UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

MEMORANDUM

Subject: Region 9 Quality Management Plan (2014) Senior Management Signatures

To: Monica Jones, Quality Staff

From: Serena McIlwain, Assistant Regional Administrator (MTS-1)

It is with great pleasure that I submit the Region 9 Quality Management Plan. This document describes the Region's commitment to a technically astute and dynamic quality system that supports all our environmental decisions. The Region 9 Quality Management Plan describes Region 9's quality system; as a demonstration of the Region's alignment with the national program; and as a model for state, tribal and other organizations to use as they develop their own quality systems.

The underlying principle is that quality is everyone's responsibility. This year's National Honor Awards announcement acknowledges the highest level of commitment to that principle by the Region. The Air Quality Analysis and Quality Assurance Technical System Audit Team won the Barbara Metzger Environmental Data Quality Assurance Manager and Team Award and the Contracts Management Award went to the Region 9 Remedial Action Contract (RAC) Award Team that included two members of the Quality Assurance staff.

If you have any questions, please contact Eugenia McNaughton (415-972-3411, mcnaughton.eugenia@epa.gov) of my staff.

REGION 9 QUALITY MANAGEMENT PLAN
September 2014

CONCURRENCE:

October 3, 2014

Jared Blumenfeld — Date
Regional Administrator

9/26/14

Serena McIlwain — Date
Assistant Regional Administrator

9/25/14

Eugenia McNaughton, Manager — Date
Quality Assurance Office

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EXECUTIVE SUMMARY

USEPA requires that all Programs, Laboratories and Regions operate within a quality management system that specifically addresses the collection, production or use of environmental data. This commitment to a quality system supports Agency decisions with data of known quality that may be presented with the confidence that they are credible and defensible. Each Program and Region has a Quality Management Plan that describes its commitment to and support of its quality system. Its intended to be useful internally, to inform Region management and staff and externally, as a model for state, tribal and local agencies and contractors receiving funds from EPA to perform environmental data collection.

The Quality Assurance Office reviews and revises the Quality Management Plan every five years. The Manager asks all Divisions and Offices to review it, particularly as it addresses their specific data collection-related activities, and to indicate by signature that they agree to adhere to the commitments, roles and responsibilities that are described therein. It is then submitted to the Quality Staff (Office of Environmental Information) for review and approval.

The current version of the Region 9 Quality Management Plan reflects the many changes that have taken place in the Region over the last five years. An Enforcement Division is now in place and the Communities and Ecosystem and Waste Divisions merged to become the Land Division. The document also includes Region 9's responses to several initiatives that have become policies addressing federal government, Agency and Regional commitments to collect and use data of known and appropriate quality to support decision making, including the Information Quality Guidelines (Region 9 Pre-Dissemination Review Policy), the Laboratory Competency Policy and the Field Operations Guidelines Policy. These are also described in the Quality Management Plan.

Sections 1. Quality System Foundation and 2. Region 9 Organization present the national Quality policy and outlines the roles and responsibilities of Region 9 management and the Quality Assurance Office to support the Quality system; Section 3. Quality System describes the Region 9 Quality Assurance Office's customized approach to working with grantees and contractors, with Quality Staff and, by extension, the national EPA Quality community in planning environmental data collection projects. Sections 4. Implementation, 5. Assessment and 6. Quality Improvement detail the activities that comprise the Quality system as practiced by the Quality Assurance Office and other Region 9 organizations, such as the Region 9 Laboratory and Enforcement Division and other staff involved in taking environmental measurements.

FOREWORD

The Quality Management Plan (QMP) of the U.S. Environmental Protection Agency (EPA) Southwest Region 9 (Region 9) represents the commitment of the Region to comply with the requirements of the the *Policy and Procedure for Environmental Data Operations* (CIO 2105 and CIO 2105-P-01 to have a strong quality system in place to support all aspects of environmental data collection, analysis, and reporting. The objective of this system is to support regional management with data of known quality upon which they may base defensible and appropriate environmental decisions. The QMP defines the planning and oversight activities that are in place relating to data collection activities conducted in the Region and defines the roles and responsibilities for implementing those activities.

1.0 Quality System Foundation

EPA uses environmental measurements collected by the Agency, other governmental agencies, grantees, regulated parties, non-governmental organizations and academia to make decisions affecting public health and the environment. The Quality System (System) requires that each Program Office and Region establish such a system to ensure that data of known quality are generated by and for the Agency.

The System is employed throughout the life cycle of a project; it informs the planning, implementation and assessment activities of a project. This QMP describes the System in place in EPA Region 9. Section 1 provides an overview of the System; Section 2 lists the related roles and responsibilities of Region 9 management and staff; Sections 3.0, 4.0 and 5.0 discuss the activities in detail; the appendices include organization charts of the Regional Office and other organization charts that relate to Regional QA activities. Section 6 affirms the commitment to maintaining a dynamic and responsive Quality System.

1.1 Regional Quality Assurance Goals and Policies

The responsibility to implement the System rests with all Regional staff and managers involved in data collection activities, including use of data in decision making. Responsibility for developing and overseeing the implementation of the System resides with the QA Office (QAO). The QMP describes the management and technical processes in place to plan, implement and assess the effectiveness of System operations in Region 9. It defines the roles, responsibilities and authorities for implementation. The benefits of having such a system in place include:

- Scientific Data Integrity – Data produced, reviewed and used are of known and documented quality.

- Reliable and Defensible Decisions – Decisions made based on data of known quality are more likely to be upheld if challenged.

- Effective Management of Internal and External Activities - All activities during planning, implementation and reporting stages of data generation are transparent.

- Reduced or Justifiable Resource Expenditures - Resources may be used more efficiently as information collection activities are better aligned with information needs.

Region 9's QA policies and activities are consistent with the requirements of CIO 2105.0, and other relevant Agency mandates. The basic goals and specific policies are summarized below.

1.1.1 Quality Assurance Basic Goals

- Environmental data, including models and data from other sources, used in decision-making are of known quality.

- Data collected are of the type and quality needed and meet established objectives.

1.1.2 Quality Assurance Policies

The following policies apply to all environmental data collection activities conducted by Region 9 personnel and its contractors, grantees, and interagency agreement recipients:

- Appropriate QA planning documents such as this QMP, Quality Assurance Program Plan (QAPrP), Quality Assurance Project Plan (QAPjP), Sampling and Analysis Plan (SAP), Field Sampling Plan (FSP), or Work Plan (WP) are developed and approved for each environmental data collection activity prior to the initiation of data collection.

- Intended use(s) and data quality objectives (DQOs) of environmental data are identified prior to collection in the appropriate QA planning document.

- Implementation of projects and tasks involving environmental data collection conforms to information provided in approved QA planning documents.

- Oversight of data collection activities is performed and deficiencies promptly corrected.

- Programs and projects that use existing data or data from modeling or secondary sources have an approved QA Plan. The plan specifies the quality system that will be used to determine the suitability of the data for the proposed use.

- Quality Assurance oversight is performed to ensure that entities such as

laboratories generating environmental data used in Agency and Regional decision making are competent to provide usable and defensible results.

- Region 9 Policies and/or Orders to strengthen on going field activities and to implement a sustainable management system that incorporates all ten of the Field Operations Group guidelines are in place by February 15, 2016

Overall responsibility for QA in Region 9 resides with the Regional Administrator, who makes the commitment to ensure that adequate resources are allocated to accomplish Program and Regional goals. Quality Assurance is an integral part of the process of development and execution of all projects and tasks involving environmental measurement. The Regional Administrator's responsibility to QA is outlined in Section 2.1.

The responsibility for planning, developing and implementing the Region's Quality System resides with the Regional Quality Assurance Manager (RQAM). The RQAM reports to the Assistant Regional Administrator (ARA), Management and Technical Services Division (MTS) (see Appendix B). The ARA is independent of the Divisions responsible for collecting environmental measurements, except for the Region 9 Laboratory that is in MTS. The RQAM supervises the Quality Assurance Office (QAO). The RQAM's responsibilities are described in Section 2.3.

Other personnel who have specific QA responsibilities include senior staff and technical personnel located in the Air Division Air Quality Analysis (AQA) Office (see Section 2.6.1), the Enforcement Division (see Section 2.6.2), the Land Division (see Section 2.6.5), the Superfund Emergency Response Team (see Section 2.6.7) and the Water Division (see Section 2.6.8). Staff throughout the Divisions who have quality assurance experience may support the planning document review process as requested.

2.0 Region 9 Organization

Region 9 is organized into three Offices: Regional Administrator, Public Affairs and Regional Counsel and six Divisions: Air, Enforcement, Land, Management and Technical Services, Superfund and Water (see Appendix C). The Region also maintains a Laboratory in Richmond, California, and field offices in Los Angeles CA, San Diego CA and Honolulu HI. There are place-based staff in Carson City NV and Phoenix AZ. Each Division has programs and offices that may generate or oversee environmental data collection activities.

2.1 Regional Administrator

The Regional Administrator:

- Retains overall responsibility for the Quality System in Region 9 as described in this QMP and ensures that all Regional programs comply fully with the requirements of *EPA Quality Manual for Environmental Programs* (CIO 2105).

- Ensures that quality management activities are supported by resources adequate to accomplish program goals.

2.2 Assistant Regional Administrator/Senior Information Officer

The Assistant Regional Administrator:

- Supervises the QAO, the Regional Laboratory, Comptroller and Information Resources Branches, the Human Resources, Facilities/Health & Safety and Grants Offices.

- Acts as a senior management liaison between the QAO and senior managers in other divisions.

- Serves as the Senior Information Officer (SIO) for the Region. In this capacity, s/he is responsible for resolving disputes related to the Information Quality Guidelines and the Data Quality Act (PL 106-554 HR 5658 Section 515) and QA implementation issues that may arise within Region 9.

- Retains overall responsibility for the implementation of the quality management system within Region 9.

2.3 Senior Management

- Has responsibility for ensuring that division and grant recipient data collection activities conform to Regional quality assurance policies as described in this QMP.

2.4 Regional QA Manager

The RQAM supervises the QAO in the Management and Technical Services Division (see Appendix B).

The Regional Quality Assurance Manager

- Serves as manager of the Regional QA Program and supervises a group of nine professional employees.

- Prepares the Region 9 QMP, monitors its implementation for all internal monitoring, measurement, and data collection, review and utilization activities.

- Ensures that standards are in place requiring managers and staff to perform specific quality management functions.

- Approves all QA planning documents prepared by or on behalf of the Agency for

projects or programs within the region.

- Develops policies and procedures for implementation of Quality Assurance/Quality Control (QA/QC) within the Region.
- Reviews and signs the Quality Assurance Review Form (QARF) for contracts.
- Reviews and approves Funding Recommendations and prepares grant conditions as needed relating to environmental data collection.
- Reviews and approves Interagency Agreements.
- Oversees QA training for internal and external organizations upon request.
- Prepares and submits annual reports to Regional management and Office of Environmental Information Quality Staff. Reviews, revises and submits the QMP to the Quality Staff every five years for review.
- Works with Quality Staff, and Regional, State, and Tribal counterparts to promote mutual understanding and coordination in development of QA requirements and implementation of the System.
- Represents the Region on QA matters.
- Addresses quality disputes or challenges. Represents Region 9 on the national technical Field Operations Group (FOG).

2.4.1 Mandatory Independence of the Regional Quality Assurance Office

Neither the RQAM nor the QAO is directly connected with any of the media or regulatory programs within the region. Neither is involved in the collection or analysis of any samples, and is not responsible for the acquisition and use of secondary data.
In the event of a disputed QA finding, discussion is initiated at the most appropriate level. If staff and supervisors cannot come to an agreement, the issue may be brought to the attention of the Division Director. In some instances, it may be useful to seek the advice of the Quality Staff or other experts. The RQAM and staff may bring any issue related to QA directly or where a dispute or challenge cannot be satisfactorily addressed to the attention of the ARA, s/he may raise the issue to the ARA.

Since the Regional Laboratory is accredited by The National Environmental Laboratory Accreditation Conference Institute (TNI), that organization might be called upon to facilitate a resolution process, if necessary. Although both the Regional Laboratory and the QAO report to the ARA, the two organizations are geographically and functionally

separate. The Regional Laboratory has its own QA system, which the QAO audits every other year.

2.5 Quality Assurance Office

A table of QA Office GS series, responsibilities and years in service can be found in Appendix A. The Quality Assurance Office:

- Acts as point of contact for information relating to EPA QA concepts and practices.
- Ensures that all applicable programs delegated to State, Tribal and local governments or organizations taking environmental measurements pursuant to regulatory programs comply fully with EPA QA requirements.
- Implements those provisions in the Regional QMP that apply to oversight of grantees and other organizations using EPA funding to collect environmental measurements.
- Coordinates the review and approval of alternate test methods according to the requirements of the Clean Water Act (CWA) Alternate Test Procedure program.
- Ensures that QA training and technical support needs are identified and prioritized.
- Provides training to assist Federal, State, Tribal, local governments, and non-profit organizations performing environmental data operations and environmental technology activities under assistance agreements with EPA.
- Performs periodic management assessments of Regional organizational units performing environmental monitoring programs.
- Performs periodic management assessments of EPA funded projects and programs conducted by State, Tribal, and local governments.
- Reviews QA planning documents prepared by or for EPA for projects or programs by EPA staff, contractors, responsible parties, EPA-funded agencies, or grantees.
- Develops and provides guidance in the preparation and implementation of QAPrPs, QAPjPs, SAPs, FSPs and other QA planning documents.
- Facilitates effective planning, implementation, and assessments of data collection systems through scoping meetings and other forms of technical support.
- Oversees Superfund technical service contracts such as the Contract Laboratory Program (CLP) and the Environmental Services Assistance Team (ESAT).

Manages contract Delivery Orders and Task Orders for technical support of QA-related work.

- Manages and implements the Regional project-specific performance evaluation (PE) sample program; assists EPA programs with the selection of appropriate PE materials and with the development or procurement of new or customized PE samples; provides technical assistance in the interpretation of results and with laboratory corrective action processes.

- Performs management and technical system audits of Regional and State environmental monitoring programs to verify the effectiveness of QA/QC implementation; ensures that deficiencies or problems identified through audits are corrected.

- Provides assessment of data quality related to its usability for Region 9 programs and their contractors.

- Reviews and approves state Discharge Monitoring Report-Quality Assurance (DMR-QA) Study waiver requests in coordination with the Office of Enforcement and Compliance and Region 9 Enforcement Division.

2.6 Regional Organizations with QA responsibilities

2.6.1 Air Division

The Air Division is responsible for implementing the provisions of the Clean Air Act (CAA) within the geographic boundaries of Region 9, including the Mexican border. The Air Program guides the federal management, implementation, and technical oversight of ambient and indoor air quality, including control of pollution from stationary and mobile sources, prevention of radiation exposure and protection of the stratospheric ozone layer. In assuring compliance with the requirements of the CAA, the Division performs a wide variety of functions, including developing, reviewing, and implementing air quality plans (State Implementation Plans) and related regulations/rules; issuing permits; administering grants to state and local agencies, tribes, and non-governmental organizations (NGOs); and ensuring compliance with the CAA.

The Division works with the QAO to perform the ambient air monitoring quality assurance functions required by the CAA such as Technical System Audits. The QAO also provides technical support for air methods development and oversees a voluntary quality improvement program through round-robin performance evaluation studies. Grants managed by Programs in the Division are reviewed by the QAO to ensure quality assurance planning document requirements are addressed. The QA Office reviews internal QAPjPs and State and Tribal QMPs, QAPrPs and QAPjPs (www.epa.gov/region9/air).

2.6.2 Enforcement Division

The Region 9 Enforcement Division was created on February 11, 2013. The new organization consolidates the region's civil enforcement responsibilities under the federal air, water, waste, pesticides, and toxics statutes. The Environmental Justice and National Environmental Protection Act programs are located in this Division. The QAO reviews inspection SAPs.

EPA has undertaken a national effort to strengthen its field activities and to implement a consistent management system that incorporates Field Operations Group guidelines no later than February 15, 2016. The Field Operations Lead or Point of Contact (POC), reporting to the Deputy Director of the Enforcement Division, oversees the implementation of this system in Region 9. The POC conveys information and training materials within Region 9 and assists each unit conducting field activities to implement the FOG Guidelines. (www.epa.gov/region9/enforcement). The QA Manager represents the Region on the national FOG technical group and works with the POC and the Region 9 Laboratory QA Officer to support this effort.

2.6.3. Land Division

The Land Division, a new division formed by bringing together the Community and Ecosystem and Waste Divisions, is responsible for providing leadership and direction on regional multimedia issues, emphasizing and promoting cross-program and place-based approaches to address regional environmental issues. The Division oversees, manages, and directs the activities related to Communities (Tribes, Pacific Islands and Mexico Border), Pollution Prevention (Toxics, Toxic Substances Control Act (TSCA), Pesticides and Zero Waste (Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), Asbestos Hazard Emergency Response Action (AHERA), the Asbestos School Hazard Abatement Act (ASHAA), Section 313 (Toxics Release Inventory) of the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Food Quality Protection Act (FQPA) and the Resource Conservation and Recovery Act (RCRA) (Corrective Action Permits and Underground Storage).

Grants managed by the Division are reviewed by the QAO to ensure quality assurance plauning document requirements are addressed (www.epa.gov/region9/waste). The QAO reviews data collection SAPs for several Land Division programs.

2.6.4 Management and Technical Services Division

The Management and Technical Services Division provides overall infrastructure support and services for EPA Region 9, including its field offices, in the following areas: physical space, contract and grant administration, financial, human resources, health and safety, information resources, environmental analysis and quality assurance. The Division provides leadership in strategic planning, performance tracking, and accountability. It is responsible for audit management and the management integrity programs

(www2.epa.gov/aboutepa/organization-chart-epas-pacific-southwest-office#mts). The Division manages implementation of the Region's mandatory QA Program (www.epa.gov/region9/qa), operates the Region 9 Laboratory (www.epa.gov/region9/laboratory) and provides scientific and technical support to the Region.

2.6.5 Office of Public Affairs

The Office of Public Affairs communicates Region 9 program activities and policies to its stakeholders, including the public, the media, state and local governments, state legislatures and Governors' offices, Congress, the international community, the academic community, and special interest and non-governmental organizations. It serves as the gatekeeper for all Region 9 information products, ensuring quality, coordination and consistency with Agency priorities and standards. The Office works with the Information Resources Branch and the QAO to ensure that communications are consistent with the Region's and the Agency's policies relating to the Data Quality Act and the Information Quality Guidelines (www.epa.gov/region9/mediacenter).

2.6.6 Office of Regional Counsel

The Office of Regional Counsel is responsible for preparing administrative, judicial and criminal cases against violators of environmental laws. The primary statutes enforced by the EPA are the Clean Air Act, Clean Water Act, Safe Drinking Water Act, Toxic Substances Control Act, Resource Conservation and Recovery Act, Comprehensive Environmental Response, Compensation and Liability Act (Superfund) and the Federal Insecticide, Fungicide and Rodenticide Act. The Office of Regional Counsel works collaboratively with State, Tribal, and local governments to implement national environmental laws.

In addition to preparing enforcement actions, attorneys are also responsible for counseling the Regional Administrator and Program Division Directors on the interpretation of environmental laws, regulations and policies. Attorneys are expected to participate in civil or criminal litigation of cases referred to the Department of Justice and to represent the Agency in administrative proceedings.

The QAO provides attorneys with technical and QA-related information (www.epa.gov/region9/orc) upon request.

2.6.7 Superfund Division

The Superfund Division is responsible for implementing the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, the Brownfields Initiative, the Emergency Planning and Community Right-to-Know Act (EPCRA), the Clean Air Act 112(r) and the Oil Pollution Act (OPA) within EPA Region 9. The

Division is charged with conducting all activities for these programs, except enforcement litigation activities. The Division works with other federal, State, Tribal and local agencies, and the private sector to correct uncontrolled hazardous waste site problems.

The Division coordinates with the QAO, Regional Laboratory and the Contracts Office. The Emergency Response Team has an approved QMP to support quality assurance requirements for data collection in emergency situations. Grants administered by the Division in the Brownfields program are reviewed by the QAO to ensure quality assurance planning document requirements are addressed. The QAO reviews internal QAPjPs and State and Tribal QMPs, QAPrPs and QAPjPs and provides technical support for emerging issues, such as sampling design for vapor intrusion studies (www.epa.gov/region9/superfund).

2.6.8 Water Division

The Water Division implements the provisions of the Clean Water Act (CWA), as amended, the Safe Drinking Water Act (SDWA), as amended, and the Marine Protection, Research and Sanctuaries Act (MPRSA) within the geographic boundaries of Region 9. The Division has the ultimate responsibility for assuring that the chemical, physical and biological integrity of the region's waters are restored and maintained so that water pollution does not constitute a threat to public health, safety, well-being and the environment. The QAO staff who evaluate Alternate Test Procedure applications communicate with the Division's National Pollution Discharge Elimination System (NPDES) Permits Office. Grants administered by the Division are reviewed by the QAO to ensure quality assurance planning document requirements are addressed. The QA Office reviews internal QAPjPs and State and Tribal QMPs, QAPrPs and QAPjPs (www.epa.gov/region9/water).

3.0 Regional Quality System

3.1 Overview

It is Agency and Regional policy that systematic planning be used for all projects involving collection of environmental measurements. Managers make decisions based on information provided by staff, technical advice and regulatory requirements. The QAO supports all planning efforts by helping staff understand the level of data quality needed to make informed decisions and to weigh the short-term and long-term costs associated with that level of quality.

3.1.1 The Graded Approach

As the different programs have specific requirements for data upon which decisions are to be made, Region 9 uses a graded approach to fit the level of planning to program requirements. This approach applies to all stages of data generation activity and to the use

of environmental data subsequent to its collection. Implementation of the graded approach is discussed in the following sections.

3.2 System Level Planning

If an organization is of such size and complexity that it encompasses several programs with different data collection requirements, management support for quality is documented in a QMP (www.epa/gov/qa/r-2). The Region 9 QMP is available on line at www.epa.gov/region9/qmp. This policy document describes the organization's quality system, management and staff roles and responsibilities, and the general systematic planning process that are expected for all programs.

3.3 Program Level Planning

The objective of environmental data collection is to provide information that may be used to implement environmental programs such as State and Tribal environmental programs funded under the federal environmental laws including theComprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Clean Air Act (CAA), the Clean Water Act (CWA), the Brownfields Program, the Safe Drinking Water Act (SDWA), the Resource Conservation and Recovery Act (RCRA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For some programs, human health-based criteria defined in the legislation or their State or Tribal equivalents guide decision making; in others, presence/absence, registration or permit defined requirements drive the data collection process. The criteria associated with each program should be cited in QAPrPs to allow appropriate technical and policy review of the steps being taken to ensure that data generated are of known quality.

The QAPrP (www.epa.gov/region 9/qa/pdfs/mngmt-plan_guidance_2012) provides a detailed record of the scope and objectives of the data collection and Quality Assurance/Quality Control (QA/QC) procedures to be used throughout a program, and defines a quality assurance system that will include development of supporting documents, such as QAPjPs and SAPs.

3.3.1 Graded Approach at the Organization or Program Level

The QAO works with grantees and other organizations to determine the type of planning document most appropriate for the program. The QAO may require that a QMP with supporting QAPrPs, or a combination QMP/QAPrP be prepared. In some cases, a waiver may be granted. For example, for Tribal organizations with grants in only one or two media areas, preparation of QAPjPs may be sufficient. This is evaluated on a case-by-case basis. If a grantee organization has a staff of fewer than five individuals, the preparation of a QMP or a QAPrP is generally not resource effective. A State program generally prepares a QAPrP, but may prepare a QMP or a hybrid QMP/QAPrP, depending on the scope and the structure of its quality system. The QAO works with the State or Tribal organization to determine the most appropriate planning document.

As the QA function in the Region is centralized and the QAO assists all Divisions in implementing the QMP, the Divisions are not required to prepare separate QAPrPs. Most measurement activity conducted directly by the Region is covered under project specific documents prepared by EPA staff or by contractors who work directly for EPA. For example, the Pesticide Enforcement Program has an approved QAPrP that covers the activities of EPA inspectors or inspectors for State and Tribal agencies working under Federal authority. The Emergency Response Team has developed a QMP, based on the specific need to ensure that the work conducted under emergency conditions is also of known and legally defensible quality.

3.4 Project Level Planning

3.4.1 Scoping Meetings

Many organizations that conduct environmental measurement collection activities have a good understanding of the type of QA planning document their work requires. They usually proceed without consulting with the QAO. However, whenever appropriate, the QAO encourages an organization to participate in a scoping meeting before a plan is written. Scoping meetings, which can be held in person or by teleconference, are attended by the EPA Project Officer (PO) or Remedial Project Manager or his or her designee, the EPA Task Manager if an EPA contract is involved, a representative of the organization preparing the plan, and QAO staff.

The QAO considers scoping meetings to be integral to the effectiveness of the Region 9 Quality System. During these meetings, the participants systematically review all aspects of a project, including the objectives, decisions, sample design, collection activities, data analysis, quality control, and data assessment. Decisions are made as to the type of QA planning document that should be prepared, the appropriate analytical methods to be used, and the level of quality control necessary to achieve project objectives. Finally, the common understanding reached at a scoping meeting will facilitate review when the planning document is submitted to the QAO for review and approval.

3.4.2 Setting Project Data Quality Objectives

Data Quality Objectives (DQOs) are quantitative and qualitative statements that specify the acceptable error rates associated with environmental measurements for decision making purposes. The DQO process is designed to ensure that the type, quantity, and quality of the environmental data collected are appropriate to support specific decisions or regulatory actions. Working through the DQO process helps the project proponent define the criteria that data collection design must satisfy, including what type of data are needed, why they are needed, how they will be used and who will use them; the tolerable error rate and level of QA/QC to be implemented; an evaluation of alternative data collection and analytical approaches; the level of data review, self-audits to be performed, corrective actions to be implemented, and any constraining factors. This process of selecting DQOs, which is detailed in *Data Quality Objectives Process* (www.epa.gov/quality/qs-docs/g4-final.pdf), is the primary systematic planning tool for

developing projects performing environmental measurements, but the Region is flexible and open to the use of other planning tools or approaches that meet project requirements.

For some routine monitoring programs and regulatory programs, the EPA National Program Offices have developed DQOs, usually in the form of regulatory standards. Those DQOs are adopted by the delegated agencies that are primarily charged with implementing these programs. They are incorporated into planning documents for specific activities. For projects initiated in the Region, the PO is responsible for defining, citing, or developing DQOs as part of the planning process.

3.4.3 Graded Approach at the Project Level

Region 9 supports a wide variety of environmental data collection projects. It is Region 9 policy to ensure that the type of QA planning document required and the level of QA/QC to be implemented are commensurate with the objectives of the project. For some projects, a narrative description of the quality system may be sufficient. Other projects may require a QAPjP with appendices containing sampling and analytical Standard Operating Procedures (SOPs). Although use of Agency or Regional guidance for preparing documents is generally recommended, some project activities do not lend themselves to these formats and EPA staff, grantees, or contractors may need to work directly with the QAO to develop an appropriate document.

3.5 QA Annual Planning

Annual planning for the QAO ensures that resources are used efficiently to accomplish the Region's QA activities. Planning is undertaken at two levels: QAO goals are included in the Region 9 Management and Technical Services Division Operating Plan and annual planning goals are included in the Quality Assurance Annual Review and Workplan (QAARWP) that is submitted to the Agency Quality Staff.

3.5.1 Regional QA Planning Process

The primary vehicles for annual planning in the region are the budget process, the Annual Commitment System (ACS), State/EPA annual grant workplan process and the Regional Operating Plans. The Deputy Regional Administrator allocates resources to each division for the management and operation of specific programs, based on the Region's anticipated budget. Support from the QAO helps the Region meet Agency Government Performance Results Act (GPRA) goals, program goals, and ACS commitments.

Most Regional work activities are mandated by policy and tracked via the commitments made in Program Office Strategic Plans. The Strategic Operating Plan contains commitments in the form of the coming fiscal year's activities. The QAO seeks input from the divisions with which it works in preparing its Strategic Operating Plan.

3.5.2 National QA Planning Process

The Region's Quality Assurance Annual Report and Work Plan (QAARWP) is prepared as part of the annual Regional planning process and contains descriptions of Regional, State and Tribal activities. It also includes information about the range of activities completed, the significant fiscal year QA accomplishments and provides updates to the Regional QMP. The QAARWP is submitted by the Region to the Director of the Quality Staff in the Office of Environmental Information, who uses the information for short- and long-term planning purposes.

3.5.3 QA Office Planning Process

The QAO uses several resources to assess the adequacy of the quality system during the year, including referring to the QA document review database for the status of all types of QA documents; occasional meetings with the Superfund QA liaison and Regional Laboratory; regular meetings with the Air Quality Analysis Office; and follow up meetings with State and Tribal grant POs in the Air, Land and Water Divisions as grants are awarded during the year. As necessary, the RQAM meets with State program managers and Quality Assurance Officers to discuss quality system issues. Audits and trainings are scheduled based on information from these sources.

3.6 Planning Documentation

3.6.1 Policies

- All environmental measurement projects conducted by Agency personnel, its contractors, grantees and interagency agreement recipients are required to have an appropriate QA planning document approved by the QAO prior to the initiation of data collection. The document is developed in accordance with regional and national guidance, which is available on the QA Web page (http:/ /www .epa.gov/region09/QA/r9-QAdocs.html).

- Projects that use existing data or data from secondary sources are also required to have an approved QA Plan. The plan should specify the quality system that will be used to determine the suitability of the data for the proposed use. States or Tribes conducting regulatory programs that provide data to Region 9 are required to have their own QA systems in place. These QA systems are subject to QAO review and approval.

- After approval, the final documents are retained by the project manager. Approved QA planning documents remain in effect for five years; they are up-dated annually as necessary. After five years, they are reviewed and revised to reflect the current activities being performed, and submitted to the QAO for approval.

- A State program that has an approved QMP and/or QMP/QAPrP(s) in place that has been evaluated by the QAO to ensure that it meets EPA requirements may

review and approve internal- and contractor-generated QAPjPs, SAPs and FSPs.

3.6.2 Types of QA Planning Documents

3.6.2.1 Quality Management Plans

A QMP outlines the structure of an organization's quality system and its underlying QA management policies. EPA generally requires that a QMP be in place for organizations with which it has contracts, grants and cooperative agreements, but the Region takes a flexible approach in implementing this policy. Region 9 requires that QMPs follow the guidance *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA/240/B-01/002, March 2001). An organization may also work with the QAO to develop an alternative approach. Such an approach must still contain the major elements found in QA/R-2, but may emphasize or delete certain sections. In some cases, Region 9 accepts documentation of an organization's quality system in a combination QMP/QAPrP.

3.6.2.2 Quality Assurance Program Plans

QA Program Plans (QPPrPs) are formatted and prepared according to *EPA Region 9 Guidance for the Preparation of Quality Assurance Program* Plans (R9/3.2, June, 2012), which is based on the requirements in *EPA Guidance for QA Project Plans (QA/G-5)* EPA/240/B-01/003, March 2001. The guidance expands the scope of the QA/G-5 guidance to reflect a programmatic perspective. A QAPrP is appropriate in situations where an organization using environmental data has multiple on-going and similar measurement activities, such as collecting monitoring data or performing inspections, or where a grant recipient serves as an umbrella organization and uses EPA funding to support its own grants and contracts.

A QAPrP may incorporate elements of a QMP. QAPrPs are expected to cite regulatory objectives and criteria for decision making. The program should define the documentation requirements for its activities. Either EPA guidance or independently developed guidance may be specified. QAPrPs should include copies of relevant sampling or other field standard operating procedures (SOPs), copies of relevant laboratory QA Plans/Manuals and/or SOPs or laboratory Statements of Work, and discuss data reporting and review procedures.

3.6.2.3 Quality Assurance Project Plans

The planning of project-specific data collection activities is documented in QAPjPs or equivalent documents, such as SAPs (discussed in Section 3.6.2.4). QAPjPs may be prepared by Region 9 staff or contractors, grantees, responsible parties, or contractors employed by these organizations. When implemented as written, the QAPjP provides a detailed record of the scope and objectives of data collection activities, procedures, and QA/QC requirements. QAPjPs are prepared using one of the several guidance documents available on the Region 9 Quality Assurance website

(www.epa/region09/quality/documents).

QAPjPs may be used to describe program activities that are limited in scope in lieu of a QAPrP. QAPjPs should be reviewed by the organization every year, but must be approved by the Region 9 PO or Remedial Project Manager and QAO every five years.

3.6.2.4 Sampling and Analysis Plans

Sampling and Analysis Plans (SAPs) combine elements of a QAPjP and an FSP (see Section 3.6.2.5), and are prepared for one-time sampling events that are intended to be limited in scope. Although any format is acceptable provided it covers the necessary material, two guidance documents, *Sampling and Analysis Plan (SAP) Guidance and Template, Version 4 (R9QA/009.1, May 2014)* or *Sampling and Analysis Guidance and Template, Version 3, Brownfields Assessment Projects (R9QA/008.1, August 2012)* are available for use on the Region 9 website (www.epa.gov/region9/qa/projplans).

3.6.2.5 Field Sampling Plans

Field Sampling Plans (FSPs) are planning documents for activities taking place within a longer-term project that has a QAPjP in place; the larger project usually includes multiple sampling events that have specific data quality objectives. There is no specific guidance for FSPs; an abbreviated version of *Sampling and Analysis Plan (SAP) Guidance and Template, Version 4 (R9QA/009.1, May 2014)* may be used. The QAO review focuses on reviewing the sampling design, as it is assumed that information about project data quality objectives, intended uses of the data, sampling methods, analytical methods, and data review is available in the overarching QAPjP. Approval of an FSP is limited to the specific sampling event.

3.6.2.6 Other Quality Assurance Planning Documents

If the standard elements of a QA planning document are not relevant to a specific project, a narrative statement or expanded workplan may be sufficient. Specialized QA planning documents may be appropriate for projects involving the use of databases, secondary data or models. Alternatives such as the Region 9 guidance for recipients of wetlands grants or the Office of Research and Development QAPjP for research projects may also be appropriate. Questions as to which guidance to use or approach to take should be directed to the QAO.

3.6.3 Review and Approval of QA Planning Documents

QA planning documents must be approved by the Region 9 QA Manager. Documents produced by responsible parties (Superfund), or by grantees (other media programs) are reviewed by the QAO. In the case of QAPrPs or QAPjPs for the air program, the QAO approves the document with concurrence from the Air Division Air Quality Analysis Office. The PO overseeing the grant reviews the planning document for conformance to program requirements.

3.6.4 Quality Assurance Guidance Documents

Guidance for preparing planning documents for all types of projects may be found on the EPA website (http://www.EPA/home/quality). Region 9 has prepared several guidances to assist organizations in writing QA planning documents, including the QAPrP guidance, SAP guidance documents and the QAPjP guidance for wetlands projects (http://www.epa/region9/qa). In addition, a CD ROM containing guidance material, a template, SOPs and references for surface water monitoring (http://www.epa.gov/region9/qa/tribes.html) is available. Although the CD ROM was developed for Tribal programs, it contains information applicable to any surface water monitoring program. It is available on the Region 1 QA website (epa.gov/region1/lab/qa/qaprojectplandevtool).

4.0 Implementation

4.1 Overview

The Quality System is implemented throughout the Regional Office. Review of planning for environmental data collection activity and subsequent implementation oversight are the responsibility of the QAO; other relevant and ancillary activities are supported by other Region 9 Divisions and Offices.

4.2 Document Review

4.2.1 Quality Assurance Office Review Process

A primary responsibility of the QAO is document review. Documents may be submitted to the QAO by Remedial Project Managers, POs or external organizations. Staff that have appropriate expertise in the subject area and document type are assigned to perform the review. A peer review process within the QAO is completed before a memo relaying information about the status of a quality assurance document is submitted to the QA Manager for signature. Occasionally, a PO or Remedial Project Manager with QA expertise will review a document. The QAO makes the final evaluation regarding the consistency of the review with Agency and Regional QAO policy. The service standard for document review is 120 days for QMPs and QAPrPs, and 25 days for QAPjPs, SAPs and FSPs, although this is subject to negotiation.

During the course of its review, the QAO assesses whether the document is consistent with national and Regional QA guidance and whether the proposed QA/QC activities support the program or project data quality objectives. The QA reviewer may interact directly with planning document authors throughout the planning process (see Section 3.4.1). Formal comments that identify areas of project QA vulnerability are prepared. The author responds to the review to address the comments and resubmits the plan. This iterative process continues until the planning document is approved.

Comments from POs or Remedial Project Managers may be incorporated into the review

memorandum or letter. Reviews may be transmitted independently of the QAO or, in the case of Tribes and air districts, may be sent by the QAO directly to the grantee, as requested by the programs.

4.2.2 Other Document Review

One office in the Region has been delegated responsibility for review of QA documents: the Emergency Response Team in the Superfund Division. The Emergency Response Team has an approved QMP that describes how the Quality System will be implemented by the organization, which often operates within very tight deadlines.

A State or Tribe having a quality system in place that has been described in an EPA-approved QMP or a QAPrP may receive authorization from EPA to review and approve its ownQA documents. The QAO must be satisfied that the State or Tribe's implementation of its quality system is sufficiently rigorous to ensure that reviews meet EPA Region 9 standards.

4.3 Training

The QAO provides a variety of traimings designed to meet the needs of specific target audiences. The training may be generated by the QAO based on an internal assessment or in response to a program or external request. Trainings may be designed to be informational or practical.

4.3.1 Quality Assurance Office Staff Competency

4.3.1.1 Document Review

New reviewers and reviewers working in areas outside their original expertise are trained by performing parallel reviews with senior staff until it can be demonstrated that they understand how to interpret and apply the appropriate guidance. They are encouraged to take additional training on-line and in classroom format as time and resources permit.

4.3.1.2 Technical Training

QAO staff are classified as chemists and environmental scientists with backgrounds that include specialized training in inorganic chemistry, organic chemistry, hydrogeology, engineering, biochemistry and biology. Staff are encouraged to keep current in their specialties and to expand their areas of expertise to meet emerging needs. Staff maytaken training in bioassessment, air quality monitoring, chemistry, hydrology, and genomics offered by EPA or state agencies. Staff who oversee contractors as Contract Officer Representatives (COR) take contract management and technical training required to maintain the mandatory COR and federal FAC-COTR certification.

4.3.1.3 Documentation of Training

Documentation of all formal training is maintained in the individual's personnel file. Contract management training and certification is documented in the FAITAS database. Other required training is documented in the e-learning (Skillport) database.

4.3.2 In-House and External Training

The QAO uses surveys and interviews to identify training needs for programs and grantees. In this way, the training may be customized to meet specific needs. In general, the QAO responds to all training requests for standard presentations and specific topics. The QAO also sponsors training from outside sources. Examples of QAO trainings include:

- Introduction to QA for new Superfund Remedial Project Managers
- Introduction to QA for Division managers
- Uniform Federal Policy and QA Planning, a sponsored training for federal and state agencies
- How to work with the QA Office for Water Tribal Program POs
- Preparing a QAPP for Tribal Pesticide Enforcement Officers
- Clean Water Act 106 and 319 QA requirements for Tribes
- QA and related Statistics for Hawai'i Department of Health Clean Water Branch
- QA policy for collecting Volatile Organic Compounds in soil for internal field staff
- Bioassessment training for staff and Tribes
- Implementing the Laboratory Competency Policy for Grants
- Clean Air Act Program Introduction to Quality Assurance/Quality Control Requirements
- Vapor Intrusion Study Design

4.4 Procurement of Items and Services

4.4.1 Procurement Activities

The procurement activities in the QAO consist of purchases under $3000 (microprocurement) are made through the Management and Technical Services Division, Office of the Director. Simplified Procurements are those procurements for supplies and services under $100,000 and basically are of an off-the-shelf type. The Regional Contracts Office places and administers selected contracts over $100,000; places and administers orders against Government Wide Agency Contracts and Schedule Contracts of other agencies; and administers those contracts put in place for the Region by the Office of Acquisition Management at Headquarters (HQ). Contract activities for other Program Offices are developed by the user in the appropriate Division.

4.4.2 Contracts Involving Environmental Measurements

Regional procurements involved several steps. A Program Office first identifies its

requirements and develops the technical specifications, evaluation criteria, and any certifications that may be required. These are documented on an Electronic Purchase Request Form that is electronically reviewed and approved by the Section Manager and Division Director, funded by the funding control staff, and submitted to the Contracting Officer (CO) for action. Changes to procurement requirements undergo the same electronic review and approval sequence.

Whether it is to be made at the Headquarters or Regional Contracting Office, procurement of the requested items or services is undertaken by the CO according to Federal Agency regulations detailed in the Federal Acquisition Regulations (FAR), EPA Acquisition Regulations (EPAAR), EPA Contracts Management Manual, and the Procurement Policy Notice (PPN) Regulation No.01 -02, *Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions* March 2001, which provides guidelines for addressing EPA quality requirements for environmental data collection and use. The procurement process is documented in the contracts file pertaining to the particular action.

When environmental measurements are performed by contractors, QA requirements are integrated into the statements of work. In accordance with PPN No. 01-02, the contract-level COR generates a Quality Assessment Review Form (QARF), which defines the appropriate types of QA planning and oversight activities and is signed by the RQAM. In many cases, a QMP or QAPjP is due with the proposal or soon after contract award. The QAO may review the QA provisions of the Request for Proposal (RFP) or contract. If a contract includes environmental data collection activities, the QAO participates on the technical evaluation panel. The QAO also participates in the initial briefing session with the contractor to provide information about the Region 9 QA process. As a contract task is assigned, the appropriate QA planning document is generated and forwarded by the Work Assignment Manager (WAM) or PO for QAO review. Once the QAO completes its review and approval of the planning document, the WAM or PO has the responsibility for performing oversight to ensure the activities covered are implemented as described.

4.4.3 Grants and Financial Assistance Agreements

If States, Tribes and non-profit organizations (NGOs) that assist the Agency in carrying out its mission use EPA funding to perform environmental measurements, they are required under 40 CFR 31.45 to demonstrate that the organization has a quality system in place. These grants are processed through the Integrated Grants Management System (IGMS). The process generates Funding Recommendations (FR) that POs must complete in order to award the grant.

In Region 9, all Funding Recommendations are routed through the QAO for review and approval. The QAO reviews the description of the activity being funded and the PO's responses to specific QA questions against information in the QAO document review database. A decision is made whether to add a QA requirement to the grant Terms and Conditions. These conditions inform the grantee as to what type of QA planning document must be prepared for the project and provides a deadline for its submittal.

Once the recipient signs the grant and returns it to EPA, the grant condition is considered final. Region 9 policy does not require that QA plans or related documents be submitted with proposals or work plans; all documents are created after the grant is funded and after a scoping session has been held. This allows grant funds to be used to prepare the appropriate QA planning document.

The grantee and EPA PO work together to determine when the QA planning documents are to be submitted as a project deliverable. The PO reviews the QA planning documents for conformance with programmatic goals and work plan objectives. The document is then forwarded to the QAO for review. Once the QA Office completes its review and approves the planning document, oversight responsibilities revert to the PO or Task Monitor, unless a special request is made for further QAO involvement.

4.4.3.1 Laboratory Competency

In 2011, the Agency issued the *Policy to Assure Competency of Laboratories, Field Sampling and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions*. The intent of the policy is to ensure that all recipients of government funding take environmental measurement evaluate and attest the competency of the laboratories they use or plan to use.

Recipients of EPA grants that include taking environmental measurements: 1) are required to submit a Quality Assurance Project Plan (QAPP) or a Quality Assurance Program Plan (QAPrP) for EPA Regional QA Office approval prior to award; and 2) must submit documentation of laboratory competency for EPA awards >$200,000. Documentation concerning the laboratory may be submitted with the QAPrP or QAPjP.

Documentation of laboratory competency must be submitted to EPA prior to award of the agreement or, if not practicable, prior to beginning any work involving the generation or use of environmental data under the agreement. This policy became effective for implementation on October 1, 2013.

4.4.4 Interagency Agreements

Region 9 works with a number of other Federal agencies, including, but not limited to, the Army Corps of Engineers, the Indian Health Service, the U.S. Fish and Wildlife Service, the Bureau of Reclamation, the Bureau of Land Management, the U.S. Forest Service, the National Oceanic and Atmospheric Administration (NOAA), the Coast Guard, the Centers for Disease Control and the U.S. Geological Survey. Generally, these agencies have their own quality systems in place. However, Region 9 may require that the organization prepare a project-specific QAPjP, depending on the nature of the project.

4.5 Quality Documentation and Records

4.5.1 Regional Records Management System

A records management program provides for storage and timely retrieval, secure storage and preservation of government records, minimizes potential loss of or damage to those records, and ensures cost effective use of available storage space. All employees are responsible for ensuring that Agency records are maintained in a proper manner.

Regional records management policies and guidance are contained in Regional Order 160, *Records Management Policies and Procedures, and in the Regional Records Management Manual*. The Manual contains information on topics such as records and files management, transferring records to the Federal Records Center, requesting records from the Federal Records Center, and records retention and destruction. The disposition of records is governed by the General Records Retention Schedules and EPA Retention Schedules that specify how long EPA records must be kept and when they may be destroyed.

Records management assistance and training are provided by the Regional Records Management Officer (RMO) in the Computer Systems, LAN and Telecom Program of the Management and Technical Services Division. The RMO also serves as the primary liaison with the local Federal Records Center, coordinates the transfer and retrieval of records, and assists offices in completing necessary forms and handling special situations. As Region 9 moves to a smaller footprint within the same building, the QAO is assisting the RMO to coordinate the Division's activities relating to records management. This task is expected to continue through the move and will result in a reduction of non-current work-related documents and references being retained in Division Offices.

4.5.2 Quality Assurance Documentation and Records

4.5.2.1 Hard Copy Records

Copies of final approved versions of planning documents should be maintained by the PO for at least five years. Superfund documents are then moved to the Superfund Records Center for long term storage. The QAO keeps a comprehensive file of all signed QA reviews and some approved plans for reference. Signed reviews are also saved in .pdf format as the QAO moves to all electronic record keeping. The original memorandums are sent to the Tribe or State program (Air) and/or PO, in electronic and/or hard copy, depending on the customer's request.

4.5.2.2 QA Document Tracking Database

A Document Review database, developed by the Information Resources Management Branch (IRMB) Computer Operations Office in collaboration with the QAO, is used to monitor and track the status of reviews or approvals of QA planning documents, reviews of reports or other documents not requiring approval and audits. Each entry in the

database receives a unique document control number (DCN). The DCN tracks each document from initial submittal through one or more iterations to final approval. Once a document is approved, the database record is closed and the DCN is retired. If an approved document is later amended or revised, a different DCN is assigned to the new document. The database may be sorted in any of its fields. It can be searched by several categories, which allows workload and timeliness statistics to be calculated. For on-going grants and cooperative agreements, the database is consulted to determine the status of QA documentation so that appropriate conditions may be added to grant Funding Recommendations (see Section 4.4.3). The RQAM keeps a separate spreadsheet that lists all actions taken that require a QAO signature, including date, DCN, associated grantee, Regional and QAO staff.

4.5.2.3 Document Retention

It is Region 9 QAO policy to send approved QA documents to the Project Officer or grantee who generated them for their records or archives. The QAO requests that documents be sent electronically to reduce paper and physical storage space use. QAO will retain some QA documents informally from some programs in order to provide them to those programs to use as models for other grantees. The QAO has developed, but not finalized, a records management plan. It will become final when the building renovation is completed and our common immediate storage space is in place.

4.5.3 Quality Assurance Guidance Documents

Regional QA guidance documents have been developed for use in the absence of Agency-wide guidance on particular types of projects, or when specific Regional processes need to be documented. Examples include:

- Regional guidance documents for preparing non-Contract Laboratory Program (CLP) laboratory data packages
- EPA Region 9 Guidance in the Preparation of QAPrPs
- Wetlands QAPjP Guidance
- QAPjP Preparation Tool for Tribes (with Region 1)
- SAP Guidance and Template
- SAP Guidance and Template for Brownfields Projects

These plans are available on the EPA Region 9 Quality Assurance webpage, www.epa.gov/region09/qa with the exception of the QA Plan preparation tool for tribes, which is available in CD-ROM form by request or on line at (epa.gov/reg1/lab/qa/qaprojectdevtool).

Regional QA guidance documents are drafted by QAO staff experienced in the subject area and reviewed by the RQAM and other subject-area peers before approval by the

RQAM for distribution. Unique document control numbers are assigned to each document. Revisions are prepared and transmitted as needed.

4.6 Computer Hardware and Software

4.6.1 Regional Information Resources Management Policies

The Information Resources Management Branch in MTSD has the primary responsibility for setting policy and guidance for the management and development of computer-related programs. It supports the Local Area Network (LAN), Geographic Information Systems (GIS), information security, and application development. It includes the Desktop Services Office, which is responsible for division LAN support, training and records management. Personal Computing/Laptop coordinators in each Division act as liaisons between IRMB and division staff. Program administrators coordinate activities relating to their databases. As these are national databases, maintenance requirements are defined by the national program offices.

Regional data are collected, processed, and managed by the program divisions. IRMB manages the hardware, software and networking platforms. It also coordinates with the program divisions on hardware and software issues, purchases and upgrades, and pilot programs. Section

NIST Security Publication 800-53 requires all federal agencies to have an information security program. The issue of security impacts all aspects of the Agency's information technology infrastructure. An information security program that is consistently administered across the entire Agency is critical to its ability to sustain and maintain its ongoing operations. The Agency must achieve an appropriate balance between providing safe public access to accurate environmental information and protecting the information assets of the Agency. Region 9 is fully compliant with the requirements of NIST S.P. 800-53.

4.6.1.1 Use of Computer Hardware and Software

The purchase of computer hardware and software by Region 9 and its contractors is regulated by Regional Order R2100 *Information Resources Management Hardware Policy* and Regional Order R2100.1 *Information Resources Management Software Policy*. Regional policies are designed to ensure that computer hardware and software meet program requirements and are consistent with the Agency-wide standards.

4.6.1.1.1 Assessments of Impacts of Hardware and Software Changes

Most requests for computer system development, maintenance and enhancements are initiated by clients in the program offices. IRMB works closely with customers to determine their needs, options and implementation schedule.

4.6.1.1.2 Development of Software

Software applications developed in Region 9 are limited in scope. They are primarily user-oriented, and not expected to be shared outside the Region. Database applications are developed using existing software only. A typical example is the Lotus Notes Quality Assurance Management System (QAMS), a document tracking system developed by IRMB for the QAO, which is still maintained although the Region has changed internet platforms to Microsoft 365 (see Section 4.5.2.2). The QAMS database is managed by the QAO but is available to the Region as a read-only database. Regional personnel are discouraged from developing their own software. The development process includes the following steps:

- Meetings with the user to determine user needs
- Development, validation, and verification of the application; preparation and delivery of user documentation
- Preparation by the developer of a manual on the development process
- Feedback from the user(s)

4.6.2 Standards for Computer Generated Data

Regional IRM data standards are consistent with Agency-wide standards. Regional contracts require conformance to the Regional and Agency standards for hardware, software, and data delivery format. Division justifications for computer related purchases require the IRMB concurrence. The monitoring of compliance is the responsibility of POs.

4.6.3 Regional Environmental Data Storage and Retrieval

Some monitoring data on individual computers are part of databases developed by HQ program offices (STORET or its successor, the Water Quality Exchange (WQX) and the Air Quality System [AQS]), while others are developed for specific users (e.g., Superfund contractor data from remedial investigations). The database software includes QA routines. These routines are assumed by the user to be adequate for the intended use of the database. The responsibility for quality control of data entry and corrections belongs to the program office or division that maintains the databases.

4.6.4 Geographic Information Systems 26

The Geographic Information Systems (GIS) Center is part of IRMB. GIS policy guidance is found at http://intranet.epa.gov/gis/geopolicies.html.

The GIS Center follows guidance contained in the following documents:

- OMB Circular A-16, Coordination of Geographic Information, and Related Spatial Data Activities (http://www.whitehouse.gov/omb/circulars_a016_rev)
- OMB Circular A-130, Management of Federal Information Resources (http://www.whitehouse.gov/omb/circulars_a130_a130trans4)

- Latitude/Longitude Data Standard (http://www.exchangenetwork.net/standards/Lat_Long_Standard_08_11_2006_Final.pdf)
- EPA National Geospatial Data Policy (http://www.epa.gov/geospatial/docs/National_Geospatial_Data_Policy.pdf)
- Global Positioning Systems – Technical Implementation Guidance (http://nepis.epa.gov)
- Guidance for Geospatial Data Quality Assurance Project Plans (http://www.epa.gov/geospatial/docs/g5g-final.pdf)
- Geospatial Metadata Standards (http://www.fgdc.gov/metadata/geospatial-metadata-standards)
- National Geospatial Data Policy Procedures for Geospatial Metadata Management (http://epa.gov/geospatial/docs/2131.pdf)

The GIS Center uses the following data and GIS tool:

- EPA Metadata Editor (https://edg.epa.gov/EME/)
- Scribe: Environmental Field Data Capture Tool (http://www.ertsupport.org/scribe_home.htm)

4.7 Laboratory Program

4.7.1 Mission

The Region 9 Laboratory is a full-service state-of-the-art facility located in Richmond, CA specializing in chemical and biological analysis and field sampling services. The mission of the Laboratory is to provide quality analytical data in support of EPA regional and national programs including hazardous waste, water, air, pesticides and toxics. It primarily supports the activities of the Superfund program, for which it performs analyses generally not available through the CLP.

In addition to non-routine analytical analyses, the Laboratory develops expertise and analytical techniques to support specialized regional needs. The Laboratory also provides technical support and training to internal and external laboratories and programs.

The Laboratory has the capability to analyze all types of environmental samples, including air, water, soil, solid and liquid wastes, dust and biota (avian, fish and mammalian tissue). Analyses include general inorganic chemistry, metals, volatile organic compounds, semi-volatile organic compounds, PCBs and pesticides. Biological analyses include toxicity testing and microbiological testing. The Laboratory also offers a variety of field services, including field sampling, and field audits.

4.7.2 Facilities

The Laboratory maintains a 40,000 square foot facility located on the grounds of the University of California Richmond Field Station. The Laboratory employs 30-35 scientists, including EPA staff and ESAT contractor staff.

4.7.3 Delivery of Laboratory Services

Before samples are analyzed in the Laboratory, a QA planning document is prepared by the requester, reviewed, and approved by the QAO. The written plan contains the requester's analytical needs that are communicated electronically to the Laboratory on a "Request for Analysis" Form. The form is submitted to the Regional Sample Control Coordinator, who enters the information into a database for tracking purposes.

4.7.4 Laboratory Quality Assurance Organization

QA activities are implemented under the leadership of the Laboratory's QA Officer. She is assisted by the QA Coordinator for the ESAT contract, operating under a task directive under the contract.

4.7.5 Laboratory Quality Assurance System

The Laboratory is committed to monitoring and optimizing its performance through a variety of activities. The Laboratory's QA Program is documented in its QA Plan, which is reviewed and approved by the QA Office every three years or each time a revision is prepared.

Components of the Laboratory's QA system include document and record control; improvements and preventive actions; ethics and data integrity procedures; Corrective Action Reports, highlighting quality assurance issues which that require investigation and correction; Discrepancy Forms, documenting QC analytical problems of a more routine nature; external and internal audits; single blind and split PE samples; and thorough review of all data generated by the Laboratory prior to issuance of the final report.

The Laboratory routinely analyzes QA/QC samples and with field samples to determine laboratory performance. The specific QA/QC requirements vary with the method, but generally include the analysis of blanks, matrix spike/matrix spike duplicate samples, and laboratory control samples with each batch, along with a low level quantitation check and calibration checks. Other requirements may be specified in the appropriate SOPs or QA planning documents. All laboratory analyses and other processes are described in standard operating procedures. SOPs for routine activities are prepared, reviewed, and updated as needed. The responsibility for review and approval of Laboratory SOPs rests with the Chemistry Team Leader, the Biology Team Leader, the Laboratory QA Officer, and the Laboratory Director.

Data that the Laboratory generates are reviewed by the ESAT contractor, senior EPA personnel and, in selected instances, the Laboratory QA Officer. The Laboratory Director signs all final reports.

The Laboratory is audited by the State of Oregon in fulfillment of the requirements for accreditation by The National Environmental Laboratory Accreditation Conference Institute (TNI) every two years. The QAO performs quality system audits of the Laboratory in alternate years.

4.8 Field Operations

On March 1, 2013, EPA issued a memo *"...asking all EPA organizations conducting field activities to implement a sustainable management system that incorporates all 10 of the Field Operations Group [FOG] guidelines no later than February 15, 2016."* The ten field guidelines are based on Agency quality-related and ISO-17025 accreditation requirements. The FOG Guidelines are applicable to all organizations within Region 9 that conduct inspections/investigations and/or collect environmental samples and measurements in the field. Region 9 is developing its Field Operations Management System.

4.8.1 Organization, Roles and Responsibilities

4.8.1.1 Regional Point of Contact/Implementation Coordinator

The Regional Point of Contact/Implementation Coordinator (POC/IC) is responsible for coordinating the development and implementation of the field operations management system across all Divisions and reports directly to the Enforcement Division Deputy Director.

4.8.1.2 Division Points of Contact

The Division Points of Contact (DPOCs) have the technical knowledge to assist their organization with the implementation of the FOG Guidelines and development of SOPs. DPOCs serve on the Regional FOG Implementation Workgroup led by the Region POC/IC. These individuals may also assist in training their organization's staff.

4.8.1.3 Field Inspectors and Personnel

Region 9 field inspectors and personnel (e.g., project managers, field staff in the Region 9 Laboratory, on scene coordinators) are responsible for having an approved standard operating procedure (SOP) as well as following other relevant QA planning requirements discussed in this document prior to conducting field activities.

4.8.1.4 Subject Matter Experts

Subject Matter Experts (SMEs) are personnel competent, experienced, and knowledgeable in matters relating to the procedure, standard, guidance or other subject matter relating to the FOG. They serve on an organization-specific workgroup for FOG implementation. The RQAM is one of the subject matter experts.

4.8.1.5 Document Control, Records Management and Equipment Custodian

Depending on the size, structure, and complexity of the organization, additional personnel may be required to perform these duties if there is no such position in the current organization.

4.8.1.6 Overarching Management System Procedures

The FOG Guidelines consist of ten main categories. Each DPOC will work within his/her Division to develop management system procedures including:

- Document Control includes the preparation, review, approval, issuance, revision, revocation and archiving of SOPs and identifies a person to manage all SOPs.

- Personnel and Training outlines the requirements for the education, training, knowledge, and experience that qualify the employee to conduct field activities, including Health & Safety Requirements under EPA Order 1440.2[1] and requirements under EPA Order 3500.1[2] (Employee Credentials).

- Records Management requires that field teams maintain a records management system suited to their particular circumstances and complies with applicable Federal, Agency and Regional records management regulations and retention schedules.

- Field Documentation describes the procedures to document field activities relating to data entered into field notes, logbooks, photo logs, digital photos and mobile electronic units.

- Reports summarize results of field activities, including compliance inspections and contain the minimum requirements that are to be incorporated into all field inspection reports regardless of the Division and/or Program.

- Sampling and Environmental Data Management includes the identification, transportation, handling, protection, storage, and retention of samples and other evidence (measurements, or documentation such as field notes, instrument charts, laboratory reports, photographs, or technical reports) collected in the field.

- Field Equipment Logs track the record of maintenance, calibration, verification, inventory, and records of equipment used for field sampling and measurement activities.

- Field Inspections and Investigations procedures are found in national program guidance documents (i.e., RCRA Inspector Guidance, NPDES Compliance Inspection Manual, etc.). The Region may develop one procedure for Inspections/Investigations to incorporate these guidance documents by reference or the Divisions/organizations may choose to develop specific procedures for their inspections/investigations.

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[1] **EPA Order 3500.1 A1** *Training and Development for Individuals Who Lead Compliance Inspections/Field Investigations,* December 23, 2002.

[2] **EPA Order 1440.2** *Health and Safety Requirements for Employees Engaged in Field Activities*, July 12, 1981.

- Internal Audits are conducted periodically by field teams to verify that their operations comply with the guidelines.

- Corrective Actions address the findings from internal audits through corrective actions whenever nonconformities are identified.

4.9 Standard Operating Procedures

Data collection procedures may be standardized and published as written protocols for inclusion by reference in QAPrPs, QAPjPs, SAPs, FSPs, contracts and similar documents, and for use as guidance and technical assistance documents. SOPs are prepared using *Guidance for the Preparation of Standard Operating Procedures (G-6)* (EPA/600/B-07/001, April 2007). The responsibility for preparing, updating and approving SOPs rests with the party using them.

Routine activities that are performed by a Division or Office on a regular basis, especially if they are complex and/or sequential, may be usefully described in an SOP. This will ensure consistency of application, accountability for changes and will reduce data gaps that might otherwise occur during a change in personnel or reorganization. The QAO reviews internal SOPs as requested.

Region 9 does not currently have an overarching policy for preparing, reviewing and approving, maintaining and replacing SOPs. A Region 9 policy/order will be put in place to govern SOPs for field operations. The Region 9 Laboratory has an SOP policy, which is described in the Laboratory QA Plan and lists the Laboratory SOPs on the Region 9 Laboratory intranet webpage. The QAO may review these documents as part of its review of QA planning documents or audits it conducts, but it does not approve SOPs. The Region 9 Laboratory also has an extensive collection of SOPs, including both field and analytical procedures, available upon request.

4.10 Measurement Quality Objectives/Data Quality Indicators Tables

The Region 9 QAO has developed Measurement Quality Objective (MQO) tables of data quality indicators (DQIs) for most of the more commonly requested analytical methods. These may be used by grantees or Region 9 staff in procuring request for analytical services. The tables specify detailed calibration and QC requirements for each analytical method, including quality control limits and corrective action procedures. DQI tables are available on the Region 9 quality assurance web page (www.epa.gov/region9/qa/datatables).

4.11 Information Quality Guidelines

The Region 9 Office of Public Affairs follows the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (www.epa.gov/quality/informationguidelines/) in reviewing information from all Divisions that is disseminated to the public through its communication networks. The review process ensures that such products meet the performance goals stated in the guidance:

- Dissemination of information should adhere to a basic standard of quality, including objectivity, utility, and integrity
- Principles of information quality should be integrated into each step of EPA's development of information, including creation, collection, maintenance, and dissemination.
- Administrative mechanisms for correction should be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into EPA's information resources management and administrative practices.

Following the national Information Quality Guidelines, the QAO, OPA and IRMB have developed a Regional policy, the Pre-Dissemination Review, that outlines procedures the Region follows in conformance with the national policy (http://intranet.epa.gov/9online/sites/communications/pdf/pre-dissemination-review.pdf).

4.12 Peer Review

Peer review is a documented critical review of a specific Agency scientific and/or technical work product. Peer review is conducted by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. Peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and consistent with established quality principles. EPA's peer review process is described in the *Peer Review Handbook, 3rd Edition* (EPA/100/B-06/002). Work products requiring formal peer review may be entered in the Science Inventory (www.epa.gov/si). The RQAM is the Point of Contact for Peer Review and the Science Inventory for Region 9. An annual call for entries is sent out on the R9 Communicator.

5.0 Assessment

5.1 Overview

The audit is the standard mechanism for performing oversight of the effectiveness and adequacy of a quality system of a program or project collecting environmental measurements. During an audit, the data quality needs of the program as articulated in

the quality assurance planning documents are compared against the implementation information and quality of the data obtained.

The audit process is expected to identify strengths and weaknesses; suggest corrective actions to be taken to resolve problems; facilitate the initiation of changes to enhance the QA program; serve as a vehicle for providing technical assistance; enhance awareness and understanding of QA/QC policies and procedures; and provide a measurement of the effectiveness of QC in assuring the quality of data. Audits or reviews are scheduled and performed by the QAO on Regional programs as needed and as resources allow.

QAO staff responsible for conducting these audits are trained to perform these reviews and have experience in performing the types of environmental measurements. While most Region 9 QAO staff have taken and, in some cases, provided, training in performing audits, when regulations or assignments change or new collection activities are introduced, they are strongly encouraged to take training in auditing the new area. This is reflected in their Individual Development Plans. Staff performing audits must complete ethics training and financial disclosure statements, if required, each year to ensure that they are not aware of any real or perceived conflict of interest in the work being assessed.

An auditor may gather information in any form, through interviews and observations, and inspection of records and data tracking documentation. The QAO develops findings during an audit, presents preliminary findings during the exit briefing and prepares a draft report, ideally within a month of the audit. The auditor may consult with the audited agency to clarify issues or discuss potential corrective actions before the final report is issued. The results of the communication may be included in the report. Depending on the nature of the findings, the QAO may follow up to ensure that the corrective action plan is being implemented or may review the status of the implementation at the next scheduled audit. If there is a question about the findings, the issue may be raised to the next level of organization management up to and including the Regional Administrator. The approach for each type of audit is presented in Table 1. Descriptions of each type of audit is found in the following sections.

Table 1. Region 9 QA Office Audits

Type of Audit	Frequency	Assessment tool used	Reports
Division within the Regional Office review of QA requirements	Not regularly scheduled	Interview and checklist	Division Director or designee
State MSRs*	Not regularly scheduled	Audit checklist	Executive Director
Air PQAO TSA	Every three years	Audit checklist	District Executive
Regional Laboratory	Every two years	Audit checklist	Laboratory Director
Other laboratories	On demand	Audit checklist	Project Manager
Performance Evaluation Samples	As per recommendation in QAPrPs and on demand	Review of reported results	Project Manager/ Superfund, Air Districts, DMR-QA reports
Data Verification/Validation	As per recommendation in QAPrPs	Review of reported results	Project Manager
To be added			
Field system	As per FO guidance	Audit checklist	FO POC
Field	As per FO guidance	Audit checklist	FO POC

*Prior to 2005, State QA programs were audited on an ad hoc basis. Since 2005, the QAO has focused on reviewing State Quality Management and Program Plans. With many of those reviews in the process of being up dated, we are developing a process and a schedule for conducting state MSRs. Travel restrictions limit most of these MSRs to desk audits. Restricted travel to perform air districts audits, as required every three years by the Clean Air Act, has led to the substitution of in person by desk top audits for every other audit in the cycle. Using this process, however, along with follow-up Performance Evaluation Samples, the QAO is able to gather current information about quality management systems throughout the Region.

5.2 Assessment Tools

The assessment tools used by the Region are management systems review (MSR), technical systems audit (TSA), performance evaluation samples (PES) and data validation.

5.2.1 Management System Reviews (MSRs)

A Management Systems Review (MSR) is an evaluation of the management of the QA program being implemented in the Region, States and some Tribes, including the level of management support, systematic planning and planning documentation, data quality assessment, internal audit procedures, and the effectiveness and consistency of corrective

actions.

The QAO may conduct MSRs to determine whether the documented quality system is being implemented and to evaluate its effectiveness. The management and technical activities for ensuring the collection of data of known quality are reviewed, along with the roles, responsibilities, and authorities of the individuals implementing the system.

Regional MSRs are conducted in accordance with the *Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews* (EPA QA/G-3, March, 2003). In fulfillment of the TNI laboratory accreditation requirement, an MSR is conducted every year at the Regional Laboratory. An MSR may be triggered by serious or persistent quality control failures or non-compliance identified through routine and standard field/lab audits and other quality checks. As States update their QMPs and QAPrPs, the QAO, working with the state QA Officers, will evaluate the need to develop a schedule to conduct MSRs of their quality systems.

5.2.2 Technical Systems Audits (TSAs)

A technical systems audit (TSA) evaluates aspects of the actual performance of specific projects or data generation activities, implementation of QA planning documents and evaluation of field and laboratory activities.

In accordance with Federal regulations at 40CFR Part 58, EPA regional offices are required to conduct TSAs of each Primary Quality Assurance Organization (PQAO) at least once every three years. A PQAO is a monitoring organization or a coordinated aggregation of such organizations that is responsible for a network of air monitoring stations that share data quality standards. Conducting a TSA is one of the ways that EPA provides oversight to ensure air quality data collected by state and local agencies meet EPA's data quality requirements.

In Region 9, there are eleven PQAOs which include: California Air Resources Board, Bay Area Air Quality Monitoring District, South Coast Air Quality Monitoring District, San Diego Air Pollution Control District, Nevada Division of Environmental Protection, Washoe County, Clark County, Hawaii Department of Health, Arizona Department of Environmental Quality, Maricopa County and Pima County. Four Tribes are considered to be PQAOs: Morongo, Pechanga, Gila River and Salt River.

Technical System Audits (TSAs) of state air PQAOs are conducted jointly by the Air Division AQA Office and the QA Office. Each district is audited once every three years. Because there are 15 PQAOs, and considering staff time and travel resource limitations, desk top audits are conducted on alternate TSA cycles. The AQA and QAO perform equipment audits of other air monitoring programs as requested. TSAs of the Tribes are conducted by an EPA contractor.

The AQA Office oversees the ESAT technician who conducts compliance audits of equipment used by air districts for the Air National Performance Audit Program (NPAP)

and Performance Evaluation Program (PEP) on a regular basis and as needed. The QAO continues to provide technical support as requested.

Field audits are conducted by staff at the Region 9 Laboratory; the QAO may participate or conduct the audit as requested by the Laboratory field team. The QAO conducts field audits of vapor intrusion investigations for the Superfund Division upon request.

The Laboratory and QAO staff may audit laboratories working for Responsible Parties, Federal Facilities, Resource Conservation and Recovery Act (RCRA) owner/operators, National Pollution Discharge Elimination System (NPDES) dischargers and Superfund contractors upon request or as needed.

Laboratory certification audits of State, Territory, and Tribal drinking water laboratories are conducted by Regional Laboratory certification officers once every three years. Procedures and checklists for these audits are defined in the laboratory certification manuals published by the National Exposure Research Laboratory (NERL), Cincinnati.

Since The NELAC Institute (TNI) became a completely private organization, QAO no longer participates in Accrediting body evaluations. Staff at the Regional Laboratory continue to participate in these evaluations.

For both field and laboratory audits, prepared reports describe when, how and by whom the audit was conducted, what specific procedures were reviewed, a summary of the findings, and recommendations for corrective action. The audit report is transmitted to the audited office, the program manager, and the PO, as appropriate. The audited organization is responsible for ensuring that prompt corrective action takes place. Follow-up activities vary according to project objectives.

5.2.3 Performance Evaluation Samples (PEs)

Performance evaluation samples (PEs) are samples of the chemical of interest in a known concentration that may be sent as a known performance sample or an unknown environmental sample to verify the ability of a laboratory to produce reliable data.

Performance evaluation samples are used to assess laboratory capability and performance prior to contract award and on an on-going basis as an external means to evaluate laboratory performance and ensure data reliability. Federal facilities are required to use PEs on a regular basis, as indicated in planning documents. For EPA-lead sites, the EPA contractor must use them, as indicated in the QAPjP.

The QAO provides single blind (identification of performance sample of unknown concentration) or double blind (sample is not identified as a PE and is prepared using media resembling the site) audit samples to evaluate laboratory performance. The QAO recommends the use of PEs to evaluate the capability of a laboratory to perform the requested analysis and to determine whether laboratory performance is consistent for on-going projects. Laboratories also participate in regularly-scheduled EPA-wide Water

Supply and Water Pollution (WS/WP) PE studies. The Regional Laboratory uses PEs in a self-evaluation program.

5.2.4 Data Review: Verification and Validation

Data review is a continuum of processes, including review or verification and validation, to determine whether data have been generated according to specifications, satisfy acceptance criteria, and are appropriate for their intended use. Data verification evaluates completeness, correctness, and compliance of data to defined methods, procedures, and control limits. Data validation expands verification to assess the data and the methods used against project objectives, and may point out areas needing corrective action in future efforts. In Region 9, the terms "verificationand "review" may be used interchangeably to cover a range of processes, according to a graded approach.

5.2.4.1 Responsibility for Data Review

The QAO performs data review primarily for Superfund Fund-lead projects and through contractors, although contractors do not evaluate the usability of data for intended uses. Upon request, QAO staff may perform data validation and oversight of data reviews for other projects from the Superfund Division (e. g., Potentially Responsible Party-lead, State-lead, Federal Facility-lead, or Brownfields) or other Divisions. All other data review defined in QA planning documents is performed by the project team. The EPA project manager is responsible for making the final determination as to whether the data may be used for their intended purpose; the QAO provides technical assistance as requested.

5.2.4.2 Tiered Data Review

The QAO follows a data evaluation system, in which the level of effort of the review increases with successive tiers. The tier is appropriate to project DQOs and financial and temporal resource constraints.

Tier 1 is a relatively streamlined review of quality control (QC) information. Data review may be limited to reviewing reported QC results against acceptance limits, possibly using a software program, with no review of the raw data. The inherent risk of mischaracterizing data quality must be assumed to be acceptable for project needs.

Tier 2 is a targeted review of specific components of the data package, typically specific samples or analytes of particular interest. Tiers 1 and 2 are suited to projects that have sufficient historical data.

In Tier 3, a full data review is performed, including but not limited to method details, instrument printouts and logs, including calculation checks. Tier 3 reviews are intended to evaluate the legal defensibility of the data. For Superfund projects, Tier 3 validation is performed using the *Superfund Functional Guidelines for Evaluating Laboratory Data* (OSWER 9240.1-46, July 2007) for organic and inorganic analyses generated through the

Contract Laboratory Program (CLP). Although the guidance is used principally to validate Superfund data, it may be used in other programs.

6.0 Quality Improvement

The QAO is committed to continual improvement of the Region 9 Quality System. The staff meets regularly as an office and as needed in designated or self-identified teams to discuss quality issues related to projects and the quality system in general. The Office may identify areas where a general policy needs to be established or changed.

6.1 Planning documents

The QA Office is committed to supporting internal and external efforts to create QA planning documents that are dynamic and useful. We believe that the process of writing the document should help the author articulate management, program and project objectives that are clearly stated and consistently supported. QA documentation should be familiar and available for reference to all levels of an organization. To facilitate that effort, the QAO has developed a number of specific templates that are posted on the R9 website. Staff are available to provide further assistance.

6.2 Training

The QAO supports continuous training for staff in quality assurance, in technical subjects related to their area of expertise and in new areas of interest or of emerging importance to the Agency and to Region 9 Divisions.

6.3 Audits

The Clean Air Act requires EPA to audit air districts within the Region every three years. The QAO continues to collaborate with the Air Division Air Quality Analysis Office to complete the QA elements of Technical System Audits, contribute findings to reports and to follow up on corrective action plans on a regular schedule.

6.4 Standard Operating Procedures

The QAO has a set of SOPs that describe various office activities. They are peer reviewed by staff and approved by the RQAM. SOPs that have been superseded are archived. The QAO SOPs will be posted on the Region 9 Quality Assurance webpage.

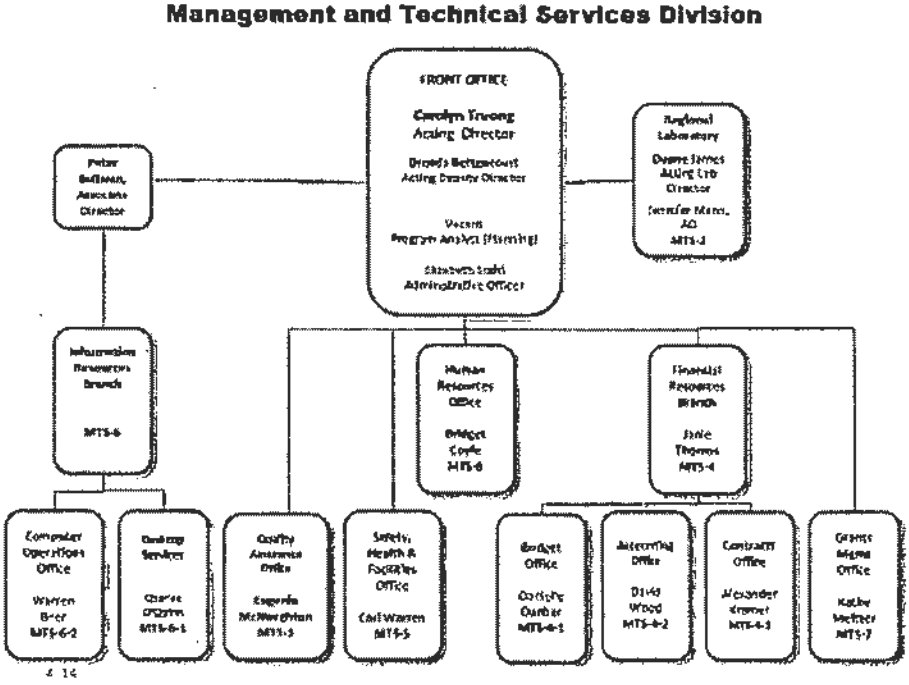
APPENDIX A

Quality Assurance Office

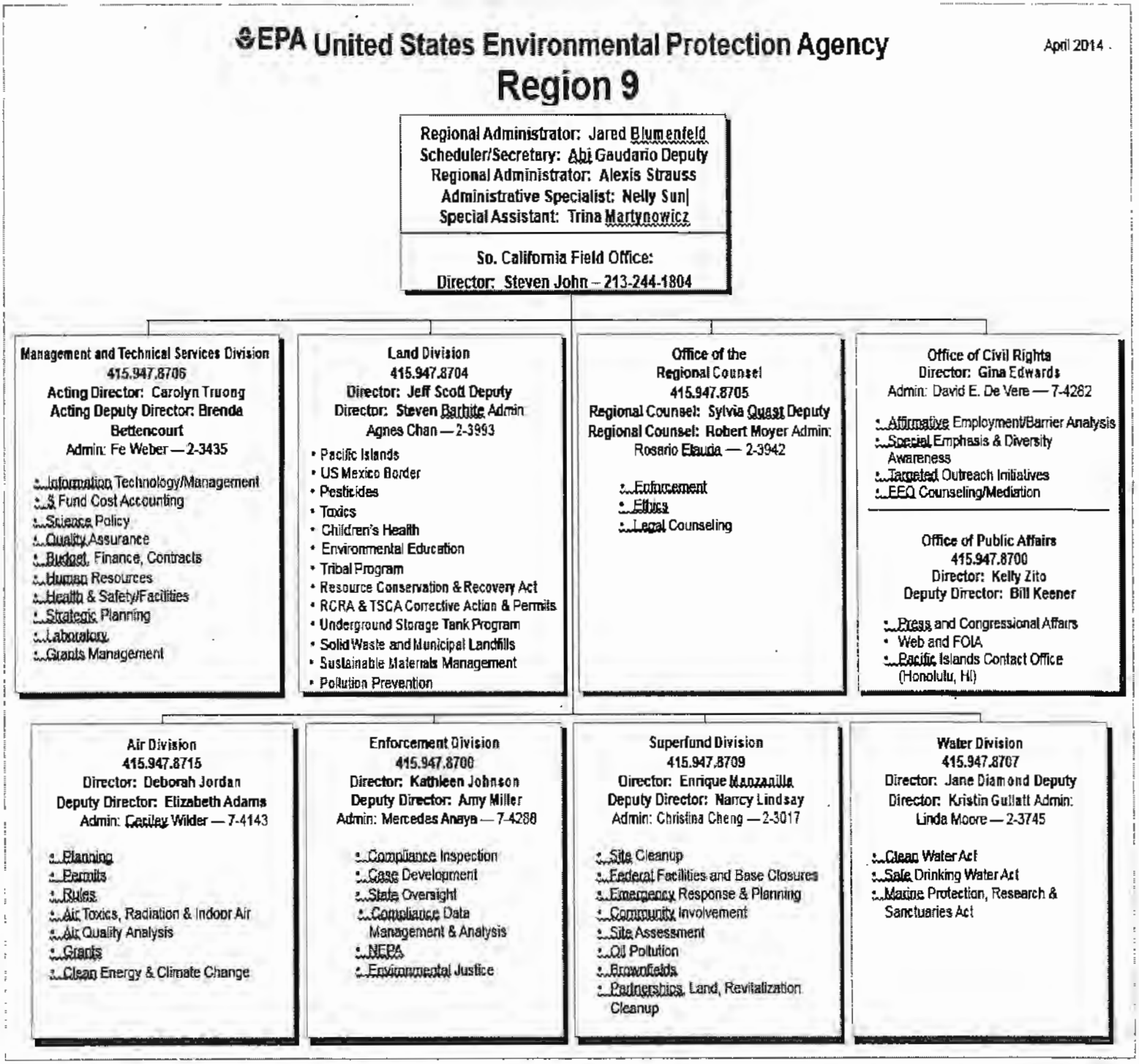
Grade Series	Responsibilities	Years in QA
1320 Chemist	QMPs, QA Program Plans, small program QA, training, audits	>20
1320 Chemist	Superfund CLP TOPO/ audits, PE program, Air audits and PEs, Water ATP coordinator	>20
1320 Chemist	Superfund and RCRA reviews and audits, ESAT COR for data validation	~20
1301 Environmental Scientist	Superfund and Water review, groundwater expertise, website manager	>20
1301 Environmental Scientist	Brownfields review and training, Water, Regional Science Counsel co-chair	>20
1301 Environmental Scientist	Air QA reviews, audits, Superfund and Air training, vapor intrusion expert	>15
1301 Environmental Scientist	Air QA reviews, audits, Superfund groundwater, place-based in Hawai'i	>20
1301 Environmental Scientist	Superfund, Water QA reviews, training, audits, statistics, sampling design	>20
1109 Grants Management Specialist	NEIEN Project Officer, delegation officer, division records management liaison	>20
503 Financial Assistant (on detail)	ESAT assistant COR, Brownfields QAPP reviewer	>1

APPENDIX B

MANAGEMENT and TECHNICAL SERVICES DIVISION



APPENDIX C


EPA United States Environmental Protection Agency
April 2014
Region 9
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Scheduler/Secretary: Abi Gaudario Deputy
Regional Administrator: Alexis Strauss
Administrative Specialist: Nelly Sun
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: $ Fund Cost Accounting
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: Quality Assurance
: Budget, Finance, Contracts
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: Strategic Planning
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• US Mexico Border
• Pesticides
• Toxics
• Children's Health
• Environmental Education
• Tribal Program
• Resource Conservation & Recovery Act
• RCRA & TSCA Corrective Action & Permits
• Underground Storage Tank Program
• Solid Waste and Municipal Landfills
• Sustainable Materials Management
• Pollution Prevention
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: Legal Counseling
Office of Civil Rights
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Admin: David E. De Vere — 7-4282
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: Community Involvement
: Site Assessment
: Oil Pollution
: Brownfields
: Partnerships, Land, Revitalization Cleanup
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: Safe Drinking Water Act
: Marine Protection, Research & Sanctuaries Act

REGION IX

QUALITY MANAGEMENT PLAN

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