US EPA REGION 1
QUALITY PROGRAM

EPA REGION 1
QUALITY MANAGEMENT PLAN GUIDANCE

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Document Revision Page

Date	Rev. #	Summary of Changes	Applicable Sections
June 10, 2025	0	N/A	N/A

Contents

1. Acronyms and Abbreviations

CIO	Chief Information Officer
EI	Environmental Information
EIO	Environmental Information Operations
EPA	Environmental Protection Agency
IM	Information Management
IT	Information Technology
QA	Quality Assurance
QA#	EPA Region 1 QA Tracking Number
QC	Quality Control
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure

2. Audience

This *EPA Region 1 Quality Management Plan Guidance* is intended for external, non-EPA organizations who are required to have an EPA-approved QMP according to the terms and conditions of their extramural agreement with EPA Region 1. Your EPA Region 1 program contact, such as your project officer, Tribal coordinator, or contract officer's representative, can confirm if a QMP is required for your agreement.

3. Introduction

3.1 Background and Purpose

All EPA and non-EPA organizations performing environmental information operations are required to participate in the EPA Agency-wide quality program by adhering to applicable EPA quality directives, including the *Quality Management Plan Standard* (CIO 2105-S-01).

A QMP is a document that describes an organization's quality program, including its structure, procedures and commitment to a robust quality program. The QMP includes the processes to evaluate the effectiveness of quality management practices for all environmental programs conducted or overseen by the organization. In contrast to a Quality Assurance Project Plan, which is specific to a project or program, the QMP is an organization-level document that describes overarching policies and procedures as they pertain to all EPA-funded environmental operations or programs managed by the organization.

The EPA Region 1 QA Branch has composed this guidance as a supplement to the Agency-wide *QMP Standard*. This document does not supersede the EPA Agency-wide *Environmental Information Quality Policy*, *Quality Procedure* or Quality Directives, including the *QMP Standard*. This guidance:

- Discusses the *QMP Standard*, including notable changes between the current and former EPA requirements documents;
- Discusses the roles and responsibilities of the EPA Region 1 program office, the EPA Region 1 QA Branch and the QMP organization;
- Describes the process for submission, review and approval of QMPs;
- Provides information and examples for addressing the 18 *QMP Standard* elements; and
- Provides resources for developing a QMP, including the QMP Framework (Appendix A) and a QMP Completion Checklist (Appendix B).

3.2 *QMP Standard* and QA/R-2 Comparison

In February 2023 the EPA issued the *QMP Standard* to define minimum requirements for QMPs prepared by and for the EPA. The *QMP Standard* replaces the longstanding *Requirements for Quality Management Plans* (QA/R-2). For more information and to access the most current versions of all Agency-wide QA Directives visit epa.gov/quality.

Terminology

The *QMP Standard* adopts new terminology consistent with the EPA *Environmental Information Quality Policy* and *Quality Procedure*. Most notable is the use of "environmental information" and "environmental information operations". EI is largely synonymous with environmental data but is meant to include non-measurement data, such as maps, models, software or other environmental technology tools. EIO is a collective term for the collection, production, evaluation or use of environmental information; it also includes the design, construction, operation or application of environmental technology.

Throughout this guidance "environmental information" is used interchangeably with "environmental data" and "environmental information operations" with "environmental operations".

Format and Content

Like QA/R-2, the *QMP Standard* identifies elements that are required to document an organization's quality program. The *QMP Standard* contains 18 elements compared to QA/R-2's 10 elements, however many of the requirements are similar. Table 1 provides a comparison of the *QMP Standard* and QA/R-2 and notes key differences. Specific content requirements for each *QMP Standard* element are described in Section 4.

Adapting your QMP from QA/R-2 to the *QMP Standard*

If your organization has an existing QMP that is formatted according to QA/R-2, follow the Table 1 crosswalk to match sections of your existing QMP to the 18 elements of the *QMP Standard*. Copy the content into the QMP Framework or a new document. Then review the content specifications in Section 4.0 to ensure all applicable details are addressed. If an element is not applicable to your organization include it in your QMP and state that it is not applicable. It is acceptable if your QMP contains additional content that is not required by the *QMP Standard*.

Table 1: QA/R-2 and *QMP Standard* Crosswalk and Notable Changes		
QA/R-2	***QMP Standard***	**Notable changes**
	1. Title Page	A formal title page is required
Management and Organization	2. Approval Page	Separated into its own element
	3. Organization's Quality Statement	"Quality Statement" replaces "Quality Policy", though content requirements remain similar
	4. Organizational Chart	Separated into its own element
	5. Roles, Responsibilities and Authorities	Distinguishes three roles within an organization: the QA Manager, Operations Manager(s) and Senior Manager
	6. Technical Activities and Programs Supported by the QMP	Separated into its own element
	7. Conformance with Policies, Procedures, Standards, and Regulations	Documents the quality-related terms and conditions, policies, procedures, standards and/or regulations that apply to your quality program
	8. QA Field Activities	Identifies quality management processes for consistent implementation of field activities
Computer Hardware and Software	9. Computer Hardware and Software	Documents compliance with specific EPA IT/IM directives
	10. Information Quality Guidelines	Does not apply to non-EPA organizations
Personnel Qualifications and Training	11. Organizational Competence	Separated into its own element and replaces "qualifications" with "competence"
	12. Personnel Training	Separated into its own element
Procurement of Items and Services	13. Procurement of Items and Services	Ensures that any of your organization's subcontractors or subgrantees conduct environmental operations in compliance with the EPA quality requirements and your QMP

Table 1: QA/R-2 and *QMP Standard* Crosswalk and Notable Changes		
QA/R-2	***QMP Standard***	**Notable changes**
Documents and Records	14. Document and Record Processes	Ensures document and record processes satisfy the EPA and your organization's extramural agreement, programmatic or regulatory requirements
	15. Plan, Do, Check, Act (PDCA) Quality Model	Introduces the Plan-Do-Check-Act quality model by combining planning, implementation of work processes and assessment and response into one element
Planning	15a. Plan	Separated into its own sub-element
Implementation of Work Processes	15b. Do (Implementation)	Separated into its own sub-element and includes general processes for implementing environmental operations
Assessment and Response	15c. Check (Assessment and Oversight)	Separated into its own sub-element and details requirements for annually reviewing your quality program with senior management
	15d. Act (Corrective Actions and Improvement)	Separated into its own sub-element
Management and Organization	16. Dispute Resolution Process	Separated into its own element
Quality Improvement	17. Continual Improvement	"Continual improvement" replaces "quality improvement"
	18. Data Review, Validation, and Verification and Data Usability Reporting	Describes general processes for how your organization conducts data review, verification, validation and usability reporting
Dark gray shading indicates there is no corresponding QA/R-2 element		

3.3 Roles and Responsibilities

The development, review and approval of QMPs is a cooperative process between your organization, the EPA Region 1 program office and the EPA Region 1 QA Branch.

Your Organization

Your organization is responsible for developing a QMP or reviewing your existing QMP to ensure it accurately reflects your organization's quality program. All EPA-funded environmental programs and activities conducted by your organization must be included. You may choose to include other non-EPA funded programs and activities. Review your organization's QMP at least annually and revise it as needed. See Section 3.5 for annual review and revision process.

EPA Region 1 Program Office

The environmental programs or operations managed by your organization support one or more EPA Region 1 program offices. The EPA Region 1 program contact works with the EPA Region 1 QA Branch and your organization to ensure your QMP is up-to-date and within its five-year approval window. If not, the program contact ensures you develop or revise a QMP and submit it to the EPA for review and approval.

EPA Region 1 QA Branch

The EPA Region 1 QA Branch is responsible for reviewing and approving QMPs. The QA reviewer may be the regional QA manager or designee. See Section 3.4 for the EPA review and approval process.

The QA Branch maintains a list of organizations with EPA Region 1-approved QMPs. When a QMP is due to expire within six months, the Region 1 QA Branch will typically reach out to the Region 1 program contact and the QMP organization to notify them of their upcoming due date to revise and submit their QMP.

3.4 EPA Region 1 QMP Submission, Review and Approval Process

When your new or revised QMP is ready for review it must be submitted to both the EPA Region 1 program contact and the EPA Region 1 QA Branch at R1QAPPS@epa.gov (Figure 1). Remember to always copy your Region 1 program contact when submitting documents.

After submission you will be notified that the QMP has been received by the Region 1 QA Branch and that a QA reviewer has been assigned. The EPA QA reviewer will conduct their initial review within 30-days of receipt. The EPA QA reviewer checks the document against the *QMP Standard* and prepares comments to address any missing or deficient QMP elements. The QA reviewer's comments are shared with the EPA Region 1 program contact and your organization's QA manager or designee. The EPA Region 1 program contact may add comments in addition to those provided by the QA reviewer.

Revise the QMP based upon the EPA's comments and prepare a response-to-comments memorandum which describes how and where revisions were made. The revised QMP and response-to-comments memorandum can be sent directly to the QA reviewer and Region 1 program contact. The EPA QA reviewer will perform another review to ensure comments have been addressed and revisions have been incorporated. If the EPA QA reviewer and program contact have no additional comments, the QMP is finalized and signed by your organization's QA manager and senior manager. The signed QMP is then submitted to the EPA QA reviewer and EPA Region 1 program contact for EPA approval.

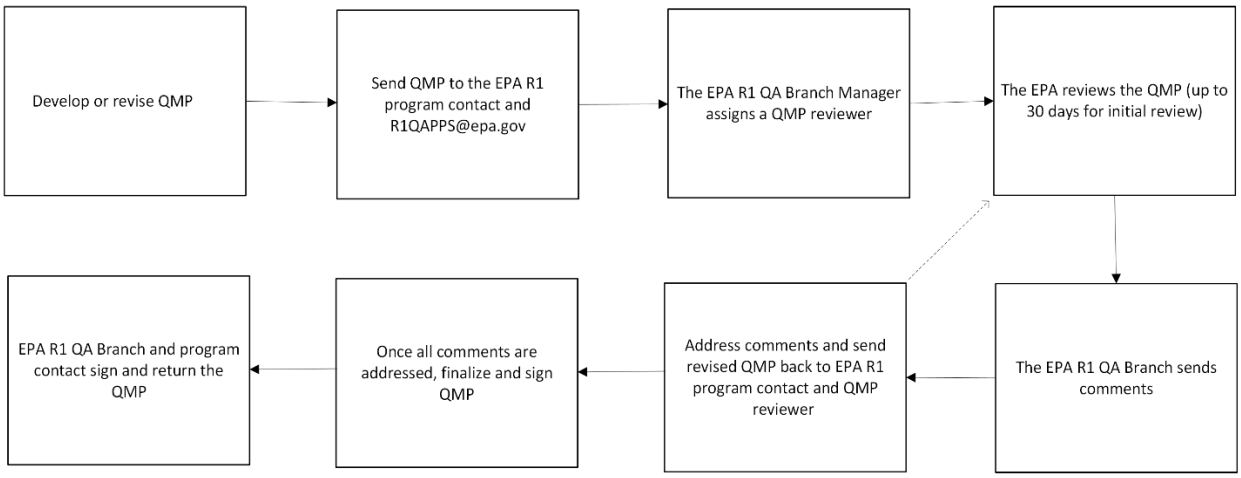


Figure 1. The EPA Region 1 QMP submission, review and approval process.

3.5 QMP Period of Performance, Annual Review and Revision Process

Period of Performance

QMPs are required to be reviewed, revised as necessary and submitted for EPA approval at least every five years. Depending on the extramural agreement with the EPA, this duration may be linked directly to the period of performance of your agreement. QMPs for continuing environmental programs can remain valid for up to five years if there are no major changes to the terms and conditions of the agreement or to the scope of programs and activities defined in your QMP. The most current agreement reference number should be documented during your annual review. A new QMP must be submitted for EPA review and approval prior to its expiration.

Annual Review

QMPs must remain current and accurate for the organization's quality program that it describes. Accordingly, you must review your EPA-approved QMP at least annually to confirm that it remains accurate and suitable for the quality management needs of your organization. Annual review of your QMP must be documented and made available to the EPA if requested.

QMP Modifications

Minor changes to a QMP are those that can be incorporated without significant impact to the performance or data quality of environmental programs or environmental operations. Minor revisions are documented in a revised QMP, QMP addendum or with a quality program annual status report to the EPA. Confirm with the EPA Region 1 program contact and the QA Branch that your proposed revisions are considered minor. Significant revisions, such as largescale changes to organizational structure, redelegation of certain quality management functions or changes in the scope of environmental programs or activities, require formal review and approval by the EPA.

Any changes, regardless of whether formal approval is required, must be documented and transmitted to the EPA Region 1 program contact and QA Branch.

4. *QMP Standard* Requirements

The *QMP Standard* has 18 elements that pertain to various aspects of an organization's quality program. These elements document and describe how your organization manages its environmental programs and activities, including:

- Roles, responsibilities and authorities of individuals in the organization who manage and participate in the quality program;
- How quality management procedures are planned, implemented and assessed; and
- How the organization will continually review, assess and seek to improve its quality management practices.

For each QMP element the following sections provide the purpose of the element, specifications to be addressed and guidance for effectively addressing the element. Additional content expectations for EPA Region 1 are included when applicable.

1: Title Page

Purpose: The title page presents the administrative information of your QMP.

Guidance for completing this section:

Include the following information:

- ✓ Name of document; title must include "Quality Management Plan"
- ✓ Date of QMP preparation
- ✓ Name of your organization
- ✓ Identification reference number of your extramural agreement, as applicable
- ✓ Period of performance
- ✓ Version control information (e.g., Revision 0)

Period of Performance

Most QMPs received by EPA Region 1 are associated with continuing environmental program agreements. Therefore, the QMP may span two or more award cycles of the assistance agreement. In these cases the QMP period of performance is five years from the date of EPA approval.

When a QMP is required for acquisition agreements or one-time assistance agreements the period of performance corresponds to the length of the extramural agreement with the EPA but cannot exceed five years from the date of EPA approval.

EPA Region 1 Expectations:

- ✓ Include the EPA Region 1 QA Tracking Number on your title page. You will receive a QA# after submitting your QMP to the Region 1 QA Branch.

2: Approval Page

Purpose: The approval page identifies the key organization officials responsible for the management and implementation of your quality program and documents their approval of the QMP.

Guidance for completing this section:

The approval page must include the following individuals.

Your organization's:

- ✓ QA manager: the person in your organization with authority to conduct independent oversight of your organization's quality program.
- ✓ Senior manager: the person with executive authority for your organization, managers, QA staff, technical staff and others involved with environmental programs or operations.
- ✓ Managers organizationally between the senior manager and the QA manager.

The EPA Region 1:

- ✓ Regional QA manager or designee
- ✓ Program contact

For detailed descriptions of roles and responsibilities see Element 5, *Roles, Responsibilities and Authorities*.

3: Organization's Quality Statement

Purpose: The quality statement affirms your organization's commitment to quality management principles, practices and resource allocation for the quality program.

Guidance for completing this section:

The quality statement is similar to a mission statement but focuses on your organization's commitment to the quality of environmental operations. The quality statement must include:

- ✓ The importance of quality in your organization's environmental programs and operations.
- ✓ General objectives and goals of the quality program and QMP.
- ✓ A description of management and staff responsibilities for implementing the QMP.
- ✓ Your organization's commitment to quality management principles, practices and resource allocation for the quality program.

Example quality statement that can be modified and used by your organization: "*Our organization recognizes the importance of quality assurance to make and support sound environmental decisions for our environmental programs. The primary goal of the quality program, as documented in our QMP, is to establish quality management principles, practices and responsibilities that ensure environmental data collected, produced or evaluated by our organization is of known and documented quality and suitable for its intended use. Accordingly, our senior management is responsible for providing leadership, resources and oversight of the quality program and staff are accountable for following quality procedures and contributing to a culture of quality improvement.*"

4: Organizational Chart

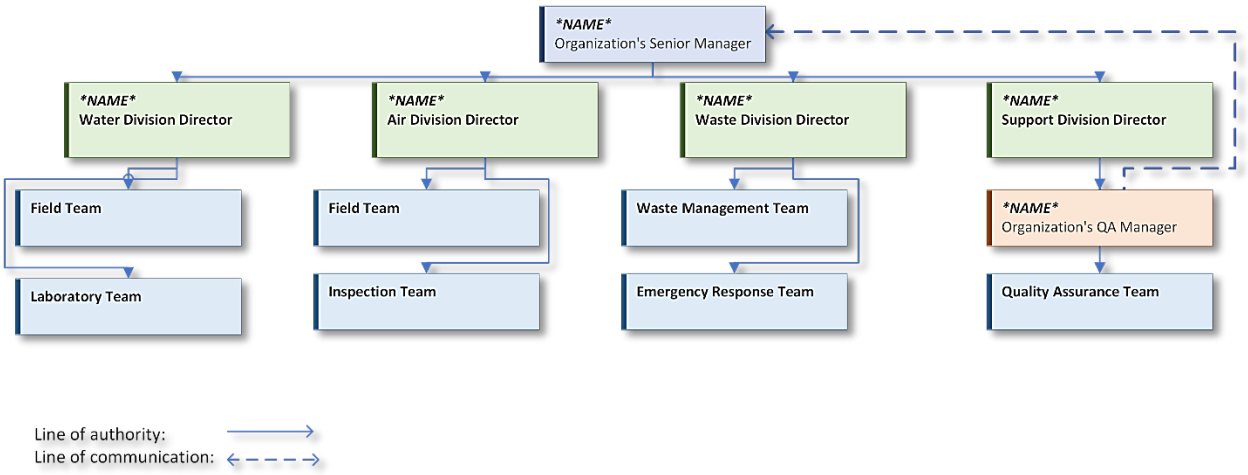
Purpose: The organizational chart identifies the environmental programs and operations to which the QMP applies and the managers and staff involved. It also documents lines of communication and authority for management and staff.

Guidance for completing this section:

The organizational chart must include:

- ✓ Your organization's QA manager.
- ✓ Your organization's senior manager.
- ✓ All environmental programs, offices or groups conducting environmental operations.
- ✓ Areas of the organization conducting QA if separate from the QA manager. For example, decentralized quality programs.
- ✓ Lines of communication and authority for each position and program. Ensure that lines of communication and lines of authority are distinct. Typically lines of authority are represented by solid lines and lines of communication are represented by dashed lines.
- ✓ Clear indication that the QA manager has a direct line of communication with the senior manager and that the QA manager and QA staff are independent of programs or groups conducting environmental operations.
- ✓ Key for deciphering the information within the chart.

EXAMPLE ORGANIZATIONAL CHART



EPA Region 1 Expectations:

- ✓ If individuals are not specified by name in your organizational chart, include a list or table of personnel as an appendix to your QMP.

5: Roles, Responsibilities and Authorities

Purpose: This section identifies the roles and describes the responsibilities and authorities of the individuals responsible for implementation, management and oversight of your organization's quality program.

Guidance for completing this section:

- ✓ Describe the role of the Senior Manager. At a minimum they must:
  - Have executive authority for your organization, managers, QA staff and technical staff who are involved in environmental operations and implement the quality program.
  - Be responsible for assuring preparation and approval of a QMP that covers all environmental programs or operations specified in the EPA extramural agreement.
- ✓ Describe the role of the QA Manager. At a minimum they must:
  - Function independently of environmental operations performed by your organization.
  - Have delegated authority to manage the quality program of your organization.
  - Have authority to conduct independent oversight of your organization's quality program.
  - Have authority to report directly to the senior manager to discuss quality-related issues.
- ✓ Document if the QA Manager functions in this role on a part-time basis or if some QA Manager responsibilities have been redelegated.
- ✓ Describe the role of the Program or Project Operations Manager(s). At a minimum they:
  - Have immediate managerial, administrative or technical control of a project or program.
  - Ensure that the quality program is implemented for all environmental operations, including that no environmental operations or activities are conducted without an approved QAPP.
  - Cannot sign QA documentation, such as QAPPs, for the QA Manager.
- ✓ Include any other roles and responsibilities of senior leadership, managers, technical staff, QA staff and others relevant to your organization's quality program.

6: Technical Activities and Programs Supported by the QMP

Purpose: This section identifies and describes all environmental programs or operations covered by your QMP.

Guidance for completing this section:

- ✓ Summarize the work of each environmental program or group within your organization. These should correspond to the programs and groups included in your organizational chart (Element 4).
- ✓ Indicate how each environmental program or group integrates QA/QC. For example, state if the program implements a Generic QAPP, project-specific QAPPs, SOPs, technical directions, program quality guidance, etc.

EPA Region 1 Expectations:

- ✓ If your organization makes subawards in support of environmental programs or activities, provide a description of the types of activities to be performed by sub-awardees.

7: Conformance with Policies, Procedures, Standards and Regulations

Purpose: This section states the policies, procedures, standards and regulations that apply to your organization's quality program.

Guidance for completing this section:

- ✓ Identify applicable EPA policies, procedures, standards and regulations and state that your organization will conform to them. At minimum list the following EPA policies and procedures:
  - The current *Environmental Information Quality Policy* (CIO 2105) - provides the policy and requirements for preparation and implementation of the EPA's quality program.
  - The current *Environmental Information Quality Procedure* (CIO 2105-P-01) - establishes management responsibilities for ensuring that EPA environmental information operations, products and services meet Agency quality-related requirements.
  - The current *Quality Management Plan Standard* (CIO 2105-S-01) - defines the minimum requirements for QMPs.
  - The current *Quality Assurance Project Plan Standard* (CIO 2105-S-02) - defines the minimum requirements for QAPPs.
- ✓ State that your organization will follow all quality-related terms and conditions and requirements specified in extramural agreements with the EPA.
- ✓ Include any State or organization-specific regulations, policies or procedures relevant to your quality program. For example:
  - Massachusetts Compendium of Analytical Methods
  - Connecticut Reasonable Confidence Protocols
  - New Hampshire Environmental Laboratory Accreditation Program

EPA Region 1 Expectations:

- ✓ Verify that references and citations for federal and internal documents are current and include working links. Cite specific sections, parts or page numbers when applicable.
- ✓ Include relevant EPA Region 1 guidance documents (see Region 1 Quality Systems Documents). For example:
  - EPA Region 1 *Quality Assurance Project Plan Program Guidance*
  - EPA Region 1 *Brownfields Program Quality Assurance Project Plan Guidance*
  - Region 1 – EPA New England *Environmental Data Review Program* Guidance and *Data Review Supplement for Superfund Specific Guidance/Procedures*

8: QA Field Activities

Purpose: This section documents your organization's quality management practices to ensure consistent implementation of field activities.

Guidance for completing this section:

- ✓ Identify the types of field activities performed by your organization. Examples of field activities include collection of environmental samples, monitoring of environmental media or inspections of environmental operations or processes.
- ✓ Describe the quality management procedures that apply to field activities. These may include but are not limited to:
  - Training and certification requirements for field personnel.

- Inventory and management of field equipment and supplies.
- Management and control of field samples.
- Management and control of field notes, observations and digital media.
- Development, review and dissemination of field reports.

✓ If your organization does not directly perform field activities state that this element does not apply to your quality program and describe quality management practices for contracted or sub-awarded field activities in Element 13.

9: Computer Hardware and Software

Purpose: This section documents how your organization will meet the EPA IT and anti-piracy standards.

Guidance for completing this section:

Computer software includes software used for design, data handling, data analysis, modeling, environmental information operations and databases containing environmental data.

✓ State that your organization will meet the EPA *Enterprise Architecture IT Standards Procedure* (CIO 2122-P-03) for hardware, software or other IT services delivered or provided to the EPA.

✓ State that software used by your organization will be appropriately licensed, approved for use, not be pirated and conform to the EPA IT/IM *Directive Policy Software Management and Piracy Policy* and *Procedure* (CIO 2104.1 and CIO 2104-P-01).

EPA Region 1 Expectations:

✓ In addition to meeting the above requirements, document:
- How computer hardware and software is developed or obtained, tested to meet the quality and technical specifications of its users, maintained, stored and upgraded.
- How access to hardware and software is controlled and prevented from unauthorized access or use. Include any processes that are implemented to ensure data integrity and prevent corruption and loss.
- Who is responsible for ensuring the EPA and your organization's IT and information management requirements are met.

✓ Include relevant IT, information management or data standards for your organization.

10: Information Quality Guidelines

Purpose: This section applies only to EPA organizations.

EPA Region 1 Expectations:

✓ Keep this section in your QMP and include the following statement:

"This section is only required for EPA organizations and does not apply to this QMP."

11: Organization Competence

Purpose: This section documents how your organization ensures personnel who manage or implement the quality program and environmental programs or operations have the appropriate qualifications.

Guidance for completing this section:

For personnel involved with implementing and managing your environmental programs, including program managers, QA staff and field staff:

- ✓ Describe how qualifications (e.g., skills, knowledge and experience) are determined.
- ✓ Describe how personnel are evaluated on their ability to do their job competently.

12: Personnel Training

Purpose: This section describes the training requirements for the quality program and environmental programs or operations in your organization.

Guidance for completing this section:

- ✓ Identify who in your organization is responsible for determining, reviewing and documenting training requirements.
- ✓ Describe the process for determining training requirements and needs of your organization.
- ✓ Identify any specific trainings or training topics for your quality program. Trainings may be task or role specific and include both technical and quality-related training. Training topics may include:
    - Your organization's QMP and the quality program
    - QAPP development or review
    - Records and document management
    - Health and safety
    - Data review
- ✓ Indicate the frequency of training and how training is tracked.

13: Procurement of Items and Services

Purpose: This section documents the procedures for ensuring the quality of procured items and services meets the needs of your organization and its environmental programs.

Guidance for completing this section:

Describe the process to ensure that procurement agreements adhere to the quality requirements documented in your QMP. Procurement agreements include subcontracts, grants and other assistance agreements with external organizations.

- ✓ Describe how procurement documents are reviewed and approved to ensure they are accurate and complete.
- ✓ Indicate that procurement documents must clearly describe the:
    - Item or services needed.
    - Associated technical and quality requirements.
    - Quality program elements that the supplier is responsible for.
    - Process for verifying the supplier's conformance to the requirements.
- ✓ Describe how responses to solicitations are reviewed and approved to ensure they:
    - Satisfy all technical and quality requirements.

  - Provide evidence that the supplier can satisfy the EPA quality program requirements defined in your organization's extramural agreement.
- ✓ Indicate how procured items and services are assessed for quality and conformance to the stated technical and quality requirements. This can include describing:
  - How sources are selected
  - How sources are inspected
  - Audits
  - How deliverables are examined
- ✓ Describe how you will review quality-related documents, such as QAPPs, quality manuals or SOPs, that are produced by external organizations.
- ✓ State that external organizations will adhere to your organization's QMP.

14: Document and Record Processes

Purpose: This section describes your organization's policies and procedures to effectively manage and control quality-related documents and records.

Guidance for completing this section:

- ✓ Identify quality-related documents and records applicable to your organization
- ✓ For your organization's quality-related documents and records provide the following:
  - Descriptions of how documents are prepared, reviewed, approved, issued, used, revised, tracked and verified.
  - Management processes for record transmittal, distribution, retention, protection, preservation, traceability, disposition and retrieval.
  - Applicable EPA record retention schedules.
  - Information about document storage, including how documents are accessed and protected from damage and loss.
- ✓ Describe how your organization ensures compliance with all statutory, contractual and assistance agreement records requirements.
- ✓ Describe the chain of custody and confidentiality procedures for evidentiary records if applicable.
- ✓ Identify the roles and responsibilities of managers and staff in document and record processes.

15: Plan, Do, Check, Act (PDCA) Quality Model

15a: Plan

Purpose: This subsection documents how your organization uses a systematic planning process to ensure the results of environmental operations and activities are of known and documented quality and suitable for their intended use.

Guidance for completing this section:

Systematic planning is an iterative process based on the scientific method that establishes clear objectives, identifies inputs of data or information, defines boundaries of a study, investigation or program and develops criteria to measure and assess performance. The results of systematic planning are documented in a QAPP.

- ✓ Describe how your organization uses a systematic planning process for all environmental operations or activities.

- ✓ State that your organization will prepare QAPPs according to the current version of the EPA *QAPP Standard*.
- ✓ Describe your organization's processes for:
  - Identifying when QAPPs are needed.
  - Developing and reviewing QAPPs internally prior to submission to EPA Region 1.
  - Notifying project members, including contractors or subgrantees, that planning documents are approved and work may begin.

EPA Region 1 Expectations:

- ✓ Provide a list of active QAPPs for all EPA-funded environmental operations. This list will be updated part of your annual review.
- ✓ If your organization maintains Program QAPPs, describe how project, site or task-specific planning is conducted and documented. For example, using SAPs, site-specific QAPP Addenda, etc.
- ✓ Identify if any of your organization's environmental programs have delegation from EPA Region 1 to review and approve QAPPs, QAPP Addenda or SAPs.

15b: Do (Implementation)

Purpose: This subsection describes how work processes are implemented to ensure that environmental data are of the needed and expected quality for their desired use.

Guidance for completing this subsection:

- ✓ Describe your organization's general processes for ensuring work is performed according to approved planning and technical documents. This may include use of SOPs, reference methods, forms or checklists.
- ✓ Describe how SOPs or similar procedural documents are managed through their lifecycle, including:
  - Identifying when SOPs are needed.
  - Developing SOPs.
  - Reviewing SOPs for initial and subsequent use.
  - Disseminating SOPs to appropriate personnel.
  - Revising or rescinding SOPs and communicating changes to personnel.
- ✓ Describe the management controls for the release, change and use of SOPs, including:
  - Obtaining necessary approvals for SOPs.
  - Determining points for implementing changes.
  - Removing obsolete documentation from physical work areas or electronic systems.
  - Verification that changes to work procedures are made as prescribed.

EPA Region 1 Expectations:

- ✓ Provide a list of quality program SOPs and include copies as an appendix or with links to the documents.

15c: Check (Assessment and Oversight)

Purpose: This subsection documents how your organization determines the suitability and effectiveness of its quality program and the performance of environmental programs or operations.

Guidance for completing this subsection:

Quality Program Assessment

Assessments of the overall quality program demonstrate your senior management's commitment to the quality program and provide an opportunity to review its effectiveness and identify and institute improvements.

- ✓ State that assessments of the quality program occur at least annually.
- ✓ State that quality program assessments will consider:
  - Quality program performance
  - Suitability of internal processes and standard procedures
  - Internal or external issues relevant to the quality program
  - Trends in performance or nonconformities
  - Review of any delegated quality management responsibilities
  - Status of any findings or actions from past management reviews
  - Opportunities for improvement
- ✓ Identify how quality program assessments are planned, conducted and documented.

Program, project or task-specific assessments

- ✓ Describe any technical assessments that are routinely conducted by your organization or indicate that they will be addressed in QAPPs. Technical assessments may include field audits, technical system audits, laboratory assessments, performance evaluations, data quality assessments or surveillance.
- ✓ State that personnel conducting assessments will be qualified based on program, project or task-specific requirements and technically knowledgeable with no real or perceived conflict of interest.
- ✓ Components of routine assessments include:
  - How often assessments are conducted
  - Roles, responsibilities and levels of participation for all management and staff involved, including who plans, conducts and documents the assessment
  - How assessment tools and performance measures are selected
  - The authority and access provided to assessors, including:
    - Access to programs, documents, records and managers.
    - Freedom to identify and report quality issues, recommend solutions to quality issues and verify that solutions are implemented and effective.
  - How, when and by whom actions shall be taken in response to findings of an assessment and determine the effectiveness of the response.
  - Types of findings that may result from assessments (e.g., nonconformance) and how each type should be addressed.

EPA Region 1 Expectations:

- ✓ State that you will provide the results of your annual quality program assessment to EPA Region 1 in a quality program status report that includes:
  - Assessments conducted by or for your organization

- Areas for improvement or quality program recommendations
- A QMP update, including when it was reviewed and any revisions made
- A QAPP inventory list (see Element 15a.)

15d: Act (Corrective Actions and Improvements)

Purpose: This subsection describes how corrective actions are documented, implemented and assessed for effectiveness.

Guidance for completing this subsection:

- ✓ Describe how management will respond to assessment results in a timely manner.
- ✓ Describe how corrective actions are developed and performed, including:
  - Identification of root causes.
  - Determination of whether the problem is unique or systemic.
  - Actions to take to prevent recurrence of the issue.
- ✓ Describe how you will track corrective actions and assess their implementation for effectiveness.

16: Dispute Resolution Process

Purpose: This section describes how quality assurance disputes are managed and resolved.

Guidance for completing this section:

- ✓ Describe the approach for resolving technical and management quality assurance disputes. For example, technical issue disputes may involve the results of technical systems audits or data quality assessments; management issue disputes may involve QMP or QAPP reviews or results of quality program assessments.
- ✓ Describe how disputes related to QMP requirements, QA and QC procedures or assessment results (e.g., non-conformances, findings or corrective actions) are addressed and by whom.

Example dispute resolution process that can be modified and used by your organization: "*Our organization attempts to resolve quality assurance issues at the lowest management level possible. This includes both quality management and technical quality assurance disputes. All parties should attempt to resolve disputes through discussion and negotiation. Trained mediators may help facilitate dispute resolution. If agreement cannot be reached at a lower level of management, then the issue will be resolved by senior management.*"

17: Continual Improvement

Purpose: This section documents how your organization continually seeks to improve its quality program.

Guidance for completing this section:

- ✓ Describe how your organization will continually improve its quality program, including how personnel at all levels are encouraged to:
  - Identify and establish communication between quality assurance and technical or programmatic staff.
  - Identify process improvement opportunities.
  - Identify quality-related issues.

- ✓ Identify who is responsible for planning, implementing and evaluating the effectiveness of quality improvement activities.

18: Data Review, Validation, and Verification, and Data Usability Reporting

Purpose: This section addresses how your organization reviews data and information to confirm project and quality objectives were met.

Guidance for completing this section:

- ✓ State data review and data usability are required components of QAPPs and will be addressed in those planning documents.

If your organization has general processes for conducting data review and usability reporting, describe:

- ✓ How results of environmental data are reviewed to confirm technical and quality objectives were met.
- ✓ How environmental data or information of undocumented quality or data and information collected previously for other purposes are reviewed for potential use.
- ✓ Any peer review processes.
- ✓ The responsibilities and authorities of management and staff in each of the above processes.

References

U.S. EPA, Environmental Information Quality Policy (EPA CIO 2105.4, March 2024)

U.S. EPA, Environmental Information Quality Procedure (EPA CIO 2105-p-01.4, March 2024)

U.S. EPA, Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4, February 2006)

U.S. EPA, Quality Management Plan Standard (EPA CIO 2105-S-02.1, March 2024)

U.S. EPA, Quality Assurance Project Plan Standard (EPA CIO 2105-S-02.1, April 2024)

U.S. EPA Region 1, EPA New England Environmental Data Review Program Guidance (June 2018)

U.S. EPA Region 1, EPA New England Environmental Data Review Supplement for Region 1 Data Review Elements and Superfund Specific Guidance/Procedures (September 2020)

U.S. EPA Region 1, Quality Assurance Project Plan Program Guidance (May 2024)

Appendix A: Quality Management Plan Framework

Please see https://www.epa.gov/quality/region-1-quality-systems-documents for a fillable version (.docx) of the framework.

Appendix B: Quality Management Plan Checklist

Please see https://www.epa.gov/quality/region-1-quality-systems-documents for a fillable version (.docx) of the QMP Checklist.