REGION IX

QUALITY MANAGEMENT PLAN

U.S. Environmental Protection Agency
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Contents

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 ensures that Agency decisions are made with data of known quality and are presented with the confidence that they are credible and defensible. Each Program and Region has a Quality Management Plan (QMP) that describes its commitment to and support of its quality system. The QMP is 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 EPA funds to perform environmental data collection.

The Quality Assurance Branch reviews and revises the QMP every five years. The QMP is submitted to the Office of Mission Support (OMS), Environmental Information (EI), Office of Enterprise Information Program (OEIP), Enterprise Quality Management Division (EQMD) for review and suggested revisions.

The Region 9 QMP reflects the Agency's decision in 2018 to realign EPA's regional organizational structure, to increase visibility into regional office operations; improve the consistent implementation of EPA regulations and policies; allow for better resource allocation; enhance operational excellence; and provide for greater transparency for EPA's customers. The QMP also includes Region 9's commitment 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 Quality Assurance Field Activity Procedures (QAFAP). In addition, Region 9 has developed a program specific Quality Management Plan to describe the practices for environmental data collection for cleanup decisions and work on Navajo Abandoned Uranium Mines (NAUMs). This document is included as an appendix within the QMP.

The Quality System is employed throughout the life cycle of a project funded by EPA; 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, 4 and 5 discuss the activities in detail; and Section 6 affirms the commitment to maintaining a dynamic and responsive Quality System. The appendices include organization charts of the Regional Office and other organization charts that relate to Regional QA activities.

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 *Policy and Procedure for Environmental Data Operations* (CIO 2105 and CIO 2105-P-01) to have a 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 related 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.

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 Branch to support the Quality system; Section 3. Quality System describes the Region 9 Quality Assurance Branch'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 which encompass the Quality system as practiced by the Quality Assurance Branch and other Region 9 organizations, such as the Region 9 Laboratory and Enforcement and Compliance Assurance Division and other staff involved in taking environmental measurements.

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. The responsibility for developing and overseeing the implementation of the System resides with the QA Branch (QAB). 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 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 Project Plans (QAPP), Sampling and Analysis Plans (SAP), Field Sampling Plans (FSP), or Work Plans (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 using existing data or data from modeling or secondary sources have an approved QA Plan. The plan specifies the quality system 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 ongoing field activities and to implement a sustainable management system that incorporates all ten of the Field Operations Group guidelines were established and implemented on February 1, 2017.

Overall responsibility for Quality Assurance in Region 9 resides with the Regional Administrator who makes the commitment to ensure 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 Director of the Laboratory Services and Applied Science Division (LSASD) (see Appendix B). The LSASD Director is independent of the other Divisions responsible for collecting environmental measurements, except for the Region 9 Laboratory, which also resides in LSASD. The RQAM supervises the Quality Assurance Branch (QAB). 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 and Radiation Division's Air Quality Analysis Office (AQAB) (see Section 2.6.1), the Enforcement and Compliance Assurance Division (see Section 2.6.2), the Land, Chemicals and Redevelopment 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 eight Divisions: Air and Radiation; Enforcement and Compliance Assurance; Laboratory Services and Applied Science; Land, Chemicals and Redevelopment; Mission Support; Superfund and Emergency Management; Tribal, Intergovernmental and Policy; and, Water (see Appendix C). The Region also maintains a Laboratory in Richmond, California, and field offices in Los Angeles and San Diego, California and Honolulu, Hawaii. 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 Laboratory Services & Applied Science Division Director /Scientific Integrity Officer

The Laboratory Services and Applied Science Division Director:

- Serves as the Scientific Integrity Officer 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.
- Supervises the Regional Quality Assurance Manager, the Regional Laboratory and the Regional Science Liaison.
- Acts as a senior management liaison between the Quality Assurance Branch and senior managers in the other divisions.
- 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 Quality Assurance Branch in the Laboratory Services and Applied Science Division (see Appendix B).

The Regional Quality Assurance Manager:

- Serves as manager of the Regional QA Program and supervises professional employees who actively support the Region by reviewing QA documents and technical assistance when requested.
- 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 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 when tasks involving environmental measurements are included in the agreement.
- Oversees QA training for internal and external organizations upon request.
- Prepares and submits annual reports to Regional management and the Quality Staff within the Office of Environmental Information, Enterprise Quality Management Division (Quality Staff). Reviews, revises and submits the QMP 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 and consults the Laboratory Services and Applied Science Division Director and/or RA if needed.

2.4.1 Mandatory Independence of the Regional Quality Assurance Branch

Neither the RQAM nor the QAB 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 LSASD 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 LSASD Director, s/he may raise the issue to the RA.

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 QAB report to the LSASD Director, the two organizations are geographically and functionally separate. The Regional Laboratory has its own QA system, which the QAB audits every two years.

2.5 Quality Assurance Branch

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

- Acts as point of contact for information relating to EPA QA concepts and practices.
- Ensures 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 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 QMPs, QAPPs, 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 Enforcement and Compliance Assurance Division.

2.6 Regional Organizations with QA responsibilities

2.6.1 Air and Radiation Division

The Air and Radiation Division is responsible for implementing the programmatic provisions of the Clean Air Act (CAA) within the geographic boundaries of Region 9, including the Mexican border. The Division conducts activities to reduce emissions so air pollution does not constitute a threat to public health, safety, well-being and the environment. To carry out its mission, the Division works with other federal agencies, state and local agencies, tribal governments, the public, and the private sector. The 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 QAB to perform the ambient air monitoring quality assurance functions required by the CAA such as Technical System Audits. The QAB also provides technical support for air methods development and oversees a voluntary quality improvement program through round-robin performance evaluation studies. Grants managed by the Division are reviewed by the QAB to ensure quality assurance planning document requirements are addressed. The QA Office reviews internal QAPPs and State and Tribal QMPs and QAPPs.

2.6.2 Enforcement and Compliance Assurance Division

The Enforcement and Compliance Assurance Division is responsible for developing and implementing Regions 9's enforcement and compliance assurance programs and statutes EPA administers in California, Arizona, Nevada, Hawai'i, the Pacific Island Territories and 148 federally-recognized tribal nations. The Enforcement and Compliance Assurance Division works closely with the other Region 9 divisions, Office of Regional Counsel (ORC), Criminal Investigations Division (CID), and Department of Justice (DOJ) to deliver a comprehensive enforcement and compliance assurance program utilizing the entire spectrum of compliance assurance tools available to the region. This includes strategic planning for enforcement, compliance monitoring and compliance assistance activities, conducting inspections, developing enforcement cases, preparing and issuing administrative actions, assessing penalties, developing judicial enforcement actions, negotiating settlements, measuring and reporting results of the Region's enforcement efforts.

The QAB reviews QAPPs, inspection SAPs and provides technical assistance to staff as requested.

2.6.3. Laboratory Services and Applied Science Division

The Laboratory Services and Applied Science Division provides laboratory analytical support for the region's media programs and enforcement programs, as well as dedicated field services. The Division coordinates with regional media and enforcement programs to ensure the effective collection and analysis of environmental data and makes certain the data collected, reported and used in the Region is properly documented and sufficiently accurate to meet the data quality objectives of program needs. The Division manages implementation of the Region's mandatory Quality Assurance System, operates the Region 9 Laboratory and provides scientific and technical support to the Region.

2.6.4. Land, Chemicals and Redevelopment Division

The Land, Chemicals and Redevelopment Division 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 the Resource Conservation and Recovery Act (RCRA), the brownfields provisions of the Comprehensive Environmental Response, Compensation and Liability Act, Federal Insecticide Fungicide, Rodenticide Act (FIFRA), Residential Lead Based Paint Hazard Reduction Act, Toxic Substances Control Act (TSCA), Asbestos Hazard Emergency Response Action (AHERA), the Asbestos School Hazard Abatement Act (ASHAA), and the Pollution Prevention Act.

Grants managed by the Division are reviewed by the QAB to ensure quality assurance planning document requirements are addressed. The QAB reviews data collection SAPs for several Land, Chemicals and Redevelopment Division programs.

2.6.5 Mission Support Division

The Mission Support Division is responsible for providing leadership, support, communications and direction to ensure efficient operations vital to EPA and regional goals. The Mission Support Division Director holds the roles of Senior Resource Official (SRO) and Senior Information Official (SIO), and advises the Regional Administrator and Deputy Regional Administrator, senior leadership, and management on regional and national policies involving strategic planning, performance tracking, technical, and resource management issues. The Division provides management and technical program development of the region's physical space, contract and grant administration, financial, human resources, health and safety, and information resources.

The QAB coordinates with the Mission Support Division to ensure the Region's QA System is integrated in the Region's grants and contracts and communicated to the Region's Project Officers. The QAB also provides technical assistance to staff as requested.

2.6.6 Office of Public Affairs

The Office of Public Affairs is located in the Office of the Regional Administrator and 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 Mission Support Division and the QAB 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.

2.6.7 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 QAB provides attorneys with technical and QA-related information upon request.

2.6.8 Superfund and Emergency Management Division

The Superfund and Emergency Management Division recommends goals, priorities, and objectives for implementation of activities pursuant to the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA); Section 311 of the Clean Water Act (CWA), as amended by the Oil Pollution Act of 1990 (OPA); the Emergency Planning and Community Right to Know Act; the National Oil and Hazardous Substance Pollution Contingency Plan (the National Contingency Plan or NCP) and the National Response Plan; aligning with the HQ's Office of Land and Emergency Management and the Office of Enforcement and Compliance Assurance (OECA). This Division has overall responsibility for ensuring that Region 9 executes its responsibility for managing resources and personnel for emergency responses, removal and remedial response actions, hazardous substance and oil spill prevention activities, cost recovery, and contingency planning and preparedness activities involving oil and hazardous substances.

The Division coordinates with the QAB and the Regional Laboratory as needed for technical assistance, field services and document review. The Emergency Response Team has an approved QMP to support quality assurance requirements for data collection in emergency situations. In 2019, the Navajo Abandoned Uranium Mine Program collaborated with the QAB to develop a QMP that communicates the practices for environmental data collection. It describes the quality system for data-driven decisions and delegates responsibility for reviewing and approving QA documentation and records retention for the complex program (Appendix D). Grants and contracts administered by the Superfund and Emergency Management Division are reviewed by the QAB to ensure quality assurance planning document requirements are addressed. The QAB reviews internal QAPPs, QARFs and State and Tribal QMPs, QAPPs and SAPs and provides technical support for emerging issues, such as sampling design for vapor intrusion studies.

2.6.9 Tribal, Intergovernmental and Policy Division

The Tribal, Intergovernmental and Policy Division was developed under the realignment and provides support to Region 9's communities including, Tribes, the Pacific Trust Territories and Freely Associated States, and the U.S.-Mexico Border. The Division also works closely with various federal agencies to provide technical assistance in complying with the National Environmental Protection Act and manages the Environmental Justice Program.

Grants administered by the Division are reviewed by the QAB to ensure quality assurance planning document requirements are addressed. The QA Branch also provides technical assistance as needed to staff.

2.6.10 Water Division

The Water Division ensures drinking water is safe, and restores and maintains watersheds and their aquatic ecosystems to protect human health, support economic and recreational activities, and provide healthy habitat for fish, plants, and wildlife. The 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 Water Division provides technical assistance to protect public health and achieve environmental results; oversees the implementation of the Clean Water Revolving Fund and Drinking Water State Revolving Fund programs; conducts oversight of delegated/authorized state and tribal programs, directly implements federal programs where not delegated/authorized; and conducts audits and assessments under the CWA and SDWA.

The QAB 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 QAB to ensure quality assurance planning document requirements are addressed. The QA Branch also provides technical assistance as needed to staff.

3.0 Regional Quality System

3.1 Overview

It is Agency and Regional policy that systematic planning be used for all projects involving the collection of environmental measurements. Managers make decisions based on information provided by staff, technical advice and regulatory requirements. The QAB 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 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 and

commensurate to program resources. 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/quality/epa-qar-2-epa-requirements-quality-management-plans). The Region 9 QMP is available online at www.epa.gov/quality/quality-management-plan-epas-pacific-southwest-region-9. 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 the Comprehensive 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 QAPPs to allow appropriate technical and policy review of the steps being taken to ensure that data generated are of known quality.

The QAPP (www.epa.gov/quality/quality-assurance-planning-epas-pacific-southwest-region-9) 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 QAPPs and SAPs.

3.3.1 Graded Approach at the Organization or Program Level

The QAB works with grantees and other organizations to determine the type of planning document most appropriate for their programs. The QAB may require a QMP with supporting QAPPs, a combination QMP/QAPP or a singular QAPP be prepared. The QAB works with the State, Tribal or grantee organization to determine the most appropriate planning document. For example, for many Tribal organizations receiving grants from the Region, preparation of QAPPs is sufficient to meet project goals and define their environmental data collection activities. This determination 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 is generally not resource effective. A State program commonly prepares a QAPP, but may prepare a QMP or a hybrid QMP/QAPP, depending on the scope and the structure of its quality system.

As the QA function in the Region is centralized and the QAB assists all Divisions in implementing the QMP, the Divisions are not required to prepare separate QAPPs. 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 QAPP 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 QAB. However, whenever appropriate, the QAB 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 (RPM) or his or her designee, the EPA Task Manager if an EPA contract is involved, a representative of the organization preparing the plan, and QAB staff.

The QAB 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 QAB 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/sites/default/files/2015-06/documents/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 QAPP 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 QAB to develop an appropriate document.

3.5 QA Annual Planning

Annual planning for the QAB ensures resources are used efficiently to accomplish the Region's QA activities. Planning is undertaken at two levels: QAB goals are included in the Region 9 Laboratory Services and Applied Science Division Operating Plan and annual planning goals are included in the Quality Assurance Annual Review and Workplan (QAARWP) 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 QAB 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 QAB 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 Enterprise Quality Management Division 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 QAB 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 their Quality Assurance branches 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 QAB prior to the initiation of data collection. The document is developed in accordance with regional and national guidance, and is available on the Quality QA Web page.
- 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 QAB 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 updated annually as necessary. After five years, they are reviewed and revised to reflect the current activities being performed and submitted to the QAB for approval.
- A State program that has an approved QMP and/or QMP/QAPP(s) in place which has been evaluated by the QAB to ensure that it meets EPA requirements may review and approve internal- and contractor-generated QAPPs, SAPs and FSPs.

3.6.2 Types of QA Planning Documents

The success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making. Decisions depend significantly on the adequacy of the quality assurance planning documents developed for the organization, project or sampling effort.

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 QAB 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/QAPP.

3.6.2.2 Quality Assurance Project Plans

The planning of project-specific data collection activities is documented in QAPPs or equivalent documents, such as SAPs (discussed in Section 3.6.2.3). QAPPs may be prepared by Region 9 staff or contractors, grantees, responsible parties, or contractors employed by these organizations. When implemented as written, the QAPP provides a detailed record of the scope and objectives of data collection activities, procedures, and QA/QC requirements. QAPPs are prepared using *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (QA/R-5, March 2001).*

It is encouraged that QAPPs be reviewed by the submitting organization every year. However, every five years QAPPs must be reviewed and revised, if appropriate, by the submitting organization and sent to the QAB and the Region 9 PO/RPM for approval.

3.6.2.3 Sampling and Analysis Plans

Sampling and Analysis Plans (SAPs) combine elements of a QAPP 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)* and *Sampling and Analysis Guidance and Template, Version 3, Brownfields Assessment Projects (R9QA/008.1, August 2012)* are available on the Agency Quality website for use.

3.6.2.4 Field Sampling Plans

Field Sampling Plans (FSPs) are planning documents for activities taking place within a longer-term project that has a QAPP 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 QAB 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 QAPP. Approval of an FSP is limited to the specific sampling event.

3.6.2.5 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 QAPP for research projects may also be appropriate. Questions as to which guidance to use or approach to take should be directed to the QAB and are often discussed in the scoping meetings described in Section 3.4.1.

3.6.3 Review and Approval of QA Planning Documents

Region 9's QA planning documents are approved by the Region 9 QA Manager, unless another process has been described for review and approval in a Region-specific QMP (examples include the Region's Emergency Response QMP and the NAUM QMP). Documents produced by grantees to describe media project goals are reviewed by the QAB and approved by the Region 9 QA Manager. 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 Quality website (www.epa.gov/quality). Region 9 has prepared several guidance documents which exist on the Quality website to assist organizations in writing QA planning documents, including the QAPP guidance, SAP guidance documents and the QAPP guidance for wetlands projects. In addition, a CD ROM containing guidance material, a template, SOPs and references for surface water monitoring is available.

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 QAB; other relevant and ancillary activities are supported by other Region 9 Divisions and Offices.

4.2 Document Review

4.2.1 Quality Assurance Branch Review Process

A primary responsibility of the QAB is document review. Documents may be submitted to the QAB 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 QAB is completed before a memo (for internal reviews) or a letter (to

the grantee) relaying information about the status of a quality assurance document is submitted to the QA Manager for signature. Occasionally, a Remedial Project Manager with QA expertise will review a document. The QAB can evaluate such reviews to ensure consistency with Agency and Regional QAB policy. The service standard for document review is 120 days for QMPs, and 60 days for QAPPs, SAPs and FSPs, although this timeframe is subject to negotiation.

During the course of its review, the QAB 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 document and sent via review memorandum or letter. Reviews may be transmitted independently of the QAB through the PO/RPM or, may be sent by the QAB 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.

The NAUM QMP also describes a collaborative process by which the Remedial Project Manager or the On-Scene Coordinator works closely with QAB to review and approve QAPPs.

A State or Tribe having a quality system in place that has been described in an EPA-approved QMP may receive authorization from EPA to review and approve its own QA documents. The QAB 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. Currently, no State or Tribal organization has authorization to review and approve QAPPs that describe environmental data collection funded by EPA.

4.3 Training

The QAB provides a variety of trainings designed to meet the needs of specific target audiences. The training may be generated by the QAB 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 Branch Staff Competency

Region 9 ensures the QAB staff have a combined technical knowledge including a variety of environmental science backgrounds and certifications. The staff are trained to interpret information and apply appropriate guidance while performing their daily work.

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 online and in-classroom format as time and resources permit.

4.3.1.2 Technical Training

QAB 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 may take 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 database.

4.3.2 In-House and External Training

The QAB 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 QAB responds to all training requests for standard presentations and specific topics. The QAB also sponsors training from outside sources. Examples of QAB 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 QAB that consist of purchases under $3000 (microprocurement) are made through the Mission Support Division. 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 involve 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 QAPP is due with the proposal or soon after contract award. The QAB may review the QA provisions of the Request for Proposal (RFP) or contract. If a contract includes environmental data collection activities, the QAB participates on the technical evaluation panel. The QAB 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 QAB review. Once the QAB 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 QAB for review and approval. The QAB reviews the description of the activity being funded and the PO's responses to specific QA questions against information in the QAB 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 QAB 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 QAB 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 collecting and using environmental measurements evaluate and attest the competency of the laboratories they use or plan to use.

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

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 U.S. 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 QAPP, 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 the Agency's *Records Management Policy CIO 2155.4, August 22, 2018*. The Policy 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 Mission Support 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.

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 as a grant deliverable. Superfund documents are then moved to the Superfund Records Center for

long term storage. The QAB keeps a comprehensive file of all signed QA reviews and approved plans for reference, if needed. Signed reviews are also saved in .pdf format as the QAB moves to all electronic record keeping. The original memorandums are sent to the Tribe or State program 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 spreadsheet 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 spreadsheet 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 spreadsheet 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 spreadsheet 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 ongoing grants and cooperative agreements, the spreadsheet 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 QAB signature, including date, DCN, associated grantee, Regional and QAB staff.

4.5.2.3 Document Retention

It is Region 9 QAB policy to send approved QA documents to the Project Officer or grantee who generated them for their records or archives. The QAB requests that documents be sent electronically to reduce paper and physical storage space use. QAB will also retain QA documents from some programs in order to provide them to those programs to use as models for other grantees.

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 QAPPs
- Wetlands QAPP Guidance
- QAPP 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 Quality Assurance webpage at www.epa.gov/quality.

Regional QA guidance documents are drafted by QAB 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 Infrastructure Services Branch (ISB) in the Mission Support Division 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 ISB 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. ISB 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.

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. ISB 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. An example is the Lotus Notes Quality Assurance Management System (QAMS), which was a document tracking system developed by ISB for the QAB, and is no longer maintained in the Region. The QAMS database was managed by the QAB 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 ISB 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

The Geographic Information Systems (GIS) Center is part of ISB. GIS policy guidance is found at www.epa.gov/frs/gis-applications.

The GIS Center follows guidance contained in the following documents:

- OMB Circular A-16, Coordination of Geographic Information, and Related Spatial Data Activities (www.whitehouse.gov/omb/information-for-agencies/circulars/)
- OMB Circular A-130, Management of Federal Information Resources (www.whitehouse.gov/omb/information-for-agencies/circulars/)
- Latitude/Longitude Data Standard (www.exchangenetwork.net/standards/Lat_Long_Standard_08_11_2006_Final.pdf)

- EPA National Geospatial Data Policy: (www.epa.gov/geospatial/epa-national-geospatial-data-policy)
- Global Positioning Systems – Technical Implementation Guidance (nepis.epa.gov)
- Guidance for Geospatial Data Quality Assurance Project Plans (www.epa.gov/fedfac/guidance-geospatial-data-quality-assurance-project-plans
- Geospatial Metadata Standards (www.fgdc.gov/metadata/geospatial-metadata-standards)
- National Geospatial Data Policy Procedures for Geospatial Metadata Management (www.epa.gov/geospatial/national-geospatial-data-policy-procedure-geospatial-metadata-management)

The GIS Center uses the following data and GIS tool:

- EPA Metadata Editor (www.epa.gov/geospatial/epa-metadata-editor)
- Scribe: Environmental Field Data Capture Tool (www.ertsupport.org/Scribe)

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's 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, and is then reviewed and approved by the QAB. The written plan contains the

requester's analytical needs, which 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. S/he 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 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 QAB performs quality system audits of the Laboratory in alternate years.

4.8 Field Operations

On February 2, 2017 Region 9 implemented the Quality Assurance Field Activities Procedure (QAFAP). The ten field guidelines were developed by the Region and are based on Agency quality-related and ISO-17025 accreditation requirements. The QAFAP Guidelines are

applicable to all organizations within Region 9 that conduct inspections/investigations and/or collect environmental samples and measurements in the field.

The Field Operations Lead or Point of Contact (POC), 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.

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 and Compliance Assurance 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 QAFAP 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.
- 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 QAPPs, 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

[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.

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 QAB 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 QAB 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 QAB 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 requests 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 QAB, OPA and ISB 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 (https://cfpub.epa.gov/si/). The Regional Science Liaison 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 QAB on Regional programs as needed and as resources allow.

QAB 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 QAB 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 QAB 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 QAB 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 QSRs*	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 QAPPs and on demand	Review of reported results	Project Manager/ Superfund, Air Districts, DMR-QA reports
Data Verification/Validation	As per recommendation in QAPPs	Review of reported results	Project Manager
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 QAB 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 QAB 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 quality systems review (QSR), technical systems audit (TSA), performance evaluation samples (PES) and data validation.

5.2.1 Quality System Reviews (QSRs)

A Quality Systems Review (QSR) 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 QAB may conduct QSRs 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 QSRs 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 QSR 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 QAPPs, the QAB, working with the state QA Officers, will evaluate the need to develop a schedule to conduct QSRs 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 also PQAOs: Morongo, Pechanga, Gila River and Salt River.

Technical System Audits (TSAs) of state air PQAOs are conducted jointly by the Air and Radiation Division's Air Quality Analysis Office (AQAO) and the QA Branch. 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 AQAO and QAB perform equipment audits of other air monitoring programs as requested.

The AQAO 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 QAB continues to provide technical support as requested.

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

The Laboratory and QAB 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 Office of Ground Water and Drinking Water's Technical Support Center, Cincinnati.

Since the NELAC Institute (TNI) became a completely private organization, neither QAB or staff at the Regional Laboratory participates in accrediting body 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 a Region 9 approved QAPP.

The QAB 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 QAB 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 "verification and "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 QAB 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, QAB 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 QAB provides technical assistance as requested.

5.2.4.2 Tiered Data Review

The QAB 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 l 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 QAB 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.

In addition, the QAB has initiated and implemented the EPA Lean Management System (ELMS) to track actions as they move through QAB's process in order to respond and resolve challenges quickly and thoroughly using Lean principles and tools. QAB's current project tracks the time it takes for eligible State and Tribal QAPPs to be approved by the QAB. The QAB goal is to review and approve eligible State and Tribal QAPPs in 60 days, not counting the time the grantee takes to respond to comments. Progress in meeting the goal is tracked in a National performance measure maintained by the Agency's Quality Staff.

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 QAB has developed a number of specific templates that are posted on the Agency's quality website. Staff are available to provide further assistance.

6.2 Training

The QAB 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. Trainings are held at the request of the media divisions or provided to grantees as needed.

6.3 Audits

The Clean Air Act requires EPA to audit air districts within the Region every three years. The QAB continues to collaborate with the Air and Radiation Division's 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 QAB 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 QAB SOPs will be posted on the Region 9 Quality Assurance webpage.

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APPENDIX A: Quality Assurance Branch Staff Qualifications

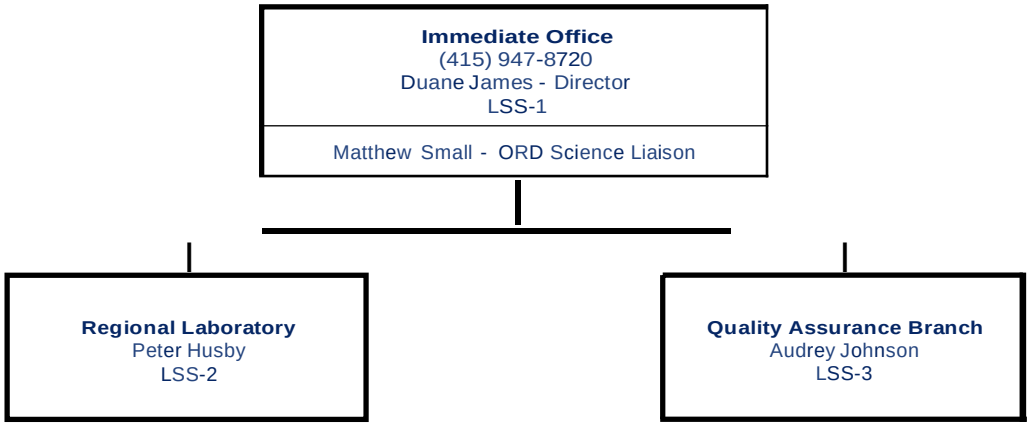
Quality Assurance Branch

Grade Series	Responsibilities	Years in QA
401 Supervisory Life Scientist	Manages QAB	2
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	Air QA reviews, audits, Superfund and Air training, vapor intrusion expert	~20
1301 Environmental Scientist	Air QA reviews, audits, Superfund groundwater, Water ATP coordinator	>20
1301 Environmental Scientist	Superfund, Water QA reviews, training, audits, statistics, sampling design	>20
819 Environmental Engineer	Air QA reviews, audits, Superfund technical assistance, vapor intrusion expert	~3
28 Environmental Protection Specialist	ESAT COR, Brownfields QAPP reviewer	~3

APPENDIX B: Organization of the Laboratory Services and Applied Science Division

Environmental Protection Agency - Region 9

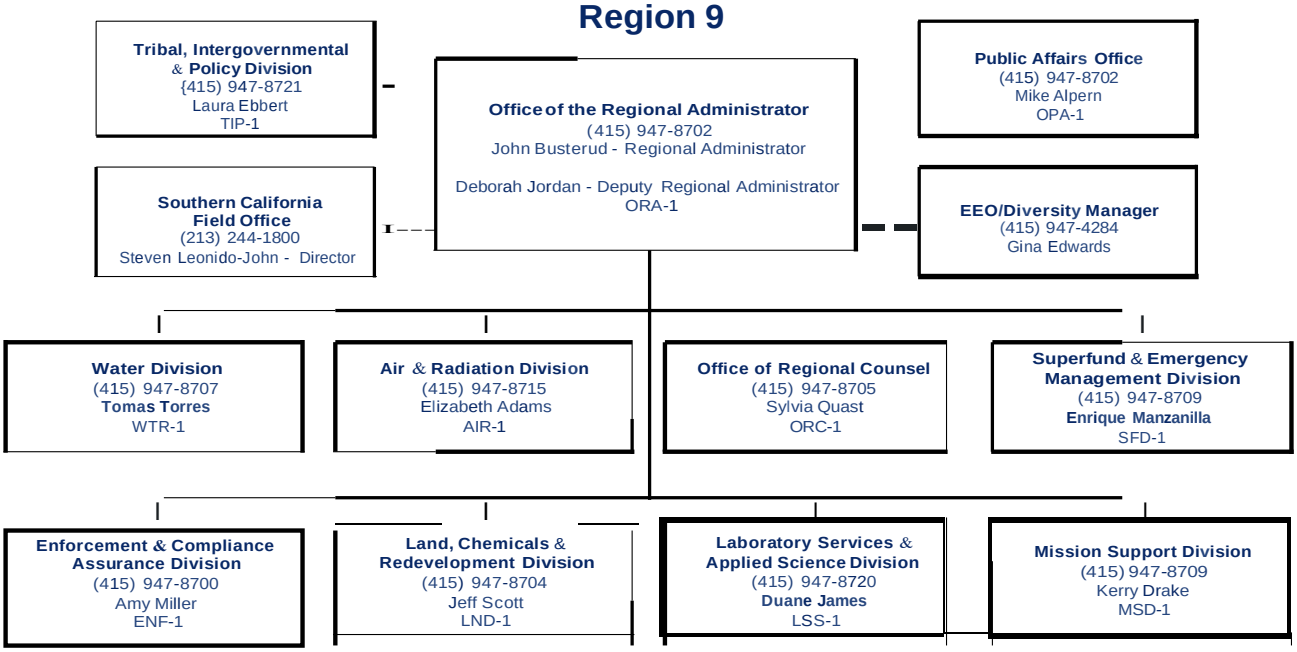
Laboratory Services & Applied Science Division



APPENDIX C: Region 9 Organization

Environmental Protection Agency

Region 9



APPENDIX D: Navajo Abandoned Uranium Mine QMP

EPA Region IX
Navajo Abandoned Uranium Mines Program
Quality Management Plan

September 1, 2020

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

EPA Region 9
Navajo Abandoned Uranium Mines Program
Quality Management Plan

September 1, 2020

CONCURRENCES AND APPROVALS

Will Duncan
Assistant Director, Tribal Land Cleanup and Remedial Support Branch

Signature: WILL DUNCAN Digitally signed by WILL DUNCAN Date: 2020.09.02 12:12:06 -07'00' **Date:** _____

Audrey L. Johnson
Manager, Quality Assurance Branch

Signature: Audrey L Johnson Digitally signed by Audrey L Johnson Date: 2020.09.02 10:04:36 -07'00' **Date:** _____

John W. Busterud
Regional Administrator

Signature: JOHN BUSTERUD Digitally signed by JOHN BUSTERUD Date: 2020.09.05 13:42:57 -07'00' **Date:** _____

Standards, methods, and approaches described in this Quality Management Plan are intended for use by U.S. Environmental Protection Agency personnel for all data collection efforts for Superfund cleanup projects at Navajo Abandoned Uranium Mine Program sites.

PURPOSE AND BACKGROUND

Introduction

This Quality Management Plan (QMP) describes practices for environmental data collection for cleanup decisions on United States Environmental Protection Agency (EPA) Region 9 work on Navajo Abandoned Uranium Mine (NAUM) Program sites. This QMP is a program-specific amendment of the EPA Region 9 QMP and describes a system to ensure that data-driven decisions meet agency requirements for:

- Scientific integrity
- Legal defensibility
- Transparency
- Accountability
- Efficiency

The principal components of the system described are planning (e.g., scoping meetings and Quality Assurance Project Plan [QAPP] development), verification (e.g., data validation and audits), and documentation. Policies or specifications that facilitate implementation of work under this QMP are provided. Quality assurance (QA) policies, when applicable, apply to all data generation and collection activities, and the burden is on the project team to evaluate and modify any element of the quality system as necessary on a site-by-site basis.

This document not only supplements the EPA Region 9 QMP but also provides additional information typically found in a QAPP. The functions of the QMP and QAPP have been combined into one comprehensive document for efficiency and to accomplish the QA objectives of the NAUM Program. One major focus of this QMP is to describe the radiological environmental data collection and analysis practices of the NAUM Program in compliance with EPA QA policies. This effort supplements the chemical analysis QA already included in the EPA Region 9 QMP.

Key objectives of this QMP include:

- Ensuring that the data are of sufficient quality to support the project objectives and the data end uses. This QMP presents the practices, program organization, functions, and QA and quality control (QC) requirements designed to meet the objectives of the NAUM Program.
- Providing guidance that establishes the analytical protocols and documentation requirements to ensure that data are collected, reviewed, and analyzed in a consistent manner.

The elements of the NAUM QA program are presented in Figure 1-1 and defined in EPA QA guidance. This QMP focuses on the implementation of these elements when performing cleanup activities on the Navajo Nation. The NAUM Program is in the process of developing implementation documents as resources for Remedial Project Managers (RPMs) and On-Scene Coordinators (OSCs) to effectively carry out a defensible QA program. The project documentation column in Figure 1-1 lists the documents necessary to ensure that the required QA steps have been carried out appropriately.

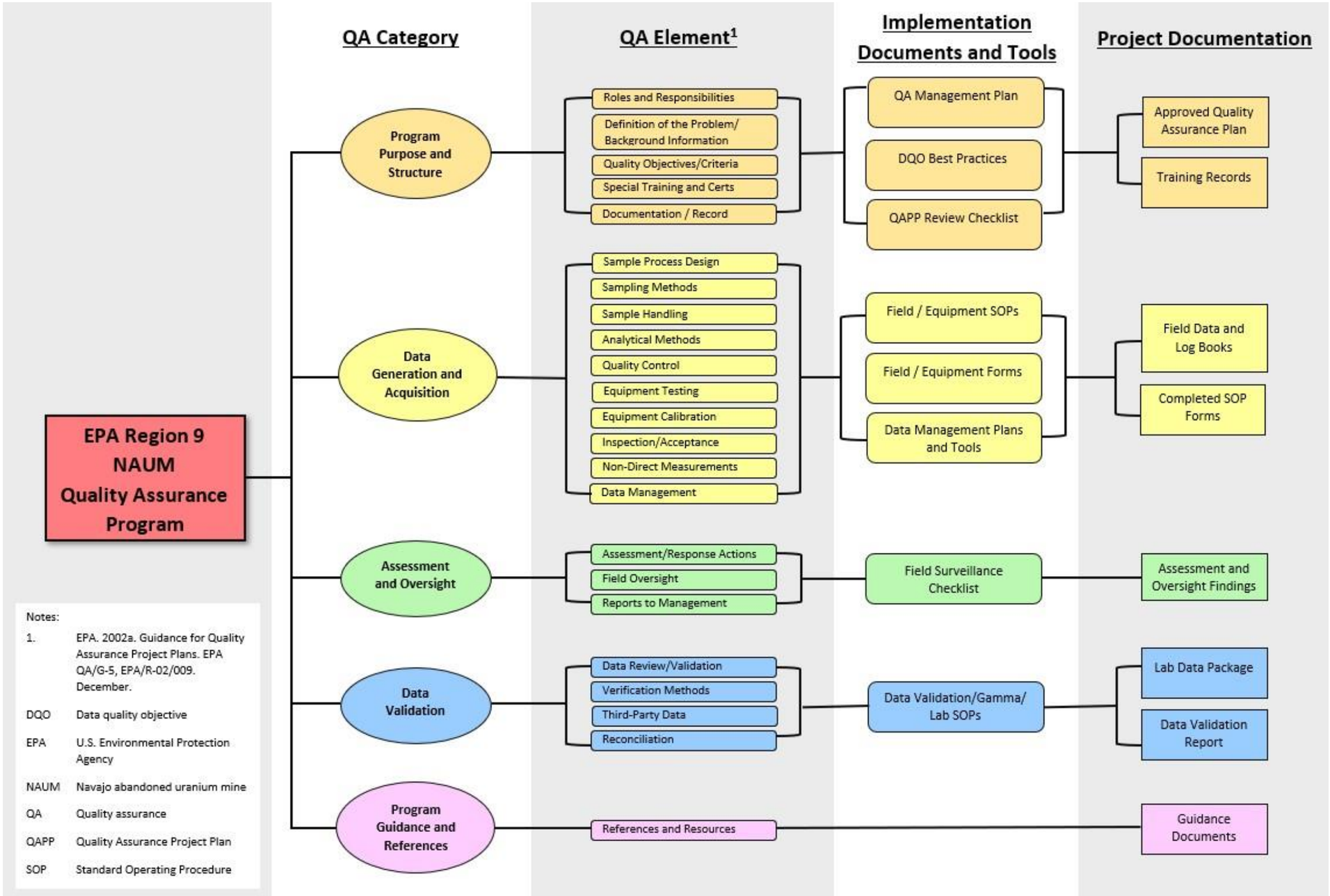
Development of this first version of the NAUM QMP focuses primarily on the investigation phase of NAUM cleanup since most of the field work is currently focused on the collection of data for

investigation purposes. This QMP includes key implementation tools such as data quality indicator (DQI) and measurement quality objective (MQO) tables, a field surveillance checklist, and data validation standard operating procedure (SOP). Additional topics include NAUM-specific guidelines on:

- Review and approval of QAPPs
- Field oversight
- Validation of data
- Laboratory competency
- Continuous improvement
- Deterrence of fraud

This QMP was developed with contractual support and then went through a subsequent review for technical accuracy by experts under a different contractor. As part of the continuous improvement process, this QMP is envisioned as a living document and will be revised and expanded to cover additional topics such as a corrective action tracking system, an annotated QAPP review checklist, and additional implementation tools. The QMP will be expanded to incorporate information specific to data collection under the Navajo Nation Contaminated Structures Program and for site clearances, such as data collected during the Final Status Survey.

Figure 1-1 – NAUM QA Program Overview



Definition of the Problem and Background Information

The Navajo Nation, roughly the size of West Virginia, encompasses more than 27,000 square miles and extends into northeastern Arizona and parts of southeastern Utah and northwestern New Mexico. Over 30 million tons of uranium ore were extracted during mining operations on or near the Navajo Nation from 1944 to 1986 for developing the U.S. nuclear weapons stockpile and supplying the nuclear power industry. Uranium mining activities no longer occur on the Navajo Nation, but the legacy of these activities remains. More than 500 abandoned uranium mines (AUMs) or mine claims remain on or near the Navajo Nation with more than 1,000 mine features.

Waste piles and other sources of contamination remain on many AUMs. Many structures and water sources contain elevated levels of uranium, radium, and other radionuclides. Uranium and other elements (selenium, arsenic, etc.) associated with mine and mill sites also occur naturally at elevated levels in rock, soil, surface water, and groundwater across the Navajo Nation and the broader Four Corners region. Health effects as a result of exposure to these elements can include lung cancer, bone cancer, and impaired kidney function.

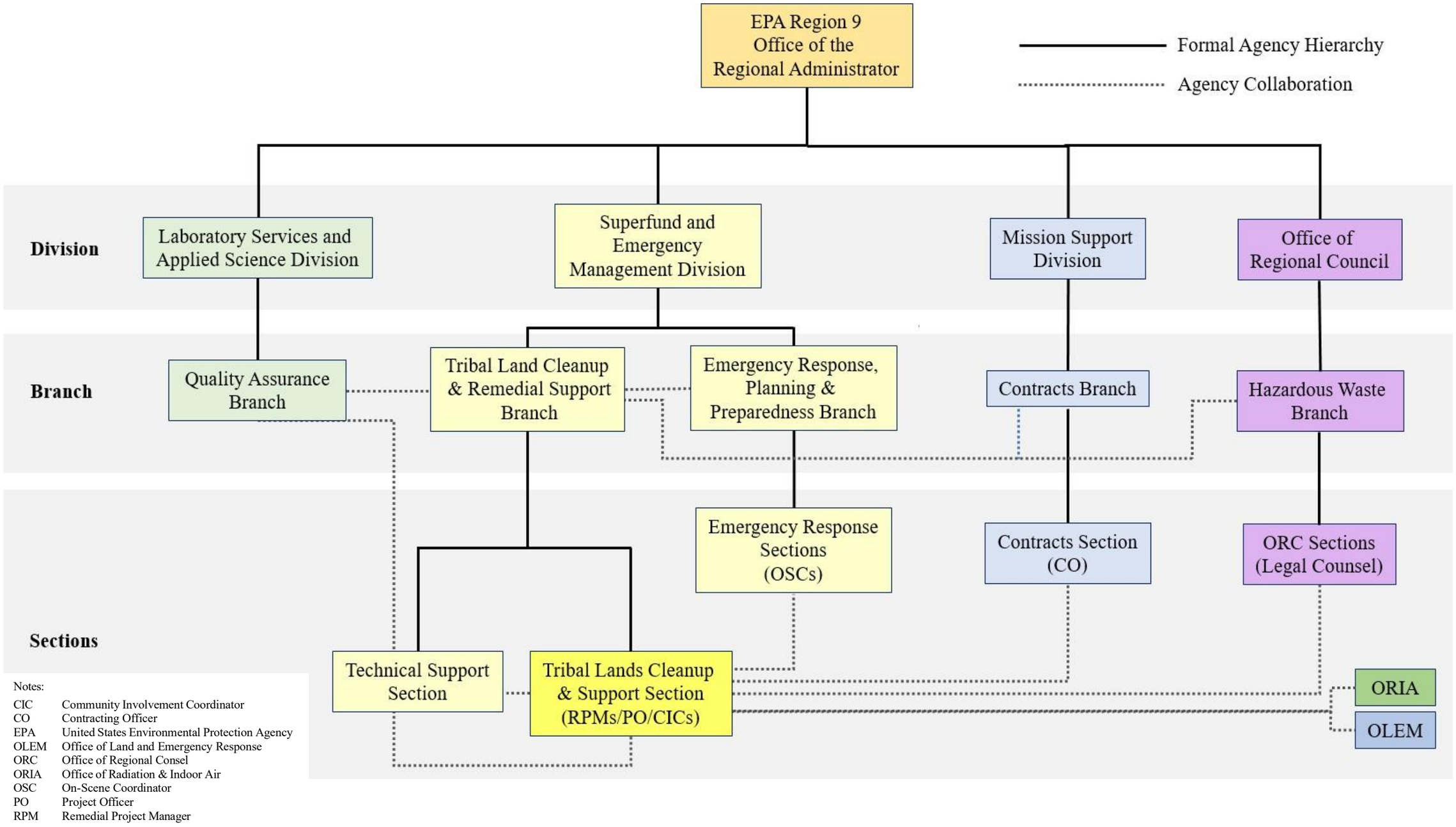
Program Description

EPA, other federal agencies, and the Navajo Nation are working together to address the legacy of uranium mining and milling on the Navajo Nation. EPA Region 9's NAUM Program comprises professionals within the Superfund and Emergency Management Division and draws support from numerous colleagues within the region and throughout the agency. The NAUM Program uses Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) authority to oversee assessment and cleanup work at Navajo AUMs, coordinating with the Navajo Nation Environmental Protection Agency (NNEPA), other Navajo agencies, communities, stakeholders, and other federal partners. The goal of these efforts is to reduce the health and environmental risks associated with past uranium mining activities and find long-term solutions to the remaining uranium issues on Navajo lands.

Roles and Responsibilities

EPA NAUM Program personnel are responsible for the quality of work and must be knowledgeable of the requirements, processes, capabilities, and tools utilized to accomplish tasks at their site. Figure 1-2 shows the EPA NAUM Program organizational chart. The primary NAUM program includes the RPMs, Community Involvement Coordinators (CICs), Project Officers (Pos), and managers in the Tribal Lands Cleanup and Support Sections shown in the bright yellow box below in Figure 1-2. This NAUM team is located in the Superfund and Emergency Response Division, and is supported by technical support, Quality Assurance, legal, contracting, OSCs, and other staff and managers in multiple Divisions throughout the region. Table 1-1 includes the roles of key EPA positions within the NAUM Program for the purposes of QA.

Figure 1-2 – EPA NAUM Program Organization Chart



Notes:

CIC	Community Involvement Coordinator
CO	Contracting Officer
EPA	United States Environmental Protection Agency
OLEM	Office of Land and Emergency Response
ORC	Office of Regional Consel
ORIA	Office of Radiation & Indoor Air
OSC	On-Scene Coordinator
PO	Project Officer
RPM	Remedial Project Manager

Table 1-1 – EPA NAUM Program Key Responsibilities

NAUM Program Supervisors
• Ensure that adequate procedures are in place to address QA requirements in all applicable program operations, including those delegated to other agencies • Ensure that resources needed to implement QA requirements are identified and provided • Ensure that QA training is available for RPMs and OSCs implementing the CERCLA process at NAUMs • Ensure adequate QA reviews or audits are performed on a routine basis • Ensure an appropriate system to track and implement corrective actions is in place (to be developed) • Coordinate NAUM QA matters with the RQAM to ensure that all QA policies and methods are in accordance with EPA national and regional guidelines • Ensure routine assessment of QA needs occurs and that any identified improvements needed are implemented, which may include revisions to the NAUM QMP, developing new trainings, etc. • Collecting NAUM QA information for the RQAM for consolidation into the Region 9 QA Annual Report and Work Plan • Facilitate opportunities for routine technical discussions among NAUM RPMs and OSCs to ensure consistency between projects and continuous improvement in implementation (see Section 1.4.5)
NAUM Project Managers (RPM/OSC)
• Ensure that all NAUM projects involving the generation of environmental data are performed in accordance with the NAUM QMP • Review, comment on, and approve project-specific QAPPs for all NAUM projects • Perform QA reviews and oversight with assistance from the RQAM or other technical experts as needed • Perform or arrange for QA audits as appropriate • Ensure individual corrective actions are taken based on recommendations contained in the QA review findings report • Identify NAUM QA and QC needs and respond to problems or questions with assistance of the RQAM or other technical experts as necessary • Identify NAUM QA training needs in coordination with the RQAM

Notes:

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA	United States Environmental Protection Agency
NAUM	Navajo abandoned uranium mine
OSC	On-Scene Coordinator
RPM	Remedial Project Manager
RQAM	Regional Quality Assurance Manager
QA	Quality assurance
QAPP	Quality Assurance Project Plan
QC	Quality control
QMP	Quality Management Plan

Tribal Land Cleanup and Remedial Support Branch Manager

The NAUM Program is led by the Tribal Land Cleanup and Remedial Support Branch Manager. The Branch Manager oversees two Tribal Lands Cleanup Sections, which include the two Section Managers, RPMs, a Project Officer, and Community Involvement Coordinators. The Branch Manager also oversees technical support staff and is supported by various program managers both within the division and throughout the region, including:

- Emergency Response
- Quality Assurance
- Contracting
- Office of the Regional Council

The Section Managers maintain the authority, responsibility, and accountability for overall program planning and implementation, contract utilization, and interaction with other partner agencies.

Project Manager

EPA RPMs and OSCs manage specific projects within the NAUM Program. RPMs and OSCs serve as the primary decision-maker and are responsible for establishing data quality objectives (DQOs) while clarifying information necessary to successfully manage the site. RPMs and OSCs are also responsible for directing operations associated with the project, working with agency and contractor personnel to develop project teams with the appropriate level of technical input, as well as ensuring the health and safety of project personnel. RPMs and OSCs oversee project QA, environmental compliance, environmental sampling, environmental data management, records management, and project delivery.

RPMs and OSCs are responsible for obtaining adequate support on projects using contractors or program support staff, including:

- Community Involvement Coordinators
- QA Officer (QAOs)
- Data management experts
- Health and Safety Officers
- Regional counsel
- Health Physicists
- Statisticians
- Risk Assessors
- Geologists
- Ecologists
- Biologists
- Engineers

Quality Assurance Branch

The Region 9 QA Manager is responsible for the implementation of the Region 9 QA Program and Region 9 QMP, as well as defined responsibilities in the NAUM QMP, which include:

- Coordinating with the NAUM Program Section Managers for QA support activities
- Providing and interpreting agency QA policies and procedures
- Jointly with Program Managers, developing, maintaining, and implementing processes to ensure NAUM Program decisions are based on sound, defensible, and documented information
- Approving QAPPs, as appropriate, and Regional Contract QA requirements
- Ensuring independent reviews of data quality are performed
- Providing QA training on regional policies and procedures for EPA-implemented projects, assignment of a QAO to work as an integral member of a project specific team to ensure implementation of QAPP requirements and serve as a point of contact for Quality Assurance Branch (QAB).

Data Management Team

The EPA NAUM Program Data Manager oversees the development of the NAUM Data Portal. Each RPM and OSC is responsible for data management at a project level, and Data Management Plans (DMPs) may be developed on a site-by-site or project-by-project basis. The Data Manager works with project teams and data management staff, including geographic information systems (GIS) analysts, database developers, and programmers to facilitate generated data being uploaded to the NAUM Data Portal. The overall NAUM DMP is in development.

Data Manager responsibilities include:

- Managing and overseeing NAUM data management systems for receiving, reviewing, and verifying data deliveries from parties conducting work
- Coordinating joint data needs with program stakeholders (such as Navajo departments and agencies)
- Coordinating NAUM Program management needs, such as status of projects, with data systems
- Ensuring all projects within the NAUM Program receive data management support and are incorporated into NAUM Program data systems (e.g., the NAUM Data Portal)
- Reviewing project-specific DMPs and providing NAUM Program data management guidance that RPMs and OSCs can provide to data collectors

The Data Manager works with EPA GIS and data systems specialists to ensure NAUM Program compliance with agency regulations on data management and compatibility with agency guidance and protocols for data systems.

Office of Radiation and Indoor Air

The EPA Office of Radiation and Indoor Air (ORIA) develops protection criteria, standards, and policies to protect the public and the environment from the risks and impacts of radiation and

indoor air pollution. ORIA supports the EPA regions by performing radiochemical analysis of environmental samples and providing guidance on QA, evaluating and assessing sites contaminated with radioactive material, providing advice on radiological health and safety programs, and providing scientific guidance on radiation dose and risk assessment. ORIA, through its National Analytical Radiation Environmental Laboratory (NAREL), supports the NAUM Program by providing technical review of radiochemical methods, conducting oversight for laboratory data validation, and completing quality reviews of radiological data packages. NAREL supports the Superfund program by providing guidance on the implementation of the *Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) Manual* (EPA 2004). MARLAP provides guidance on the planning, implementation, and assessment phases of projects requiring laboratory analysis of radionuclides. The National Center for Radiological Field Operations assists the NAUM Program with field oversight to ensure that field work is performed according to planning criteria. The Radiation Protection Division of ORIA supports the Superfund program by providing guidance on the implementation of the *Multi-Agency Radiation Survey and Site Investigation Manual* (MARSSIM) (EPA 2000b). MARSSIM provides a nationally consistent consensus approach to conducting radiation surveys and investigations at potentially contaminated sites and describes how to demonstrate that a site cleanup is in compliance with federal and state radiation regulations.

Office of Land and Emergency Response

EPA's Environmental Response Team (ERT) in the Office of Land and Emergency Response (OLEM) provides on-site health physics support, technical advice, and support related to radiological contamination in all EPA regions. Support can include federal workers and contractor reach-back support for a wide variety of health physics needs at emergency response and remedial sites for exposure rate, contamination, and airborne concentration measurements. ERT provides nuclide-specific airborne concentration limits for on-site worker protection for respiratory protection and site boundary monitoring and has additional caches of standardized radiological instrumentation that regions can use for larger site needs. ERT also houses specialized equipment for remote exposure rate monitoring with the SkyLink and ShortLink systems, swipe and air filter concentration screening, gas flow proportional gross alpha/beta floor monitors, and gamma contour mapping that is compatible with ESRI ArcGIS software tools. In addition, EPA's Airborne Spectral Photometric Environmental Collection Technology (ASPECT) airplane is located near Dallas, Texas, and is part of EPA's Consequence Management Advisory Division, also under OLEM. The ASPECT airplane has been used as a tool to collect radiological data for NAUMs in several areas of the Navajo Nation. This information, collected from approximately 300 to 500 feet in altitude, is a screening tool for understanding where ground investigations may be warranted. However, cleanup decisions are based on data collected on the ground.

Partner Agencies

EPA NAUM Program personnel will often coordinate with other stakeholder agencies based on unique project-specific factors. While all NAUM projects require coordination with the Navajo Nation government and affected communities throughout the process, many projects may require coordination with other federal agencies before, during, or following project implementation. Partner agencies will often review EPA deliverables and data and participate in the determination of project recommendations. Potential partnering agencies are identified during the initial project planning process. Table 1-2 shows the list of common partner agencies at EPA NAUM sites. If

private lands are involved, coordination with the States of Arizona, New Mexico, or Utah may also be required.

Table 1-2 – Partner Agencies

Agency	Abbreviation
United States Environmental Protection Agency Region 9	EPA Region 9
United States Environmental Protection Agency Region 6	EPA Region 6
Navajo Nation Environmental Protection Agency	NNEPA
Navajo Abandoned Mine Lands Reclamation Program	NAMLRP
United States Army Corps of Engineers	USACE
Bureau of Indian Affairs	BIA
Indian Health Service	IHS
United States Coast Guard	USCG
United States Geological Survey	USGS
Agency for Toxic Substances and Disease Registry	ATSDR
Nuclear Regulatory Commission	NRC
United States Department of Energy	DOE

NAUM Standard Quality Practices

Every NAUM project should include sufficient QA to assess and document the suitability of the data used for decision-making; the level and type of effort should be commensurate with decision significance and risks to ensure optimal use of limited resources. The QMP should be reviewed at least annually as part of NAUM Program's continuous improvement process and will be revised at least every 5 years.

The NAUM Program has adopted specific approaches to implement its QA program in a uniform and efficient manner. These standard practices supplement or adapt requirements in the Region 9 QMP or guidance referenced therein.

This QMP supplements existing EPA guidance in the following areas:

- Review and approval of QAPPs
- Field oversight
- Validation of data
- Laboratory competency
- Continuous improvement
- Deterrence of fraud

Review and Approval of QAPPs

The NAUM Program's QAPP review and approval process is described below. This process ensures consistency, transparency, and conformance to EPA data quality policies.

Responsibilities for Implementation of the Review and Approval Process

Table 1-3 describes the responsibilities of the NAUM Program Supervisor, Project Managers, and the RQAM or delegated QA Reviewer for the implementation of the QAPP review and approval process. Table 1-4 presents the NAUM QAPP approval guide.

Table 1-3 – Responsibilities for Implementation of the Review and Approval Process

NAUM Program Supervisors
• Ensure that the approval process is implemented and complete • Coordinate with the RQAM to obtain any necessary program support • Ensure appropriate training for RPMs and OSCs • Resolve conflicts between technical reviewers and consult with the RQAM when necessary • Provide guidance to RPMs and OSCs for the level of effort for a QAPP review (see Section 6 of 1.4.1) • Primarily for unforeseen circumstances, any significant deviations from the NAUM QMP, consult with affected parties and the RQAM
NAUM Project Managers (RPM/OSC)
• Initiate appropriate reviews, including determining scope, approach, and the level of effort for a QAPP review • Coordinate comments and review of revisions • Consult with the RQAM for any unusual QAPP specifications to ensure consistency and conformance to EPA policies and standards • Inform the RQAM of any significant QA concerns identified that could recur or be a systematic problem affecting other projects or sites • Sign the QAPP to document agency approval (see Table 1-4) • Ensure that required external signatures are obtained or otherwise document process deviations • Document other approvals as appropriate
RQAM or Delegated QA Reviewer
• Assist RPM/OSC with tasks listed above • Ensure QAPP policies and procedures meet Agency requirements via reviews • Ensure the level of reviews are commensurate with decision risks, primarily defined by the NAUM RPM requesting a specific QAPP review • Periodically, at least annually, consult with NAUM management about any ongoing concerns or priorities • Provide training, as necessary or requested, about EPA QA policies and procedures • Sign QAPPs requiring R9QAM approval (See Table 1-4)

Notes:
[1]

EPA	United States Environmental Protection Agency	QAPP	Quality Assurance Project Plan
NAUM	Navajo Abandoned Uranium Mine	QMP	Quality Management Plan
OSC	On-Scene Coordinator	RPM	Remedial Project Managers
QA	Quality Assurance	RQAM	Regional Quality Assurance Manager

Table 1-4 – NAUM QAPP Approval Guide

Project Type	Project Category	QAPP Approval Signature Requirements[1]			
		EPA		External Partner	
		RPM/OSC	RQAM[2]	Navajo EPA	Implementing Entity[3]
PRP-Lead	All	✓			✓
Trustee	All	✓		✓	✓
EPA-Lead	RSE	✓			✓
	RI/FS/ Final Status Survey	✓	✓		✓
	Time Critical[4]				
EPA Funded Interagency Agreement/Grant	All	✓	✓		✓

Notes:

[1] Approvals are required by EPA regulation or policies, or enforcement agreement (in the case of the trustee). In the rare case that the non-EPA entity may refuse or does not have authority to sign the QAPP, the reason for this deviation must be well documented.

[2] EPA may form teams where other EPA organizations (i.e., ERT) perform site work under the direction of the EPA NAUM RPM. Factors such as efficiencies, roles, responsibilities, and authorities should be considered by the NAUM RPM and RQAM to determine if, on a project-specific basis, another EPA organization's QAM can substitute for the RQAM.

[3] The implementing entity could be a PRP, trustee, EPA contractor, another federal agency, grant recipient, etc.

[4] Time Critical QAPPs do not have a mandatory approval process; however, a predefined model QAPP is typically used.

EPA United States Environmental Protection Agency
ERT Environmental Response Team
NAUM Navajo abandoned uranium mine
OSC On-Scene Coordinator
PRP Potentially responsible party
QAM Quality Assurance Manager
QAPP Quality Assurance Project Plan
RI/FS Remedial Investigation/Feasibility Study
RPM Remedial Project Manager
RQAM Regional Quality Assurance Manager
RSE Removal Site Evaluation

1.4.1.1 Documentation of QAPP Approval

Documentation Methods. For any QAPP requiring an approval signature (see Table 1-4), the NAUM RPM or OSC is responsible for ensuring that all appropriate signatures are obtained for EPA records. However, the NAUM Program allows the RPM or OSC to accommodate unusual circumstances that preclude a timely signature. Methods of documenting a QAPP approval are:

- Signature block on the QAPP (preferred; see Appendix A for an example signature pages)
- Physically attaching or merging electronically into one PDF an approval memorandum to a QAPP

- NAUM RPM or OSC providing a hand annotation of the QAPP that documents who approved the document, the date of approval, and the method of approval communication

Date of Approval. Generally, the date of approval is the date the QAPP or approval memo is signed. In absence of a recorded date, the date of receipt of the EPA RPM or OSC approval communication, such as an email, is the effective date.

Verbal Approval. There are two circumstances for verbal approvals:

- Extenuating circumstances, such as the NAUM RPM or OSC is in a remote location and there is urgency to approve a QAPP to meet a deadline
- QAPP amendments and addenda that are not complex and do not substantively change an umbrella QAPP and there is risk of not meeting a deadline should a formal approval process be followed

The NAUM RPM or OSC should document verbal approvals by annotation of the QAPP document with the name of the approver and the date of approval. The approval documentation should be submitted/retained in the Superfund Records Center, preferably as an integral part of the archived QAPP. If the approval is archived as a stand-alone document, the site record index should clearly identify the associated QAPP.

1.4.1.2 Reviews for QAPP Nomenclature Variations

Environmental programs frequently use document structures, such as a work plan, sampling and analysis plan, program plan, sampling plan, investigation plan, and characterization plan. When a document by any name addresses elements of the QAPP, those QAPP elements should be reviewed as a QAPP, QAPP amendment, or QAPP addendum. The NAUM RPM or OSC is responsible for this determination.

1.4.1.3 QAPP Amendments and Addenda

Both amendments and addenda to a previously approved QAPP are common for environmental work and both should be treated as a QAPP for determining the appropriate approval process. Frequently, changes described by amendments and addenda are not complex and do not substantively change the umbrella QAPP. In this case, the NAUM RPM or OSC may decide not to request a formal review by the RQAM; however, the RPM or OSC shall annotate such documents with corresponding rationale.

1.4.1.4 Level of Review

Minimum Level of Review. The level of detail for a QAPP approval review will vary based on the NAUM RPM's determination of the project's significance or vulnerabilities. In general, the minimal level of effort is a professional judgment determination whether a good-faith effort to address each of the QAPP elements specified in the *EPA Requirements for Quality Assurance Project Plans* (EPA 2001a) has been made and whether EPA policy requirements have been met.

Scope of Review. The RPM may request assistance with the technical QAPP review from the RQAM or from an EPA contractor. QAPP reviewers exercise judgment about whether to independently verify references, cross-references, calculations, documentation adequacy for professional judgment and assumptions, completeness of conceptual models, adequacy of the level of detail in procedures, and appropriateness of applied standards and methodology.

Tailored QAPP Reviews. QAPP reviewers commonly review a subset of the QAPP planning elements as requested by the NAUM RPM. Typically, these are aspects related to conformance to EPA policies, new methods or contractors, or QA-related concerns found in technical reviews.

RQAM and Laboratory Method Reviews. Traditionally, the RQAM is responsible for reviewing the technical adequacy of laboratory methods specified in a QAPP; however, for radiochemical methods, the Region 9 QA Branch does not currently have an adequate level of expertise. In the interim, the NAUM RPM is responsible for obtaining, as necessary,[2] a technical review of QAPP-specified radiochemical methods from EPA's oversight contractor, NAREL, or ERT.

1.4.1.5 Technical Standard for QAPP Reviews

EPA encourages the use of consensus standards when relevant and appropriate. These include ASTM International (ASTM), Uniform Federal Policy for Quality Assurance Project Plans, and MARSSIM. Regardless of the approach to QAPP development, the QAPP is evaluated using *EPA Requirements for Quality Assurance Project Plans* (EPA 2001a). (See the QAPP Review Checklist in Appendix B.)

Field Oversight Tools and Considerations

All NAUM field activities should be monitored by planned EPA oversight of the type and level sufficient to mitigate vulnerabilities. The NAUM Program has no default list of oversight activities as the vulnerabilities from field activities vary with site-specific circumstances. Hence, EPA applies a framework with tools, triggers, and goals. In general, every project involving sampling is under EPA surveillance with random spot checks to typically corroborate the sample locations, sampling approach, and time of sampling. More complex oversight activities, such as split

samplings, are performed either as a program-wide minimum effort or in response to identified project-specific risks.

Section 3.2 and Appendix C provide guidance to assist RPMs in planning for oversight.

Validation of Data

The Region 9 QMP[3] and references therein are amended to account for radiochemical data. Responsibilities for initiating or implementing data validation are described in Table 1-5.

Laboratory data used for NAUM projects should undergo data validation based on a graded approach described in existing EPA guidance. Chemical data should be validated using regional QA guidance. Radiochemical data should be validated in a manner consistent with the specifications below. Aspects of implementing radiochemical validation, when not defined in regional guidance, should be defined in a QAPP. Chemical data validation is based on relevant national functional guidelines.[4] Radiochemical data validation for the NAUM Program is based on the American National Standards Institute (ANSI) 41.5 Standard.[5]

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[2] Most of the NAUM projects are in the investigation phase and use the same laboratory methods for identical DQOs where other factors, such as the field contractor and laboratory, are the same. In these cases, an additional technical review is not performed.

[3] Section 5.2.4 of the September 2014 Region 9 QMP.

[4] EPA guidelines can be found at https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review.

[5] Available for purchase at https://webstore.ansi.org/standards/ansi/ansians412012.

Region 9 QA uses the terms Tier 1, Tier 2, and Tier 3 to describe the type of verification required for data validation:

- Tier 1 validation under Region 9 QA guidance is ANSI verification.
- Tier 2 or Tier 3 validation is a subset of checks covered by ANSI verification and validation. The EPA Region 9 Radiochemical Data Validation SOP in Appendix D defines the subset of ANSI checks covered by Tier 3 validation.

Radiochemical data validation for the NAUM Program should meet the following specifications:

1) Validation should be based on the consensus standard *Verification and Validation of Radiological Data for Use in Waste Management and Environmental Remediation* (American Nuclear Society 2012).
2) The data validator should be independent of the laboratory performing the measurements. This is applicable to both chemical and radiochemical data. For significant site decisions or when other oversight monitoring suggests a laboratory-related quality problem, radiochemical data validation should be performed by a third party relative to the sampler, laboratory, and responsible party. For most projects, a third party is the EPA Region 9 QA Branch, NAREL, or another EPA organization. The validator should be described in a project-specific QAPP.

   The intent of this specification is to ensure that the data validation conclusions about data quality are acceptable to all stakeholders and to deter laboratory fraud found historically on some CERCLA projects.

   The RQAM will request a "Quality Review" from NAREL for radiological laboratories on a periodic basis as necessary. When such a review is necessary, a minimum of one batch of data (typically 20 samples or less) for each radiological method should be reviewed. The intent of this requirement is to mitigate risks of undetected systematic laboratory problems. The RQAM will maintain a list of reviewed laboratories on the NAUM SharePoint website.
3) A validator performing Tier 3 validation (EPA Region 9 QA system) should meet qualification requirements in ANSI Standard 41.5. Validators performing Tier 1 validation need only meet qualification requirements established for validation of inorganic chemical data by the EPA Contract Laboratory Program. A Tier 3 validation report should document whether the validator meets this qualification or not.
4) Levels of validation effort for radiochemical data should be defined on a project-specific basis in a QAPP based on regional QA guidance.
5) The Regional QA Branch should be consulted for any clarification about what and when to validate data.
6) NAREL, as EPA's center of excellence for radiological laboratory methods, should be consulted for any significant technical disagreements surfaced in data validation reviews and used to referee any significant method disagreements between EPA and an outside organization.

Table 1-5 – Data Validation Responsibilities

NAUM RPM
• Selects data for validation • Determines the appropriate amount of data to validate • Initiates the validation process with the oversight contractor, NAREL, or RQAM • Ensures that data validation report conclusions are provided to data users
NAUM RQAM
• Monitors the validation processes for consistency via spot checks of systemwide validation reports • Informs NAUM Supervisors of project consistency concerns • Provides guidance and consultation on EPA QA policies and EPA Region 9 procedures • Provides validation services for non-radiological data • Provides Tier 1 validation for radiological validations

Notes:
EPA United States Environmental Protection Agency
NAREL National Analytical Radiation Environmental Laboratory
NAUM Navajo abandoned uranium mine
QA Quality assurance
RPM Remedial Project Manager
RQAM Regional Quality Assurance Manager

Laboratory Competency

Laboratories used for NAUM projects should be pre-qualified to meet project data quality objectives. For chemical data laboratories, EPA guidance should be consulted for relevant pre-qualification requirements. For radiochemical laboratories[8], the pre-qualification requirement can be met by meeting applicable chemical laboratory guidance and the following specifications:

1) Radiochemical laboratories must be accredited by a generally recognized consensus body to meet applicable and relevant laboratory certification standards. For example, the laboratory can be accredited to meet the most current relevant United States Department of Defense (DOD) and United States Department of Energy's (DOE) Consolidated Quality Systems Manual (QSM) for Environmental Laboratories.[9]
2) Radiochemical laboratories must have acceptable performance on a relevant interlaboratory calibration study or a performance test sample in accordance with its accreditation. For example, this requirement can be met by providing acceptable results of an annual performance test, preferably on a similar matrix. Alternatively, when available for the specific project matrix and analytes, a commercial interlaboratory study can be used.

Continuous Quality Improvement

The NAUM Program is committed to continuous improvement with regard to efficient use of EPA's limited resources through adoption of best practices and lessons learned. NAUM team meetings, quality system training, data quality assessments, and peer review activities provide opportunities to identify areas for improvement that can be addressed in subsequent projects. Some

[8] Details about evaluating and overseeing a laboratory's performance can be found in Chapter 7 of MARLAP.
[9] The DOD and DOE QSM standard can be found at www.denix.osd.mil/edqw/documents/.
The accreditation status of a laboratory can be verified at www.denix.osd.mil/edqw/accreditation/accreditedlabs/.

of these examples are already in place to identify process improvement opportunities and propose solutions for problems. Other measures may be developed more fully in the future.

1. Encouraging Staff to Identify and Implement Quality Improvements

NAUM Program Managers ensure periodic technical meetings occur to provide a forum for staff to share best management practices. These interactions are critical for RPMs to share lessons learned from the identification of issues adverse to quality. These discussions encourage staff to identify process improvements and propose corrective actions.

2. Program-Level Improvement

The Region 9 QA Branch routinely performs quality system assessments of the various regional programs. These internal quality system assessments are conducted with the objectives of verifying that the program is complying with the requirements of Region 9's quality system as documented in the regional QMP; identifying areas for improvement; and serving as an educational opportunity to enhance understanding of the quality system and how it can be applied in specific project areas. Where necessary, aspects are modified to address evolving programs and changing needs, and the modifications will be documented in a revision to the QMP.

3. Project-Level Improvement

NAUM staff members are all accountable for the continuous improvement of the quality of their products. The process of continuous quality improvement leads to a better and more responsive program. Supervisors, RPMs, and other technical staff are encouraged to identify opportunities for improving the quality system through discussion with their management or by contacting regional QA Branch staff.

4. Tracking System, Record Keeping, or Annual Presentation

It is important that lessons learned from past activities are communicated among NAUM team members for the improvement of project planning, field and laboratory procedures, data management, record keeping, safety, and cost effectiveness. The NAUM Program will document lessons learned from previous data gathering activities and incorporate them into future efforts. The implementation of a tracking system will be developed.

Deterrence of Fraud

The NAUM Branch Manager ensures that an active ethics program, which provides a clear understanding of staff responsibilities and how staff can report any concerns, remains an integral part of the NAUM Program. An annual 1- or 2-hour presentation from an invited speaker, such as the EPA Office of Inspector General (OIG), will be provided with a focus on describing types of fraud and how they can be detected. A relevant presentation or training on a region-wide basis may substitute for NAUM-specific training as determined by the NAUM Branch Manager.

EPA RPMs will periodically verify that work performed under contracts is managed under a program with clear ethics statements, responsibilities, and information about who to contact should staff have concerns. Generally, EPA RPMs can meet this specification by observing appropriate information being provided to field staff as an internal contractor program (e.g., at a tailgate meeting) or by verifying informally that field staff are aware of the EPA OIG reporting hotline program.

EPA RPMs will verify or designate responsibility to verify that appropriate best practices for

laboratory and data review described in *Best Practices for the Detection and Deterrence of Laboratory Fraud* (California Military Environmental Coordination Committee 1997) are incorporated into project implementation plans. This verification is typically part of the review process to approve a QAPP.

For field activities (sampling in particular), NAUM RPMs will follow NAUM Program field oversight practices (see Section 3.2), which recommend a minimal surveillance effort supplemented with audits based on a graded approach. By following these practices, EPA RPMs will ensure that applicable oversight required in EPA's Chief Information Officer (CIO) directive 2105-P-02.0 (EPA 2014) or referenced guidance is applied during project implementation based on a graded approach.

Quality Objectives and Criteria for Measurement Data

This section introduces several important terms used by EPA QA policy and guidance that govern how NAUM projects generate data of known quality and sufficient quantity for decision-making. These terms include DQOs, DQIs, and MQOs. Correct application of these concepts will ensure that data quality is sufficient to support all NAUM project activities including adequately and accurately determining the nature and extent of contamination; performing human health and ecological risk assessments; evaluating and selecting remediation alternatives; monitoring and assessing remediation activities; and, ultimately, demonstrating that cleanup goals have been achieved.

The NAUM QMP describes data quality specifications at two levels:

1) At the level of the decision or study question (i.e., DQOs)
2) At the level of the measurements used to support the decision (i.e., DQIs and MQOs)

EPA's systematic planning process (the DQO process) is used to plan and design the study and investigation activities. The DQO process is utilized to frame the important study questions and decisions that will need to be carried out for each project in the context of site-specific conditions and limitations. The outputs of the seven-step DQO process are then used to specify the level of data quality necessary for the measurements used to support the decision or study question.

QA planning is a proactive process that is preventative in nature; it recognizes vulnerabilities in the data generation activities and puts a process in place to address and control those vulnerabilities. The QAPP documents, as part of the QA planning process, provide the approaches, techniques, methods, and processes that ensure project DQOs will be met. QA planning must be completed before QC can be implemented.

QC is a part of the overall QA system that focuses on detecting issues with the data and is reactive in nature. QC activities monitor and verify that the approaches, techniques, methods, and processes used to manage and create data have been followed correctly and that the project deliverables meet the defined quality standards. Field surveillance and data validation are two examples of QC implementation.

Data quality refers to the level of acceptability associated with a particular data set or data point for its intended uses. Performance and acceptance criteria for measurement data are often expressed in terms of DQIs. The principal indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity. Acceptance thresholds or QC goals for project data are expressed in terms of MQOs and serve a critical purpose during the data

review and validation process. Additional information regarding project DQOs, DQIs, and MQOs can be found in Section 2.

DATA GENERATION AND ACQUISITION

This section addresses the following data acquisition activities: sampling design, sampling methodology, sampling documentation, analytical testing, QC, and data management.

Sampling Process Design

The sampling design is a fundamental part of data collection for scientifically based decision-making. A well-developed sampling design plays a critical role in ensuring that data are representative and sufficient to draw the conclusions needed.

Representativeness may be considered as the measure or the degree to which data captures the "true" site conditions. EPA utilizes the systematic planning process, otherwise known as the seven-step DQO process, to design a site-specific sampling approach that will result in the collection of a representative data set.

Data Quality Objectives

DQOs are qualitative and quantitative statements that specify the field and laboratory data quality necessary to support specific decisions or regulatory actions. DQOs describe which data are needed, why the data are needed, and how the data will be used to meet the needs of the sampling program. DQOs also establish numeric limits for the data to allow the data user (or reviewers) to determine whether the data collected are of sufficient quality for their intended use. The seven-step DQO process, as set forth in EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process* (EPA 2006), should be followed to establish project-specific DQOs for data collection activities. The seven steps of the DQO process are:

1) State the problem
2) Identify the decision
3) Identify inputs for the decision
4) Define the boundaries of the study
5) Develop a decision rule
6) Specify limits on decision errors
7) Optimize the design

The NAUM Program has established a workgroup to explore best management practices regarding systematic planning and DQOs for site investigations.

Data Quality Indicators

The quality of data is expressed by DQIs. The principal DQIs are precision, accuracy, representativeness, comparability, completeness, and sensitivity (PARCCS) and are used as a ruler for the question of "How good is the project data?"

QC procedures are needed to define the tolerable errors in quantitative measurements that estimate the true value or concentration of a physical or chemical property. Uncertainty in analytical data comes from variability in sample collection, sample handling, and the conditions associated with

the specific samples, as well as analytical variability. Appropriate MQOs for analytical data are established as quantitative measures of performance against selected DQIs as described below.

Precision

Precision is a measure of the reproducibility of measurements. Typically, analysis of field duplicate samples provides an estimate of the precision of environmental data.

Analytical precision is estimated by laboratory duplicate analyses typically on laboratory control samples, spiked samples, or field samples. For chemical analyses, precision is evaluated using the relative percent difference (RPD). For radiochemical data, precision is evaluated using the Duplicate Error Ratio (DER).Accuracy

Accuracy is the closeness of measurements to an accepted reference value. Generally, accuracy is reported as a percent recovery of analytes in samples of known concentrations of analytes (e.g., QC samples).

Representativeness

Representativeness is the degree to which a sample accurately characterizes environmental conditions at the time of collection. Representativeness is dependent on the adequacy of the sampling design defined in the QAPP.

Comparability

Comparability expresses the confidence with which one data set can be compared to another and describes the ability and appropriateness of making collective decisions with two or more data sets. Many variables may affect the descriptive value of the data and include:

- Variables of interest in each data set
- Use of common units
- Similarity of methods and QA/QC
- Time frames
- Season
- Weather
- Equipment

Completeness

Completeness is a measure of the amount of usable data obtained from a measurement system expressed as a percentage of the number of measurements that should have been collected according to the study design (i.e., the measurements that were planned to be collected).

Sensitivity

Sensitivity refers to the capability of a method or instrument to detect a given analyte at a given concentration and reliably quantitate the analyte.

Measurement Quality Objectives

MQOs are the acceptance windows, thresholds, or goals for project data and serve a critical purpose during the data review and validation process.

Laboratory analytical method parameters (precision, accuracy, and sensitivity) should be compared against project or program DQIs established during the DQO planning process with defined acceptable levels of uncertainty throughout the analytical process. Typical NAUM measurement performance criteria are included in Tables 2-1 through 2-4.

Radiochemical Measurement Quality Objectives

The MQOs that determine acceptable analytical laboratory decision errors are usually obtained from other similar sampling events based on calculation in the DQO process or based on programmatic defaults.

Combined Standard Uncertainty (CSU)

The uncertainty of radiochemical measurements is typically expressed as a standard uncertainty (or one-sigma uncertainty), also referred to as "counting uncertainty," and is expressed as one standard deviation (1σ or "1 sigma" CSU).

The CSU value may be multiplied by a specified factor called a coverage factor (e.g., 2 or 3) to obtain an expanded combined uncertainty (a 2σ or 3σ uncertainty), which describes an interval about the result that can be expected to contain the true value with a specified probability.

All laboratory radiochemical measurements should be reported with the associated CSU and the laboratory's definition of the CSU. Coverage factors are not standardized between laboratories and must be documented in data reports.

Minimum Detectable Concentration (MDC)

The MDC is used to evaluate laboratory method performance. Results above the MDC are deemed to have been reliably detected. Generally, the MDC is used to select laboratory methods to ensure adequate sensitivity for project objectives. The MDC with another statistical measure (critical value) are sometimes used in data validation.

All sample results for the NAUM Program should be reported with corresponding instrument- and method-specific MDC.

For laboratory instruments, the MDC is defined in the MARLAP Manual in Sections 20.4.2 and 20A.3 (EPA 2004); however, the exact procedure used by any laboratory should be defined in its laboratory QA manual or method SOP.

For field scanning instruments, the MDC is described in Sections 6.7.1 and 6.7.2 of MARSSIM (EPA 2000b) and NUREG-1507 (United States Nuclear Regulatory Commission 1998). MDCs should be calculated following instrument calibration and verified during function checks because instrument background is a key component of the MDC. The MDC, and specific inputs and formula used to calculate the MDC, should be documented with the reported results.

Minimum Quantifiable Concentration (MQC)

Results must meet an acceptable critical value and exceed the MDC to be considered quantified.

Unlike chemical measurements, the accuracy of each radiochemical result is reported. At the level of the MQC, reported results will have a quantitative uncertainty that is small, is relative to the reported value, and will allow for control of decision errors even though the sampling uncertainty (which is generally assumed to be approximately three times the analytical uncertainty) is not quantified and incorporated into the reported results. In practice, the MQC is not used to make specific data use decisions as the CSU allows for a more precise and specific evaluation. The MQC concept is retained in the QMP to integrate chemical and radiochemical data interpretation approaches.

Precision

Precision is an important measure of the repeatability of a measurement as all real-world measurements can be affected by random fluctuations. Various quality control measure the precision of measurements.

Overall Precision (Field + Laboratory). Field duplicates as a measure of combined field and laboratory precision are evaluated using a Z-score, also called a normalized difference, as defined below. The frequency of a field duplicate sample is defined in a project-specific QAPP and is typically about 1 per 20 site samples.

Laboratory Precision. Laboratory duplicates are typically used at a rate of 1 in 20 site samples to evaluate laboratory precision. Matrix spikes (MSs) and matrix spike duplicates (MSDs) are also sometimes used. The results of the analysis of duplicates and each MS/MSD pair are evaluated using a Z-score. An acceptable Z-score should be within limits defined by the laboratory's QA system or the method SOP. If not specified, precision will be evaluated using a factor of 2 or 3 depending on the project DQO.

Definition of Z-Score

A Z[10]-score for two results is calculated using the following general equation:

$$Z = \frac{|\, X_1 - X_2 \,|}{\sqrt{CSU_{X1}^2 + CSU_{X2}^2}}$$

Where:

X1	=	The value of the first measured result (sample)
X2	=	The value of the second measured result (duplicate)
CSU	=	The reported CSU (at 1σ) associated with X1 and X2

The Z-score for a measured parameter is used to evaluate the significance of the difference between the two results.

Chemical Measurement Quality Objectives

The chemical MQOs that determine acceptable analytical laboratory decision errors are usually obtained from other similar sampling events based on calculation in the DQO process or based on

[10] Commonly referred to as Decision Error Ratio (DER)

programmatic defaults.

Method Detection Limit (MDL)

For chemical analyses, the MDL, as defined in 40 *Code of Federal Regulations* Part 136, is used to evaluate measurement performance. The MDL is the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero.

Reporting Limit (RL)

For chemical analyses, the RL is the lowest concentration that can be reliably achieved within limits of precision and accuracy during routine operating conditions. The RL is generally 5 to 10 times the MDL, and the implied accuracy of results greater than the RL is defined by the method SOP.

Precision

Overall Precision (Field + Laboratory). Field duplicates as a measure of combined field and laboratory precision are evaluated using a RPD calculation as defined below. The frequency of the field duplicate measurement is defined in a project-specific QAPP and is typically about 1 in 20 site samples.

Laboratory Precision. Analytical precision is evaluated by analyzing laboratory duplicates or MS/MSD pairs. The results of the analysis of duplicates and each MS/MSD pair will be used to calculate a RPD for evaluating precision. Laboratory measurement duplicates will be performed once for every 20 samples. An acceptable RPD is defined by the laboratory's QA system or method SOP.

Relative Percent Difference Definition

The RPD is calculated as:

$$RPD = \frac{|Sample - Duplicate|}{\left(\frac{Sample + Duplicate}{2}\right)}$$

Where:

Sample = The first sample value (original)

Duplicate = The second sample value (duplicate)

Field Sample Collection Methods

Field measurements and sample collection procedures will follow the QAPP and are developed based on agency and industry guidance and standards, such as EPA methods, ASTM standards, industry SOPs, and instrument manufacturers' recommended procedures. Procedures will identify the methods employed to obtain representative field measurements and samples of specified media, as well as the equipment, instruments, and sampling tools that are needed and, where appropriate, performance criteria (e.g., special handling, operational checks, and field calibrations)

to ensure the quality of the field data.

Laboratory Analytical Methods

The analytical techniques and methods to be used will be documented in the site-specific QAPP. The laboratory shall have SOPs that detail how the required method or technique is implemented. Method performance shall meet the requirements specified in the site-specific QAPP. Typical analytical techniques used for NAUM projects are included in Figure 2-1.

Quality Control Requirements

Field Sampling Quality Control

A variety of instruments, equipment, sampling tools, and supplies will be used to collect samples and to monitor site conditions. Proper inspection, calibration, maintenance, and use of the instruments and equipment are required to ensure field data quality. The QC objective of data collection activities is to obtain reproducible and comparable measurements to a degree of accuracy consistent with the intended use of the data.

Field QC samples are used to quantitatively and qualitatively evaluate the analytical performance of the laboratory and to assess external and internal effects on the accuracy and comparability of the reported results. Field QC samples will be uniquely identified in a manner consistent with the project sample-numbering scheme. Site-specific QAPPs identify the appropriate type of field QC samples, such as temperature blanks, equipment blanks, and field duplicates.

Temperature Blanks

Where ice is used, each sample cooler shall contain a temperature blank. The temperature blank should be supplied by the receiving laboratory and can be either a 40- milliliter (mL) vial or a 100-mL plastic bottle filled with reagent grade water. The purpose of the temperature blank is to document the temperature of the representative solution contained within the same transport cooler as the collected field sample.

Equipment Blanks

Where non-dedicated equipment is used to collect samples, equipment rinsate blanks should be collected at a rate of one per day to evaluate field decontamination procedures.

Field Duplicate Samples

Duplicate soil samples should be collected at locations that are chosen randomly in the field and should be designated for collection at a specified frequency in the site-specific QAPP (typically, a rate of at least 1 for every 20 field samples).

Laboratory Quality Control

Laboratory QC is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical processes to improve the quality of the results reported by the laboratory. The QC system includes measurement performance criteria for DQIs and MQOs as described in Sections 2.1.2 and 2.1.3 and in Tables 2-1 through 2-4.

Laboratory QC samples generally include preparation and reagent blanks, laboratory control

samples, and, if required by the project, MS/MSD pairs.

Instrument and Equipment Testing, Inspection, Maintenance

A variety of instruments, equipment, sampling tools, and supplies will be used to collect samples and to monitor site conditions. Proper inspection, calibration, maintenance, and use of the instruments and equipment are required to ensure field data quality.

Field equipment, instruments, tools, gauges, and other items used in performing work tasks that require preventive maintenance will be serviced in accordance with manufacturers' recommendations and instructions. When applicable, technical procedures will identify the manufacturers' instructions and recommended frequency for servicing the equipment. Preventive maintenance for calibrated measuring and test equipment will be performed either by field or laboratory personnel who are knowledgeable of the equipment or by a manufacturer's authorized service center as part of routine calibration tasks. Records of equipment calibration, repair, or replacement of controlled instruments will be filed and maintained in accordance with the applicable records management requirements described in the site-specific QAPP.

Field equipment, instruments, and associated supplies used to obtain field measurements and collect samples are described in the site-specific QAPP. Any item, data, or process found to be in noncompliance with specified requirements will be documented as defined in Section 3.1.2.

The project roles and responsibilities provided in the site-specific QAPP should define the technical or field lead who is responsible for ensuring the overall maintenance, operation, calibration, and repairs made to field equipment, instruments, and tools are in conformance with SOPs and manufacturers' recommendations and that the field records adequately document maintenance, repairs, and calibrations performed in the field.

Instrument and Equipment Calibrations and Frequency

Equipment and instruments used to obtain data will be maintained and calibrated with sufficient frequency and in such a manner that accuracy and reproducibility of results are consistent with the manufacturers' specifications. Calibration of equipment and instruments will be performed at approved intervals, as specified by SOPs or manufacturers' recommendations, or more frequently as conditions dictate. Calibration standards used as reference standards will be traceable to the National Institute of Standards and Technology (NIST) or other recognized standards when available. In some instances, calibration periods or operational response checks will be based on usage rather than periods of time. Equipment will be calibrated or response checked as a part of its operational use. Calibrations and operational checks will be performed and documented in accordance with procedure requirements. Calibration procedures for field equipment are described in the Work Plan and manufacturers' equipment manuals.

The responsibility for the calibration of laboratory equipment rests with the selected laboratory. Each type of instrumentation and each EPA-approved method have specific requirements for the calibration procedures, depending on the analytes of interest and the sample medium. Calibration procedures and calibration frequency for the equipment used to perform the analyses will be in accordance with requirements established by the EPA methods.

The laboratory is ultimately responsible for ensuring that the laboratory instrumentation is maintained in accordance with specifications. Individual laboratory SOPs will be followed for corrective actions and preventative maintenance frequencies.

Gamma Scanning Field Measurements

This subsection has been written specifically for field gamma scanning; however, other field techniques (e.g., X-ray fluorescence) may be added to the NAUM Program as they become more frequently utilized.

The NAUM Program relies heavily on field gamma scanning measurements to interpret, characterize, and delineate the extent of contamination. Various field equipment QA procedures can be utilized to ensure that field gamma scanning is consistent with project DQOs.

To utilize the gamma scanning data for decision-making, EPA must ensure that adequate QC steps are performed and documented. Therefore, general QC checks, such as those included in Appendix E, should be considered when reviewing any gamma scanning SOPs identified in the project QAPP. The checklist for gamma scanning will be further developed in the future.

Non-Direct Measurements

Sources and types of secondary data useful for this project include the following:

- Historical records
- Previous investigations
- Regulatory agency files
- Topographic maps
- Historical aerial photographs
- Visual site reconnaissance
- Interviews

The quality of these secondary data sources must be evaluated to ensure that they are of the type and quality necessary to support their intended uses. When evaluating the reliability of secondary data and determining limitations on their uses, the source of the data, time period during which they were collected, data collection methods, potential sources of uncertainty, type of supporting documentation available, and comparability of data collection methods to the currently proposed methods should be evaluated. With respect to secondary analytical data that will be utilized to support critical decisions, such as a comparison of contaminant levels with applicable standards, a detailed review of the data will be necessary to determine the usability of the data.

For additional information and guidance, see Chapter 3 of EPA's *Guidance for Quality Assurance Project Plans* (EPA 2002a).

Gamma Data Validation Considerations

An example oversight checklist for gamma scanning activities is under development (see Appendix E) and will be available in future revisions of this QMP. Examples of parameters which may be included in this checklist are listed below.

Performance checks validate that equipment is working correctly and verify the accuracy of gamma scanning data, including:

- Meter and source checks
    - Document the calibrations and daily source checks before and after daily use

- Use NIST-traceable sources
- Check meter battery life, settings, and calibration due dates
- Check daily source count results against a control chart
- Complete equipment logs

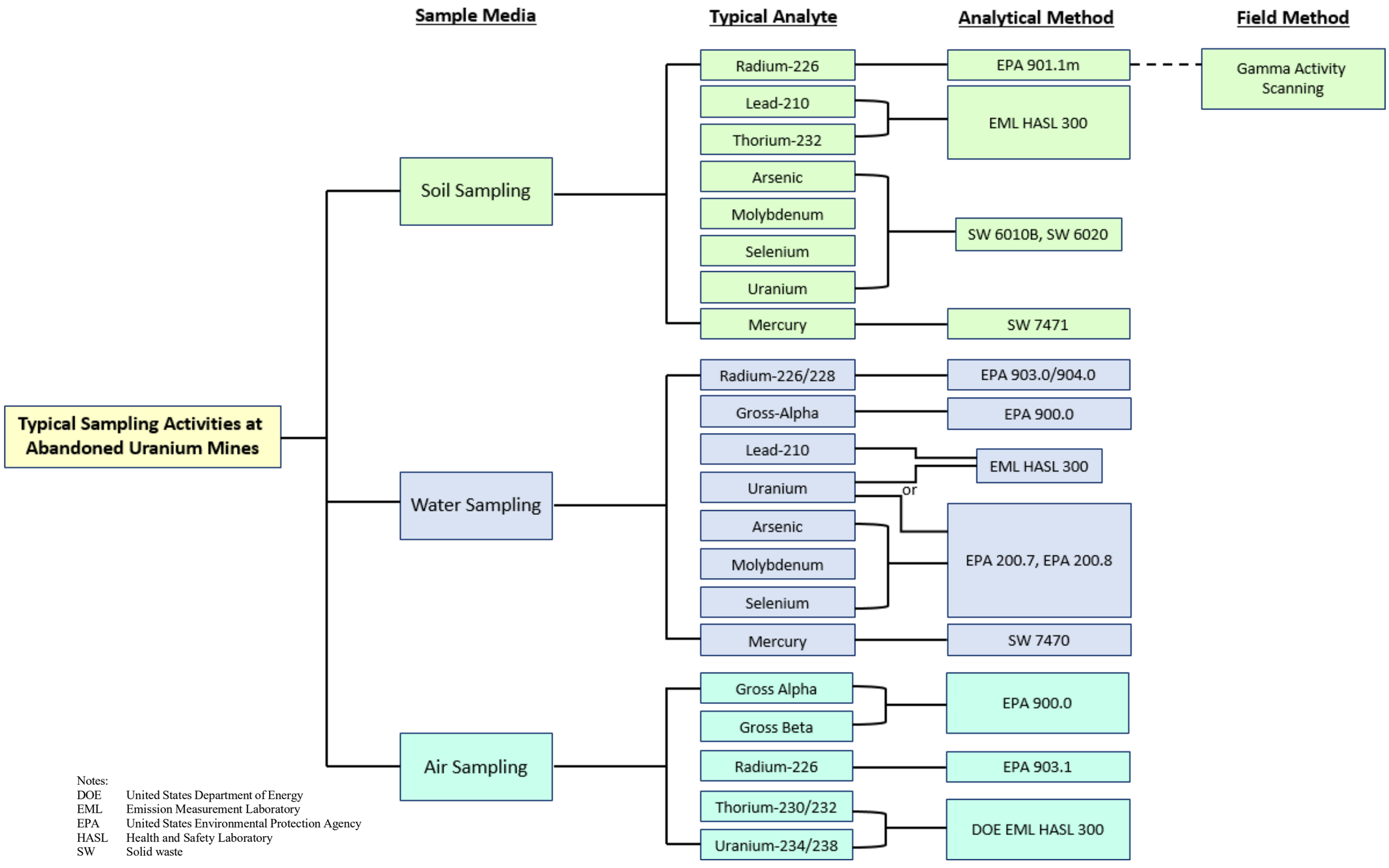
- Data collection evaluation
  - Ensure that scanning rates (the speed that the radiological technician walked) are not too fast, and that the instrument was paused when the surveyor stopped walking for any reason
  - Ensure that coverage was adequate by looking at the number of mapped points measured within a specific time period and area, etc.
  - Control the stand-off distance of detector(s) from the surface using a mechanical device

- Global positioning system (GPS) accuracy
  - Check GPS data against a benchmark for accuracy (Terrasync tracks data on horizontal accuracy that could be evaluated)

- Coverage evaluation
  - Continually review maps and check to make sure that all of a desired area was monitored and that no parts of the area were missed as indicated by no measurement points

- Data delivery
  - Define specific formats and data delivery streams to access and review raw and modified data, including:
    - Spatial gamma scanning sensor and GPS data
      - Mesa2: GSF
      - Trimble: SSF
      - ArcGIS: SHP, DBF
      - Metadata: XML
    - Waypoints and areas of interest
      - Pressurized Ion Chamber (PIC) data: CSV
      - SCRIBE electronic data deliverable: CSV
      - Sample locations: CSV, GSF, SSF
      - Static measurement locations: CSV, GSF, SSF
      - Areas of interest: CSV, GSF, SSF, XML
    - Operational viewers and portals
      - Document archive: NAUM Portal
      - Operational viewer: Geoviewer
      - VIPER: Viper.net

Figure 2-1 – Typical Analytical Techniques



Notes:
DOE United States Department of Energy
EML Emission Measurement Laboratory
EPA United States Environmental Protection Agency
HASL Health and Safety Laboratory
SW Solid waste

Table 2-1 – Typical NAUM Laboratory Methods

Analyte	Matrix	Analytical Method	Parameters	Method Modifications	Sample Prep	Other?	Preservative	Holding Time	Volume	Container	Screening Level[1,2]	Reporting Limit[3]	Method Detection Limit[3]
Arsenic	Soil/ Sediment	SW 6010B, SW 6020	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	4°C	180 days	4 oz	Glass / Poly	0.29 mg/kg	0.25 mg/kg	0.02 mg/kg
Lead - 210	Soil/ Sediment	EML HASL-300 Method Ga-01-R	Gamma radioassay, 21 day in-growth	--	--	--	None	N/A	4 oz	Poly / Ziploc	N/A	1 pCi/g	0.1 pCi/g
Mercury	Soil/ Sediment	SW 7471	Mercury by cold vapor atomic adsorption spectrometry	--	--	--	4°C	28 days	4 oz	Glass / Poly	11 mg/kg	1 mg/kg	0.0036 mg/kg
Molybdenum	Soil/ Sediment	SW 6010B, SW 6020	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	4°C	180 days	4 oz	Glass / Poly	390 mg/kg	1 mg/kg	0.47 mg/kg
Selenium	Soil/ Sediment	SW 6010B, SW 6020	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	4°C	180 days	4 oz	Glass / Poly	0.26 mg/kg	0.158 mg/kg	0.158 mg/kg
Uranium	Soil/ Sediment	SW 6010B, SW 6020	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	4°C	180 days	4 oz	Glass / Poly	14 mg/kg	0.1 mg/kg	0.001 mg/kg
Radium-226	Soil/ Sediment	EPA 901.1m	Radium-226 (with 21-day in-growth), including other gamma emitters (e.g., uranium-238 progeny, thorium-232 progeny, and potassium-40)	Radiological laboratory-specific procedures may modify the method with specific instrument models, count times, geometry for sample containers, container sealing procedures, or other details without invalidating the data.	No sample treatment. Typical sample preparations include grinding, mixing, homogenizing, aliquoting samples into standardized containers, and sealing containers to ensure that radon gas does not escape prior to counting the sample. Alternate grow-in periods shorter than 21 days are possible but likely result in increased counting error.	Sample containers may be jars, bottles, or poly bags. No sample treatment or preservation required.	None	N/A	2 kg	Poly / Ziploc	N/A	1 pCi/g	0.1 pCi/g

Table 0-1 – Typical NAUM Laboratory Methods (Continued)

Analyte	Matrix	Analytical Method	Parameters	Method Modifications	Sample Prep	Other?	Preservative	Holding Time	Volume	Container	Screening Level[1,2]	Reporting Limit[3]	Method Detection Limit[3]
Thorium-232	Soil/ Sediment	EML HASL 300	Thorium-232 by alpha spectroscopy – EML HASL Method 300 TH-01-RC Modified, using alpha spectroscopy	--	--	--	None	N/A	4 oz	Poly / Ziploc	N/A	1 pCi/g	0.1 pCi/g
Arsenic	Water	EPA 200.7, EPA 200.8	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	HNO_3, 4°C	180 days	4 oz	Poly	10 µg/L	10 µg/L	2 µg/L
Lead-210	Water	EML HASL-300 Method Ga-01-R	Gamma radioassay, 21 day in-growth	--	--	--	HNO_3, 4°C	N/A	1,000 mL	Poly	15 µg/L	1 µg/L	1 µg/L
Mercury	Water	SW 7470	Mercury by cold vapor atomic adsorption spectrometry	--	--	--	HNO_3, 4°C	28 days	250 mL	Poly	2 µg/L	0.2 µg/L	0.2 µg/L
Molybdenum	Water	EPA 200.7, EPA 200.8	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	HNO_3, 4°C	180 days	4 oz	Poly	1000 µg/L	1 µg/L	1 µg/L
Selenium	Water	EPA 200.7, EPA 200.8	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	HNO_3, 4°C	180 days	4 oz	Poly	5 µg/L	1 µg/L	1 µg/L
Uranium	Water	EPA 200.7, EPA 200.8	Metals by ICP-MS: uranium, arsenic, molybdenum, selenium, and vanadium	--	--	--	HNO_3, 4°C	180 days	4 oz	Poly	30 µg/L	1 µg/L	0.1 µg/L
Uranium Isotopes	Water	DOE HASL 300 U-02-RC	Uranium-234, Uranium-235, Uranium-238	--	--	--	HNO_3, 4°C	180 days	1 gallon	Poly	30 µg/L	1 µg/L	0.1 µg/L

Table 0-1 – Typical NAUM Laboratory Methods (Continued)

Analyte	Matrix	Analytical Method	Parameters	Method Modifications	Sample Prep	Other?	Preservative	Holding Time	Volume	Container	Screening Level[1,2]	Reporting Limit[3]	Method Detection Limit[3]
Combined Radium-226 +228	Water	EPA 903.0/904.0	Radium-226 (water) by alpha spectroscopy/ scintillation counting	Lab-specific procedures may modify the sample volume, treatment, and count times without invalidating the data.	At collection, nitric acid is added to pH 2 (or untreated samples should be received at the lab), acidified in the original sample container, and held for at least 16 hours before processing. Typical sample preparation includes barium co-precipitation to isolate radium via wet chemistry.	Sample containers: plastic bottle preferred over glass to prevent breakage. Alpha scintillation counting or gas proportional counting if interference from radium-223 or radium-224 is expected. Ingrowth of decay products may interfere with counting.	HNO_3	180 days	1 L	Poly	5 pCi/L	1 pCi/L	1 pCi/L
Gross-Alpha Radiation	Water	EPA 900.0	Gross alpha by scintillation counting.	Lab-specific procedures may modify the sample evaporation/solid concentrating and plating process, the instrument model, the count time, and other details of the procedure without invalidating the data.	At collection, nitric acid is added to pH 2 (or untreated samples should be received at the lab), acidified in the original sample container, and held for at least 16 hours before processing. Typical sample preparations include aliquoting based on total dissolved solid levels in the sample and evaporation of water from the aliquot to plate the solids on a planchet,	Sample containers: plastic bottle preferred over glass to prevent breakage. Sample density on the planchet should be about 5 mg/cm^2. Gas flow proportional counters are acceptable, but reabsorbed moisture and static interference may reduce analytical sensitivity through increased self-absorption and erratic counting, respectively. Scintillation counters are preferred.	HNO_3	180 days	500 mL	Poly	15 pCi/L	5 pCi/L	1 pCi/L

Table 0-1 – Typical NAUM Laboratory Methods (Continued)

Notes:

[1]	Soil/Sediment values are EPA Regional Screening Levels for Protection of Groundwater.
[2]	Water values are EPA Maximum Contaminant Levels.
[3]	Standard values are shown, but reported values on laboratory data reports may vary based on sample conditions and results of sample preparation.
--	Not applicable
µg/L	Microgram per liter
DOE	United States Department of Energy
EML	Emission Measurement Laboratory
EPA	United States Environmental Protection Agency
HASL	Health and Safety Laboratory
HNO_3	Nitric acid
ICP-MS	Inductively coupled plasma-mass spectrometry
L	Liter
mg/cm^2	Milligram per square centimeter
mg/kg	Milligram per kilogram
mL	Milliliter
N/A	Not applicable
NAUM	Navajo abandoned uranium mine
oz	Ounce
pCi/g	Picocurie per gram
pCi/L	Picocurie per liter
SW	Solid waste

Table 2-2 – Typical Data Quality Indicators for Soil and Sediment Samples

Analyte[1]	Screening Level[2]	Reporting Limit[3]	Method Detection Limit[3]	Accuracy (Percent Recovery for Laboratory Control Sample)	Precision (Relative Percent Difference for Matrix Spike / Matrix Spike Duplicates and Field Duplicates)	Z-Score[4]	Percent Complete
Arsenic	0.29 mg/kg	0.25 mg/kg	0.02 mg/kg	75-100%	≤ 35%; ≤ 50% for field duplicates	-	≥ 90%
Lead-210	N/A	1 pCi/g	0.1 pCi/g	75-100%	≤ 35%; ≤ 50% for field duplicates	< 2.0	≥ 90%
Mercury	11 mg/kg	1 mg/kg	0.0036 mg/kg	75-100%	≤ 35%; ≤ 50% for field duplicates	-	≥ 90%
Molybdenum	390 mg/kg	1 mg/kg	0.47 mg/kg	75-100%	≤ 35%; ≤ 50% for field duplicates	-	≥ 90%
Selenium	0.26 mg/kg	0.158 mg/kg	0.158 mg/kg	75-100%	≤ 35%; ≤ 50% for field duplicates	-	≥ 90%
Thorium-232	N/A	1 pCi/g	0.1 pCi/g	75-100%	≤ 35%; ≤ 50% for field duplicates	< 2.0	≥ 90%
Uranium	14 mg/kg	0.1 mg/kg	0.001 mg/kg	75-100%	≤ 35%; ≤ 50% for field duplicates	-	≥ 90%
Radium-226	N/A	1 pCi/g	0.1 pCi/g	75-100%	≤ 35%; ≤ 50% for field duplicates	< 2.0	≥ 90%

Notes:

1 Typical analyte of concern at Navajo abandoned uranium mines.

2 Values are soil/sediment EPA Regional Screening Levels for Protection of Groundwater

3 Standard/typical values are shown, but reported values on laboratory data reports may vary based on sample conditions and results of sample preparation.

4 $Z = \frac{X_1 - X_2}{\sqrt{CSU_{X1}^2 + CSU_{X2}^2}}$ Where X1 = first measured result (sample); X2 = second measured result (duplicate); and CSU = reported CSU (at 1σ) associated with X1 and X2.

CSU Combined standard uncertainty
EPA United States Environmental Protection Agency
mg/kg Milligram per kilogram
N/A Not applicable
pCi/g Picocurie per gram

Table 2-3 – Typical Data Quality Indicators for Water Samples

Analyte[1]	Screening Level[2]	Reporting Limit[3]	Method Detection Limit[3]	Accuracy (Percent Recovery for Laboratory Control Sample)	Precision (Relative Percent Difference for Matrix Spike / Matrix Spike Duplicates and Field Duplicates)	Z-Score[4]	Percent Complete
Arsenic	10 µg/L	10 µg/L	2 µg/L	75-100%	≤ 35%	-	≥ 90%
Lead-210	15 µg/L	1 µg/L	1 µg/L	75-100%	≤ 35%	< 2.0	≥ 90%
Mercury	2 µg/L	0.2 µg/L	0.2 µg/L	75-100%	≤ 35%	-	≥ 90%
Molybdenum	1000 µg/L	1 µg/L	1 µg/L	75-100%	≤ 35%	-	≥ 90%
Selenium	5 µg/L	1 µg/L	1 µg/L	75-100%	≤ 35%	-	≥ 90%
Uranium	30 µg/L	1 µg/L	0.1 µg/L	75-100%	≤ 35%	-	≥ 90%
Uranium Isotopes	30 µg/L	1 µg/L	0.1 µg/L	75-100%	≤ 35%	-	≥ 90%
Combined Radium-226+228	5 pCi/L	1 pCi/L	1 pCi/L	75-100%	≤ 35%	< 2.0	≥ 90%
Gross-Alpha Radiation	15 pCi/L	5 pCi/L	1 pCi/L	75-100%	≤ 35%	< 2.0	≥ 90%

Notes:

1 Typical analyte of concern at Navajo abandoned uranium mines.

2 Values are EPA maximum contaminant levels.

3 Standard/typical values are shown, but reported values on laboratory data reports may vary based on sample conditions and results of sample preparation.

4 $Z = \frac{X_1 - X_2}{\sqrt{CSU_{X1}^2 + CSU_{X2}^2}}$ Where X1 = first measured result (sample); X2 = second measured result (duplicate); and CSU = reported CSU (at 1σ) associated with X1 and X2

µg/L Microgram per liter
CSU Combined standard uncertainty
EPA United States Environmental Protection Agency
pCi/L Picocurie per liter

Table 2-4 – Typical Data Quality Indicators for Gamma Scanning (Under Development)

Table under development.

ASSESSMENT AND OVERSIGHT

This section describes NAUM program oversight efforts to verify that information gathered from field activities meet the intended use of the information.

Assessment and Response Actions

The following subsections describe the assessments and corresponding response actions for oversight of sampling activities.

Audits

Audits shall be conducted periodically to assess conformance to this QMP and the project-specific Work Plan. Any changes and deviations from this QMP or project-specific Work Plan during field activities will be documented. Corrective action procedures will be implemented when deviations that could potentially impact data quality and usability are noted by project personnel outside the formal assessment process. Any such incidents will be documented and resolved using the procedures and personnel that were detailed for planned assessments.

The two specific types of audits that will generally be performed are project audits and field audits. These audits will be performed on an as-needed basis.

Project Audits

Project audits will be conducted to evaluate the quality, completeness, and timeliness of individual project task assignments. Audits will be conducted, and nonconformance issues will be reported in compliance with the project-specific Work Plan and QAPP.

Field Audits

Field audits are conducted to ensure that field personnel are adhering to proper sampling, administrative, and health and safety SOPs. Field audit considerations should include sample documentation; sampling plan adherence; equipment operation, maintenance, and calibration; proper handling of standards, calibration gases, and preservatives; sampling techniques; decontamination methods; data management and review; sample custody; packing and shipment procedures; and health and safety practices. Field audits will be conducted on a random basis and in response to reports or findings of poor performance or noncompliance with this QMP, project-specific Work Plan, or sound engineering practices.

Performance and System Audits

Technical systems and performance audits will be performed as independent assessments of sample collection and analysis procedures, if necessary (i.e., when there is incomplete performance or audit history). Audit results will be used to evaluate the ability of the laboratory or field sampling contractor to:

- Produce data that fulfill the objectives established for the project
- Comply with the QC criteria presented in this QMP

- Identify any areas requiring corrective action

The systems audit is a qualitative review of the overall sampling or measurement system while the performance audit is a quantitative assessment of a measurement system and includes both internal and external audits. EPA program and project personnel will conduct internal audits with contractor support as necessary.

Nonconformance and Corrective Actions

Corrective action is the process of identifying, recommending, approving, and implementing measures to counter unacceptable procedures or out-of-control performance that may affect data quality. The RPM is responsible for overseeing, documenting, and verifying the adequacy of implementation of any corrective action. If requested, the QA staff can assist the RPM in verifying that the corrective action has been implemented. To correct a quality problem or work deficiency, corrective action should generally be taken at the time the problem is identified. The individual who identifies the problem will be responsible for notifying the appropriate project- or program-level personnel. Corrective actions should not be initiated without prior communication of findings through the proper channels.

Any nonconformance with the established QC procedures specified in the project-specific Work Plans or this QMP will be identified and corrected in accordance with the applicable planning documents. Once implemented, corrective actions must be documented in the field logbook or project-specific location.

The goals of corrective action are to resolve the immediate problem, prevent future occurrences of the problem, and improve processes. Significant problems with corrective actions should be shared with other NAUM RPMs in regular section or branch meetings. A system for issuing, tracking, and documenting the completion of formal corrective actions will be developed in the future..

The following three special and rare types of corrective action are highlighted for management attention:

- Unusual patterns of significant problems for EPA-lead projects: the RPM will inform the EPA Contracting Officer, and NAUM management, and if applicable, the RQAM.
- Failures that appear to be intentional and significant: the RPM will consult with NAUM management and specifically consider whether the EPA OIG should be informed.
- First-hand receipt of whistleblower fraud allegations: the RPM will immediately report by email to NAUM management and the EPA OIG.

Reconciliation of Data with Data Quality Objectives

Assessment of data quality is an ongoing activity throughout all phases of a project. The following outlines the methods to be used by the contractor for evaluating the results obtained from the project.

Review of the DQO outputs and the sampling design should be conducted by project personnel prior to sampling activities designated in project-specific Work Plans. The reviewer will submit comments to the appropriate project personnel for action, comment, or clarification. This process will be iterative.

A preliminary data review will be conducted by appropriate project personnel. The purpose of the

review is to look for problems or anomalies in the implementation of the sample collection and analysis procedures and to examine QC data for information to verify assumptions underlying the DQOs and the project-specific Work Plan (including the Field Sampling Plan and QAPP). When appropriate to sample design, basic statistical quantities may be calculated, a statistical hypothesis test conducted, and assumptions underlying the test identified.

Data collected during the field activities should be reconciled with the requirements of the data user. The end users may perform statistical evaluations to determine confidence levels along with a subjective evaluation of the data qualifiers, which will determine any bias or skewing of the results and usability of the data for the overall project.

If the validated data are determined to be not usable for the project or the data are found to have deviated significantly from the DQI goals, the impacts will be documented. If critical data points are affected that impact the ability to complete the project objectives, the data users will report these findings immediately to the appropriate project personnel to discuss potential corrective actions.

Field Oversight

The Tribal Land Cleanup and Remedial Support Branch field oversight program is implemented to deter fraud, prevent systematic problems, ensure compliance with approved planning documents such as a SOP or QAPP, and promote best practices for work quality and safety. Field oversight comprises spot checks, surveillance, triggered checks, and field audits; see Section 3.2.1 for definitions of these activities. As the quality of environmental work is strongly affected by non-technical factors, which are often site-specific factors, the Tribal Land Cleanup and Remedial Support Branch's oversight of NAUM cleanup projects is primarily project specific.[8]

The Tribal Land Cleanup and Remedial Support Branch's NAUM project oversight must be performed by personnel independent of those performing the work. An EPA RPM, an EPA contractor, or a Navajo Nation or other government agency staff member who is part of the project planning team typically meet this independence requirement.

EPA often uses contractors for field oversight of potentially responsible party (PRP) work; however, when an EPA contractor performs site work, the EPA Task Order Contracting Officer's Representative (usually the EPA RPM) should perform all necessary field oversight.

The level and type of effort for field oversight is commensurate with risks of an incorrect EPA decision, public concern, available resources, and project-specific evaluation factors as described below.

Types of Field Oversight Activities

A *spot check* is a random check of in-progress activities at a time and place convenient to the person performing the oversight without negatively affecting work schedules or quality. These checks would normally be used to decide if an additional level of oversight should be performed. Spot checks are normally performed by an EPA RPM or delegate and documented in a field notebook. Documentation can include only summary information or specific, detailed

[8] Guidance to develop a project-specific oversight approach is considered more effective than program-wide prescriptive requirements for field oversight for a variety of reasons, including 1) the quality of work processes vary with site-specific human factors and 2) site-specific risk and benefit considerations directly impact the level of assurance EPA needs to provide stakeholders.

observations. A spot check differs from a surveillance in that a spot check is focused on one particular component of QA and generally involves asking questions, inspecting documentation, and comparing any gathered information against a standard of performance, such as a SOP.

A ***surveillance*** is a planned visual inspection of field operations with a focus on the overall management practices that generally relies on the judgment and experience of the RPM or delegate. Typically, a surveillance will 1) confirm the presences of appropriate equipment and staff, 2) confirm the location and time of activities, 3) observe whether management and implementation practices appear efficient and organized, 4) confirm that samples are appropriately stored under custody and with proper preservation, and 5) confirm that any critical checks specified in the umbrella QAPP or task-specific SOP are being performed (e.g., required calibrations occur timely, subcontractor oversight by a technically qualified person, etc.). Often, multiple field operational activities occur in parallel, and a surveillance will have a goal of broad coverage of each type of activity or work that has the most impact on subsequent decisions, such as observing each sampling team or activity as appropriate. Surveillance activities can be documented in field notebooks, a completed checklist, or, for concerns that may require additional follow-up, a brief field report or memorandum summarizing findings. Surveillance activities may take place for a portion of or all of a field sampling event.

A ***triggered check*** is a planned oversight activity to directly verify or refute a significant nonconformance concern or other special circumstance. For example, if samples were previously received by a laboratory in broken bottles, the RPM may inspect all shipping containers for appropriate shipping precautions and interview the samplers to determine whether practices need to be changed. These checks can be performed by an EPA RPM, an EPA contractor, or other government agency personnel. Triggered checks can be documented in field notebooks, a completed checklist, or, for significant concerns with nonconformance findings, a formal field report or through the initiation of a corrective action process.

A ***focused audit*** is a formal planned review of a specific site process and generally used when passive visual observation alone is inadequate to verify the acceptability of work and the work quality cannot be established by routine supporting documentation. Generally, these audits are based on SOPs, employ checklists, and result in a formal report. Example focused audits include sampling audits and split sampling. Focused audits are typically initiated by the NAUM program or QAB and generally performed as a response to project-specific findings or as part of a program-wide requirement. Audits are generally planned activities because they involve extensive interaction with field personnel and have an impact on project schedules.

Field Oversight Goal

Generally, the purpose of field oversight is to independently and affirmatively corroborate[9] that field work is performed in accordance with umbrella planning documents, such as a QAPP or Health and Safety Plan (HASP), and to ensure that there are no unanticipated circumstances that could affect work quality. The Tribal Land Cleanup and Remedial Support Branch has a minimum field oversight goal for certain oversight activites[10] as described in Table 3-1. The minimum

[9] As opposed to independent verification and assessment of the acceptability of each step of a process, all steps of a process, or all aspects of a project that could vary from planning expectations.

[10] The oversight goal reflects that some minimum level of affirmative information is needed to validate the quality of EPA decisions for stakeholders. These oversight goals describe a minimum effort on a program-wide basis that would generally occur in the situation where no actual or perceived quality concerns are found for a NAUM

oversight goal is developed to provide the NAUM program with a regular assessment of the quality of field work, which allows for continuous quality improvement.

Field oversight typically has a focus on aspects of data collection that can only be verified in the field and complements other oversight activities performed in the office, such as data assessment and documentation reviews.

The oversight approaches and actions for trustee-lead projects are developed in partnership with NNEPA; however, oversight for all projects should be coordinated with NNEPA so that the agency can participate when available. Field oversight for data collected under an EPA grant or as a time-critical action are not subject to a minimal level of EPA oversight.[11]

Program-Wide Field Oversight

An annual assessment of oversight implementation will be made by Tribal Land Cleanup and Remedial Support Branch management in the first quarter of every fiscal year. Oversight implementation will depend on the number, type, and goals of field activities planned for the year. As described in Table 3-1, for PRP and trustee projects, the NAUM Program has a minimum goal of one split sampling event per year and one field audit event per year on a program-wide basis. In addition, the Program has a minimum goal of perform a field audit on an annual basis for EPA projects. Branch management will decide which projects will be used to meet the program-wide goal.

Project-Specific Field Oversight

Project-specific oversight approaches should be developed within budget, time, and resource limitations. Frequently, general approaches used in recent similar NAUM projects are an appropriate starting point. Site-specific concerns or special circumstances may arise that influence the type and frequency of oversight activities required to meet oversight goals. An important factor to consider is who will perform specific activities to ensure both independent and competent oversight occurs. The EPA RPM should be alert for and identify vulnerabilities or processes that vary unacceptably and would have the most significant negative impact on project decisions. To meet these objectives, EPA RPMs often strategically apply support from contractors or other EPA and governmental organizations.

project. There is no maximum or typical level of field oversight. However, if no problems are found, no additional oversight activities are triggered on a project-specific basis. Establishing minimum oversight goals rather than required oversight specifications eliminates the risk of unnecessarily slowing down a cleanup or misallocating human and financial resources where they may not be needed.

[11] Data collected under an EPA grant are covered by terms and conditions for the grant. Data collected as time-critical or emergency actions are only subject to oversight determined as appropriate by the project RPM or OSC.

Table 3-1 – Program Minimum Oversight Goal and Responsibility

Oversight Activity	Project Type	Approach	Frequency	Responsibility
Surveillance	PRP Lead Trustee Lead EPA Lead	Project-specific Project-specific Project-specific	Every sampling event Every sampling event Every sampling event	RPM RPM RPM
Split sampling	PRP Lead or Trustee Lead	Program-wide	1 sampling event per year	Designated RPM[1]
Field audit	PRP Lead or Trustee Lead	Program-wide	1 sampling event per year	Designated RPM
	EPA Lead	Program-wide[2]	1 sampling event per year	Designated RPM

Notes:
[1] The designated RPM is the RPM for the project identified to fulfill the program-wide oversight goal.
[2] Program-wide EPA contractor oversight.
EPA United States Environmental Protection Agency
PRP Potentially responsible party
RPM Remedial Project Manager

Field Oversight Responsibilities

Most of field oversight responsibility lies with individual RPMs (Table 3-1); however, the approach is expected to vary as the program develops.

This QMP addresses how a contractor is used to perform field work for EPA. As one contractor may work with multiple RPMs and multiple projects, EPA monitors system performance via corrective action reports or performs assessment of work products. The regional QAB will monitor internal corrective action reports, project-specific surveillance reports, data validation reports, and the results of any audits. If a trend of poor performance is observed that is not project specific, EPA will address the concern in a systematic way. For example, the Tribal Land Cleanup and Remedial Support Branch could initiate focused audits of all or multiple projects and coordinate with the regional QAB and the EPA Contracting Officer.

In cases where EPA personnel or other federal agency staff (e.g., the United States Coast Guard [USCG], United States Geological Survey [USGS], etc.) perform actual field work, the QAB approving the umbrella QAPP or the Tribal Land Cleanup and Remedial Support Branch Assistant Director should initiate any oversight activities in consultation with the project manager designated in the QAPP.

Specific field oversight responsibilities of management and staff are described in Table 3-2.

Table 3-2 – Field Oversight Responsibilities

Tribal Land Cleanup and Remedial Support Branch Section and Branch Managers are responsible for the following program oversight:
• Ensure annually that program-wide minimum oversight goals are met • Ensure that meetings are held regularly to share project-specific oversight findings • Provide guidance to RPMs on the type and level of field oversight in response to new or unusual vulnerabilities identified • Verify reasonableness and program-wide consistency of project-specific field oversight • Plan program-wide EPA field oversight activities to adequately address vulnerabilities during the first quarter of every fiscal year • Ensure that any whistleblower complaints are reported to the EPA Office of Inspector General
NAUM Project Managers (RPM/OSC) are responsible for the following project-specific field oversight activities:
• Initiate any oversight activity • Coordinate and ensure implementation of activities • Ensure that properly qualified personnel are performing activities (technically competent and independent) • Document oversight activities, findings, and actions taken and include this documentation in the project site file • Develop and/or approve of corrective actions required to resolve quality issues • Ensure the appropriate response to any oversight finding • Share oversight findings with other Tribal Land Cleanup and Remedial Support Branch RPMs and, as appropriate, partner agencies
The QAB is responsible for the following RPM support for field oversight:
• Inform RPMs of poor-quality planning documents that have been submitted for review, primarily in areas of internal management practices, technical SOPs, and quality control • Inform RPMs about any quality concerns detected in data assessments and validations • Make recommendations to RPMs that address findings from periodic checks of EPA contractor quality assurance corrective actions • Assist the Tribal Land Cleanup and Remedial Support Branch in updating program planning documents, such as this QMP • Ensure consistency in project-specific planning documents with overall QMP goals

Notes:
EPA United States Environmental Protection Agency
NAUM Navajo abandoned uranium mine
OSC On-Scene Coordinator
QAB Quality Assurance Branch
QMP Quality Management Plan
RPM Remedial Project Manager
SOP Standard operating procedure

Field Oversight Tools and Considerations

To assist the RPM with field oversight responsibilities and documentation, an example checklist is included in Appendix C. This checklist provides a comprehensive list of process elements for RPM surveillance; however, the specific subset of elements to be checked is determined by the RPM. This checklist does not take the place of any site-specific HASP checks. The RPM can use the Field Surveillance Checklist, modify the checklist, or document oversight activities in another way, such as entries in a logbook. The documentation should be included in the site file in the Superfund records center to document that QA activities are appropriately implemented in the field. If field oversight activities uncover QA areas of concern, in addition to implementing corrective actions, the RPM may want to consider additional tools, such as a triggered check or a focused audit. If the concern is minor and easily addressed, the corrective action could be immediately implemented in the field at the time the concern is identified with appropriate written documentation of the change. However, if the concern is more complex, the RPM may need to consult with the project QAB to determine an appropriate course of action, which may include a focused audit. Additional tools for gamma scanning activities are under development.

Table 3-3 lists the noted problems in historical Region 9 CERCLA programs and serves as a starting point for oversight planning for RPMs. Root causes of QA problems often are lack of effective communication, lack of adequate training, and lack of available resources (time, people, and equipment).

Resources for Planning and Implementing Field Oversight

Project oversight must be performed by personnel independent of those performing the work. The following resources typically meet this independence requirement and can be used to plan and implement field oversight of the NAUM Program:

- EPA Emergency Response Team
- EPA ORIA
- EPA Oversight Contractor (for PRP-lead projects)
- EPA Region 9 Technical Support Team
- EPA Region 9 Field Team
- EPA Region 9 QAB
- NNEPA
- USCG
- USGS

Table 3-3 – Noted Problems in CERCLA Programs and Oversight Considerations

Problem	Frequency CERCLA Wide	Impact on Decisions	Field Oversight Strategy
Inadequate sample preservation	High	Low to severe	Spot check
Unreadable sample labels	Moderate	Low to severe	Spot check
Incomplete chain of custody	Moderate	Low to severe	Spot check
Rushed workload with increased risk for errors	Moderate	Low to severe	Surveillance, spot check
Inadequate care for cross-contamination/cleaning	Moderate	Low to severe	Spot check, focused audit on sampling technique
Improper field QC	Moderate	Low to severe	Spot check
Switched samples	Low	Moderate to severe	Focused audit on organization
Significant field variances	Low	Moderate to severe	Triggered check, corrective action process, focused audit based on findings
Out of spec field instrument calibration	Low	Low to severe	Spot check, field Performance Evaluation[1] sample
Inexperienced samplers	Low	Low to severe	Spot check
Inadequate sampling volume	Low	Low to severe	Spot check
Improper use of field instruments	Low	Low to severe	Spot check
Sample location error (e.g., GPS error)	Low	Low to severe	Spot check, focused audit on experience and procedures, independent location record
Field variances (low significance) without documentation and approval	Low	Low	Triggered check, surveillance
Slow work because of poor organization/preparedness	Low	Low to moderate	Surveillance, spot check
Unsupervised subcontractor	Low	Low to moderate	Spot check
Deliberate falsification of sample location	Very low	Severe	Deterrence by split sampling, spot check

Notes:

[1] Performance Evaluation samples are used to test the proficiency of an analytical method or field measurement procedure

CERCLA Comprehensive Environmental Response, Compensation, and Liability Act

GPS Global positioning system

QC Quality control

Reports to the Project Manager

The Project Manager will receive reports from designated project personnel on programmatic issues as they occur. The roles and responsibilities of project management personnel will be defined in the project-specific Work Plan. Generally, Project Managers will receive reports on all issues that arise during the project that could affect data quality, data use objectives, project objectives, or project schedules. The types of reports that could be supplied to both program and project management personnel include the following:

- Field audit
- Laboratory audit
- Field activities summary
- Project status calls and meetings
- Data validation report
- Data usability report

DATA VALIDATION AND USABILITY

Data Review and Validation

Data validation will be performed according to EPA's *Region 9 Superfund Data Evaluation/Validation Guidance* (EPA 2001c) and Section 1.4.3. Upon completion of validation, data will be classified as one of the following: acceptable for use without qualifications, acceptable for use with qualifications, or unacceptable for use. Analytical data will primarily be generated by commercial analytical laboratories.

Data Review and Validation Procedure

Data review is the process to evaluate whether 1) analytical data are generated and documented in a technically sound and defensible manner; 2) analytical data meet the applicable QC criteria; and 3) data usability and the extent of impact to the data from technical deficiencies and QC outliers are acceptable through independent verification.

Data packages are reviewed for technical deficiencies or potential issues impacting the validity of the reported results depending on the analytical program and validation level. The basic procedure is as follows:

- Determine the completeness of data package
- Evaluate the data for DQIs and issues that could impact reliability or usability
- Apply appropriate qualifiers to data
- Prepare the validation report
- Complete an internal review of validation report
- Submit the validation report
- Finalize the validation report

Variances from the QA/QC objectives will be addressed as part of the data validation summary reports.

Data Usability Assessment

The data usability assessment is considered the final step in the data evaluation process and evaluates whether underlying assumptions used during systematic planning are supported, sources of uncertainty have been accounted for and are acceptable, data are representative of the population of interest, and the results can be used as intended with the acceptable level of confidence. The following general steps will be followed to conduct a data usability assessment:

- Step 1 – Review the project's objectives and sampling design
- Step 2 – Review the data verification and data validation outputs
- Step 3 – Verify the assumptions of the selected statistical method (if applicable)
- Step 4 – Implement the statistical method (if applicable)
- Step 5 – Document the data usability and draw conclusions

All data will be assessed for usability regardless of the data evaluation and validation process implementation. Data usability goes beyond validation in that it evaluates the achievement of the DQOs based on the comparison of the project DQIs and individual study-specific work plans with the obtained results.

Primarily, the assessment of the usability will be conducted according to the process outlined below.

1) **Sampling and Analysis Activities Evaluation.** The first part of the data usability assessment will include a review of the sampling and analysis activities in comparison to project-specific DQIs. Limitations to the data will be determined and documented.
2) **Achievement of DQIs.** The second part of the data usability assessment pertains to the achievement of the project-specific DQIs. Designated project personnel will compare the performance achieved for each data quality criterion against the expected and planned performance. In general, this comparison will follow from the DQIs used to define each DQO. This comparison is the most critical component of the assessment process. Any deviation from planned performance will be documented and evaluated to determine whether corrective action is advisable. Potential corrective actions will range from resampling and reanalyzing the data to qualification or exclusion of the data for use in the data interpretation. If corrective action is not possible, any limitations of the data with regard to achieving the DQOs will be noted.

   In conjunction with the DQI achievement review, decisions for the use of qualified values must be considered. Data qualifiers are applied to individual data results, and data usability decisions should be made based on the assessment of the usability of each of these results for their intended purpose. The evaluation will describe the uncertainty (bias, imprecision, etc.) of the qualified results. Cumulative QC exceedances from the DQIs may require technical judgment to determine the overall effect on the usability of the data. Finally, data users may choose to determine final data usability qualifiers as a result of this overall examination and decision process.
3) **Achievement of DQOs.** The final part of the data usability assessment concerns the achievement of the DQOs. Once the data set has been assessed to be of known quality, data limitations have been documented, and overall result applicability and usability for its intended purpose has been determined, the final data assessment can be initiated by determining if the DQOs have been achieved.

Where data gaps are identified as a result of problems, biases, trends, etc., in the analytical data, or if conditions exist that were not anticipated in the development of the DQOs, a solution or corrective action should be formulated. It is particularly important that each data usability assessment specifically address any limitations on the use of the data that may result from a failure to achieve the stipulated DQO.

When the data do not meet the project DQOs, the root cause to the deficiency should be investigated. Reasons could include laboratory operation, such as the failure of laboratory RLs to meet site criteria. Corrective actions may include:

- Resampling for all or some of the parameters
- Preparing a technical memorandum detailing limitations to the data
- Validating the data at a higher tier level to better qualify the results
- Preparing a technical memorandum determining the bias of field results

RELEVANT PROGRAM GUIDANCE

EPA Policy and Program Requirements for the Mandatory Agency-Wide Quality System, EPA Order, CIO Policy 2105.0 (EPA 2000a).

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

EPA Guidance for Quality Assurance Project Plans, EPA QA/G-5, EPA/R-02/009 (EPA 2002a).

EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, EPA/240/B-06/001 (EPA 2006).

EPA Region 9 Quality Management Plan (EPA 2014).

EPA Region 9 Guidance for Quality Assurance Program Plans, EPA R9QA/03.2 (EPA 2012).

EPA Region 9 Laboratory Documentation Required for Data Evaluation, EPA R9QA/004.2 (EPA 2001b).

EPA Region 9 Superfund Data Evaluation/Validation Guidance, EPA R9QA/006.1 (EPA 2001c).

EPA Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) Manual, EPA 402-B-04-001A (EPA 2004).

EPA Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), EPA 402-R-97-016 (EPA 2000b).

EPA Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, Third Edition, Final Update III-A, EPASW-846-3.3a, March (EPA 1999).

EPA Methods for the Determination of Inorganic Substances in Environmental Samples, EPA/600R-93-100 (EPA 2002b).

REFERENCES

American Nuclear Society. 2012. *Verification and Validation of Radiological Data for Use in Waste Management and Environmental Remediation*. ANSI/ASI-41.5-2012.

California Military Environmental Coordination Committee. 1997. *Best Practices for the Detection and Deterrence of Laboratory Fraud*. Version 1.0. March

United States Environmental Protection Agency (EPA). 1980. *Prescribed Procedures for Measurement of Radioactivity in Drinking Water*. EPA/600/4-80-032. August.

EPA. 1999. *EPA Test Methods for Evaluating Solid Waste: Physical/Chemical Methods*. Third Edition, Final Update III-A. EPA SW-846-3.3a. March.

EPA. 2000a. *EPA Policy and Program Requirements for the Mandatory Agency-Wide Quality System*. EPA Order, Chief Information Officer (CIO) Policy 2105.0. May 5.

EPA. 2000b. *Multi-Agency Radiation Survey and Site Investigation Manual*. EPA 402-R-97-016, Rev. 1. August.

EPA. 2001a. *EPA Requirements for Quality Assurance Project Plans*. EPA QA/R-5, EPA/240/B-01/003. March.

EPA. 2001b. *Laboratory Documentation Requirements for Data Evaluation*. EPA Region 9. EPA R9/QA/00.4.2. August.

EPA. 2001c. *Region 9 Superfund Data Evaluation/Validation Guidance*. EPA R9/QA/006.1. December.

EPA. 2002a. *Guidance for Quality Assurance Project Plans*. EPA QA/G 5, EPA/R-02/009. December.

EPA. 2002b. *Methods for the Determination of Inorganic Substances in Environmental Samples.* EPA/600R-93-100. December.

EPA. 2004. *Multi-Agency Radiological Laboratory Analytical Protocols Manual*. EPA 402-B-04-001A. July.

EPA. 2006. *Guidance on Systematic Planning Using the Data Quality Objectives Process*. EPA QA/G-4, EPA/240/B-06/001. February.

EPA. 2012. *EPA Region 9 Guidance for Quality Assurance Program Plans*. EPA R9QA/03.2. March.

EPA. 2014a. *Region 9 Quality Management Plan*. October.

EPA. 2014b. *EPA QA Field Activities Procedure.* CIO Directive 2105-P-02.0. September.

United States Nuclear Regulatory Commission. 1998. *Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions.* NUREG-1507.

ACRONYMS AND ABBREVIATIONS

ANSI	American National Standards Institute
ASPECT	Airborne Spectral Photometric Environmental Collection Technology
ASTM	ASTM International
AUM	Abandoned uranium mine
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CIO	Chief Information Officer
CSU	Combined standard uncertainty
DMP	Data Management Plan
DOD	United States Department of Defense
DOE	United States Department of Energy
DQI	Data quality indicator
DQO	Data quality objective
EPA	United States Environmental Protection Agency
ERT	Environmental Response Team
GIS	Geographic information system
GPS	Global positioning system
HASP	Health and Safety Plan
MAPEP	Mixed Analyte Performance Evaluation Program
MARLAP	*Multi-Agency Radiological Laboratory Analytical Protocols*
MARSSIM	*Multi-Agency Radiation Survey and Site Investigation Manual*
MDC	Minimum detectable concentration
MDL	Method detection limit
mL	Milliliter
MQC	Minimum quantifiable concentration
MQO	Measurement quality objective
MS	Matrix spike
MSD	Matrix spike duplicate
NAUM	Navajo abandoned uranium mine
NAREL	National Analytical Radiation Environmental Laboratory
NIST	National Institute of Standards and Technology
NNEPA	Navajo Nation Environmental Protection Agency
NRC	Nuclear Regulatory Commission
ORC	Office of Regional Counsel
OIG	Office of Inspector General
OLEM	Office of Land and Emergency Response
ORIA	Office of Radiation and Indoor Air
OSC	On-Scene Coordinator

PARCCS	Precision, accuracy, representativeness, comparability, completeness, and sensitivity
PRP	Potentially responsible party
QA	Quality assurance
QAB	Quality Assurance Branch
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality control
QMP	Quality Management Plan
QSM	Quality Systems Manual
RL	Reporting limit
RPD	Relative percent difference
RPM	Remedial Project Managers
RQAM	Regional Quality Assurance Manager
SAP	Sampling and Analysis Plan
SOP	Standard operating procedure

Appendix A-1
Example QAPP Signature Block Template
PRP-Lead, RSE type QAPPs (see Table 1-4)

Insert Document Title

Prepared by:

_____ _____ ____
_____
Approved by: Contractor, Project Manager Phone Date

_____ _____ ____
_____
Approved by: Contractor QA Officer Phone Date

For EPA use:

Approved:

_____ ____
_____
(*Insert Name*) EPA Project Manager, Date

Received by QA Branch: Date: _____

Appendix A-2
Example QAPP Signature Block Template
Trustee-Lead type QAPPs (see Table 1-4)

Insert Document Title

Prepared by:

_____ _____ _____

Approved by: Contractor, Project Manager Phone Date

_____ _____ _____

Approved by: Contractor QA Officer Phone Date

Approved:

_____ _____

(*Insert Name*) EPA Project Manager, Date

_____ _____

(*Insert Name*) Navajo EPA Project Manager, Date

Received by QA Branch: Date: _____

Appendix A-3
Example QAPP Signature Block Template
EPA Funded Interagency Agreement/Grant,
EPA-Lead Final Status Survey (See Table 1-4)

Insert Document Title

Prepared by:

_____ _____ ____
_____
Approved by: Contractor, Project Manager Phone Date

_____ _____ ____
_____
Approved by: Contractor QA Officer Phone Date

For EPA use:

_____ _____ __
_____
Approved by: (*Insert Name*), EPA Project Manager Phone Date

Received by QA Branch: Date: _____Expedited review? ☐Yes ☐No

Reviewed by:

_____ _____
Region 9 QA Reviewer Date

Approved:

Region 9 QA Manager, Date

Appendix B
QAPP Review Checklist

Appendix C
NAUM Field Surveillance Checklist

Appendix C: Field Surveillance Checklist

Site Name:	
Lead Agency:	
Remedial Project Manager:	
Work Order No.:	

Date:			**Time on Site:**		**Time off Site:**	

On-Site Field Group Personnel:

Affiliation	Name(s)

Abandoned Uranium Mines Visited:		**Global Positioning System (GPS) Coordinates:**		

Weather:		**Temperature:**	

Summary of Activities:

Region/Office Division/Unit Name and Location:
Date(s) of Assessment:
Name(s)/Affiliation of Assessor(s):

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
1 Personnel and Training					
1.1 Personnel responsible for field activities have appropriate qualifications, education, training, and experience, and a satisfactory knowledge of the requirements of the activities to be carried out.					
2 Procedures – Availability					
2.1 Field sampling and measurement activities are conducted in accordance with applicable standard operating procedures, quality assurance project plans (QAPPs), and sampling and analysis plans.					
2.2 All instructions, standards or written procedures, worksheets, checklists, and reference data relevant to the field investigations/inspections are current, accurate, and readily accessible by the staff.					
2.3 Key personnel identified in the QAPP are present and implementing quality assurance checks identified in the QAPP.					
2.4 Field groups identify, document, and implement any required corrective actions.					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
3 Records Management – Legibility and Traceability					
3.1 Within the context of field oversight activities, records provide objective evidence of actions taken and observations made. Examples of field records include (but are not limited to): field logbook entries, electronic field measurement data log, completed chain-of-custody forms, instrument calibration and recalibration records, daily results of source checks and performance chart comparisons, instrument damage or fault reports, photographs, maps, completed inspection forms, QAPPs, etc.					
3.2 Field groups maintain and utilize established procedures to ensure:					
a) All records are legible and stored and retained in such a way that they are readily retrievable, either electronically or in hard copy format.					
b) Observations, calculations, and measurement entries are clearly and permanently recorded at the time they are made.					
c) Technical records associated with field activities include the identity of personnel responsible for the sampling or inspection activities.					
d) Each page of project-related records is traceable back to the project.					
e) Information that is to be included in files that contain project records is defined.					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
f) Electronic records have back-up processes and protection from unauthorized access or amendment.					
g) Records that have been recorded manually are recorded in permanent ink. When weather conditions do not make it feasible to use permanent ink, then entries can be made in non-smear pencil. The penciled entries shall be captured permanently by photocopying or photographing the penciled entries or other acceptable manner.					
h) Error corrections do not obliterate entries in the original record. Corrections are made by marking through the error with a single line and then initialing and dating the correction.					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
4 Data Management – Custody and Security					
4.1 Field groups maintain and utilize procedures for the identification, transportation, handling, protection, storage, and retention of samples and other appropriate environmental data during field activities. The procedures ensure:					
a) Field samples and appropriate environmental data are maintained under custody at all times during field studies, investigations, and inspections. Samples and data are in custody if they are: i) Within the direct possession or the control (i.e., within the view) of an individual designated to have sample handling responsibilities ii) Placed in a designated secure area to prevent tampering iii) Maintained in a manner that ensures the integrity of the samples is not compromised when placed in an unsecure area.					
b) All samples, measurements, and other appropriate data are uniquely identified to ensure items cannot be confused physically or when referred to in records or other documents.					
c) A chain-of-custody record shall be maintained for the collection of environmental samples that details each person who takes possession of the samples.					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
d) If electronic systems (i.e., bar coding of potential evidence/samples, Scribe, etc.) are used for sample labeling or chain-of-custody generation, hardcopy/manual systems should be available in the event of the failure of the primary electronic system or device.					
5 Field Documentation – Completeness					
5.1 For field measurements and sample collection, documentation includes, as appropriate, but is not limited to:					
a) Date and time of measurement or sample collection.					
b) Location description and/or global positioning system (GPS) coordinates.					
c) Measurement/sample identification.					
d) Measurement/sample collection method.					
e) Measurement/sample collection equipment used, including identification numbers and the manufacturer name/model number as appropriate.					
f) Calibration standards, buffers, etc., including manufacturer, lot numbers, and expiration date.					
g) Initial and continual calibration data and meter end checks.					
h) Measurement values for non-logging equipment.					
i) Sample containers (number and type).					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
j) Sample preservation (chemical, ice, etc.).					
k) Physical description of matrix measured or sampled.					
l) Maps/sketches.					
m) Conditions that may adversely impact the quality of measurements/samples if applicable (for example, radiological interferences [shine], rain, wind, smoke, dust, extreme temperatures, etc.).					
n) Photograph log.					
6 Equipment – Validation/Certification					
Field groups implement procedures for field equipment that ensure:					
a) All measurement equipment is uniquely identified (i.e., identification number).					
b) Measurement equipment is calibrated before being put into service and thereafter according to an established procedure.					
d) Up-to-date instructions on the use and maintenance of measurement equipment, including any relevant manuals provided by the manufacturer of the equipment, are readily available for use by the appropriate personnel.					

General Requirement	Assessment			Source[1] (I, O, D)	Assessor Comments
	Y	N	NA		
e) Equipment that has been shown to be defective or outside specified quality control limits is taken out of service. Such equipment shall be isolated to prevent its use and clearly labeled/marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.					
f) Whenever practicable, equipment requiring calibration shall be labeled, coded, or otherwise identified to indicate the status of calibration, including the date when calibration is due. The date when last calibrated and performance chart comparisons may also be included.					
i) Records shall be maintained to document the check sources, standards, reagents, etc. used to calibrate equipment and may include, as appropriate, the manufacturer, standard/reagent lot number, expiration date of the standard/reagent; and date and activity of a check source.					

Note:
[1] I = Interview; O = Observation; D = Documentation

Appendix D
Radiochemical Data Validation SOP

Appendix E
Gamma Scanning Checklist
(Under Development)

Appendix E
Gamma Scanning Checklist (Under Development)

Checklist Under Development