US EPA Region 1

Quality Program

EPA Region 1

Quality Management Plan

Guidance

June 2025

## ***Appendix B: Optional QMP Completion Checklist***

*Use of checklist is optional and not required with submission to EPA Region 1.*

**NOTE:** Each element must be addressed. If an element does not apply to an organization’s quality program, the QMP must justify why it does not apply.

| **Element** | **Purpose & Content** | **Specifications** | **Included?** | **Comments** |
| --- | --- | --- | --- | --- |
| 1. Title Page | Organizational and administrative identifying information | * Include “Quality Management Plan” in title * Date of QMP Preparation * Name of Organization * Extramural agreement identifier (e.g., Grant or Contract Number), if applicable * Period of performance (i.e., <5-years from approval) * Version Control Information |  |  |
| 1. Approval Page | Documentation of QMP approval by org.’s senior manager, QA Manager, and managers between them | Signature lines for:   * Organization’s QA Manager * Senior Manager * Managers organizationally between senior manager and QAM (e.g., “senior line management”) * EPA QA Manager (or designee) |  |  |
| 1. Organization’s Quality Statement | Expression of the organization’s commitment to quality in its environmental programs and operations | Statement includes (at a minimum):   * The importance of quality in the org.’s environmental information operations * General objectives and goals of the QMP * A description of management and staff responsibilities for implementing the QMP * Commitment to quality management principles, practices and resource allocation for the org.’s Quality Program |  |  |
| 1. Organizational Chart | Displays all components of the organization covered by the QMP, including positions, lines of communication and authority, and lines of reporting for the QAM and QA Staff. It documents the independence of the QAM from groups conducting environmental information operations (EIO) | * Identify organizational positions and their lines of communication and authority * Identify lines of reporting for the QAM, including QAM’s ability to report to the organization’s senior manager, even if outside of direct supervisory chain (indicated with dashed line on org. chart). * Document independence of the QAM from groups conducting direct EIO * Identify environmental programs within organization conducting EIO |  |  |
| 1. Roles, Responsibilities, and Authorities | Describes the responsibilities and authorities of the QA Manager, Senior Manager, and other managers and staff in context of the overall organizational structure | * Describe roles and responsibilities of the senior manager with executive authority for the organization, managers, QA staff, technical staff, and others involved in implementing the QMP   For QA Managers, specifically:   * Document the QAM’s delegation of authority for management of the QMP. If QAM procedures/processes are redelegated to others in the organization, that shall also be documented. * State that QAM has authority to conduct independent oversight of the quality program and functions independently of direct EIO. * Document QAM’s ability to access and discuss quality-related issues with their organization’s senior manager, even if the senior manager does not directly supervise the QAM * State that Operations Managers do not have authority to sign QA documentation for the QAM, nor will the QAM have authority to sign documentation for operations |  |  |
| 1. Technical Activities and Programs Supported by QMP | Documents the environmental programs and/or technical activities supported by the QMP | * Identify and describe all parts of the organization to which the QMP applies (correlating to organization chart) * Identify and describe environmental programs and/or technical activities involving EIO to which the QMP applies * Describe how programs will integrate QA procedures and quality planning documents (i.e., QAPPs) into all its environmental programs and operations |  |  |
| 1. Conformance with Policies, Procedures, Standards, and Regulations | Documents the quality-related requirements and terms and conditions specified in the organization’s extramural agreement(s) with EPA | * Identify extramural agreement(s) and their terms and conditions and requirements * Describe implementation of these terms and conditions or requirements |  |  |
| 1. QA Field Activities | Describes how field activities involving EIO are applied consistently | * Describe, reference, or confirm that organizations have quality-related procedures for field activities involving EIO |  |  |
| 1. Computer Hardware and Software | Ensures information produced from or collected by computers meet applicable requirements and standards | * Describe/reference internal processes to satisfy the requirements of   + ***EPA CIO 2122-P-03 Enterprise Architecture IT Standards Procedure***   Summary: If hardware, software, or other IT services will be delivered to EPA by the external org., they must meet EPA IT Standards   * + ***EPA CIO 2104.1* and *CIO 2104-p-01 Software Management and Piracy Policy* and *Procedure***   Summary: Ensures all software used by the Agency or those receiving financial assistance from the Agency is appropriately licensed, approved for use, and is not pirated. |  |  |
| 1. Information Quality Guidelines | **Does not apply to non-EPA organizations** | **Does not apply to non-EPA organizations** |  |  |
| 1. Organization Competence | Documents the process for ensuring adequate competence for personnel conducting EIO | * Document how the organization determines minimum requirements for personnel conducting EIO * Document how the organization evaluates personnel competency for their roles based on appropriate knowledge, skills, education, training, and/or experience |  |  |
| 1. Personnel Training | Documents the process for determining training requirements and training needs | * Describe the process for determining training requirements and needs * Identify who is/are responsible for defining, planning, reviewing, and documenting training requirements |  |  |
| 1. Procurement of Items and Services | Describes the processes and authorities to ensure quality requirements are included and implemented in procurements and extramural agreements | Describe how the organization:   * Reviews and approves procurement and extramural documents prior to issuing solicitations to ensure that the documents are accurate, complete, and contain appropriate quality requirements * Ensures agreements will document supplier’s responsibility to meet quality program requirements, and how suppliers will address technical and quality requirements * Provides procedures for verifying how supplies will conform to the organization’s requirements * Reviews all responses to solicitations to ensure that technical and quality requirements are met * Provides evidence of the supplier’s capabilities to satisfy EPA quality program requirements as defined in the extramural agreement or applicable federal regulation * Ensures that procured items and services are of acceptable quality * Reviews quality-related documentation (QMPs or QAPPs) from contractors * Ensures sub-contractors performing EIO comply with quality requirements specified in the organization’s extramural agreement(s) with EPA |  |  |
| 1. Document and Record Processes | Describes the document and records processes for quality-related documents and records prepared, reviewed, approved, issued, used, revised, tracked, and verified within the organization | * Describe how record management requirements are met, including the responsibilities of management and staff * Describe how documents and records, including revisions, are reviewed for conformance with new requirements and terms and conditions of extramural agreements, and are approved by authorized personnel before use * Describe/reference the management process that ensures documents and records accurately reflect completed work, including specific records keeping requirements defined in policies, procedures, standards, or regulations * Identify or reference how quality-related records are disposed of in accordance with regulatory requirements or schedules * Describe/reference the document and records processes for planning documents (e.g., QAPPs, QMPs, SOPs) prepared, reviewed, approved, issued, used, revised, tracked, and verified within the organization; Specifically:   + Identify quality-related documents and records requiring management and control   + Reference EPA Record retention schedules   + Reference EIO records requirements stated by program regulations and/or contract and extramural agreements   + Describe/reference processes and roles of management and staff for handling quality-related documents and records to ensure accessibility, protection from damage and deterioration, and means of retention   + Describe/reference measures for controlling the release, change, and use of planning documents and records including description of how technical guidance and planning documents are prepared, reviewed, approved, issued, used, revised, tracked, and verified   + Describe/reference processes for ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and provides adequate preservation of key records necessary to support the mission of the organization   + Describe/reference procedures for establishing and implementing chain of custody and confidentiality procedures for evidentiary records |  |  |
| 1. Plan-Do-Check-Act (PDCA) Quality Model   A. Plan | Documents how EIO will be planned within the organization to ensure that data collected are of the needed and expected quality for their intended use | * Describe/reference the processes for determining systematic planning and the development of acceptance/performance criteria to perform EIO * Document the systematic planning process for EIO based on the scientific method and a common sense, graded approach to ensure the level of detail is consistent with the intended use and degree of confidence needed in the data quality (i.e., confirm that projects involving EIO will follow the required elements of the EPA QAPP Standard) * Describe the QAPP planning and documentation process including organization-specific requirements by project-type |  |  |
| 1. Plan-Do-Check-Act (PDCA) Quality Model   B. Do (Implementation) | Documents how work processes will be implemented within the organization to ensure that data collected are of the needed and expected quality for their intended use. | * Describe how the organization will implement work processes to ensure EI (environmental information) is of known and documented quality, scientifically valid, legally defensible, and appropriate for its intended use; Specifically, describe general processes for:   + Documentation of implementation procedures (e.g., SOPs or reference methods)   + Testing and evaluation of procedures to confirm their performance   + Work is being performed to approved plans   + Deviations and waivers form approved procedures   + Use of measurement and testing equipment and models   + Use of environmental information obtained from other sources   + The integrity of samples and environmental information   + Performance monitoring * Describe/reference how the release, change, and use of quality program implementation documentation is managed * Describe/reference the process for identifying the need for implementation procedures and documents (e.g., SOPs, checklists, templates, forms), developing SOPs, and using SOPs * Describe/reference the process by which SOPs are reviewed for initial and subsequent use, approval, distribution, revision, and rescission |  |  |
| 15. Plan-Do-Check-Act (PDCA) Quality Model  C. Check (Assessment and Oversight) | Documents how the organization will determine the suitability and effectiveness of the quality program and the environmental programs to which the quality program applies. | * Describe the management commitment and approach to assessing the organization’s quality program; specifically:   + Identify how assessments will be planned, conducted, and documented at least annually to assess the QP’s effectiveness, institute improvements, and demonstrate senior management’s commitment to implementation of the QP   + Describe the management review process to review, assure, and document the QP’s continuing suitability, adequacy, and effectiveness, including delegation(s), status of actions from previous management reviews, trends, prior assessment results, and opportunities for improvement   + Retain documentation of the results and/or outputs of management reviews, such as continual improvement opportunities or needed changes to the Quality Program * For project, program, or task-specific assessments, describe/confirm that personnel conducting assessments are qualified based on project-specific requirements and technically knowledgeable with no real or perceived conflict of interest * For the types of assessments conducted by the organization, describe:   + Assessment frequency   + How and by whom assessments are planned, conducted, evaluated, and documented   + Processes by which management and the QAM choose an assessment type or tool   + Processes for planning, scheduling, and implementation of assessments   + Responsibilities, levels of participation, and authorities for all personnel and staff participating in the assessment process   + How personnel conducting assessment will have sufficient authority, access to personnel and documentation, and freedom to identify quality issues, identify and cite noteworthy practices, propose recommendation for resolving quality issues, and independently confirm implementation and effectiveness of solutions   + How the level of competence, experience, and training will be determined to ensure the capability of personnel performing assessments   + How, when, and by whom actions will be taken in response to the findings of assessments and determine the effectiveness of the response   + Roles and responsibilities of management and staff for documenting, reporting, and reviewing assessment results   + Type of assessment findings (e.g., conformance, non-conformance, opportunity for improvement) that may be used and appropriate response to each |  |  |
| 15. Plan-Do-Check-Act (PDCA) Quality Model  D. Act (Corrective Actions and Improvements) | Documents how corrective actions are implemented, tracked, and reviewed for effectiveness | * Describe/reference how corrective actions and improvements will be performed * Describe/reference how management will respond to assessment results (i.e., findings, non-conformances, corrective actions, recommendations) in a timely manner * Verify that when corrective actions are needed, responses will be timely and included identification of root causes, determination of whether the problem is unique or systemic, and action(s) to prevent recurrence of the issue(s) * Indicate how corrective actions will be tracked and their implementation assessed for effectiveness |  |  |
| 1. Dispute Resolution Process | Describes how the organization will address program management, technical, and quality-related disputes | * Describe dispute resolution processes for technical and program management disputes * Describe/reference the dispute resolution process for issues pertaining to quality * Describe how disputes, if encountered because of audits or assessments, are addressed and by whom |  |  |
| 1. Continual Improvement | Describes how the organization’s quality program will be continually evaluated for opportunities for improvement | * Describe how the organization will continually improve its quality program, including how staff at all levels are encouraged to identify process improvement opportunities * Identify who is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities * Describe the roles and responsibilities of management and staff on the process to ensure continual improvement |  |  |
| 1. Data Review, Validation and Verification, and Data Usability Reporting | Describes general processes for how the organization reviews, validates, and verifies environmental data for data usability reporting | * Describe/reference general processes for how the organization conducts reviews, validation, and verification of environmental data * Include/reference responsibilities of management and staff in the review, validation, and verification of environmental data and data usability reporting * Describe/reference general processes for:   + Reviewing results of environmental data to confirm technical and quality objectives were met   + Reviewing environmental data of undocumented qualtiy for potential use, or data collected previously for other purposes   + Planning, implementing, and resolving peer review considerations. |  |  |