

EPA REGION 5 QUALITY MANAGEMENT PLAN




REVISION 1

NOVEMBER 2020


APPROVALS

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ACRONYMS

AA - Assistant Administrator

ASHERA - Asbestos Hazard Emergency Response Act of 1986

AIRS - Aerometric Information Retrieval System

ANSI - American National Standard Institute

AO - Administrative Order

AOC - Area of Concern

ARA - Assistant Regional Administrator (U.S. EPA Region 5)

ARD - Air and Radiation Division (U.S. EPA Region 5)

ASAO - CERCLA Administrative Settlement Agreement and Order on Consent for Removal Actions

ASB - Analytical Services Branch

ASHAA - Asbestos School Hazard Abatement Act of 1984

ASQ - American Society for Quality

CA - Cooperative Agreements

CAA - Clean Air Act

CERCLA - Comprehensive Environmental Response, Compensation and Liability Act (Superfund)

CFR - Code of Federal Register (United States)

CID – Criminal Investigations Division (U.S. EPA)

CIO – Chief Information Officer (U.S. EPA)

CMM - Contract Management Manual (EPA Directive 1900, revised April 2004)

COR - Contracting Officer's Representative (aka Contracts Project Officer, Work Assignment Manager, Task Order Manager, Delivery Order Manager, etc.)

COTS - commercial off-the-shelf software

DL – QA Office Divisional Leads (U.S. EPA Region 5)

DOD - U.S. Department of Defense

DOJ - Department of Justice (United States)

DQA - Data Quality Assessment

DQO - Data Quality Objectives

DRA - Deputy Regional Administrator (U.S. EPA Region 5)

EA - Enterprise architecture

ECAD - Enforcement & Compliance Assurance Division (U.S. EPA Region 5)

EI – Environmental Information (U.S. EPA)

ECO - External Communications Office (U.S. EPA Region 5)

EnPPA - Environmental Performance Partnership Agreement

EPA - Environmental Protection Agency (United States)

EPCRA - Emergency Planning and Community Right-to-know Act

EQMD – Enterprise Quality Management Division

ERB - Emergency Response Branch

ERRS - Emergency Rapid Response Service

FIFRA - Federal Insecticide, Fungicide and Rodenticide Act

FAR – Federal Acquisition Regulation

FOG - Field Operations Group

FSP - Field Sampling Plans

FTE – Full-Time Employee

GAP - General Assistance Program
GSS - general support systems
GIS - Geographic Information System
GLLA - Great Lakes Legacy Act
GLNPO - Great Lakes National Program Office (U.S. EPA Region 5)
GLRI - Great Lakes Restoration Initiative
GLWQA - Great Lakes Water Quality Agreement
GOTS - government off-the-shelf software
IDQTF - Interagency Data Quality Task Force
IQG - Information Quality Guidelines
ISO - International Organization for Standardization
IT - Information Technology
LCRD - Land, Chemicals and Redevelopment Division (U.S. EPA Region 5)
LSASD - Laboratory Services and Applied Science Division (U.S. EPA Region 5)
MSD - Mission Support Division (U.S. EPA Region 5)
MSR - Management System Review
NCP – National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR Part 300)
NELAC - National Environmental Laboratory Accreditation Conference
NEPPS - National Environmental Performance Partnership System
NIST - National Institute of Standard and Technology
NPM - National Program Manager
NTOC - National Tribal Operations Committee
OEIP – Office of Enterprise Information Programs (U.S. EPA)
OITO – Office of Information Technology Operations (U.S. EPA)
OMB - Office of Management and Budget
OMS – Office of Mission Support (U.S. EPA)
ORA - Office of Regional Administrator (U.S. EPA Region 5)
ORC - Office of Regional Council (U.S. EPA Region 5)
OSC – On-Site Coordinator
PARCC – Precision, Accuracy, Representativeness, Comparability, Completeness
PCS – Permit Compliance System
PDRG - Pre-Dissemination Review Guidelines
PE - Performance Evaluation
PO - Project Officer
POC – Points of Contact
PPA - Performance Partnership Agreement
PPA - Pollution Prevention Act of 1990
PRP - Potentially Responsible Party
PT - Proficiency Testing
QA - Quality Assurance
QAARWP - Quality Assurance Annual Report and Work Plan
QAFAP - Quality Assurance Field Activities Procedure
QAM - Quality Assurance Manager
QAPP - Quality Assurance Project Plan
QAPrP - Quality Assurance Program Plans

QARF - Quality Assurance Review Form
QC - Quality Control
QMP - Quality Management Plan
QS - Quality System
QSA - Quality System Assessment
RA - Regional Administrator (U.S. EPA Region 5)
RCRA - Resources Conservation Recovery Act
RCRIS - Resource Conservation and Recovery Information System
RQAM - Regional Quality Assurance Manager (U.S. EPA Region 5)
RP - Responsible Party
RTOC - Regional Tribal Operations Committee
SAP – Sampling and Analysis Plan
SEE - Senior Environmental Employee Program
SEMD - Superfund & Emergency Management Division (U.S. EPA Region 5)
SEMS – Superfund Enterprise Management System
SLCM - System Life Cycle Management
SOP - Standard Operating Procedure
START - Superfund Technical Assessment & Response Team
SQAB - Science and Quality Assurance Branch (U.S. EPA Region 5)
TC - Technical Contact
TMPO - Tribal & Multi-Media Programs Office (U.S. EPA Region 5)
TSA - Technical System Audit
TSCA - Toxic Substance Control Act
UFP-QAPP - Uniform Federal Policy for Quality Assurance Project Plans
WCX – Water Quality Exchange database
WD - Water Division (U.S. EPA Region 5)

EXECUTIVE SUMMARY

U.S. EPA requires that all Program Offices, Laboratories, and Regional Offices operate within a quality management system that specifically addresses the collection, production or use of environmental data. This commitment to a quality system supports Agency decisions with data of known quality that may be presented with the confidence that they are credible and defensible. Each Program and Region has a Quality Management Plan (QMP) that describes its commitment to and support of its quality system. It 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 funds from EPA to perform environmental data collection activities.

FOREWARD

EPA Region 5's (henceforth Region 5 in this document) QMP describes the policies, procedures, and management systems within the organization that govern quality assurance and quality control activities. The Region 5 QMP is intended to comply with CIO 2105.0, CIO 2105-P-01-0 and ASQ/ANSI E-4-2014 (or current revision). The QMP also addresses the requirements stated in EPA QA/R-2 and documents the quality assurance policies and management structure used to implement Region 5's Quality System. This QMP revision specifically incorporates changes to Region 5's organization and quality system since the 2015 revision of the Region 5 QMP.

This QMP is applicable to all environmental programs, operations and activities conducted by Region 5 that involve the collection, production, and use of environmental data. [As defined by the Agency](#), environmental data refers to “any measurements or information that describe environmental conditions, locations, and processes; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature.” Examples include but are not limited to:

- direct measurements of environmental parameters or processes;
- analytical testing results of environmental conditions (e.g., geophysical or hydrological conditions);
- data on physical parameters or processes collected using environmental technologies;
- calculations or analyses of environmental data;
- data provided by environmental data models; and
- environmental data compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources.

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

1.0 MANAGEMENT AND ORGANIZATION

To implement Agency policy, EPA Laboratories, Program Offices, and Regional Offices are required to prepare a QMP covering all intramural and extramural environmental programs which generate and use environmental data. This QMP was prepared according to EPA Requirements for Quality Management Plans, EPA QA/R-2, March 2001, reissued May 2006 and Chapter 3 of the EPA Quality Manual for Environmental Programs, CIO 2105-P-01, May 5, 2000 to document the quality assurance policies and management structure to be used in implementing the Region 5 Quality System.

1.1 Data Collection Activities Covered by the Quality Management Plan

The Region 5 QMP encompasses quality assurance policies and requirements for all environmental data operations (inclusive of environmental data and environmental technology) directly generated by Region 5 programs, their contractors, or grantees; as well as data obtained for Region 5 programs from other sources. It applies to all parties working under administrative orders or consent decrees. The QMP also covers environmental data that Region 5 programs require States, tribal governments, and grantees to collect.

1.2 Region 5 Programs Covered by the Quality Management Plan

The Region 5 QMP is applicable to all Region 5 environmental programs. This includes field and laboratory data-gathering activities or investigations that involve the determination of chemical, physical, locational measurements, or biological characteristics related to the environment, the collection of observations and samples, as well as investigations or studies that involve acquired data.

1.3 Region 5 Mission

Region 5's environmental vision is achieving a sustainable environment in which air, water and land resources are restored and protected to benefit all life through a professional, dedicated and diverse workforce. Region 5's missions include:

- protection of human health and preservation of natural resources;
- prevention and abatement of pollution to improve the environment;
- serving the public with education, innovation, action, and results; and
- protection and restoration of the Great Lakes and all Midwest ecosystems.

The U.S. EPA's current [Strategic Plan \(FY 2018-2022\)](#) documents EPA's commitments by identifying the measurable environmental and human health outcomes and how those results will be achieved during the 5-year plan. Region 5's priorities are based on the Agency's Strategic Plan, Headquarters Offices' annual planning (i.e. National Program Manager (NPM) planning) as well as Region 5's environmental agreements with states, Tribal governments and other partnerships.

1.4 Region 5 Quality Assurance Policy

It is Region 5's policy that environmental data collected or compiled by, or on behalf of the Region including delegated environmental programs and those funded through interagency agreements and grants, for use in Agency's decision-making must be of the type and quality needed and expected for the particular decision or use specified. It is also Region 5's policy that any project performed by, or for, the Region at any stage of its implementation must be assessed based on the approved project

objectives using a graded approach.

The primary goal of Region 5's quality system is to ensure that the quality assurance (QA) policy of the Region is achieved and that quality products and/or decisions are generated or made. Region 5, State agencies, Indian Tribal Governments, local agencies, grantees and contractors shall ensure that all environmental data operations have appropriate, documented processes to systematically plan, implement and assess:

- activities which influence the quality of data which are performed by appropriately trained personnel;
- methods included in Region 5 approved project-level quality documentation (i.e. such as a QAPP) or EPA-required/approved methods (i.e., such as drinking water methods required under 40 CFR Parts 141-143); and
- each environmental data operation which has a documented QA/QC program.

1.4.1 Graded approach

Graded approach is defined as the process of basing the level of details and comprehensiveness of quality documentation applied to environmental operations/programs according to the intended use of the results and the degree of confidence needed in the quality of results. The principle of graded approach recognizes that a 'one size fits all' approach to quality requirements will not generally work in organizations conducting activities as diverse as environmental programs, and the managerial controls are applied according to the scope of the program and/or the intended use of the outputs from a process. Region 5's policy is to utilize a graded approach to ensure that required quality documentation is commensurate with the intended use of data and the level of confidence required in the results.

1.5 Organization

Region 5 is organized into seven Divisions: Air and Radiation Division (ARD); Enforcement & Compliance Assurance Division (ECAD); Laboratory Services and Applied Science Division (LSASD); Land, Chemicals & Redevelopment Division (LCRD); Mission Support Division (MSD); Superfund and Emergency Management Division (SEMD); and Water Division (WD); and five Offices: Office of the Regional Administrator (ORA); Tribal and Multi-Media Programs Office (TMPO); External Communications Office (ECO); Great Lakes National Program Office (GLNPO); and Office of Regional Counsel (ORC). This QMP reflects the overall [regional organization for Region 5](#).

Figure 1 depicts the basic components of the Region's organization and structure in terms of quality assurance reporting and authority. The RQAM and Regional QA staff are assigned to the Laboratory Services and Applied Science Division (LSASD) and report to the Branch Chief of the Science and Quality Assurance Branch (SQAB). The RQAM does, however, have recourse to elevate issues to higher levels of senior management, that is, the Deputy Regional Administrator (DRA).

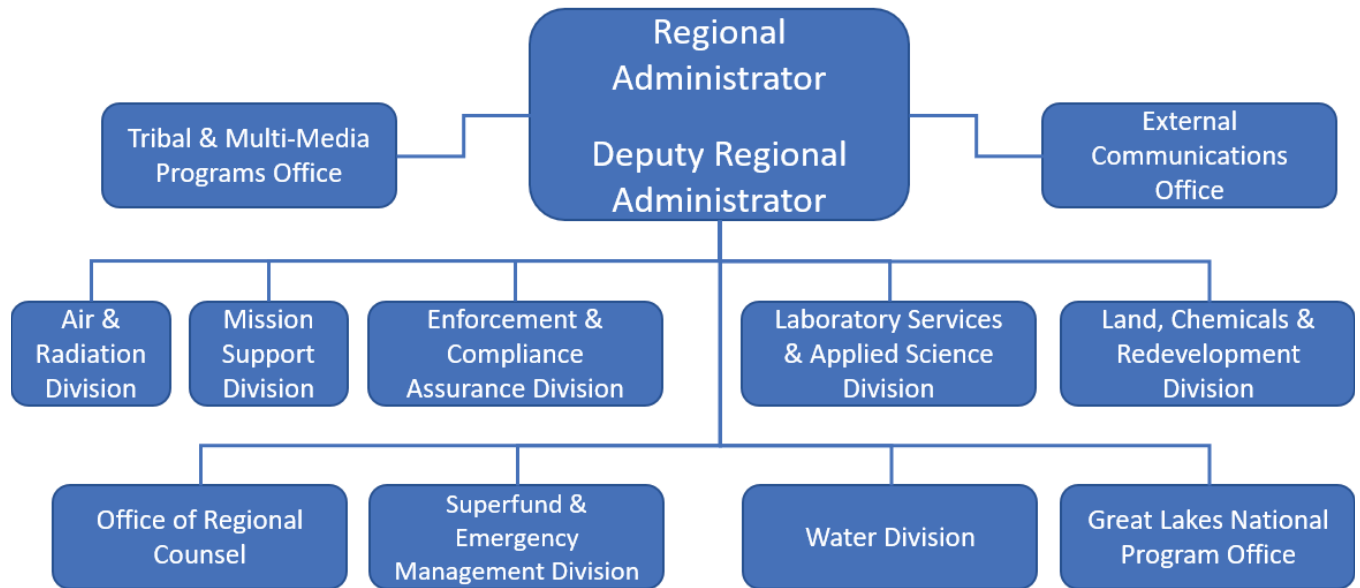


Figure 1: Region 5 Organizational Chart

1.6 Assignment of Responsibility / Delegation of Authority

[The U.S. EPA Delegation of Authority Chapter 1-41 Mandatory Quality Assurance Program](#) (1200 TN 496 01/28/2000, updated 11/3/2020) specifies that the Agency's Chief Information Officer (CIO) is authorized to develop and coordinate the mandatory Agency Quality Program and direct its implementation among program offices, laboratories, regional offices, contractors, and grantees producing environmental information for EPA. The CIO has re-delegated the authority, under the Re-Delegations of Authority Manual Chapter 1-41, effective 11/3/2020, to the Office Director, Office of Enterprise Information Programs, for reviewing and approving Quality Management Plans (QMPs) and conducting management assessments of EPA quality systems

Region 5 has a centralized quality system, in which the Regional Administrator has delegated QA responsibilities to the Regional Quality Assurance Manager (RQAM) and Regional QA staff. The RQAM is responsible for developing and documenting Regional QA policies, procedures and guidance; overseeing the implementation and assessment of the Regional quality system; and providing QA training.

1.6.1 Regional Administrator and Deputy Regional Administrator

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

- Designate at least one representative (RQAM) for quality management activities to advise and assist the RA and senior managers in the planning, implementation,

documentation, and assessment of the quality management systems for organizations under their responsibility;

- Ensure that all Regional components and programs comply fully with the EPA data quality standard, including the preparation of a QMP for the Region, implementation of an effective Regional quality system, and the timely submission of QA Annual Reports and Work Plans (QAARWPs) to the EQMD;
- Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in this QMP;
- Ensure that all environmental programs implemented through extramural agreements comply fully with applicable requirements of the EPA data quality standard;
- Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments meet minimal program data quality objectives, are of sufficient quantity and adequate quality for their intended use, and are used consistent with such intentions;
- Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA and QC activities that they may be expected by EPA to perform;
- Ensure that assessments are performed every three to five years (or more frequently where necessary) of internal Regional organizations conducting environmental programs to determine the conformance of their mandatory quality management system to their approved QMPs and the effectiveness of their implementation;
- Ensure that deficiencies highlighted in the assessments are appropriately addressed;
- Identify QA and QC training needs for all levels of Region 5 management and staff and provide for this training; and
- Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) (CEs), or language within existing CEs, that are commensurate with the quality management responsibilities assigned by this QMP.

The RA authorizes the Division and Office Directors to be responsible for quality assurance development and implementation in accordance with this QMP. The RQAM within LSASD has been authorized to conduct oversight and management of the Region 5 quality system.

1.6.2 Laboratory Services and Applied Science Division Director

The Laboratory Services and Applied Science Division Director serves a dual role as Director of a Regional division and as the Senior Staff member with oversight of the Regional quality system.

1.6.3 Science and Quality Assurance Branch (SQAB) Chief

The Branch Chief of SQAB serves as the first line supervisor of the RQAM and the QA Staff. Major responsibilities include:

- Supporting the RQAM and other QA Staff with required resources;
- Meeting regularly with QA Staff to provide feedback and guidance on QA matters;
- Reviewing and approving recommendations relating to QA matters; and

- Acting as an advocate for the QA program and QA office needs for effective implementation and oversight of EPA's QA policies and working to overcome barriers;
- Analyzing the level of Region 5 QA activities, assessing QA resources, and providing recommendations to senior management on the adequacy of QA resources to accomplish program and Regional goals;
- Assisting with resolving QA-related issues at the lowest staff or management level feasible;
- Reviewing and approving QA documentation, as needed.

1.6.4 Regional Quality Assurance Manager (RQAM)

The Regional Administrator has delegated the responsibility and authority to implement the Regional quality system to the RQAM. The RQAM works with the QA Staff and managers to ensure implementation of the Quality System. As explained in Section 1.5 of this QMP, the Regional QA Manager position is located within the Science and Quality Assurance Branch of the Laboratory Services and Applied Science Division. The Regional QA Manager has independence in all QA matters and has the ability to directly and independently interact and communicate with the DRA. This direct access to the DRA allows the RQAM to independently elevate critical quality-related issues at his/her discretion without challenge. Conditions which might require management intervention involving issues the QA Office does not have the authority to unilaterally decide upon could include, but not be limited to:

- Significant or fundamental changes to Regional QA policy as set forth in this QMP;
- New or changing QA training requirements different from what is documented in the QMP;
- The need for additional QA resources such as full-time employees (FTEs), travel funds, training dollars; and
- Regional personnel or financial assistance recipients who knowingly and willfully refuse to comply with Agency and/or Regional QA requirements.

The process to obtain management intervention would begin by the RQAM working through the SQAB Chief and LSASD Deputy Division Director for their support and assistance in addressing the issues and for contacting other managers who may need to be involved. For those issues that cut across programs and divisions, the LSASD Director would send an email to the RA and DRA asking to be placed on the agenda for the weekly Senior Staff meetings to brief them about the situation and to get their concurrence on changes to Regional QA policy; their agreement with new or changing QA training requirements; their support for additional QA resources; their help with addressing any Regional personnel or financial assistance recipient who refuses to comply with Agency and/or Regional QA requirements; or their assistance with any other situation that might require management intervention. If this process leads to disputes, the dispute resolution as described in Section 1.7 is followed.

The main responsibility of the RQAM is quality assurance oversight and ensuring that all personnel understand the QMP and their QA and QC responsibilities. The RQAM reviews and approves a variety of quality system documents and provides additional QA support as needed. The RQAM responsibilities include:

- Facilitating QMP development and approval and preparing updates to the approved QMP;
- Representing the organization to OMS, EI, OEIP, EQMD and other groups on matters pertaining to the EPA Data Quality Standard, general quality management issues, and to QA and QC activities;
- Providing expert assistance to staff in the organization on QA and QC policies, requirements, and procedures applicable to procurement and technical activities;
- Ensuring systematic planning processes are used to determine technical and QA/QC activities for intramural and extramural environmental data operations; that the results of the planning process are documented in planning documents, such as a quality assurance project plan (QAPP) or sampling and analysis plan (SAP); and that technical procedures and practices are documented in standard operating procedures (SOPs);
- Reviewing and approving QMPs, QAPPs, SAPs and other quality documents submitted by intramural programs, and by holders of extramural agreements prior to initiation of field activities;
- Delegating approval authority for QA project plans in accordance with Sections 4.1.3.1 and 7.2.6 of this QMP;
- Identifying QA and QC training needs for the Region;
- Overseeing QA and QC implementation in the environmental programs conducted by or for the Region;
- Conducting Technical Assessments; identifying non-conformances; documenting findings; requiring documented responses and corrective actions to findings; and monitoring the effectiveness of the implemented corrective actions;
- Conducting Quality System Assessments; identifying non-conformances and program weaknesses; documenting findings; requiring documented responses and corrective actions to findings; and performing follow-up reviews to assess the effectiveness of the implemented corrective actions;
- Preparing Regional QA policies, procedures, and guidance to facilitate implementation of National QA requirements;
- Working with Regional programs to ensure appropriate QA language is developed and incorporated into contracts, financial assistance agreements, memoranda of understanding/agreement, administrative orders, consent decrees, and other agreements which address environmental data operations;
- Providing input to and comment on Agency-wide QA policy by performing peer review of documents and participating in National workgroups;
- Preparing QA Annual Reports and Work Plans (QAARWPs) and submitting to senior management and OMS, EI, OEIP, EQMD;
- Implementing program record-keeping procedures to ensure tracking and maintenance of quality-related documents and records; and
- Assisting with resolving QA-related issues at the lowest staff or management level feasible.

The RQAM has sufficient authority and organizational freedom to carry out the above responsibilities. The RQAM will identify any issues associated with these responsibilities and bring such issues to the attention of senior management including the RA and DRA. The RQAM will recommend solutions to quality issues through appropriate management chains channels. If the issues or recommendations for solutions remain in dispute, Section 1.7 of this QMP addresses potential routes for dispute resolution.

1.6.5 Science and Quality Assurance Branch – QA Staff

The QA staff provide assistance to the SQAB Branch Chief and RQAM in the oversight and management of the quality system. The responsibilities of the permanently assigned QA staff include:

- Assisting the RQAM with the development and maintenance of the QMP;
- Providing input to the QAARWP as requested;
- Reviewing QMPs from contractors, regional state, tribal, local, or other government program offices;
- Assisting with the development of quality system documents and policies;
- Reviewing QAPPs, SOPs, Quality Assurance Review Forms (QARFs), and other program and project-level documents as requested, and recommending approval actions;
- Developing and presenting QA training as assigned by the RQAM or SQAB Chief;
- Providing technical assistance on QA-related issues as requested;
- Providing assistance to staff in the Region on QA and QC policies, requirements, and procedures applicable to procurement and technical activities;
- Ensuring systematic planning processes are used to determine technical and QA/QC activities for intramural and extramural environmental data operations; that the results of the planning process are documented in planning documents, such as a quality assurance project plan (QAPP) or sampling and analysis plan (SAP); and that technical procedures and practices are documented in standard operating procedures (SOPs);
- Identifying QA and QC training needs for the Region;
- Assisting the RQAM in overseeing QA and QC implementation in the environmental programs conducted by or for the Region;
- Conducting Technical Assessments as assigned by the RQAM or SQAB Chief; identifying non-conformances; documenting findings; requiring documented responses and corrective actions to findings; and monitoring the effectiveness of the implemented corrective actions;
- Providing input on Regional QA policies, procedures, and guidance to facilitate implementation of National QA requirements;
- Working with Regional programs to ensure appropriate QA language is developed and incorporated into contracts, financial assistance agreements, memoranda of understanding/agreement, administrative orders, consent decrees, and other agreements which address environmental data operations;
- Providing input to and comment on Agency-wide QA policy by performing peer review of documents and participating in National workgroups;

- Assisting with resolving QA-related issues at the lowest staff or management level feasible and working in coordination with the RQAM.

Certain QA Staff within SQAB are assigned to focus areas and serve as QA Office Divisional Leads (DL). The RQAM and DLs work closely to coordinate and communicate on, and support, the QA needs of the Region 5 Divisions and/or Offices. The DLs are the primary points of contact within LSASD for their assigned divisions and liaise with the RQAM and POC (below). This allows for coordinated, efficient management of communication pathways on division-specific issues, needs, documents, and policies. DLs support fellow QA Staff with training as needed. DLs are responsible for leading on all responsibilities described above for their assigned division/office.

1.6.6 Division Directors and Deputy Division Directors

The Division and Office Directors have overall responsibility for their respective quality system. The Director is responsible for ensuring that quality assurance is an identifiable activity within their program(s), for providing adequate resources to support quality system efforts, and for accomplishing the quality assurance objectives of all intramural and extramural environmental data activities within their program(s).

1.6.7 Supervisors and Program Managers

Supervisors are ultimately responsible for the quality of data and environmental operations and include all supervisory personnel at the branch, unit, and section levels. The responsibilities for supervisors include:

- Assessing staff members' QA training needs and arranging for such training with the RQAM;
- Participating in a systematic planning process;
- Assuring that QAPPs are in place before projects begin;
- Ensuring that all sampling, analytical, and data-handling procedures performed within the organization are consistent with accepted scientific principles and EPA mandates, are documented, and adequately reviewed; and
- Ensuring that corrective actions identified in assessments/audits are implemented.

1.6.8 Divisional Project Officers/Project Managers/Work Assignment Managers/Contract Officer Representatives

Project managers are defined, in the context of this QMP, as those individuals assigned the responsibility of handling, directing, or managing a task, site, project, contract, grant, or activity. Region 5 project managers can include, but not be limited to, the following:

- Project officers;
- Team leaders;
- Technical Contacts;
- Work assignment managers;
- Compliance officers;
- Remedial project managers;

- Inspectors; and
- On-scene coordinators

For the purposes of this QMP, the term Project Manager will be used generically to indicate any of the above positions or any other individual acting in the capacity of a Project Manager. Project Managers are responsible for ensuring that the quality assurance requirements in this QMP are met as they relate to their responsibilities. It is recognized that the Project Manager may not have experience in quality assurance. Therefore, it is critical that they work closely with the QA Office to be sure QA issues are appropriately addressed including QA requirements related to grants, contracts, cooperative agreements (CAs), interagency agreements, enforcement-related documents, and special initiatives/projects. Project Managers have primary responsibility for coordinating the following QA and QC activities:

- Ensuring that work assignments, work plans, sampling plans and contract deliverables include appropriate QA documents;
- Ensuring that QAPPs prepared by grantees and contractors are reviewed by QA office staff;
- Ensuring that QAPPs are developed, approved, and implemented for intramural and/or extramural projects;
- Coordinating with the QA Office on the selection and design of audits and performance evaluation materials appropriate for the project;
- Identifying, resolving, and implementing project-specific QA and QC issues (which may include data quality assessment, information management, data integration, and data validation); and
- Providing review and approval of all appropriate QA documents from a programmatic perspective.

1.6.9 Divisional/Office Point of Contact

Division/Office Points of Contact (POC) are defined, in the context of this QMP, as those individuals assigned the responsibility of liaising with the QA Office on QA matters (i.e. QA policies, Regional or the Division's Quality Manuals, QAPPs and SOPs). Divisions/Offices are responsible for the assignments to be entered into SQAB SharePoint site. While the QA Office works with any staff or managers within the division, the POC/Technical Contact (TC) should/may help coordinate certain document reviews and electronic sign-off. Divisional staff work directly with the LSASD Analytical Services Branch for laboratory services and the Science and Quality Assurance Branch for QA support, issues, policies, needs, and training through the QA Office and the request form on the [SQAB SharePoint site](#).

1.7 Dispute Resolution

All parties should make every effort to resolve disputes through discussion and negotiation. For those situations in which issues regarding quality assurance are in dispute, resolution should be sought at the lowest management level practicable. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, management system reviews).

Should agreement not be reached at the lowest management level, the issue will be resolved by the Region 5 senior management team (office and division directors). The Region 5 Deputy Regional Administrator has final dispute authority on all Region 5 quality assurance issues.

1.8 Environmental Data Programs and Operations

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

1.8.1 Office of the Regional Administrator

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

1.8.1.1 Tribal and Multi-Media Programs Office

The Tribal and Multi-Media Programs Office encompasses these Programs:

Tribal Assistance Program – is responsible for helping tribes strengthen their abilities to manage environmental programs in Indian country and to ensure that tribes have a voice in decisions that affect their land, air, and water. This includes the Regional Tribal Operations Committee (RTOC) which serves critical functions in maintaining the government-to-government relationship between EPA and the federally recognized tribes located within Region 5. The RTOC assists with advancing the protection and improving the conditions of tribal health and the environment in Indian country. It serves as a liaison between the National Tribal Operations Committee (NTOC), the tribal nations of Region 5, and EPA Region 5 personnel on national policy issues, and communicates environmental needs and concerns of the RTOC to the NTOC. Region 5 serves 35 federally recognized tribes within the Region.

International Coordinator – assists the Agency with international projects and requests for expertise abroad. The International Coordinator also works with management to distribute announcements for projects abroad assisting foreign governments to establish environmental rules and regulations.

Environmental Education Program – increases public awareness and knowledge about environmental and conservation issues and provides the skills that communities need to make informed decisions and take responsible actions toward the environment. Few environmental data operations are undertaken directly by this program, however, when it does undertake any environmental data operations, all Regional quality policies and procedures are followed.

Environmental Justice Program – U.S. Environmental Protection Agency Region 5 works to achieve environmental justice in its enforcement, permitting and community-

based work, as part of a comprehensive national commitment to consider environmental justice in all aspects of EPA's decision-making process.

National Environmental Policy Act (NEPA) - Using the NEPA process, agencies evaluate the environmental and related social and economic effects of their proposed actions. Agencies also provide opportunities for public review and comment on those evaluations.

Healthy Schools Program – establishes and enhances healthy school environments.

Children's Health Program - serves as the central point of coordination around the protection of children, primarily through an integrated approach to improving indoor environments, e.g. healthier housing and healthier learning environments.

Opportunity Zones and Smart Sectors Program - EPA grants and other financing, technical assistance, tools, and publications can help communities ensure that new investment brings environmental and public health benefits, in addition to economic revitalization. Qualified Opportunity Zones are census tracts of low-income and distressed communities designated by state governors and certified by the Department of Treasury. These are areas where new investments, under certain conditions, may be eligible for preferential tax treatment.

1.8.1.2 External Communications Office

The External Communications Office (ECO) is responsible for external communications to the media and the public regarding Region 5 activities. The ECO includes two sections: the Public Affairs Section and the Web Communications Sections.

1.8.2 Air and Radiation Division

The Air and Radiation Division (ARD) implements the programmatic aspects of Clean Air Act (CAA) within the geographic boundaries of Region 5, except for inspections and enforcement, which are principally managed by the Enforcement and Compliance Assurance Division (ECAD).

Under this statute and in accordance with implementing regulations and agency guidelines, the Division conducts activities to reduce emissions so that air pollution does not constitute a threat to public health, safety, well-being and the environment. To carry out its mission, the Division works with other federal agencies, state and local agencies, tribal governments, the public, and the private sector. The Division coordinates with the Headquarters Office of Air and Radiation to ensure national consistency and strives to meet legal deadlines imposed by the Clean Air Act (CAA).

1.8.3 Mission Support Division

The Mission Support Division (MSD) provides leadership, support, communications and direction to ensure efficient operations vital to EPA and Regional goals. MSD is a resource management office responsible for: personnel, facilities, and space; financial management, including budgeting; information services; grants, contracts, and procurement; and other support

services. No significant environmental data operations are performed directly by this office. Its role in supporting environmental programs is discussed below.

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

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

The Information Management Branch (IMB) consists of the Information Technology Section and the Information Services Section. IMB is the central point for Region 5 information technology solutions and management of information resources, in support of EPA's mission, through efficient use of infrastructure and resources. This Branch is also responsible for the Region's Local Area Network and related Information Technology (IT) infrastructure, the purchase and upkeep of computer hardware and software and technical support for the Region's Geographic Information Systems (GIS), providing web access, desktop computing, IT security and local applications development support. Additional information on these functions can be found in Section 6.0 of this QMP.

The Health and Safety Team is a part of the Employee Services Branch of the Mission Support Division. The Health and Safety Team provide support to all Region 5 personnel in order to ensure a safe and healthy workplace is maintained. The Team provides support in the following areas:

- Provides support and guidance to senior management for implementation and compliance with all aspect of the Region's safety, health and environmental management programs;
- Provides support to the region to ensure compliance with all EPA health and safety orders, rules and regulations, OSHA, State and local regulations;
- Implementation of the Occupational Medical Surveillance Program through Federal Occupational Health; and
- Implementation of the Region's respiratory protection program.

1.8.4 Enforcement and Compliance Assurance Division

The Enforcement and Compliance Assurance Division (ECAD) is responsible for developing and implementing Region 5 enforcement and compliance assurance programs and statutes EPA administers in Indiana, Illinois, Michigan, Minnesota, Wisconsin and Ohio and authorized Tribes.

ECAD works closely with the other Region 5 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. The program includes:

- developing strategic planning for enforcement;
- engaging in compliance monitoring and compliance assistance activities;
- conducting inspections;
- developing enforcement cases;
- preparing and issuing administrative actions;
- assessing penalties;
- developing judicial enforcement actions;
- negotiating settlements; and
- measuring and reporting results of the Region's enforcement efforts.

This Division also implements the following programs:

- Asbestos School Hazard Abatement Act of 1984 (ASHAA)
- Asbestos Hazard Emergency Response Act of 1986 (AHERA)

1.8.5 Laboratory Services and Applied Science Division

The Laboratory Services and Applied Science Division (LSASD) provides laboratory analytical support for the region's media programs and enforcement programs, as well as limited field services, the Region's quality assurance program, and the drinking water laboratory certification program.

LSASD coordinates with regional media and enforcement programs to ensure effective collection and analysis of environmental data. It ensures that data collected, reported and used in the region is properly documented and sufficiently accurate and precise to meet data quality objectives. It also ensures that the quality assurance programs of the environmental programs in the Region's states, tribes and local governments conform with EPA quality assurance guidance as well as helps facilitate corrective actions, when needed, in coordination with programs (e.g. lab fraud cases).

LSASD provides limited field support for regional programs, such as risk assessments and other toxicology support. It ensures the integrity of technical products, peer review, science inventory, science hub services, and general regional scientific integrity issues.

LSASD also advises the Regional Administrator and senior management on regional and national policies and issues in these areas.

1.8.6 Land, Chemicals and Redevelopment Division

The Land, Chemicals and Redevelopment Division (LCRD) implements portions of the Resource Conservation and Recovery Act, including management of hazardous waste, solid waste, underground storage tanks, and leaking underground storage tanks. It also implements the regional Brownfields program, as well as programs associated with the:

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Residential Lead Based Paint Hazard Reduction Act
- Toxic Substances Control Act (TSCA)
- Pollution Prevention Act of 1990 (PPA)

LCRD responsibilities include:

- Remediating hazardous waste at sites where human health or the environment are threatened;
- Helping states develop state programs under the statutes above and authorizing and approving state programs;
- Issuing permits under those statutes; and
- Implementing joint EPA/state/tribal multi-media plans and recommending the award of program grants to states and tribes.

Work is accomplished through interaction with other federal agencies, states, tribes, local governments, non-profit organizations, the regulated community, and the public.

1.8.7 Office of Regional Counsel

The Office of Regional Counsel (ORC), under the supervision of the Regional Counsel, serves as a central legal office providing regional and national leadership in the environmental arena, particularly in the area of enforcement.

1.8.8 Superfund & Emergency Management Division

The Superfund and Emergency Management Division (SEMD) implements and enforces the Comprehensive Environmental Response, Compensation and Liability Act (Superfund) (CERCLA), the Oil Pollution Act, the Emergency Planning and Community Right to Know Act, the National Oil and Hazardous Substance Pollution Contingency Plan and the National Response Plan.

SEMD provides emergency response capability, and implements emergency planning, preparedness and prevention activities in preparation for hazardous materials responses during environmental incidents.

SEMD also is responsible for implementing regulatory/enforcement authorities and conducting inspections under: Section 112(r) of the 1990 Clean Air Act Amendments (Risk Management Program); EPCRA Section 304 and CERCLA Section 103 (chemical release notification); EPCRA Section 311 (material safety data sheet submission); EPCRA Sections 312 and 313 (annual chemical release / toxic release inventory reporting); and Section 311 of the Clean Water Act (as amended by the Oil Pollution Act) –the Spill Prevention, Control, and Countermeasure Plan Program.

The remedial response function implements Superfund site evaluation, site investigation, site remediation, long-term stewardship and revitalization programs for NPL sites and for long-term removal (non-time critical and certain time critical) sites.

1.8.9 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 Water Division implements the Clean Water Act, the Safe Drinking Water Act, and the Marine Protection, Research and Sanctuaries Act, except for inspections and enforcement, which are principally managed by the Enforcement and Compliance Assurance Division. The Water Division also supports cross-cutting EPA programs such as the Urban Waters program, Healthy Watersheds Protection and Restoration, and other geographic initiatives.

1.8.10 Great Lakes National Program Office

The Great Lakes National Program Office (GLNPO) coordinates U.S. efforts with Canada under the Great Lakes Water Quality Agreement to restore and maintain the chemical, physical and biological integrity of the Great Lakes Basin ecosystem.

GLNPO manages and implements programs pertaining to Areas of Concern, the Great Lakes Legacy Act, science-based activities related to the health of the Great Lakes, binational lakewide management, and nutrients.

GLNPO brings together federal, state, tribal, local, and industry partners under the strategic framework of the Great Lakes Restoration Initiative to accomplish the objectives of GLRI) action plan which in turn fulfills the aims of the Great Lakes Water Quality Agreement (GLWQA). GLNPO:

- remediates contaminated sediments under the Great Lakes Legacy Act (GLLA);
- works to reduce persistent toxic chemicals, and identify emerging contaminants;
- identifies, protects and restores important habitats;
- monitors and reports on environmental status and trends;
- supports community-based Remedial Action Plans for Areas of Concern (AOCs) and for Lakewide Action and Management Plans;
- assists Great Lakes partners through grants, interagency agreements and contracts.

2.0 QUALITY SYSTEM COMPONENTS

To meet its stated mission to use environmental data as defined in QMP section 1.1, Region 5 must implement a quality system that assures environmental data are of known quality and can be used for their intended purpose. The principal components of the Region 5 quality system are quality system documents, management assessments, quality planning, project planning documents, standard operating procedures, project-level assessments, and quality assurance training for managers and staff.

The following tools are employed to implement the principal components of Region 5's quality system:

- Quality Management Plans (quality system documents)
- Quality Assurance Annual Report and Work Plan (quality system documents)
- Quality System Audits and Management System Reviews (management evaluations)

- Quality Assurance Project Plans (project-level documents)
- Systematic Planning Processes (project-level planning)
- Data Quality Assessments (project-level evaluations)
- Technical System Audits (project-level evaluations)
- Performance Evaluations and Proficiency Testing (project-level evaluations)
- Peer Review (project-level evaluations)
- Quality Assurance Program Plans (program-level documents)
- Standard Operating Procedures (routine procedures documents)
- Information Quality Guidelines (routine procedures documents)
- Consistent Field Operations (routine procedures documents)
- Quality Assurance Training (quality system personnel standards)

Requirements, guidance documents and related resources associated with these and related quality systems tools are identified below and in the References section of this QMP.

2.1 Quality System Documents

2.1.1 Internal Quality Management Plan (QMP)

The Region 5 QMP contains the quality assurance policies, procedures, and management systems which govern the Region 5 quality system. The document describes the quality system in terms of the organizational structures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing activities conducted. Region 5 management is implementing these quality assurance policies to ensure that all environmental data generated and/or used for or by Region 5 are of known and acceptable quality that meet the intended purpose. The Region 5 QMP serves as the umbrella document for all Regional QA operations.

The QMP is developed by the RQAM with assistance from the QA staff and Division and Office Directors. The QMP is intended for use by all Regional staff. A hardcopy of the QMP will be maintained by the Regional QA Office. The QMP will also be accessible to all Regional staff through the Regional Intranet and to external organizations through the Region 5 home page. Approval of the QMP will include the RQAM, Division/Office Directors, and the Regional Administrator. It will then be submitted for approval to the Director of the Enterprise Quality Management Division (EQMD). The approval is effective for up to five years, pending changes to the organization or results from management system reviews. On or before the five-year anniversary, the QMP will be updated as necessary and resubmitted for approval by the RQAM, Division/Office Directors, Regional Administrator, and the Director of EQMD.

2.1.1.1 QMP Reciprocity

If an external organization has a QMP that has been approved by another EPA Organization (i.e. Region, Program Office, ORD Laboratory, etc.) it can be accepted reciprocally by EPA Region 5 as an approved QMP under certain conditions. Those conditions include that the Regional QA Staff shall be able to verify the approval period or expiration date of the QMP, that the EPA organization previously approving the QMP

did actually approve it, and that the QMP addresses the pending work to be performed. The decision to accept a QMP under reciprocity requires a recommendation to do so from the applicable Division/Program and approval by the RQAM. The Division/Program's recommendation is essential to assure the QMP adequately covers the type of work being performed.

2.1.2 External Quality Management Plans for Financial Assistance Agreements

All applicants for Region 5 financial assistance involving environmental data generation or use must prepare a QMP according to the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2. The QMP must describe the management policies, objectives, procedures, organizational authority, roles, and responsibilities to be implemented by the organization to ensure environmental data are of the type and quality needed for their intended use. The QMP will be reviewed by the RQAM or designee for compliance with R-2 and the QMP Review Checklist (<https://www.epa.gov/quality/epa-quality-management-tools-organizations-and-programs>). The QMP must be approved by the RQAM, the Division Directors, and the Regional Administrator for organizations receiving assistance for a multi-divisional environmental programs. The QMP must be approved by the RQAM and the individual Division Director (or delegated Branch/Section Chief), for organizations receiving assistance for an individual program/Division.

The approval of a QMP is effective for up to five years unless significant changes are needed. Extramural organizations (i.e. State agencies), with QMPs approved by Region 5, are required to annually: review their QMPs, assess whether the QMPs reflect their current quality system and report their status (including anticipated or completed revisions of their QMP) to Region 5. On or before the five-year anniversary date, the organization must resubmit the QMP for the same approval as the original document; otherwise, the QMP will be considered out-of-date and no longer applicable. If the anniversary date cannot be met, the organization can request a one-time extension from the RQAM, not to exceed three months beyond the anniversary date.

Under the EPA quality system, QMPs are supported by project-specific QAPPs; however, there may be situations when a single document is applicable. Because of these situations and the fact that the Region supports the use of the graded approach, the RQAM may grant exceptions or modifications to the requirement for a QMP from an organization receiving financial assistance from Region 5. Each exception or modification will be determined on a case-by-case basis and documented by the QA Office. A quality planning/management document in place of a QMP will still be required but the content of this document will be defined by the RQAM. In general, organizations receiving financial assistance may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

- small grants as defined by the EPA [Small Grants Policy](#);
- one-time, short-term, and special projects or projects of limited scope; and
- organizations using or generating environmental data through Environmental Education grants (EE Grants), will not publish the data. If data is to be published as a result of an environmental education grant, a full QAPP along with review/approval by the QA Office will be required.

If an organization is granted an exemption or modification, it will be documented on the Programmatic Certification-Authorization to Award an Assistance Agreement form or QARF and will only apply to the QMP requirement.

2.1.3 Quality Assurance Annual Report and Work Plan (QAARWP)

The QAARWP summarizes Region 5's QA activities of the previous fiscal year and the planned QA activities for the upcoming fiscal year. The Region 5 QAARWP is prepared based on Chapter 4 of CIO 2105-P-01-0 by the RQAM with input provided by the Division/Office Representatives. The QAARWP will be electronically submitted by the RQAM to the EQMD by the date specified in the call memo from the CIO. The QAARWP will also be used to identify minor changes/updates to the Region 5 QMP. If significant changes have been made to the Region 5 QMP, such as changes in organization or Regional policies, a copy of the revised Region 5 QMP will be submitted along with the QAARWP to the EQMD for review and approval by the CIO. Additional discussion of the QAARWP is provided in Section 7.1.2.

2.1.4 Division/Office Quality Manuals

Divisions/Offices may choose to develop and maintain Quality Manuals specific to their programs. These manuals would provide a more in-depth explanation of how QA is handled in these specific Divisions/Offices. The manuals will comply with this QMP. Review and approval of such Quality Manuals will be done at the Division/Office level. The QA Branch will not be an approver of these documents. As requested by the Division, the QA Branch may review the documents to ensure they are consistent with the Regional QMP. If the QA manual is found to be inconsistent with the Regional QMP, then the Regional QMP will be followed.

2.2 Management Evaluations

2.2.1 Quality System Audits (QSAs) and Management System Reviews (MSRs)

The success of the Region 5 quality system depends on its continuing effectiveness in meeting the Regional mission requirements. In order to ensure the on-going effectiveness of the Regional quality system, periodic internal management assessments will be conducted to provide managers with an evaluation of the program. Management system reviews (MSRs) and/or quality system assessments (QSAs) will be used to determine the effectiveness of, and adherence to, the quality system and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. In addition to periodic internal management assessment, Region 5's quality system is subject to external assessments by the EQMD at least once during the 5-year QMP approval period.

Additional information on MSRs and QSAs of Region 5 and external organizations is provided in Sections 9.2.1 and 9.2.2.

2.3 Project-Level Documents

2.3.1 Quality Assurance Project Plans (QAPPs)

EPA policy requires that all work performed by or on behalf of EPA involving environmental data operations shall be implemented in accordance with an approved Quality Assurance Project Plan (QAPP). A QAPP is a document describing in comprehensive detail the necessary QA, QC and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria or quality. The QAPP is a critical planning document for any environmental data operation since it documents how environmental data operations are planned, implemented, documented, and assessed during the life cycle of a project/task. The ultimate success of a project depends significantly on the adequacy of the QAPP and its effective implementation. In some circumstances, quality planning documentation other than a traditional QAPP may be more applicable to a specific situation. For samples to be accepted at the laboratory, a minimum of a generic QAPP must be on file, detailing SOPs to be used for the analysis being conducted. If work comes into the lab stating that QA documentation is not necessary, there must be a form on file, approved by the RQAM, documenting this determination.

Requirements for the preparation, review, approval, implementation and revision of QAPPs are described in Sections 7.2.2- 7.2.3.

2.3.2 Systematic Planning Process

Projects involving environmental data operations shall be planned using a systematic planning process. The systematic planning process is based on a graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources. All program and project managers are responsible for (1) specifying their data quality needs prior to the initiation of data collection and/or usage; (2) providing adequate resources to ensure that the needs will be satisfied; and, (3) ensuring that the quality control and quality assurance requirements are written and satisfied for all environmental data operations. This includes modeling projects and the use of historical data for decision making purposes. All personnel involved with environmental data operations, including field, laboratory, project and data processing personnel have the responsibility for ensuring the quality of the data associated with those measurements.

A documented systematic planning process, such as U.S. EPA's data quality objectives (DQO) process shall be used as a mechanism for balancing the sometimes-conflicting demands and data quality needs to ensure that environmental data operations will effectively support decision-making. Divisional Project Officers and Technical Contacts must be involved in project planning sessions, such as scoping meetings. The process focuses attention on the relationship between data quality and the likely effectiveness of the final decision that will be based on the data. This allows the decision maker to balance the concrete costs of environmental data operations against the less tangible costs, or risks, of making a decision based on uncertain data.

Sections 7.2 and 9.2 provide additional detail regarding the use of systematic planning as well as guidance for the DQO process.

2.4 Project-Level Evaluations

2.4.1 Data Quality Assessments (DQAs)

During the assessment phase, the data are verified and validated to ensure that the sampling and analysis protocols specified in the QAPP were followed, and that the measurement systems performed in accordance with the criteria specified in the QAPP, and the DQA proceeds using the validated data set to determine if the quality of the data is satisfactory. Data verification and data validation processes used by Region 5 are discussed in section 9.4.

Data Quality Assessment (DQA) is a statistical and scientific evaluation of the data set to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The DQA completes the data life cycle by providing the assessment needed to determine if the planning objectives were achieved. DQA begins with a review of the planning documentation and end with an answer to the question posed during the planning phase of the study. Section 9.5 describes Region 5's DQA policy and process.

2.4.2 Technical System Audits (TSAs)

The technical systems audit (TSA) is a thorough, systematic, typically on-site, qualitative inspection of facilities, equipment, personnel, training, procedures, record-keeping, quality control practice and data validation, data management, and reporting aspects of a system. The TSA applies to both field and laboratory audits. The TSAs are performed prior to, and during the data collection activities in order to verify the existence, and to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the QAPPs. Additional system audits (e.g., field audits of sample collections, laboratory analysis, etc.) may be conducted during the data collection activity as needed. Section 9.3 provides additional information on conducting TSAs.

2.4.3 Performance Evaluation (PE) and Proficiency Testing (PT)

Performance Evaluation (PE) is defined as a type of assessment in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst, measurement system/device, or laboratory. The key component of a PE assessment includes the incorporation of a calibrated device or material traceable to a known reference standard into the measurement system to check the analytical procedure. Samples used for the purpose of performance evaluation are often called "PE samples". These samples are used to control and evaluate the accuracy and precision of the measurement systems, and to determine whether DQOs have been satisfied. These samples can be introduced into the measurement system as single blind (the sample composition is known, but concentration is not) or as double blind (both sample composition and concentration are unknown).

Proficiency Testing (PT) is a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source (NELAC standard, June 2000) which has been approved by the National Institute of Standard and Technology (NIST). These unknown samples are called "PT samples" which is equivalent to "PE samples".

2.4.4 Peer Review

Peer review is a critical part of the environmental data generation process that enhances the credibility and integrity of scientific and technical documents and ensures the quality of products disseminated by Region 5. Peer reviews are documented reviews of scientific and technical work products by qualified individuals (or organizations) that are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is performed to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

To be most effective and efficient, peer review of a scientific or technical work product must be incorporated into the up-front planning of any decision or action that will be made or taken based on the work product. The planning for peer review activities should occur at the time of overall project planning and includes obtaining the proper resource commitments and establishing realistic schedules to accommodate the peer review process. Peer review is not restricted to the nearly final version of a report or similar work product. In fact, peer review of the planning documents such as QAPPs, study designs or research plans can often be extremely beneficial to avoid fundamental and costly errors in the study design. Proper advance planning by the project or program manager is essential to ensuring a positive and seamless peer review experience.

The peer review requirements are different depending on the nature of the work product and/or relevant statutory requirements. Per EPA's 2006 Peer Review Policy, whatever the nature of the work product, "peer review is encouraged and expected for all scientific and technical information that is intended to inform or support Agency decisions". General guidelines for informal and formal peer review are outlined in the EPA Peer Review Handbook, 3rd edition (2006) and its 2009 Addendum.

2.5 Program-Level Documents

2.5.1 Quality Assurance Program Plans (QAPrP)

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

A QAPrP may incorporate elements of a QMP. QAPrPs are expected to cite regulatory objectives and criteria for decision making. The program should define the documentation requirements for its activities. Either EPA guidance or independently developed guidance may be specified. QAPrPs should include copies of relevant sampling or other field standard

operating procedures (SOPs), copies of relevant laboratory QA Plans/Manuals and/or SOPs or laboratory Statements of Work and discuss data reporting and review procedures.

Requirements for the preparation, review, approval, implementation and revision of QAPrPs are described in Sections 7.2.3- 7.2.5.

2.6 Routine Procedures Documents

2.6.1 Standard Operating Procedures (SOPs)

Standard operating procedures (SOPs) are written documents that describe the steps to be taken to complete an operation, analysis or action with thoroughly prescribed techniques and steps. Regional routine technical and administrative activities will be documented in an SOP to ensure consistency in the quality of the product. The SOPs will include described steps and techniques, will be sufficiently clear to be understood by a person knowledgeable in the general concept of the procedure, and will be officially approved as the method for performing certain routine or repetitive tasks.

Details regarding the Regional SOP System, the preparation, and the review and approval process for SOPs are described in Section 8.1 of this QMP.

2.6.2 Information Quality Guidelines (IQGs)

EPA's Information Quality Guidelines (IQGs) describe EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. Thus, the IQGs are integral to the Regional Quality System for ensuring the quality of EPA's data products and information. "Information" generally includes any communication or representation of knowledge or position/policy such as facts or data in any medium or form. This includes "preliminary" information that EPA has endorsed or adopted as well as conclusions or facts drawn from or based upon other existing information. This QMP incorporates by reference all definitions, principles, policies and procedures found in EPA's IQGs: Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

Section 7.1 of EPA's IQGs require that each organization (Region 5 in this case) implement procedures to ensure that information is reviewed before it is disseminated and has developed Pre-Dissemination Review Guidelines (PDRGs).

To be most effective and efficient, both the IQGs and pre-dissemination review should be incorporated into the up-front planning for any information that will be disseminated by Region 5. That is, the plans for and process of pre-dissemination review must be addressed in the program's and/or project's QAPP or other QA document(s).

During the planning process and prior to information release, staff should inform their direct supervisor of information products that are being developed for dissemination as described in the IQGs. Questions regarding applicability of the IQGs to a particular information product can be directed to the Region 5 Information Quality Guidelines Officer. Supervisors are responsible for ensuring that information subject to the IQGs is identified before it is disseminated by their

group. Supervisors should also determine what mechanism for reviewing the information is appropriate before it is disseminated. Each Project Manager is responsible for ensuring that the IQGs and PDRGs are applied appropriately to their respective projects.

2.6.3 Consistent Field Operations

The U.S. EPA Regional Science & Technology (RS&T) Field Operations Group (FOG) developed the Quality Assurance Field Activities Procedure (QAFAP) (a.k.a., Field Operations Guidelines or FOG) to ensure consistency in managing field practices and to reduce potential vulnerabilities. The ten FOG Guidelines are based on best practices for data collection as determined by EPA field groups, EPA quality requirements, and concepts of management systems established by the International Organization for Standardization (ISO) including ISO 17025 and 17020. They are intended to apply to any field activities such as sampling, measurements, and observations used by EPA for any purpose, such as routine ambient monitoring, research, clean-ups, risk management, studying new/revised regulations, screening, compliance monitoring, and enforcement.

The FOG Guidelines provide the foundation for ensuring the quality of the data generated by EPA and used for decision making. If the data quality is compromised at any point from collection to reporting, costly mistakes could result and undermine the Agency's sound science foundation. Therefore, it is of great importance that all data within the Agency be generated using consistent processes.

The FOG Guidelines are minimum requirements for establishing a quality management system to support field activities for the Agency. The basis of the FOG Guidelines is CIO 2105.0 and Agency QMPs as required under CIO 2105-P-01-0 and EPA QA-R2. As CIO 2105.0 applies to all programs that collect, evaluate, and use environmental data for EPA, the FOG Guidelines were developed specifically for implementing field activities under CIO 2105.0. The FOG Guidelines are relevant and beneficial to all Agency organizations that collect environmental data, regardless of the data's intended use. Implementing the FOG Guidelines will reduce potential vulnerabilities and will increase EPA's ability to make reliable, cost-effective, and defensible decisions.

The FOG Guidelines have been formally incorporated into CIO 2105-P-02.0 EPA QA Field Activities Procedure (September 2014). This CIO Procedure has effectively documented the FOG Guidelines as requirements for EPA organizations.

It is the Agency's goal that all EPA organizations will fully implement the FOG Guidelines with the Enforcement & Compliance Assurance Division and Laboratory Services and Applied Science Division jointly coordinating Region 5's implementation. In addition to infrastructure development such as tracking systems and processes/procedures, aspects of the QAFAP Guidelines will be incorporated into the Region 5's quality system documentation and all applicable project-level quality planning documentation which involve field environmental data operations.

The following summarizes the ten FOG guidelines:

1. Personnel/Training. Personnel responsible for field activities will have appropriate records documenting qualifications, education, training, experience, and competency for carrying out requirements of field activities.
2. Document Control. Field groups will maintain a system for the control of all documents relating to their field activities, including the preparation, review, approval, issuance, revision, revocation, and archiving of documents. Controlled documents (policies, SOPs, SOP compendiums, guidance, blank template forms, and checklists) are generated internally for each organization and describe how work will be conducted.
3. Records Management. Field groups will maintain a records management system to suit their particular circumstances and to comply with applicable federal, EPA, and regional records management regulations and retention schedules.
4. Evidence Management/Sample Handling. Evidence includes samples, measurements, and documentation, such as field notes and instrument charts. Field groups will establish and maintain procedures for the identification, transportation, handling, protection, storage, and retention of samples and other potential evidence during field studies in accordance with federal criteria for various types of evidence.
5. Field Documentation. Field groups will establish and maintain procedures to document all field activities to ensure the credibility of all observational, measurement, photographic, and sample collection information.
6. Field Equipment. Field groups will establish and maintain procedures for field equipment to ensure all equipment is properly identified, maintained, and calibrated.
7. Field Inspections and Investigations. Field groups will establish and maintain procedures for planning field investigations and inspections, taking into consideration all applicable EPA and program-specific requirements.
8. Reports. Field groups will establish and maintain a procedure describing minimum standards for the preparation of a written report to summarize results of field activities and compliance inspections.
9. Internal Audits. Field groups will establish procedures to conduct internal audits to verify that their operations comply with these guidelines. The personnel performing the audits will be qualified and independent from the functions being audited whenever possible.
10. Corrective Actions. Field groups will establish and maintain a procedure for addressing findings from internal audits through corrective actions whenever nonconformities with these guidelines are identified.

2.6.4 Quality Assurance Training

Region 5 relies on QA training to assure that QA requirements, policies, and responsibilities are recognized, understood, and implemented by Regional staff and managers. All Regional personnel and management involved with environmental data generation or use will be required to have QA training. The specific QA training requirements for the different levels of Regional personnel are detailed in Chapter 3 of this QMP.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

It is Region 5's policy to provide the quality assurance and quality control training necessary to ensure that all persons involved in generation or use of environmental data understand Region 5's quality system. The following sections describe Region 5's QA training program and the requirements for regional personnel involved with environmental data use and generation.

3.1 Region 5's QA Training Policies

Both CIO 2105.0 and CIO 2105-P-01-0 require that EPA quality systems provide appropriate training for all levels of management and staff to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation. It is Region 5 policy to ensure that staff and managers are properly trained and qualified to perform their assigned duties and fulfill their required QA responsibilities. This training policy applies to project managers/officers, laboratory staff, field personnel, data processors, modelers, technical experts, team leaders/managers, QA Managers/Coordinators, and individuals who are responsible for managing and supervising these personnel.

QA training is required for all Region 5 personnel whose job functions involve or are associated with environmental data operations. QA training is intended to ensure that Region 5 personnel understand the Region 5 quality system, their respective Division/Office's quality system and their specific QA responsibilities. Technical training which impacts the quality of environmental work is also required for Region 5 personnel who are involved with extramural agreements, lead/oversee compliance inspections, among others. The following sections describe responsibilities for Region 5's QA training program and the requirements for Region 5 personnel involved in environmental data operations.

It is important that Region 5 staff and managers maintain technical proficiency in critical discipline areas (i.e. chemistry, engineering, toxicology, geology, etc.) as well as QA requirements in order to successfully perform their assigned work functions.

3.2 Responsibilities for QA Training

The RQAM and QA Staff, in conjunction with Region 5 management, are responsible for assessing QA training needs. The QA Office is the primary forum to develop and revise QA training curriculums; design specific QA training sessions; and to identify existing QA training resources.

The RQAM and QA Staff, are responsible for initiating, developing and providing and/or facilitating new or existing QA training for Region 5 managers and staff. Program-specific training will be initiated, developed and provided and/or facilitated by the Division/Office Management, and assisted, when necessary, by the RQAM and QA Staff.

The RQAM and QA Staff will schedule a 3-day QA training workshop for Region 5 personnel and management, as well as Region 5 states and tribal entities, based on descriptions provided in the Region 5 QAARWP. This training workshop will be held every 2 years.

Divisions/Offices will also schedule their QA training commitments (TSAs, field assessments, etc.) as described in the QAARWP.

Additional training may be scheduled based on additional needs identified during each year.

In general, the first-line supervisors are responsible for ensuring that each staff member involved with environmental data operations has the necessary technical, QA, and project management training. While the staff and their respective supervisors are responsible for maintaining staff proficiency in technical areas, the responsibility of identifying QA training needs resides with the supervisor, RQAM, QA Office, and Chief of the Science and Quality Assurance Branch. Region 5 management's commitment to provide resources for required QA training is essential to implement the Region 5 quality system.

3.3 Courses

All Region 5 Quality Staff (RQAM, QA Staff, Division/Office QA Staff, etc) must have a thorough understanding and working knowledge of U.S. EPA, other federal, Regional and program QA requirements. Such knowledge may be acquired through participating in various activities: completing formal QA training/ workshops, QA-related workgroups and attending national and regional QA meetings and conferences. These basic activities will provide the opportunities to ensure that they possess the necessary training to perform their QA duties and, in turn, be able to train Region 5 personnel.

The general QA training requirements for Region 5 personnel whose primary functions involve the review and/or approval of QA documentation (i.e. QMP, QAPP, SOPs etc.) and the assessment of quality systems include the following training (included in 3 day training workshop as well as via R5 recorded webinars):

- Introduction to Quality Assurance and U.S. EPA Quality Systems
- QMP Review and Approval
- Systematic Planning and QAPP Development
- Use of Secondary Data
- QAPP Review and Approval
- Data Verification and Validation
- Conducting Management System Reviews and Quality System Assessments
- Data Quality Assessment

If it is anticipated that an individual's QA responsibilities will not include a specific area (i.e. Data Verification and Validation), the QA training above may be tailored. QA personnel who review quality documents in which the scope includes the design, construction, operations and maintenance of environmental technology may benefit from technical training in such areas. Such training is pertinent to many Region 5 programs. In some cases, the QC and QA aspects of some programs are not clearly flagged as such and training would enable QA personnel to gain a better understanding of their respective programs.

3.4 Documentation of Training

After completion of a course, attendees will receive a certificate of completion from the RQAM or whomever is hosting the training. For this reason, attendees at the courses will be recorded. The QA

Office will maintain a record of all QA training taken by all personnel in FedTalent. This database will provide the record of all QA training, the necessary recertification information, and notes about any waivers. Records for laboratory-specific training for laboratory personnel are tracked in the Qualtrax database.

At the end of each fiscal year, a summary of the QA training will be provided in the QAARWP as requested.

3.5 Training Requirements

In order for the quality system to be effective and to be implemented in a consistent manner throughout the Regional programs and organizations, staff need to be properly equipped with the appropriate level of knowledge of quality assurance policies, principles and procedures. The QA training program is intended to fulfill this need. The staff members who are directly involved in the generation and/or use of environmental data are the primary focus of the training program. However, there are others (such as supervisors, managers and projects managers) who should have at least a familiarity with QA.

Region 5's training program incorporates a tiered approach relative to the functions performed by the various groups of personnel. This section outlines the minimum QA training requirements for the various groups of personnel.

3.5.1 Management

Division and Office Directors are responsible for ensuring the Region 5 quality system is implemented as described and the resources are available in meeting the criteria of the system. Therefore, it is critical that management has a good understanding of the quality system and quality management issues described in the regional QA training course "Introduction to Quality Assurance and U.S. EPA Quality Systems". The individual Divisions and Program Offices with the necessary assistance from the RQAM and QA Office are responsible for identifying needed QA training within their organizations.

3.5.2 Supervisors

Supervisors are ultimately responsible for the quality of data. Therefore, it is critical that supervisors receive the necessary awareness training to ensure their understanding of the importance of quality assurance, their responsibilities as supervisors of environmental data activities, and specific Region 5 quality assurance policies and procedures. Toward that end, supervisors who oversee environmental programs which generate or use environmental data must attend the "Introduction to Quality Assurance and U.S. EPA Quality Systems" course. Additional training, including an introductory course tailored to supervisors' needs, may be provided depending on the specific duties and responsibilities of the individual.

On an annual basis, a report listing the QA training completed by their staff will be sent to each supervisor. A request asking the supervisor to identify any changes to their staff and QA training needs for their staff for the upcoming year accompanies this report.

3.5.3 Project Managers, Lab and Field Personnel

Project managers, lab personnel, and field personnel are responsible for ensuring that all projects are conducted with known quality and are in compliance with the agency standards. In the performance of these functions, the project manager prepares or reviews QAPPs. Therefore, it is critical that project managers receive the necessary training, including “Introduction to Quality Assurance and U.S. EPA Quality System”, “Systematic Planning and QAPP Development”, “QAPP Review and Approval”, “Use of Secondary Data” and “Data Quality Assessment”. Additional training may be identified by the project manager, their supervisor, or the RQAM.

3.5.4 SQAB QA Staff

SQAB QA Staff are responsible for working with the RQAM with quality issues and policies. As part of this responsibility, the QA Staff will assist in writing, reviewing, and/or approving quality documents, including QAPPs, SOPs, and QMPs. Therefore, it is critical that the RQAM and QA Staff receive the necessary training, including “Introduction to Quality Assurance and U.S. EPA Quality System”, “Systematic Planning and QAPP Development”, “Data Quality Assessment”, “Use of Secondary Data”, and “QMP Review and Approval”. Additional training, such as auditor training, may be identified by the SQAB Chief

3.5.5 RQAM

The RQAM is responsible for identifying training needs, disseminating information regarding available training opportunities for Region 5 staff and management, and arranging region-wide quality assurance training as appropriate. Specifically, the RQAM will ensure that:

Coordination occurs with supervisors to provide QA training for them and their staff as requested and as resources allow, including ensuring project managers and EPA personnel have adequate QA training;

- The QA training is made available to all grantees including State and Tribal personnel;
- QA Refreshers are routinely offered to ensure Regional Office staff get recertified in a timely manner; and
- Any special training requests by EPA, state, or tribal personnel are coordinated.

The RQAM is responsible for arranging or providing for the QA training needs identified by the Divisions and Program Offices.

3.6 Assurance for Grants and Contracts

Minimum QA training requirements for grant recipients or contract personnel involved with environmental data generation or use should be described in the organization’s approved QMP. Grantees with a current relationship with EPA are welcome to attend the Region 5 QA training courses. Contractors may attend the training at the written request of their contracting officer or their designee. Project Managers are responsible for providing information about the Region’s QA training to their grant recipients or contract personnel involved with environmental data generation or use to help ensure they have the necessary QA training to successfully complete their granted or contracted tasks and functions.

4.0 ACQUISITIONS AND ASSISTANCE AGREEMENTS

This Chapter summarizes the Federal, Agency and Regional regulations, directives, policies and guidance which are important for acquisition and assistance agreements which include environmental data operations.

It is Region 5's policy to state the designated quality assurance and quality control requirements when acquiring items and/or services that may result in or relate to environmental programs. Within Region 5, procurement functions are conducted in accordance with the Federal Acquisition Regulations and generally accepted business practices for the acquisition process. The Region 5 Quality System does invoke the Agency's graded approach. This approach allows the RQAM a certain degree of latitude in the requirements set forth below. Any deviation from the requirements set forth below must be documented in the project/contract file.

4.1 U.S. EPA Region 5 Policy on Quality Requirements in Extramural Agreements

U.S. EPA Region 5's standard quality requirements, for extramural agreements which include environmental data operations, shall default to terms and conditions which specify that a bidder or applicant will submit the following documentation which complies with the current version of ASQ/ANSI E4 for U.S. EPA's review and approval:

- Bidder's/applicant's quality system described in a quality management plan (QMP) with their bid or application package or at a time prior to award; and
- A project-specific quality assurance project plan (QAPP) at a designated time following notice of award for the extramural agreement.

In most situations, the quality requirements will default to EPA QA/R-2 for QMP requirements and EPA QA/R-5 for QAPP requirements. Additional or alternative quality requirements for extramural agreement may be specified by the Contracting Officer's Representative (COR) (for acquisition agreements) or the grants Project Officer (PO) (for assistance agreements) with the RQAM or a member of the QA Office.

4.1.1 Contracts

The FAR and the EPA Manual 1900 Contracts Management Manual (CMM) provide the basis for the incorporation of quality requirements in acquisition documents. All acquisition agreements, including simplified acquisitions, which include environmental data operations are subject to quality requirements.

4.1.1.1 FAR 48 CFR 46

The Federal Acquisition Regulation (FAR) under 48 CFR 46 Quality Assurance specifies higher-level contract quality requirements under 46.202-4, 46.311 and 52.246-11 for complex or critical items (defined at 48 CFR 46.203(b) and (c)) or when the technical requirements specify:

- Control of such things as work operations, in-process controls, and inspection; or

- Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology (scientific study of measurement).

Further, the higher-level contract quality requirements may be required when the EPA Contracting Officer, in consultation with technical personnel, determines that quality standards (such as ISO 9001, 9002 or 9003; ASQ/ANSI E4; ANSI-ASQ Q9001, 9002 or 9003; QS-9000; AS-9000; ANSI/ASME NQA-1) be cited as quality requirements.

4.1.1.2 EPA Manual 1900 – Contracts Management Manual (CMM)

EPA Manual 1900 – Contracts Management Manual (CMM) Chapters 7.3.5.3 Quality Assurance (QA) Requirements and 46 Quality Assurance

(<http://www.epa.gov/oamintra/policy/ctmn.pdf>) provides guidance for the use of higher-level contract quality requirements for acquisitions. Further, the CMM supplements procedures and requirements contained in FAR 46.202-4 and FAR 52.246-11. The CMM specifies that:

- A QA Review Form (QARF) be completed for all acquisition vehicles including simplified acquisitions, solicitations, contracts, Task Orders, Work Assignments, Delivery Orders and modifications to existing Task Orders, Work Assignments or Delivery Orders that involve a significant change to the Statement of Work. The QARF documents the assessment of whether environmental data operations (environmental data and/or environmental technology) are included in the scope of the acquisition document.
 - The QA review form shall be completed as required and signed by the Project Manager to assure that all environmentally related measurements which are funded by EPA or which generate data mandated by EPA are scientifically valid, legally defensible, and of known and documented quality.
- If environmental data operations are included in the scope of the acquisition, the specific type of quality requirements must be defined in the QARF.
- ASQ/ANSI E4 (current version is E4-2014) applies to the majority of EPA's work requiring higher-level contract quality requirements. Documentation for standards other than or in addition to ASQ/ANSI E4 may be applicable as determined and specified by the RQAM.

4.1.1.3 Quality Management Plans for Contracts

Region 5 contracts involving environmental programs shall submit a QMP prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans (QA/R-2), which describes the quality system implemented by the applicant. The QMP shall be reviewed and approved by the EPA Contracting Officer, the EPA Project Manager, RQAM, and/or QA Office Divisional Lead (if applicable) as a condition for award of any contract. The QMP must be submitted as part of the application.

If the QMP is not submitted as part of the application and EPA decides to award the contract, EPA will include a term and condition in the contract. This term and condition requires the recipient to submit the QMP within a specified time after award of the contract and notifies the recipient that they may not begin work involving environmental programs until the EPA Contracting Officer informs them that the QMP has been approved.

The contractor shall also be required to submit QAPPs to EPA for review and approval by the EPA Project Manager and the QA Office as described in Section 7.2.3 of this QMP before undertaking any work involving environmental programs. All QAPPs shall be prepared using the most current version of EPA Requirements for Quality Assurance Project Plans (QA/R-5), which describes the quality assurance and quality control activities to be implemented to satisfy the performance criteria for the work involving environmental programs.

There may be instances where deviations to these requirements such as submittal of a single document or use of a modified format would be appropriate. Any such deviations will be clearly documented and must have concurrence by the appropriate contracting officer and the RQAM.

4.1.2 SPECIAL CONSIDERATIONS FOR ENFORCEMENT ACTIONS:

For enforcement actions such as Administrative Orders (AOs) or Administrative Orders on Consent Decrees (AOCs), QA Document approval authority may differ from guidelines presented here. Refer to the individual Order for information about EPA's QA document approval authority.

Note: It is recommended that QA requirements are specified in each Order. Additionally, it is recommended that each Order specify the EPA person(s) responsible for approving QA documents prepared by the responsible parties or potentially responsible parties (RPs or PRPs). Generally, QMPs from PRPs are reviewed and accepted/approved by the EPA Project Manager and QA Office Division Lead. This topic may also be addressed in Division Quality Manuals.

4.1.3 Grants and Cooperative Agreements

All applicants will submit a Quality Assurance Review Form (QARF). The QARF will be used to document:

- The assessment of the scope of extramural agreements for environmental data operations;
- Existent and valid QA documentation (QMPs, QAPPs) presence that verifies the workplan's environmental data plans.
- The associated quality requirements if required; and
- Concurrence of the above by COR/TC or grants PO and QA Office member.

These assessments will be conducted throughout all major stages of the extramural agreement lifecycle: planning solicitations for bids or assistance announcements, pre-award review of bid

or application packages, and post-award activities, management and closeout of the agreement. The Region 5 QARF for Extramural Agreements is provided in Appendix C. Pdf fillable versions are available on [Region 5's QA intranet page](#).

Region 5 Divisions/Offices may use equivalent documentation to the R5 QARF. R5 Divisions/Offices may also supplement the standard Region 5 QARF with additional information or questions deemed necessary by the Division/Office or its programs, however all required information on the Region 5 QARF must be completed.

All applicants for grants or cooperative agreements involving environmental data generation or use programs shall submit a QMP prepared in accordance with the specifications provided in the most current version of EPA Requirements for Quality Management Plans (QA/R-2), which describes the quality system implemented by the applicant.

The applicant's QMP shall be reviewed and approved as described in Section 2.1.2 of this QMP as a condition for award of any assistance agreement. The QMP must be submitted as part of the application. If the QMP is not submitted as part of the application and EPA decides to fund the project, EPA will include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the QMP within a specified time after award of the agreement and notifies the recipient that they may not begin work involving environmental programs until the EPA Project Manager informs them that the QMP has been approved. Modification or exceptions to the requirement for a QMP may be granted by the RQAM as identified in Section 2.1.2 of this QMP.

The recipient shall also be required to submit QAPPs to EPA for review and approval by the EPA Project Manager and the QA Office before undertaking any work involving environmental programs. All QAPPs shall be prepared using the most current version of EPA Requirements for Quality Assurance Project Plans (QA/R-5), which describes the quality assurance and quality control activities to be implemented to satisfy the performance criteria for the work involving environmental programs.

As noted previously, U.S. EPA Region 5 standard quality requirements default to submittal of an organization QMP during pre-award and a QAPP for each project under the extramural agreement during post-award. Organizations, environmental programs and the environmental data operations require flexibility on the types of quality requirements which are incorporated into a specific extramural agreement. U.S. EPA Region 5 applies a graded approach to the quality requirements.

Small organizations have different capabilities and resources versus larger organizations including the ability to develop, document and implement a quality system. In some situations, a quality requirement for a separate QMP may not be amenable for small organizations such as Indian tribal governments or a small university research project. In such situations, a joint QMP/QAPP or simply a QAPP alone may be sufficient quality documentation for the extramural agreement. Environmental programs which include multiple projects, either of a similar or dissimilar nature, may also lend themselves to the joint QMP/QAPP with project-

level QAPP supplements or singular QAPPs. Any such deviations will be clearly documented and must have concurrence by the appropriate project officer and the RQAM.

Approval of the recipient's QMP may authorize the recipient to review and approve QAPPs, in place of the RQAM, based on procedures documented in the QMP. Sections 4.2.2.1 and 7.2.6 of this QMP describes Region 5's policy and process for this authorization. Oversight of an organization's QAPP approval process will be part of the MSR process as described in sections 9.2.1 and 9.2.2 of this QMP.

Oversight of QA requirements in the grants and cooperative agreements process is included in the MSRs and program reviews performed by the QA Office on specific environmental programs (see Sections 9.2.1 and 9.2.2 of this QMP). MSRs of both internal programs and external organizations will include a random sampling of the projects for that program or organization (a list of the projects will be requested from the program or organization as part of the MSR) to determine if the projects were correctly identified as including environmental data generation and/or use and if the QA requirements, including approved QAPPs prior to environmental data generation and/or use, were applied and adequately addressed. Additional mechanisms will be developed as needed through the Regional Grants Customer Relations Council established to provide a regionwide forum for the discussion and resolution of matters relating to the management of EPA's assistance programs. The Council includes the Senior Resource Official, the Grants Management Officer, up to two representatives from each division/office with responsibilities for managing assistance activities, grant management specialists and the Financial Management Officer.

4.1.3.1 Delegated Approval Authority

Consideration for QAPP self-approval authority for specific environmental programs delegated to a Region 5 State agency or Indian Tribal government shall be determined on a case-by-case basis but shall require:

- Concurrence by the Region 5 Regional QA Manager and the Regional Administrator on one or more Region 5 Divisions' /Offices' recommendations to provide QAPP self-approval authority;
- Region 5's approval of the state agency's or Indian tribal government's QMP which complies with QMP approval procedures as stated in the Region 5 QMP;
- Specification of annual quality system reporting requirements to be submitted by the state agency or Indian tribal government to Region 5 including:
 - The status of implementation of the approved quality system;
 - An affirmation that the quality system as documented in the approved QMP is being implemented; and
 - A description of any revisions necessary for the quality system or QMP; and
- Quarterly submittal of electronic copies of QAPPs (i.e. pdf files) prepared by, submitted to, reviewed by and approved by the state agency or Indian

tribal government for environmental data operations funded by the extramural agreement. QA Track may be used to submit such self-approved QAPPs

5.0 DOCUMENTS AND RECORDS

This Chapter summarizes the appropriate Federal, Agency and Regional controls for all quality-related documents and records which are important to Region 5's mission.

A **record** is an informational resource, in any format including e-mail messages. The following informational resources may be records if they were:

- Created in the course of business,
- Received for action,
- Needed to document Agency activities,
- Mandated by statute or regulation,
- Needed to substantiate financial obligations or legal claims, or
- Used to communicate EPA requirements.

Per the Federal Records Act 44 U.S. Code, Chapter 33, Section 3301, records are defined as: *all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them.*

Per CIO 2105-P-01-0, a **document** is any compilation of information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs.

Documents and records are maintained in order to conduct the regular business operations of the U.S. EPA. They also provide the means for continuity of operations in the event of emergency situations.

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

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

which has primary responsibility for that program or project. Each Office is responsible for establishing and implementing procedures for identifying and managing records throughout their life cycle and ensuring that procedures conform to established records retention schedules.

This Section of the QMP describes roles and responsibilities for ensuring records and documents used to administer this Quality Management Plan are properly managed. Understanding roles and responsibilities is essential because official Agency records are public assets and belong to the government not to programs, by virtue of their possession, or to individuals, by virtue of their position as Agency officials.

5.1 Records and Documents Pertaining to the Quality Management Plan

The RQAM is responsible for preparing, issuing, using, and revising the Regional QMP in accordance with the most current version of EPA Requirements for Quality Management Plans, EPA QA/R-2.

In accordance with the EPA Data Quality Standard, the EPA Region 5 QMP must be revised every 5 years and resubmitted to EQMD for review and signature approval by the CIO of OMS, EI. Also, the QMP must be reviewed annually and changes/revisions must be reported in the QAARWP. Minor changes to the QMP, as determined by the EQMD, do not require the CIO's signature approval.

The most recent version of EPA Region 5 QMP will be made available to the public on the EPA Region 5 Quality Webpage. It is maintained by the RQAM on the Region 5 SharePoint Site. Superseded versions are archived in the database for reference. All QMP citations must include the document control number and date of revision.

EPA-approved QMPs are kept on file by the Science and Quality Branch. Project Officers/Managers are responsible for providing the QA Office with the final, approved version of all QMPs. The QA Office will be responsible for uploading the final, approved version of the QMP to the R5 SharePoint site (To be created by Spring 2021). This site will be available to Project Officers for review to verify QA requirements are being met.

All SEMD QMPs will be uploaded into SEMS in the associated special collection 38195 by the SEMD QA Office Divisional Lead.

5.2 Records and Documents Pertaining to Environmental Data Operations

The EPA Project Manager is responsible for preparing, issuing, using, and revising Quality Assurance Project Plans (QAPPs), as applicable. The QA Office is responsible for reviewing and approving all QAPPs in accordance with the most current version of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5.

Each Office is the custodian of quality-related documents and records pertaining to environmental data operations that it conducts and manages. As provided for in this QMP, the QA Office has a role in the review and approval of project-specific documents; however, each Office must ensure the management of documents and records according to laws, statutes, policy and program-specific

guidance. Each Office is responsible for managing its QA-related documents (both printed and electronic), including but not limited to:

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

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

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

The RQAM QA Office is responsible for ensuring that all regional quality-related documents and records, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the policies and guidance listed above are managed properly.

Documentation of any project relevant personnel or laboratory certifications and/or accreditations will not be submitted to nor maintained by the Regional QA office but may be submitted directly to the Project Officer as requested. The Regional QA Office will provide assistance to the Project Officer in reviewing and determining the adequacy of such documentation as needed.

6.0 COMPUTER HARDWARE AND SOFTWARE

This Chapter summarizes the primary Agency Policies, Procedures, Standards and Guidance used to ensure that computer hardware, computer software and associated databases which form U.S. EPA's information infrastructure can support U.S. EPA's environmental data operations and on-going missions. Further, it is intended that these Agency Policy documents comply with Federal requirements.

The U.S. EPA's ability to fulfill its mission is dependent upon a strong information technology (IT) infrastructure and information management system. Mission objectives rely on an infrastructure that is capable of supporting environmental information and dynamic communication among EPA offices. The hardware, software, and communication components that are encompassed by IT form the foundation for environmental information and EPA-wide communications. IT management is critical to U.S. EPA's success.

The U.S. EPA OMS and the Office of Information and Technology Operations (OITO) in OMS, EI are responsible for managing the EPA's information technology infrastructure and components. In that role,

OMS, EI and the OITO have established information technology standards to manage and ensure that information technology components integrate properly into the infrastructure.

It is Region 5 policy to work closely with OMS, EI on all phases of information management system development, improvements, and updates. Region 5 will comply with all OMS directives and guidance (including those cited below) which may be found at the following intranet page:

<https://intranet.epa.gov/oms/ei>. As revisions or replacements of these documents may occur during the lifetime of this QMP, it may be useful to consult OMS, EI's list of expired policies as well:

<https://intranet.epa.gov/oms/ei>.

6.1 U.S. EPA Information Management System

The following CIO Policies and associated CIO Procedures, Standards and Guidances establish the Agency-wide requirements for IT systems (including the use of computer hardware and software) and information security:

6.1.1 CIO 2150.3 Environmental Protection Agency Information Security Policy

CIO 2150.3 Environmental Protection Information Security Policy establishes EPA's security program with respect to information and information systems. The Policy provides overarching direction and foundation for information security requirements and defines the roles and responsibilities of key Agency managers. CIO 2150.3 is supported by numerous comprehensive Procedures (under the prefix CIO 2150.3-P-) which address the planning, implementation and assessment of EPA's Information Security program.

6.1.2 CIO 2121.1 System Life Cycle Management (SCLM) Policy

CIO 2121.1 System Life Cycle Management Policy September 2012 establishes a consistent Agency framework to ensure that EPA IT systems are properly planned and managed, controllable, cost effective and that they support the Agency's mission and business goals. The Policy is intended to be consistent with federal statutes including the Clinger-Cohen Act of 1996 as well as EPA's System Life Cycle (SLC), Enterprise Architecture and Information Security requirements. This Policy and supporting documents provide EPA Offices with direction for tailoring and implementing System Life Cycle Management (SCLM) requirements to develop and manage effective and efficient IT solutions.

CIO 2121.1 applies to all EPA IT systems and application projects, both applications and general support systems (GSS). The Policy is applicable to custom developed, commercial off-the-shelf software (COTS) or government off-the-shelf software (GOTS) projects and applies to applications developed for mobile devices. It applies to systems developed on behalf of EPA by contractors irrespective of where the IT systems are hosted including cloud-based solutions. Small desktop applications (i.e. spreadsheets) are excluded from the requirements of this Policy. CIO Procedure 2121-P-03.0 System Life Cycle Management (SLCM) Procedure September 2012 and CIO 2121-G-01.0 System Life Cycle Management (SLCM) Requirements Guidance provides implementation procedures and guidance for CIO 2121.1.

6.1.3 CIO 2122.1 Enterprise Architecture Policy

Enterprise architecture (EA) aligns information management planning with the Agency's business processes, strategic planning and capital investments and EPA's mission, goals and objectives. CIO 2122.1 Enterprise Architecture Policy November 2012 establishes criteria for enterprise architecture (EA) processes, practices and resources at EPA which are required for federal agencies under the Clinger-Cohen Act of 1996, Executive Order 13011 and various Office of Management and Budget (OMB) Circulars. CIO 2122.1 defines the scope, authority, audience and responsibilities for how EA will be developed, maintained, matured and institutionalized. Lastly, CIO 2122.1 facilitates EPA's ability to provide consistent services, accessible information, scalable infrastructure and flexible technology integration.

The following CIO Procedures and Standards provide implementation guidance for the EA Policy:

- CIO 2122-P-01.1 Enterprise Architecture Governance Procedures November 2012
- CIO 2122-P-03.0 Information Technology Infrastructure Standards Procedure October 2010
- CIO 2122-S-02.0 Personal Computer Configuration and Management Standard October 2010
- CIO 2122-S-02.1 Interim Update to the Personal Computer Configuration and Management Standard November 2013
- CIO 2122-P-04.0 Data Exchange and Collection Procedure January 2011

6.2 U.S. EPA Data Standards

All Federal agencies are required to adhere to federally mandated data standards and regulations. It is the policy of Region 5 to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. EPA's data-related policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems for Region 5 and EPA and standards developed in conjunction with States, Indian tribal governments and other consensus organizations.

7.0 QUALITY PLANNING

7.1 Annual Planning

7.1.1 State and Tribal Environmental Agreements

The primary vehicles for annual planning in the Region are U.S. EPA Agency and Regional strategic planning, associated budget processes, Performance Partnership Agreements (PPAs)/National Environmental Performance Partnership System (NEPPs), and state annual program work plans. Based on the Region's budget, guidance from the U.S. EPA National Program Managers (NPMs), and Regional and State perceptions of the greatest environmental risks, the Regional Administrator and the Division/Office Directors establish the Regional fiscal year priorities for use in Regional, State and Tribal program planning. A Regional strategic plan for the fiscal year is developed which establishes the overall goals, priorities for resource utilization, and distribution of the Regional budget.

The PPAs/NEPPs describe overall operating objectives and goals between EPA and the state agencies. The individual program managers negotiate with each appropriate state agency to obtain commitments from them on the work they will complete during the fiscal year. These negotiations with the state agencies result in the preparation of the annual program work plans by the state agencies.

The end result of the above efforts is the establishment of overall operating plans for the Region to meet the goals within each program based on state, Regional, and other available resources. The planning for QA is fully integrated into this planning process. Any specific QA requirements are included in the Environmental Performance Partnership Agreements (EnPPAs), PPAs or associated work plans, and terms and conditions condition related to completing these requirements are specified in the associated grant. EnPPAs and PPAs also provide flexibility to the state agency with the ability to manage funding to individual programs in order to meet their commitments under the agreement.

The General Assistance Program (GAP) was created to assist federally recognized tribes and intertribal consortia to plan, develop, and establish the capacity to implement programs administered by the EPA and to assist in the development and implementation of solid and hazardous waste programs for Indian lands. In addition, the GAP was created to provide technical assistance from EPA to tribal governments and intertribal consortia in the development of multimedia programs to address environmental issues.

EPA recognizes tribal governments as the primary parties for setting standards, making environmental policy decisions, and managing programs for reservations, consistent with Agency standards and regulations. As a result, EPA is committed to using the GAP to build tribal capacity to administer environmental protection programs consistent with the federal laws the EPA is charged with implementing. Through the GAP, the EPA also provides technical assistance to build environmental protection program capacity for tribes that are not implementing federally authorized regulatory programs or that may wish to go beyond federal requirements. GAP helps tribes have opportunities to meaningfully participate in policy making, standard setting, and direct implementation activities potentially affecting tribal environmental protection interests. The program also provides resources for tribal governments to cooperate with and, when appropriate, enter into intergovernmental agreements with federal, state, or local governments in an informed manner.

7.1.2 Quality Assurance Annual Report and Work Plan

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 EQMD, who will submit this report to the CIO for short and long-term planning purposes.

SQAB shall be responsible for tracking and reporting on all QA activities completed by SQAB and compiling information from the other Divisions/Offices on their respective QA activities. Each Division/Office shall track their respective QA activities, not otherwise performed by SQAB, including QMP & QAPP reviews and approvals, assessments, training activities, etc. A representative from each Division/Office shall prepare their respective Division/Office

QAARWP and submit to the RQAM at least four weeks prior to the deadline stated in the annual call letter from the Quality Staff. The RQAM with the Regional QA staff will prepare the Region 5 QAARWP based on the Division/Office inputs and submit the QAARWP to EQMD.

The RQAM and Regional QA staff also identify specific QA activities in the QAARWP which they will directly perform, or coordinate based on available resources, current and projected quality initiatives from the EQMD.

7.2 Project-Level Planning

7.2.1 Systematic Planning Process

A systematic planning process shall be used for the generation and/or use of environmental data conducted by or on behalf of Region 5. The Data Quality Objectives (DQO) process, is an example of a systematic planning process, described in EPA QA/G-4 Guidance for the Data Quality Objectives Process February 2006. While the DQO process is recommended for use by Region 5 and is the default systematic planning process, it is not mandatory. Any systematic planning process may be used but must be documented in the applicable QA planning document (i.e. QAPP, inspection plan) and include the elements of a systematic planning process as defined in CIO 2105-P-01-0, Chapter 3.

For activities and personnel subject to the QAFAP requirements, all field project planning will be conducted and documented in accordance with this section of the QMP and the QAFAP overarching SOP 1740.02 Regional Field Activity Planning, current revision. Where applicable, each program will be responsible for developing and documenting any program-specific procedures for planning field projects and for documenting the results of planning field projects to supplement this QMP and SOP 1740.02.

7.2.2 Quality Assurance Project Plans

All projects and tasks involving the generation or use of environmental data (as defined in Section 2.1 of this QMP) that are conducted by or for Region 5 shall have an approved QAPP in place prior to the start of data generation or use. It is the responsibility of the Project Manager to ensure an approved QAPP is in place prior to the start of data generation or use. This includes QAPPs prepared for projects or tasks involving environmental data to be performed by Regional staff or through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), contracts (48 CFR Chapter 15, Part 1546) and enforcement agreements. Interagency agreements are addressed separately in Section 4.2.2 of this QMP. Oversight to ensure Regional projects and projects funded by EPA through financial assistance agreements or contracts will be performed through internal and external MSRs and program reviews by the Region 5 Science and Quality Assurance Branch. These reviews will include a random sampling of the projects for that program or organization (a list of the projects will be requested from the program or organization) to determine if the projects were correctly identified as including environmental data generation and/or use and if the QA requirements, including approved QAPPs prior to environmental data generation and/or use, were applied and adequately addressed.

Per EPA QA/R-5, no work “shall be implemented without an approved QAPP available prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.”

All QAPPs for projects involving the U.S. Department of Defense (DoD) federal facilities shall be prepared in accordance with the Interagency Data Quality Task Force (IDQTF) Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP). The UFP QAPP is consistent with U.S. EPA QAPP requirements as provided in EPA QA/R-5. U.S. EPA Region 5 Superfund Division requires the use of the UFP-QAPP format for all Region 5 Superfund environmental data operations which require a QAPP, unless SQAB QA staff or the RQAM agree that the EPA QA/R-5 format may be used.

In regard to some Superfund projects, the contractor generates a site specific FSP to accompany the Branch Level QAPP that EPA approves. For time and non-time critical removals within the R5 SEMD Emergency Response Branches (ERBs), the site specific FSP shall also serve as the response specific QA sampling plan. It shall reference the branch level QAPP, as appropriate, and include relevant, site specific information not in the branch QAPP, but required in a QAPP. The date of the approval memo from the QA Staff to the OSC will serve as the QAPP approval date.

For an emergency response conducted under CERCLA authorities where environmental sampling will be performed, an Emergency Response Field Sampling Plan (FSP), including all field SOPs, should be prepared for Fund lead and PRP lead projects. At a minimum, within 30 days after the response date a QA Sampling Report (or equivalent) shall be submitted for documentation. The QA Sampling Report shall describe the sampling event by containing the types of information that would have been included in the FSP.

Regarding other types of removal actions conducted under CERCLA authorities, 40 CFR 300.415(b)(4)(ii)(a,b) or CIO 2105.0 (formerly 5360.1 A2) requires that for time critical and non-time critical removals, where environmental sampling will be performed, a Sampling and Analysis Plan (SAP) be prepared for fund lead and PRP lead projects. Per the National Contingency Plan, the SAP consists of two parts, a Field Sampling Plan (FSP) and a QAPP. EPA Office of Emergency Management (OEM) guidance, Changes in Quality Assurance Policies for the Removal Program, July 2006 ([OSWER 9360.4-20FS](#)), states that to satisfy the NCP requirement, a site specific FSP should be generated for each time critical and non-time critical removal action. The removal site evaluation is part of both time and non-time critical removal actions, thus the SAP requirement applies. It also states that for fund lead removals the QAPP portion of the SAP requirement in the NCP can be satisfied jointly by a branch level programmatic QAPP (Branch QAPP) and a Response Specific QA Sampling Plan.

As a clarification, for PRP lead projects, the term "non-complex removal work" is used in CERCLA Administrative Settlement Agreement and Order on Consent for Removal Actions (ASAOC). The ASAOC requirement for "Quality Assurance and Sampling" requires the respondent(s) to: "prepare a QAPP as part of the work plan, except in circumstances involving emergency or non-complex removal work". For these purposes non-complex time critical removal sites are those sites that do not require environmental sampling to confirm the extent of

contamination or cleanup. Such non-complex removal sites may include radiation, mercury, or caustic spill sites when field instruments are used exclusively to make cleanup decisions. The OSC may waive the QAPP requirement for the PRP or fund lead non-complex removal sites. OSC's shall document waiver decisions in the site file.

For PRP Lead projects requiring QAPPs, the QAPP shall be prepared according to Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), or EPA QA/R-5 format. The EPA QA/R-5 format may be used after prior approval from the SFD QA reviewer. The site-specific QAPP shall be submitted to the SFD QAM for review and approval.

7.2.3 QAPP Review and Approval (All R5 Divisions aside from ARD & ECAD)

Quality Assurance Project Plans are prepared, reviewed and approved in accordance with the most current versions of [EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5](#), and [Guidance on Quality Assurance Project Plans, EPA QA/G-5](#). All QAPPs prepared by or for Region 5 will be approved by a SQAB QA Reviewer for QA requirements and by the Project Manager for technical and programmatic requirements. Some Divisions may have both a Project Officer (PO) and a Technical Contact (TC). When this is the case, both the PO and the TC should approve the QAPP. This includes QAPPs prepared for projects or tasks involving environmental data to be performed by Regional staff or through grants and cooperative agreements (40 CFR Parts 30, 31, and 35), contracts (48 CFR Chapter 15, Part 1546) and enforcement agreements. Interagency agreements are discussed separately in Section 4.2.2 of this QMP.

RCRA Corrective Action QAPPs will be approved within the RCRA Branch and will not require a SQAB signature. RCRA Corrective Action personnel will track all reviews and approvals and provide an annual summary to the RQAM to be included in the R5 QAARWP.

Based upon the graded approach, there may be instances when an alternate or modified QAPP format is more appropriate for a project than that required by EPA QA/R-5. Any such modifications to the EPA QA/R-5 requirements must be developed in cooperation with and approved by the RQAM.

All QAPPs must be submitted to the Science and Quality Assurance Branch for review through the Project Officer/Manager. When a QAPP is submitted to the Project Officer, the Project Officer will upload the QAPP into the [SQAB Work Request Database](#). Once a document is uploaded to this site, the SQAB Branch Chief will assign the QAPP to a member of the QA Office to begin their review. Program/Division Review and QA Review will occur simultaneously to shorten review times. Once a QAPP is received, the QA Team will review it for compliance with the requirements outlined in EPA QA/R-5 (as identified above).

A QAPP review checklist may also be used to facilitate the review. An example review checklist can be found in Appendix C in Guidance on QAPPs, [EPA QA/G-5](#).

The completed checklist is for internal use by the QA Office and is typically not provided to the Project Manager or others outside the QA Office; however, a copy of a blank QAPP review

checklist is available at the above link. Comments are provided to the Project Manager through three types of review memoranda:

- Conditionally Approved – the document was found to be incomplete in addressing some key areas to the extent of potentially jeopardizing the quality of the data. These areas are fully described in this review memorandum and can be adequately addressed by incorporation into the document. Revisions must be made and submitted within 30 calendar days.
- Approved - the document complies with R-5 and addresses the key issues satisfactorily.
- Resubmission Requested/Returned with Comments - the document was found to be insufficient in describing the key issues. Further clarification of specific issues is required prior to approval of the plan and initiation of the data collection activity.

The Project Officer will be responsible for collecting all EPA Region 5 comments and sending **one** collective set of comments back to the grantee for revision. This process will continue until the QAPP is in an approvable state. Once the QAPP is ready for approval, the PO will alert the grantee that they can sign the QAPP. When EPA receives the signed QAPP, the funding Program/Division will sign first, and the QA Branch will be the final signer of the document. The QA Branch Team Member will send the final, approved QAPP back to the PO and the PO will alert the grantee that work can begin. The funding program/division will be responsible for maintaining the final version (electronic or paper) of the approved QAPP.

The approval will be effective for the length of the project or for five years; whichever is less unless significant changes are needed (see Section 7.2.8 for how revisions are handled). If the QAPP will be used beyond the original length of the project or beyond five years, the QAPP must be submitted for the same approval as the original document.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QAPP, the QAPPs shall be reviewed at least annually by the EPA Project Manager (or authorized representative) and/or the grantee. When revisions are necessary, the QAPP must be revised and resubmitted for review and approval.

7.2.4 QAPP Review and Approval (Air and Radiation Division)

All Air and Radiation Division QAPPs prepared by or for Region 5 will be approved by an ARD Technical Contact as well as the ARD Project Officer. These QAPPs are prepared, reviewed and approved in accordance with the most current versions of [EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5](#), and [Guidance on Quality Assurance Project Plans, EPA QA/G-5](#).

Based upon the graded approach, there may be instances when an alternate or modified QAPP format is more appropriate for a project than that required by R-5. Any such modifications to the R-5 requirements must be developed in cooperation with and approved by the RQAM.

The funding program/division will be responsible for maintaining the final version (electronic or paper) of the approved QAPP.

The approval will be effective for the length of the project or for five years; whichever is less unless significant changes are needed (see Section 7.2.8 for how revisions are handled). If the QAPP will be used beyond the original length of the project or beyond five years, the QAPP must be submitted for the same approval as the original document.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QAPP, the QAPPs shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QA Project Plan must be revised and resubmitted for review and approval.

7.2.5 QAPP Review and Approval (Enforcement & Compliance Assurance Division)

All Enforcement & Compliance Division QAPPs prepared by or for Region 5 will be approved by an ECAD Technical Contact. These QAPPs are prepared, reviewed and approved in accordance with the most current versions of [EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5](#), and [Guidance on Quality Assurance Project Plans, EPA QA/G-5](#).

Based upon the graded approach, there may be instances when an alternate or modified QAPP format is more appropriate for a project than that required by R-5. Any such modifications to the R-5 requirements must be developed in cooperation with and approved by the RQAM.

The funding program/division will be responsible for maintaining the final version (electronic or paper) of the approved QAPP.

The approval will be effective for the length of the project or for five years; whichever is less unless significant changes are needed (see Section 7.2.8 for how revisions are handled). If the QAPP will be used beyond the original length of the project or beyond five years, the QAPP must be submitted for the same approval as the original document.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QAPP, the QAPPs shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QAPP must be revised and resubmitted for review and approval.

For QAPPs that span across multiple Divisions where ECAD is in charge of the enforcement and another Division is responsible for another aspect, both Divisions, along with someone from the QA Branch, will be responsible for reviewing and approving the QAPP.

7.2.6 State Agency QAPPs

Region 5 State Agencies include:

- Each State's lead environmental agency: Illinois Environmental Protection Agency (IEPA), Indiana Department of Environmental Management (IDEM), Michigan Environment, Great Lakes and Energy (EGLE), Minnesota Pollution Control Agency

(MPCA), Ohio Environmental Protection Agency (OEPA) and Wisconsin Department of Natural Resources (WDNR); and

- State Departments of Health, State Fire Marshals, Departments of Natural Resources (i.e. other than WDNR) and other state agencies with other related environmental responsibilities.

State environmental agencies, which have been delegated by Region 5 to implement specific environmental programs, may be authorized by Region 5 to review and self-approve project-level QAPPs for those programs. QAPP approval authority may be provided by Region 5 to the State agency for programs encompassed in the State agency's QMP approved by Region 5. The State agency QMP will document their QAPP review and approval procedures and responsibilities pertinent to the delegated programs. The scope of the State agency's QAPP approval authority is specified in Region 5's letter providing approval of the State agency QMP or through subsequent correspondence amending the original QMP approval. Electronic copies of State approved QAPPs will be submitted to the RQAM periodically (at least annually) and maintained by Region 5 in GLNPO QA Track or other digital databases.

Certain U.S. EPA environmental programs may not be delegated and require that final review and approval of project-level QAPPs be provided by U.S. EPA. QAPPs for Superfund pre-remedial (40 CFR 35, Subpart 0), remedial (40 CFR 35, Subpart 0), and removal projects (40 CFR 300) require approval by the Region 5 SFD for Superfund projects. QAPPs supporting the Great Lakes Legacy Act may not be delegated. QAPPs supporting the Air and Radiation Division, TSCA program, FIFRA programs, and PFAS in drinking water may not be delegated.

All non-delegated State Agency QAPPs will follow the same review and approval process that is outlined in Section 7.2.3 of this QMP.

Requests for QAPP self-approval authority may be considered by the RQAM on a case-by-case basis for such organizations with a QMP approved by Region 5 and the project-level activities are specifically encompassed by the QMP. Further considerations may include that the organization has: accepted delegation of the regulated program from Region 5, has adequate dedicated QA resources for their quality system, and is highly experienced in QAPP preparation and implementation.

7.2.7 Generic Quality Assurance Project Plans

For multiple projects or sites with the same objectives and environmental decision(s), a generic QAPP may be prepared. The generic QAPP will still be prepared according to the most current version of [EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5](#), and [Guidance on Quality Assurance Project Plans, EPA QA/G-5](#), but will address the issues which remain constant among the different projects or sites. Generic QAPP must also be supported by site-specific or project-specific addenda which address the issues unique to each site or project. The generic QAPP will specify the preparation, review, and approval of the site-specific or project-specific addenda. Generic QAPPs require a QA review and approval by the QA Office and a technical and program review by the Project Manager. The QA approval of generic QAPPs for external organizations can be authorized in a

similar manner as described in Section 7.2.3 of this QMP. The appropriateness of a generic QAPP is determined on case-by-case basis by the Project Manager in cooperation with the QA Office.

7.2.7.1 Branch Level QAPP

The Branch QAPP addresses only those elements generic to all Removal activities within the Region. In Region 5 SEMD, a contract-wide QAPP is prepared by each Emergency Response Branch (ERB) contractor for fund-lead emergency response and removal action work. The QAPP shall be prepared according to Uniform Federal Policy for QAPPs (UFP-QAPP), or EPA QA/R-5 format. The EPA QA/R-5 format may only be used after prior approval from the SEMD PO in consultation with the QA Office. Each QAPP is reviewed by the program and QA Office and approved upon contract award. These QAPPs cover the broad range of work that is routinely performed under the Emergency Rapid Response Service (ERRS) and Superfund Technical Assessment & Response Team (START) contracts. SEMD ERBs adopt these documents as the Branch Level QAPPs to satisfy the NCP requirement. The Branch QAPP is reviewed annually and updated periodically by the contractor and PO to reflect operational changes.

7.2.8 QAPP Revisions

Revisions or addendums to the approved QAPP may be required if the project's activities and/or scope changes. If these changes are significant, as determined by the Project Officer and member of the SQAB QA Team, a revised QAPP or addendum must be reviewed and approved using the same process as the original QAPP. The project manager/project officer is responsible for ensuring all appropriate personnel receive a copy of the original QAPP, previous addenda, and the revised QAPP or addendum once it is approved.

7.3 Existing Data QAPPs

As defined in Section 2 of this QMP, acquired data are data or information used for project implementation or decision making which meet some or all of the following criteria:

- Are compiled from other sources;
- Were originally collected for some other purpose; and
- Are obtained from non-measurement sources such as computer databases, programs, literature files, and historical databases.

The use of acquired data must be addressed in each project-specific QAPP to include the following information:

- The type of data needed from non-measurement sources;
- The acceptance criteria for their use;
- A description of any limitations of such data; and
- The individual(s) responsible for evaluating and qualifying the acquired data

The Project Manager is responsible for ensuring acquired data is addressed in a project-specific QAPP. For those projects which involve the compiling and use of acquired data exclusively (i.e., there will be no direct environmental data generation performed to accomplish the project), a project-specific QAPP will still need to be prepared, reviewed, and approved as described in Section 7.2.3 of this QMP. The Project Manager is responsible for ensuring a QAPP is prepared for these types of environmental data projects. Because the Region supports the use of the graded approach, the content of QAPPs for these types of projects will vary and the standard QAPP format (as identified in the R-5 document) may need to be modified to better meet the needs of these projects. Any such modifications to the R-5 requirements must be developed in cooperation with and approved by the RQAM.

7.4 Quality Assurance Program Plans

For some environmental programs, particularly those involving repetitive environmental monitoring, it may be inefficient to prepare a quality assurance project plan for each sampling event or location. In these cases, using a graded approach, a quality assurance program plan (QA program plan) may be used. These documents are hybrids, containing elements of both a QMP and a QAPP and are suitable for multiple monitoring events, inspection programs and other iterative operations. Like a QMP, the program plan should contain information on the management and organization of the program, a description of the quality system, required training, records management, planning, implementation of work processes and quality assessment of the program. Additionally, details of the data collection process need to be included such as specific field equipment and documents, safety requirements and other field SOPs. A guidance cross-walk/template for preparing QA program plans is available on the [Region 5 intranet QA page](#).

QA program plans prepared by a partnering state agency will be approved within that agency, the Division/Office, the grant project officer (when an assistance agreement is involved) and a member of the SQAB QA Team. QA program plans may be approved for up to 5 years but will be reviewed at least annually for any needed changes. Shorter approval terms (i.e. 3 years) may be defined by Division/Offices or their respective programs.

QA program plans prepared by a partnering state agency may involve multiple Divisions and multiple state programs. The signatories are the same as above for each respective Division. In general, one Division should be the lead for coordinating reviews and approvals by both Divisions. Coordination of approval terms should be mutually agreed by both Divisions at the onset of state agency's QA program plan development.

QA program plans prepared by a Region 5 Division/Office for internal environmental data operations will be approved by minimally: the Region 5 program manager(s), associated Branch Chief(s) and a member of the SQAB QA Team. If the QA program plan involves multiple Divisions, the Division Directors and the RQAM will also need to approve the QA program plan. The RQAM should be consulted on the preparation of any Region 5 QA program plans involving multiple Divisions.

7.5 Application of Graded Approach

The term graded approach has been defined in CIO 2105.0, CIO 2105-P-01-0, ASQ/ANSI E4 and other QA requirements and guidance documents. In Region 5, graded approach is defined as the use of an appropriate level of systematic planning process and documentation that is based on the:

- scope and complexity of the organization's quality system;
- scope and complexity of a project; and
- required environmental decisions.

Applying a graded approach means that quality systems for different organizations and programs and/or QA documentation will vary according to the specific objectives and the needs of the organization. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. A graded approach may be applied to areas of environmental programs and/or environmental data operations. Some examples may include:

- Simplifying the documentation of an organization's quality system for a small grant;
- Developing a hybrid QMP-QAPP (QA program plan) to sufficiently describe iterative environmental data operations such as regulatory or compliance inspections for an organization; and
- Modification of systematic planning processes or QAPP documentation for research, secondary data, environmental models and non-traditional environmental projects such as economic/social science analysis.

7.5.1 Graded Approach to Systematic Planning

Project-level systematic planning processes may be complex requiring extensive planning and coordination including numerous stakeholders, questions to be answered & decisions to be made, multiple activities, etc. Systematic planning processes such as the DQO process may need to be utilized to address planning on multiple levels of a project. On the other hand, planning processes may be relatively simple in which pre-designated discharge/ monitoring locations, permit-specified analytical methodologies, permit/compliance limits for various pollutants, required number of samples, etc. are known or are well-established.

7.5.2 Graded Approach to Quality Documentation

U.S. EPA primarily defaults to the QMP in order to document an organization's quality system and to document project-level activities through QAPPs. Use of graded approach at the organizational level may consider different options to document an organization's quality system such as a QMP, QAPP or hybrid QMP-QAPP documents, among other options. Graded approach may also consider that some required individual components or elements of each type of document (QMP, QAPP, hybrid QMP/QAPP, etc.) may not be applicable to a specific organization's situation.

Project- level documentation needs may differ substantively due to the complexity or simplicity of the project. Simple projects may require only a limited the amount of detail to complete

project tasks for simple projects. Processes and standard operating procedures (SOPs) may be "cookbook" in nature and/or be readily available and need only be referenced. It may be determined that some QAPP elements are not applicable to the type(s) of environmental data operations or environmental technology involved (i.e. may be a direct measurement). The use of graded approach may identify alternative documentation to QAPPs may better serve to document smaller, iterative types of environmental projects such as inspections.

Region 5's Divisions and Offices have the flexibility to identify the appropriate level of planning processes and documentation needed for specific applications. U.S. EPA Region 5 managers and staff who are responsible for planning, reviewing, approving and implementing U.S. EPA and extramural projects involving environmental data operations need to consult with the designated QA authorities within their Divisions and Offices to ensure the adequacy of QA documentation, particularly when graded approach is being applied.

8.0 IMPLEMENTATION OF WORK PROCESSES

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

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

8.1 Standard Operating Procedures (SOPs) (Non-Field Related SOPs)

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

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

The need for an SOP for a specific activity or operation can be identified by any staff member in the Region and can be written by any Regional staff member who is knowledgeable of the activity, equipment, procedure, or process to be addressed. SOPs should be accessible to all managers and staff through various means (hardcopy, intranet, etc.) for all those who shall use or evaluate the associated processes.

The primary guidance document for the preparation of SOPs in Region 5 is the OMS guidance document [EPA QA/G-6 Guidance for the Preparation of Standard Operating Procedure, April 2007](#) and future revisions.

All SOPs shall be reviewed and approved by the manager of the organization within the respective Division/Office originating the SOPs and the primary author of the SOP. SOPs should be also systematically reviewed on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed. When revisions of SOPs are completed, it is the responsibility of each Division/Office's management to ensure that obsolete SOPs are removed from Division/Office intranet, web pages, SharePoint and other electronic file sharing systems, and to notify managers and staff (i.e. via e-mail) regarding the newly revised SOPs. Internal assessments will verify the implementation of new or revised SOPs and that obsolete hardcopy versions of SOPs, where applicable, have been removed.

8.1.1 SOP Elements

The format of an SOP varies with the nature of the activity, process or procedure. The following provides the general format of SOP for laboratory analysis, sample collection, and others:

Laboratory Analysis SOPs:

1. Scope and Application
2. Method Summary
3. Definitions
4. Sample Collection, Handling and Preservation
5. Interferences
6. Safety
7. Equipment/Material/Reagents
8. Calibration
9. Procedures (Sample preparation/extraction, and sample analysis)
10. Calculations
11. QA/QC
12. Data Reporting Requirements
13. References

Field Sample Collection SOPs:

1. Scope and Application
2. Method Summary
3. Definitions
4. Sampling Equipment/ Apparatus
5. Safety
6. Sample Containers and QC Procedures
7. Preservatives
8. Procedures
9. QA/QC and Chain-of-Custody
10. Documentation and Reporting

11. References

General SOP Format:

1. Scope and Application
2. Equipment and Resources
3. Procedures
4. Documentation and Reporting
5. QA/QC requirements if applicable
6. References

8.1.2 Region 5 Field Operations SOPs

In order to comply with the FOG Guidelines (see section 2.6.3), Region 5 has developed guidelines for the preparation of Field SOPs which are accessible on [Region 5's Field Operations Sharepoint site](#). These guidelines include:

- R5-REG-001-r0 Preparing Field SOP Documents (aka SOP for R5 Field Operation SOPs)
- R5-FQPForm-001-r0 R5 Administrative-Programmatic Field SOP Template
- R5-FQPForm-002-r0 R5 Technical Field SOP Template

All new (2014 and later) Region 5 field operations SOPs will adhere to the above SOPs and templates. As older field SOPs are reviewed prior to revision, those SOPs will adhere to the new SOP elements and templates.

9.0 ASSESSMENT AND RESPONSE

This Chapter summarizes the primary processes used to assess the suitability and effectiveness of Region 5's quality system and, in turn, the quality and technical performance of the environmental programs and projects encompassed by the quality system.

It is Region 5 policy that all assessments conducted by Region 5 quality personnel require:

- Applicable training, experience and competence in the program or area being assessed as well as the assessment process itself;
- Independence of the program or area being assessed to minimize the potential for conflicts of interest; and
- Clear and defined senior management support to ensure that assessors have both the authority and access to all necessary personnel and information to conduct such assessments.

Training requirements for various types of assessments are discussed in Section 3.2 and 3.3. Depending on the type of assessment, the completion of applicable training requirements, experience and competency of assessment team members will be primarily evaluated by the Regional QA Manager in conjunction with the Division/Office QA representatives.

When teams are used to conduct assessments, the lead assessor (i.e. Regional QA Manager, Division/Office Representative or other assigned Region 5 quality staff) will be responsible for

identifying any potential issues with independence and/or conflicts of interest for assigned team members. Information may be based on current or past positions/responsibilities, and discussions with team members prior to the assessment, among others.

Further, the Regional QA Manager and the Division/Office Representative will assist each other to assess the potential for issues of independence or conflicts of interest for assessments. As necessary, Division/Office Representatives can request, with the concurrence of their respective managements, the assistance of their peers in other Divisions or the QA Office to lead or assist with difficult assessments.

The authority of Region 5 quality staff conducting assessments as well as their ability to access required personnel and information conducting assessments will be documented and facilitated through various means including:

- Memoranda transmitted from the assessor's senior managers announcing the assessment and requesting the cooperation of the managers and staff of the organization being assessed;
- Informal and formal communications between the senior managers of assessor's and assessed organizations as needed;
- Final assessment reports transmitted by the assessors' senior managers to the senior managers of the organization being assessed; and
- On-going active involvement by the assessors' senior managers to resolve assessment findings with the senior managers assessed organization.

9.1 Annual Review of Quality System and QMPs

The Region-wide quality assurance procedures described in the QMP will be assessed annually and the QMP updated as necessary. The RQAM will be responsible for coordinating this effort and ensuring that appropriate changes are incorporated into the QMP. Each Division and Office Director will be responsible for ensuring that appropriate staff members participate in the review of the Region-wide quality system. The Division and Office Directors will review and approve significant changes to the QMP prior to their submittal to EQMD. The annual review of the QMP and the quality system will be undertaken at the same time as the development of the Region 5 QAARWP.

9.1.1 Annual Review and Revision of Region 5 QMP

The Region 5 QMP will be reviewed annually during the 4th quarter of the FY by the RQAM, to determine if any information has changed and is consistent with current processes and procedures. The RQAM will also seek input from the SQAB QA Team, as to whether or not changes to the Region 5 QMP are needed. If changes are required, they will be made accordingly. If the changes are minor in nature, the revisions will be completed by November 1st of each year. A description of the changes will be sent out via e-mail to the SQAB QA Team with an opportunity provided to review, comment and discuss the proposed revisions. Once finalized, the revisions will be posted on Region 5's intranet with the Region 5 QMP distributed via the Region 5 e-mail to all Region 5 staff and will be submitted to the Quality Staff as an attachment to the QAARWP. The on-line version of the QMP will also be updated

to include the changes. If changes are major in nature, the revised Region 5 QMP will be subject to complete review & approval cycle including approval by Region 5 and the EQMD.

At least every five years, based upon the original approval date, the QMP will undergo a thorough review, in its entirety, and a complete approval cycle. The RQAM and SQAB QA Team will initiate the revision of QMP six months prior to the expiration date of the existing QMP. The QMP will also go through the complete approval cycle anytime changes are made to the QMP that include major reorganization, significant changes to the Region's mission, other major changes to the Region's quality system, or when the results of an MSR or QSA so dictate that comprehensive revisions are necessary.

9.1.2 Extramural QMPs

Organizational-level documents such as QMPs, may be approved for up to 5 years but may require revision and resubmission for approval in less than based on changes in organization, mission, and quality system.

Extramural organizations (i.e. State agencies), with QMPs approved by Region 5, are required to annually: review their QMPs, assess whether the QMPs reflect their current quality system and report their status (including anticipated or completed revisions of their QMP) to Region 5. Organizations with QAPP self-approval (i.e. Region 5 state environmental agencies) are also required to periodically (at least annually) submit electronic copies of the self-approved QAPPs to Region 5. Organizations are provided various options with such submittals and may provide electronic copies via email or uploads to GLNPO QA Track or relevant digital database.

9.2 Audits

Internal and external assessments and audits will be the principal means for determining compliance with and effectiveness of the quality system defined in the Region 5 QMP. Internal audits of Region 5 environmental programs are conducted by the Region 5 QA Office and technical staff (usually on a division by division basis).

External audits of the Region 5 quality system are conducted by the EQMD, Office of Inspector General auditors, or Headquarters' program office personnel. External audits of the Regional Laboratory quality system are performed by the laboratory's Accreditation Body. Audits of Region 5 states, tribes and other external organizations participating in the Region 5 quality system are performed by the Region 5 QA Office. Internal and external audits should be conducted at a frequency sufficient to ensure that appropriate quality assurance measures are being implemented. If auditing resources are limited, environmental data collection programs or activities that are highly visible will be given priority.

9.2.1 Management Systems Reviews (MSRs)

A Management System Review (MSR) is a qualitative assessment of a data collection operation and/or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. The MSR is an on-site evaluation to assess the organizations internal management

structure and its documents to determine whether the organization is implementing an adequate quality system. The effectiveness of, and adherence to the quality system described in the QMP is the basis of the MSR. The adequacy of resources and personnel provided to achieve the required data quality is also assessed. The MSR will include a mix of interviews with organization managers and staff as well as documents and file reviews which document implementation of the quality system. In general, the MSR will review:

Project planning procedures including the use of DQO development process;

- QAPP development, preparation, review and approval procedures
- Procedures for developing and approval of SOPs;
- Procedures for conducting internal audits;
- Responsibilities and authorities of the various line managers and the quality assurance program manager for carrying out the quality system (QS);
- Procedures for document control and records keeping;
- Tracking systems for assuring the implemented QS is operating, and the corrective actions to the deficiencies uncovered during the audits have been properly taken.

Both positive findings and findings requiring corrective action will be used to prepare the MSR report. The MSR report will include, at a minimum, the following:

- Title of the review;
- Review team members;
- Background information of area reviewed, purpose of the review, date the review conducted, and a summary of the review process used;
- Details of Findings;
- Summary and conclusion of the MSR and recommendation of corrective actions if needed; and
- Listing of managers/staff interviewed, documents reviewed and other applicable attachments/appendices.

EPA QA/G-3 Guidance for Assessing Quality Systems March 2003 is used by Region 5 as guidance for conducting MSRs. Region 5 has also developed and implemented MSR interview questionnaires, document checklists and templates for MSR reporting of assessments for various types of organizations including laboratories, program offices and State agencies.

The RQAM and the SQAB QA Team are responsible for leading MSRs of Region 5 Divisions and Offices and multi-program state agencies (i.e. State environmental agency). Under most circumstances, the organization's approved QMP will be the primary document used for the MSR. When an approved QMP is either not available or not required, the organization's draft QMP or other alternative documentation which provide substantive descriptions of their quality practices (i.e. QAPPs, laboratory QA manual, etc.) may be used to initiate an assessment.

The draft MSR report shall be provided by the MSR team leader to the assessed organization for review and comments. A goal will be to provide a timely draft report within 30-60 days of the assessment. Following reconciliation of any issues, the assessment report will be finalized and submitted to the senior manager of the organization with copies to the lead assessor's and

assessed organization's next level of management. The assessed organization will provide a corrective action plan including timetable for completing any corrective actions required in the final assessment report. It is expected that corrective actions will be completed within a mutually agreed, reasonable timeframe. The MSR team leader, with the assistance of the assessment team members, will evaluate any further documentation which needs to be submitted to verify completion of all corrective actions. As necessary, further on-site meetings with the assessed organization may be scheduled to further review and verify implementation of corrective actions. Additional longer-term verification shall also be included as a component of the next scheduled MSR.

9.2.2 Quality System Assessments (QSAs)

As quality systems "mature", the Quality System Assessment (QSA) assesses whether a quality system is:

- Firmly established and effective;
- Documentation conforms with EPA requirements;
- As currently implemented is consistent with the documentation; and
- Adequately supports environmental decisions.

This is accomplished by examining the processes used to plan, implement, and assess the effectiveness of the quality assurance and quality control activities as applied to programs that collect or use environmental data. In most situations, the QSA does focus on a smaller subset of the quality systems' activities and processes than does the broader scope MSR which usually reviews all major quality system components, tools, etc. of the organization. Where it is evident that specific quality components are working and fully mature, the QSA can spend more time assessing other components or processes.

QSAs are designed to assess the organization's quality system and to provide a relatively unbiased and objective source of feedback about the quality system. Like the MSR process, QSA assessors review background documentation, examine files, and interview managers and staff involved in environmental data operations. The QSA's focus is not solely on the identification of deficiencies or needed improvements, but also to seek recognition of noteworthy accomplishments or best practices which can be applied to other organizations.

QSAs may not be the most appropriate internal assessment for some organizations since the broader scope MSR may be more effective for less mature quality programs. The processes for the majority of the planning, reporting and review/verification of corrective actions are virtually the same as used for MSRs as described in 9.2.1.

9.2.2.1 QSAs by EQMD

Quality system audits and MSRs evaluate a specific quality system to determine its effectiveness and to identify areas where additional attention would bring significant benefits. Quality system audits of Region 5 will be conducted by EQMD. EQMD plans to implement independent QSAs of the Region 5 quality system once every five years. EQMD will conduct a review of Region 5's Quality Program. This may include meeting

with management, conducting personnel interviews, and performing file reviews. Results are reported to the Region through a Draft Findings Report. The Region must respond to the results of the audit and develop a Corrective Action Plan to address any issues which require corrective action. The roles and responsibilities of auditors, experience and training for audit personnel, independence of audit personnel, and headquarters' management review of and response to findings for QSAs conducted by EQMD are established by the EQMD and are beyond the scope of this QMP. The QAARWP will summarize the results of and response to any QSA conducted by the EQMD during the previous fiscal year. The Region 5 QA Manager will serve as the coordinating contact for this assessment.

9.3 Technical System Audits (TSAs)

Technical systems audits (TSAs) may be requested by the Region 5 Division/Office programs or project managers at the time the draft QAPP for the project has been developed and written and will be scheduled by the respective Division/Office Representative. The audit request will include information such as the nature of the project, the project needs (e.g., the type of monitoring activity, monitoring parameters, procedures to be used, etc.). The QAPP serves as the benchmark for the audit. The respective Division/Office Representative will be responsible for developing the audit plan/schedules, conducting the audits, and documenting/reporting the audit results. The audit reports will present a visual picture of the performance of the program to see if the minimum requirements of the Region's QS are being met. If not, deviations are identified, and recommendations made for corrections. If corrections are not made, recommendations are made to the appropriate program director for action (i.e. withholding grant or contract funds, disapproval of the laboratory).

During TSAs, EPA equipment should be inspected to determine whether the item is operating within product specifications. Any equipment failing to meet specifications should be noted in the audit reports as well as in final project reports. This documentation will be helpful in future operations requiring similar equipment. Guidance for conducting TSAs is provided in [EPA QA/G-7 Guidance on Technical Audits and Related Assessments for Environmental Data Operations](#), January 2000 (Reissued May 2006).

EPA regional offices are obligated to perform a TSA on all Primary Quality Assurance Organizations (PQAO) at least every three years and are encouraged to perform a TSA on any monitoring organization that is part of PQAO at least every six years (40 CFR Part 58, Appendix A §2.5, revised 2016).

9.4 Data Verification and Validation

Data verification and data validation are essential, prerequisite assessments conducted before an overall data quality assessment (DQA) can be completed for a project's environmental data. These assessments are necessary for data users to understand the potential qualitative and quantitative biases of environmental data. These assessments are defined as follows:

- **Data verification** is the process for evaluating the completeness, correctness and conformance/ compliance of a specific data set against method, procedural, or contractual specifications. This process may be conducted as **either internal or external** to the field, lab or other organization responsible for the generation of the environmental data

- **Data validation** is an analyte- and sample- specific process which extends the evaluation of data beyond method, procedure, or contractual compliance to determine the quality of a specific data set relative to the end use. This evaluation is **primarily performed external** to the field, lab or other organization responsible for the generation of the environmental data.

Another process, **data review**, may precede both data verification and data validation. Data review is defined as an **internal** examination of data, conducted by field or laboratory personnel, to ensure that data have been recorded, transmitted and processed correctly. Data review may include checks for errors in transcription, calculation, reduction and transformation as well as completeness of sampling information or losses of samples or data.

[EPA QA/G-8 Guidance on Environmental Data Verification and Data Validation](#), November 2002 (reissued January 2008) provides general guidance on data verification and validation processes. Examples of method-specific data validation guidance include the U.S. EPA Contract Laboratory Program (CLP) National Functional Guidelines for organic and inorganic Superfund Methods Data Review. In general, Region 5 data validation procedures for all types of field and laboratory analyses are based on the principles and general criteria provided in the CLP [National Functional Guidelines](#).

Important issues for data review, data verification and data validation:

- It is essential that all U.S. EPA Region 5 project-level planning documents (i.e. QAPPs) clearly identify the specific processes, including as necessary attaching the SOPs, which shall be used to evaluate environmental data assessed, generated or used during the project.
- Data review, data verification and data validation along with other terms have various definitions among different organizations and technical specialties. Statements such as "data will be validated" do not sufficiently describe a specific evaluation process.
- Data review, data verification and data validation, as defined above, are not usually provided in conjunction with external analytical services unless they are specifically requested and required in the QAPP or other planning documents.

To provide assistance in preparation for the data quality assessment, prior to releasing the data to the client/user, organizations that provide analytical services shall perform data verification and data validation to certify that the required QC activities are followed, and whether the data meet the requested quality. The project officer/manager is responsible for ensure that the data received from either internal or external analytical services are verified and validated prior to proceeding to data quality assessment.

9.5 Data Quality Assessment (DQA)

It is Region 5's policy that all environmental data must be assessed by the data user prior to its use for environmental decisions. Such assessments must be conducted using a graded approach and shall be based on the approved project's data quality objectives.

Region 5's approach to data quality assessment (DQA, also known as Data Usability Assessment) is intended to determine if data obtained from environmental data operations met the project objectives and if the data was the right type, quality, and quantity to support their intended use. Region 5's

DQA approach includes both the qualitative review of the project to determine if project-specific QA/QC practices are followed, and, when applicable, includes the application of statistical analyses of data. A complete or partial DQA process can be performed during the assessment phase of data life cycle, which includes the planning, the implementation and the assessment phases. DQA is used to determine if the planning objectives were achieved. During DQA:

- Data is verified and validated to ensure that the sampling and analysis protocols specified in the QAPP were followed and that measurement systems performed in accordance with the criteria specified in the QAPP; and
- The validated data is compared with original data quality objectives (DQOs) specified in the program-level or project-level QA planning document to determine if the DQOs were met.

Existing data shall be assessed using the same approach if such data may be considered for use in a new project. If there is lack of supporting information associated with the existing data (i.e. simply a list of results with no further field or lab documentation), there may be substantive limitations on its use in a new project.

Region 5's DQA approach is built on the fundamental premise that data quality is meaningful only in the context of the intended use of data, by the decision maker. DQA results should be used for two specific purposes:

- To identify modifications of the DQOs; and
- To use as a guide for the planning and acquisition of supplemental data for the project and related projects.

The scope of Region 5's DQA approach encompasses review and evaluation of three major areas:

- Project implementation;
- Conformance to approved performance criteria; and
- Achievement of project objectives.

Each Region 5 Division/Office QMP shall describe the applicable Division or program-specific QA methods which will be used and how DQAs relate to the DQOs. [EPA QA/G-9R Data Quality Assessment: A Reviewer's Guide](#), February 2006, and [EPA QA/G-9S Data Quality Assessment: Statistical Tools for Practitioners](#) February 2006 should be used as guidance for developing DQA SOPs and checklists. The outline below provides guidance for Region 5's general DQA approach for the collection of environmental data collected in the field:

1.0 Implementation (Completion of Tasks):

Field Activity

- Was chain of custody maintained?
- Any sample holding times exceeded?
- Number of samples and QC samples collected?
- Number of locations sampled?
- Field equipment calibration conduction?

- Were approved procedures used?
- Measurements conducted?
- Field data validation conducted?
- Field decontamination done?

Laboratory Analysis

- Holding time exceeded?
- Approved procedures used?
- Data validation conducted?
- Parameters reported?
- Data package completed?

Other Considerations

- Field inspections conducted?
- PE samples analyzed and reported?
- Field decision rules followed properly?
- Independent validation performed?
- Corrective actions appropriately implemented (documentation for both field and laboratory activities)?
- Decision tree followed?

2.0 Conformance to Approved Performance Criteria:

Field Activity: Valid data (PARCC, calibration, etc)?

Laboratory Analysis: Valid data (PARCC, calibration, etc)?

Other Considerations:

- PE sample results acceptable?
- Problems noted in inspections corrected?
- Ecological assessment conducted correctly?

3.0 Achievement of Project Objectives:

Were all specific objectives met?

Were overall project objectives met?

- Was data adequate for overall project objectives
- Can a valid conclusion or regulatory decision be reached?
- Were overall project objectives sound?
- Does data support original assumptions/hypothesis?
- Does data indicate the need to establish new assumption/hypothesis?

10.0 QUALITY IMPROVEMENT

This Chapter summarizes the various means used by U.S. EPA Region 5 to identify opportunities for improvement of the quality system as well as to encourage managers and staff to suggest areas for improvement.

It is Region 5 policy that quality assurance is a critical component of all work functions associated with environmental data operations. The QMP is intended to provide the basis for integrating appropriate quality assurance activities into environmental data planning, implementation and evaluation phases. If the principles outlined in the QMP are followed, problems should be detected in a timely manner, before programmatic and financial issues become critical and hinder program implementation and decision making. Some key quality improvement processes used by Region 5 to identify and resolve quality system issues are described below.

10.1 Internal Region 5 Reviews

Each year the quality system and Regional QMP will be reviewed by Region 5's Regional QA Manager as well as the SQAB QA Team as part of the QAARWP development process to ensure that the QMP is still relevant to the Region 5 mission. The RQAM is responsible for coordinating the review of the Regional QMP. The Regional QMP will be modified to reflect changing needs or additional guidance.

The RQAM discusses the annual review and update of QMPs during a regular SQAB QA Team meeting or a special SQAB QA Team meeting as necessary. A key purpose of these meetings is to identify Regional quality assurance issues of concern from various sources (i.e. external MSR/QSA by the Quality Staff, internal assessment by the SQAB QA Team, etc.). Changes made or actions taken to correct any major quality assurance deficiencies will be documented in the QAARWP and reviewed and approved by the appropriate Division/Office Director and the Regional Administrator. See Section 8.1 of this QMP for more details regarding the review and revision of the QMP and the preparation of the QAARWP.

10.2 SOP Reviews

Region 5 periodically reviews its written standard operating procedures (SOPs) particularly those used in conjunction with environmental data operations. SOPs will be reviewed to determine if they are relevant to the mission of the program, properly describe the procedures used to obtain data of known and sufficient quality to support programmatic decisions and whether the SOPs need to be updated or revised. The goal is to review each SOP at least every two years (every 5 years for LASAD Lab SOPs). It is the responsibility of the respective Division, Branch or Section managers and their designated staff to implement reviews for processes within their organization.

10.3 MSRs/QSAs

Management Systems Reviews (MSRs) or QSAs, as described in Section 9 .2, are conducted with the intent to identify opportunities to improve Region 5, Division/Office and extramural organization quality systems. Program reviews and internal MSRs will be also be utilized as a means of evaluating implementation and effectiveness of quality systems.