional Office every two years (Effective July 1, 2011, laboratories are assessed to The NELAC Institute (TNI) Standards, adopted September 2009.)

9.3.4 Environmental Agencies/Organizations

a. New England States – The goal is for quality system assessments to be conducted every three-to-five years, as resources allow.
b. New England Interstate Organizations – The goal is for quality system assessments to be conducted every three-to-five years, as resources allow.

9.4 Internal and External Assessment Reporting and Response

The quality system and technical assessments conducted by QAB personnel are tracked in the Request for Assistance (RFA) database. The assessment process and reporting are described in the *EPA New England SOPs for Quality System Assessments* and *Technical System Audits.*

Assessment and audit outcomes must include a written report which summarizes the assessment activities, includes the findings, and, provides recommendations for response actions, as appropriate.

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

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 and copies of reports are provided to the RQAM.

9.5 Corrective Actions

The assessment process is described in the *EPA New England SOPs for Quality System Assessments* and *Technical System Audits.*

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 to be done by a future date. For project activities, copies of all documentation relative to the corrective action and response must be 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.

9.6 Dispute Resolution

If a dispute is encountered during an assessment and/or follow-up activity, then the dispute resolution process outlined in Section 1.3.8 of this QMP would be applied.

10.0 QUALITY IMPROVEMENT

EPA Region 1 continuously evaluates and improves the quality system. All Regional personnel are responsible for identifying, planning, implementing, and evaluating conditions which maybe adverse to quality. Adverse conditions must be prevented, identified, and corrective actions implemented promptly, evaluated and tracked to closure to ensure actions are effective. The Region's senior management is fully committed to quality improvement as a process by which to proactively address vulnerabilities and to enhance efficiency. The Regional Administrator submitted a region wide message regarding the R1 Suggestion Box located on R1 Connect. This is a mechanism for everyone to contribute toward improvement and efficiency in the region.

Quality improvement is incorporated as a core organizational element of the Region's quality culture and philosophy and looks to correct systemic problems, improve consistency, streamline processes, re-engineer ineffective work procedures, and customize quality tools. Management and staff are encouraged to establish communications among themselves and with customers and

suppliers to explore areas for improved service. R1 personnel are expected to identify areas for process improvement and to actively participate in problem solving.

10.1 EPA Lean Management System (ELMS)

In November of 2018 the Office of Continuous Improvement (OCI) initiated the EPA Lean Management System (ELMS). The R1 deployment of ELMS was in April 2019. ELMS implementation invites teams to come together (standing, sitting, in-person or via Skype) through huddle meetings, problem solving sessions, and improvement events to examine processes to make EPA's functions timelier and more accurate.

10.2 Roles and Responsibilities

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. The R1 processes and procedures are intended to prevent quality issues, correct, solve documented quality issues from identification to resolution, all within a timely manner. Issues are identified, corrected as soon as practical, corrective actions are implemented, evaluated for effectiveness, and the process is documented by program personnel as issues are identified and corrected.

Quality issues may be referred to the QAB for evaluation and assistance. The QAB evaluation will determine if it is:

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

The QAB documents quality issues and makes recommendations for corrective actions, revising procedures and training, as applicable. Corrections and/or modifications made to work processes and procedures, are documented in new or revised standard operating procedures (SOP), or the appropriate equivalent document. It is management's responsibility to communicate to staff issues that have been identified and the resolution. All personnel are encouraged to identify areas for improvement, share the information with management and QAB personnel as appropriate, and a collaborate to address situations that have been identified.

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 the information is current and relevant. Approximately every five years, or when major changes to the quality system dictate updating the QMP, the RQAM reviews the document and submits a revised QMP to EQMD for review and approval.

The approved Regional QMP is posted on the LSASD Web page. Quality system components and tools, including guidance documents and access to standard operating procedures, are also posted on Regional internet and/or intranet sites.

10.3 Annual Reporting

A QA annual review provides the opportunity for the Region to identify areas of performance as well as components of the quality system that require correction or improvement. A QA annual review serves to communicate quality issues to senior management to assist in prioritizing workloads and allocating resources to support quality needs. Under EPA Order CIO 2105.0, when requested, the Region reports annually to OMS the status of the Regional quality system.

10.4 Organizational Improvement Based on Assessments

As discussed in Sections 8 and 9, the RQAM uses both external and internal assessment findings to initiate quality improvement. The RQAM, in collaboration with the QAB and QA Representatives, identify root causes of deficiencies; make recommendations for improvement; work with Regional management, staff and external partners to implement corrective actions; and subsequently, evaluate the effectiveness of corrective actions to substantiate necessary changes.

10.4.1 External Quality System Assessments

The EQMD typically conducts an assessment of the Region 1 quality system every three-to-five years. In addition, National Program Offices may perform assessments of Regional programs. These assessments serve to periodically evaluate the effectiveness of the quality system and quality-related procedures for Regional environmental programs; ensure consistency across the ten Regions; and to identify Agency quality system issues.

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

10.4.2 Internal Assessments

The goal is to conduct internal assessments as frequently as resources allow. 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.

ATTACHEMENT 1 – ACRONYMS

AIRS – Aerometric Information Metric System
ANSI – American National Standards Institute
AQS – Air Quality System
ARD – Air and Radiation Division
ASQ – American Society for Quality
CAA – Clean Air Act
CBI – Confidential Business Information
CFR – Code of Federal Regulations
CIO – Chief Information Officer
CLP – Contract Laboratory Program
COR – Contracting Officer Representative
CWA – Clean Water Act
CWSRF – Clean Water State Revolving Fund
DCS – Document Control System
DD – Division Director
DDD – Deputy Division Director
DERA – Diesel Emissions Reduction Act
DOJ – Department of Justice
DRA – Deputy Regional Administrator
DWSRF – Drinking Water State Revolving Fund
ECAD – Enforcement and Compliance Assurance Division
ELMS – EPA Lean Management System
EPA – Environmental Protection Agency
EPAAG - EPA Acquisition Guide
EPCRA – Emergency Planning and Right- To- Know Act
EPRB – Emergency Planning and Response Branch
EQMD – Enterprise Quality Management Division
ESAT – Environmental Services Assistance Team
FAR – Federal Acquisition Regulation
FASTAC – Field and Analytical Services Teaming and Advisory Committee
FIFRA – Federal Insecticide, Fungicide and Rodenticide Act
FMFIA – Financial Integrity Federal Managers Financial Integrity Act
FOIA – Freedom of Information Act
FSB – Field Service Branch
FSP – Field Sampling Plan
GIS – Graphic Information System
HQs - Headquarters
IA – Interagency Agreement
IASSC – Interagency Agreement Shared Service Centers
IGMS – Integrated Grants Management System
IQG – Information Quality Guidelines

ISO – International Organization for Standardization
IT – Information Technology
LAN – Local Area Network
LCRD – Land, Chemicals, and Redevelopment Division
LSASD – Laboratory Services and Applied Science Division
LSB – Laboratory Services Branch
LUST – Leaking Underground Storage Tanks
MACT – Maximum Attainable Control Technology
MPRSA – Marine Protection, Research, and Sanctuaries Act
MSD – Mission Support Division
NAAQS – National Ambient Air Quality Standards
NE – New England
NELAC – National Environmental Laboratory Accreditation Conference
NELAP – National Environmental Laboratory Accreditation Program
NERL – New England Regional Laboratory
NESHAP – National Emission Standards for Hazardous Air Pollutants
NESTS – New England Sample Tracking System
NH – New Hampshire
NPAP – National Performance Audit Program
NPDES – National Pollutant Discharge Elimination System
NPL – National Priority List
NSPS – New Source Performance Standards
NSR – New Source Review
OAR – Office of Air and Radiation
OCI – Office of Continuous Improvement
OECA – Office of Enforcement and Compliance Assurance
OGWDW – Office of Ground Water and Drinking Water
OIM – Office of Information Management
OLEM – Office of Land and Emergency Management
OMS – Office of Mission Support
OPM – Office of Personnel Management
ORA – Office of the Regional Administrator
ORC – Office of Regional Counsel
OSC – On-Scene Coordinator
OW – Office of Water
PARS – Performance Agreement Reporting System
PC – Personal Computer
PCB – Polychlorinated Biphenyl
PCS – Permit Compliance System
PDF – Portable Document Format
PDR – Pre-Dissemination Review
PEP – Performance Evaluation Program
PES – Performance Evaluation Sample

PRP – Potentially Responsible Party
PWSS – Public Water System Supervision
QA – Quality Assurance
QAB – Quality Assurance Branch
QAFAP – Quality Assurance Field Activities Procedures
QAO – Quality Assurance Officer
QAPP – Quality Assurance Project Plan
QARF – Quality Assurance Review Form
QC – Quality Control
QMP – Quality Management Plan
QS – Quality System
QSA – Quality System Assessment
RA – Regional Administrator
RCRA – Resource Conservation and Recovery Act
RFA – Request for Assistance
RFM – RCRA Facility Manager
RIC – Records and Information Center
RPM – Remedial Project Manager
RQAM – Regional Quality Assurance Manager
SAMs – Site Assessment Managers
SAP – Sampling and Analysis Plan
SDG – Sample Delivery Group
SDWA – Safe Drinking Water Act
SDWIS – Safe Drinking Water Information System
SEE – Senior Environmental Employee
SEMD – Superfund and Emergency Managment Division
SEMS – Superfund Enterprise Management System
SEMS-RM – Superfund Enterprise Management System – Records Management
SIO – Senior Information Officer
SIPs – State Implementation Plan
SOP – Standard Operating Procedure
SPSWEB – Superfund Performance Evaluation Sample Scoring Web
TMDLs – Total Maximum Daily Load
TNI – The NELAC Institute
TSA – Technical System Audit
TSCA – Toxic Substance Control Act
TTP – Through the Probe
US – United States
UST – Underground Storage Tank
VIDI – Video/Internet/Design Information
WD – Water Division

LIST OF APPENDICIES

1. Fiscal Year 2020 Requirements for Implementing Quality Assurance Policies for Assistance Agreements – Grants and Cooperative Agreements, May 2019.

2. Region 1 Procedures and Responsibilities for Implementing the Quality Assurance Review Form (QARF) for Interagency Agreements (IAs) through the Interagency Agreement Shared Service Center (IASSC), August 2018.

3. Quality Assurance Requirements for Contract Actions, Quality Assurance Review Form (QARF), July 2018.

4. Regional Organizational Charts