US EPA Region 1

Quality Program

EPA Region 1

Quality Management Plan

Guidance

June 2025

## ***Appendix A: QMP Framework***

#

*\*Your Organization\**

Quality Management Plan

* QMP Preparation Date:
* EPA Contract or Grant Reference Number:
* Period of Performance:
* Version Number:
* EPA Region 1 QA Tracking Number:

### 2. Approval Page

***\*Your Organization’s Senior Manager\****

***If applicable, your organization’s managers between Senior Manager and QA Manager***

***\*Your Organization’s QA Manager\****

***EPA Region 1 Program Contact***

***EPA Region 1 QA Manager***

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### 3. Quality Statement

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.

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| **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

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

Example Organizational Chart



### 5. Roles, Responsibilities, Authorities

* 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

* 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](#_4._Organizational_Chart)).
* 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.
* 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

* 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
* 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)](https://www.epa.gov/quality/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

* 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](#_13._Procurement_of).

### 9. Computer Hardware and Software

* 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).
* 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

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

### 11. Organization Competence

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

* 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

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

* 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 Quality Model

#### 15a. Plan

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.
* 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)

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

#### 15c. Check (Assessment and Oversight)

*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.
* 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.](#_15a._Plan))

#### 15d. Act (Corrective Actions and Improvements)

* 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

* 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.

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| **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

* 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

* 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

## Appendices