QUALITY MANAGEMENT PLAN (QMP) DEVELOPMENT FRAMEWORK FOR GRANT RECIPIENTS

A Quality Management Plan, or QMP, describes an organization's Quality Program. It also documents how the organization structures its Quality Program, including descriptions of its internal quality procedures for implementing and assessing the effectiveness of the program; criteria for and areas of application; and roles, responsibilities, and authorities. The QMP must also document all technical activities to be performed under the Quality Program and how the program will integrate quality assurance (QA), quality control (QC), and Quality Assurance Project Plans (QAPPs) into all its environmental information operations (EIO).

Environmental information operations is a collective term that encompasses the collection, production, evaluation, or use of environmental information and the design, construction, operation, or application of environmental technology.

The QMP must meet the requirements of CIO 2105-S-01, EPA's Quality Management Plan Standard (QA/S-1) (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8). In addition, this framework includes requirements for special considerations, such as Human Subjects Research (HSR) evaluations, EIO determinations, and subawardee/contractor requirements.

This framework is intended to aid Region 8 grant recipients with developing a QMP. This framework should not be used in place of QA/S-1 or the QMP Standard Crosswalk (see link in previous paragraph). Reach out to your EPA Project Officer if you need additional support or have questions about QMP development.

INSTRUCTIONS:

- The QMP must be submitted to the EPA Region 8 Regional QA Manager (RQAM) for review and approval, along with a completed Region 8 QMP Crosswalk (see link above).

- The grant recipient's Quality Program and QMP must undergo an annual review. Documentation of these reviews includes an annual report summarizing the review of the Quality Program and a completed Region 8 QMP Crosswalk for the QMP. These documents must be submitted to the RQAM.

- All standard operating procedures (SOPs) referenced in the QMP must be included as an attachment to the QMP.

- Some of the required QMP information may already be included in the project narrative/work plan. Information may be copied from the project narrative/work plan and pasted into the QMP, and it must be reviewed and updated, as necessary, to ensure it meets the requirements of QA/S-1.

- The QMP must describe quality requirements for the grant recipient, as well as quality requirements for subawardees and contractors, if applicable. See the sections below for more details.

1.   Title Page
(QA/S-1 Section 5.B.1, Page 5)

The **Title Page** must include the following information:

- ✓ Name of document, including 'Quality Management Plan'
- ✓ Date of QMP preparation
- ✓ Name of the grant recipient
- ✓ Title or identification reference number of the cooperative agreement, if applicable
- ✓ Period of performance (i.e., 5 years from the date of the RQAM approval signature)
- ✓ Version control information (e.g., Revision 0)

2. Approval Page
(QA/S-1 Section 5.B.2, Page 5)

The signatures on the **Approval Page** indicate that officials have reviewed the QMP and concur with its implementation as it is written. It is the grant recipient's responsibility to make sure all signatures are in place before work begins.

The following individuals are required to sign the **Approval Page**:

Grant Recipient Senior Manager: Grant recipient personnel with executive authority for the organization, managers, QA staff, technical staff, and other involved with EIO and implementing the QMP. The Senior Manager is responsible for ensuring the preparation and approval of a QMP that covers all EIO specified by the applicable grant, cooperative agreement, or contract and for which the organization's management is accountable.

Grant Recipient Quality Assurance Manager (QAM): Grant recipient personnel with the authority to conduct independent oversight of the organization's Quality Program. The QAM must function independently of direct EIO; remain objective regarding the Quality Program, particularly during internal assessments of the Quality Program; report directly to the Senior Manager having executive leadership of the organization; and have authority to access and discuss quality-related issues with the Senior Manager.

EPA Region 8 Regional Quality Assurance Manager (RQAM): Region 8 personnel with the responsibility for oversight and implementation of Regional and Agency QA policies. *Note: The RQAM can share any available tools and trainings with the* grant recipient *to identify QAPP projects and templates for QAPP design.*

EPA Region 8 Project Officer: Region 8 personnel with immediate managerial, administrative, or technical control of the grant recipient.

Following the Approval Page and before the Quality Statement (Section 3), add a **Table of Contents** to the QMP.

3. Quality Statement
(QA/S-1 Section 5.B.3, Page 6)

The **quality statement** must include the following information:

- ✓ The importance of quality in EIO
- ✓ General objectives and goals of the QMP
- ✓ A description of management and staff responsibilities for implementing the QMP
- ✓ The grant recipient's commitment to quality management principles, practices, and resource allocation for the grant recipient's QA Program

Note: The quality statement is different than an organization's mission statement. A mission statement addresses goals for the entire organization. A quality statement addresses senior management's specific commitments toward the quality of the organization's environmental information operations. Quality statements are implemented by the organization and documented in its QMP.

4. Organization Chart
(QA/S-1 Section 5.B.4, Page 6)

The **organization chart** must include the following information:

- ✓ All components of the organization, including the organizational position
- ✓ Lines of communication (dashed lines) and authority (solid lines)
- ✓ Lines of reporting for the QAM and QA staff
- ✓ Areas of the organization that occupy senior or executive management
- ✓ Areas of the organization conducting environmental information operations
- ✓ Areas of the organization conducting QA
- ✓ Independence of the QAM and quality staff from groups conducting direct EIO
- ✓ Display how quality management and operations management report to senior management
- ✓ A key for deciphering information within the organization chart

Please see the *example* organization chart below:
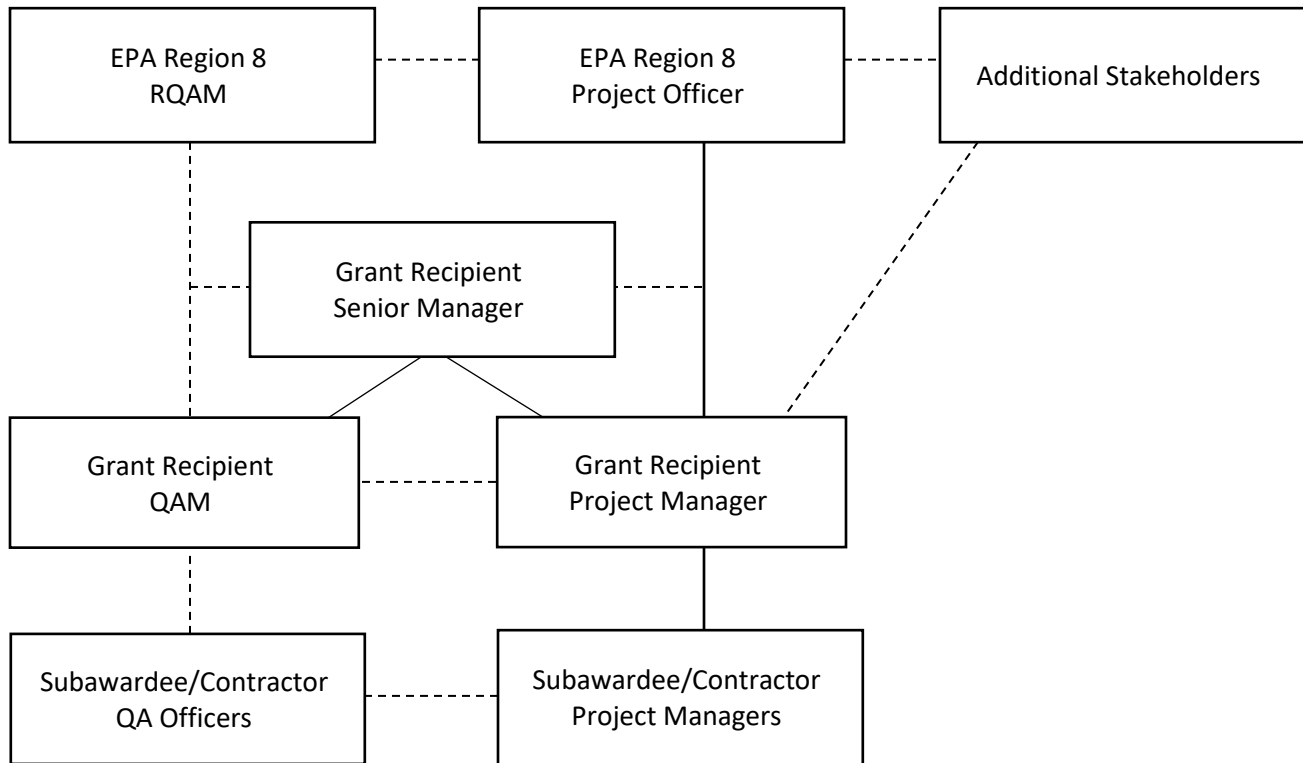
Lines of authority = ——————
Lines of communication = - - - - - - -

5. Roles, Responsibilities, and Authorities
(QA/S-1 Section 5.B.5, Page 6)

The QMP must describe the responsibilities and authority of all key project personnel. Key project personnel include, but may not be limited to, the following:

- ✓ Grant recipient Senior Manager
- ✓ Grant recipient QA Manager
- ✓ Grant recipient Project Manager (Operations Manager)

Grant Recipient Senior Manager:
- Has executive authority for the organization, managers, QA staff, technical staff, and other involved with EIO and implementing the QMP
- Responsible for assuring the preparation and approval of a QMP that covers all EIO specified by the applicable grant, cooperative agreement, or contract and for which the organization's management is accountable

Grant Recipient Quality Assurance Manager (QAM):
- Has the authority to conduct independent oversight of the organization's Quality Program
- Functions independently of direct EIO
- Conducts annual internal assessments of the Quality Program
- Reports directly to the Senior Manager having executive leadership of the organization
- Has authority to access and discuss quality-related issues with the Senior Manager
- Develops the QMP for RQAM feedback and approval
- Reviews and approves the QMP and other QA documents; reviews the QMP annually
- Develops and provides training to personnel, including contractors and subawardees, on QA policies and practices
- Identifies, assesses, and supports subawardees with QAPP needs, including making EIO determinations for the subawardees, as applicable
- Provide support to subawardees, as applicable, such as:
  - QAPP training
  - QAPP buildout support
  - Review all subawardee QAPP deliverables using the Region 8 QAPP Crosswalk (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8) to ensure all elements are addressed and complete prior to submitting QAPP deliverables to the EPA for review and approval

Grant Recipient Project Manager (or Operations Manager):
- Has immediate managerial, administrative, or technical control of a project
- Ensures that the Quality Program is employed for all activities involving EIO
- Does not have authority to sign QA documentation for the QAM
- Ensures no EIO activities are conducted without an approved QAPP

- Determines the need for Human Subjects Research (HSR) evaluations, in consultation with the QAM
- Following review by the QAM, submits all QAPP deliverables, including Region 8 QAPP Crosswalk (see link above), to the EPA for review and approval

Examples of additional roles and responsibilities that may be described in the QMP include other QA personnel, technical personnel, health and safety personnel, field personnel, and data managers.

6.   Technical Activities and Programs Supported by the QMP
(QA/S-1 Section 5.B.6, Page 7)

The QMP must document all **technical activities and programs supported by the QMP**:

- ✓ Identify and describe all parts of the organization (by name) to which the QMP applies (this description should correlate to the organization chart).
- ✓ Identify and describe all programs and technical activities involving EIO.
- ✓ Describe how the programs will integrate QA and QC procedures and QAPPs into all its EIO, as specified in cooperative agreements, and describe their implementation.

If applicable, the QMP must also describe the grant recipient's processes for the following (see Section 15 for additional details):

- ✓ Making EIO determinations based on the work plans submitted by subawardees.
- ✓ Evaluating work plans submitted by subawardees for human subjects research (HSR).
- ✓ Reviewing QAPPs prepared by subawardees using the Region 8 QAPP Crosswalk (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8) prior to submitting each QAPP for EPA Region 8 approval.

7.   Conformance with Policies, Procedures, Standards, and Regulations
(QA/S-1 Section 5.B.7, Page 7)

The QMP must explicitly identify and acknowledge **conformance with all EPA policies, procedures, standards, and regulations**, as well as internal organization procedures, processes, and standard operation procedures (SOPs) pertinent to the EIO included in the Quality Program.

All references, resource links, citations, and sources for both Federal and internal policies, procedures, standards, and regulations must be current and accessible enough to resolve all ambiguity of the material's location. (Citations of specific sections, parts, and or page numbers of source material may be necessary.)

Document all quality-related terms and conditions and requirements specified in cooperative agreement(s), grant, or contract, and describe their implementation.

8.   QA Field Activities
(QA/S-1 Section 5.B.8, Page 8)

The QMP must include a section for field procedures, if applicable, that covers environmental information operations. The QMP should describe, reference, and confirm this information in this section.

- ✓ Describe the QA field activities that will be performed by the grant recipient.
- ✓ Indicate that no work involving EIO will be performed by the grant recipient or subawardees/contractors without an approved QAPP.
- ✓ Indicate that all QAPPs prepared by the grant recipient, subawardees, or contractors will meet the requirements of CIO 2105-S-02 (QA/S-2), EPA's *Quality Assurance Project Plans Standard* (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8).

9. Computer Hardware and Software
(QA/S-1 Section 5.B.9, Page 8)

To ensure **information produced from or collected by computers** meets applicable requirements and standards, the QMP must describe or reference the internal processes the organization will use to satisfy the requirements in the current versions of:

- ✓ EPA CIO 2122-P-03.1 Enterprise Architecture IT Standards Procedure
- ✓ EPA CIO 2104.1 IT/IM Directive Policy Software Management and Piracy Policy
- ✓ EPA CIO 2104-P-01-0 Software Management and Piracy Procedure

10. Information Quality Guidelines (EPA Organizations only)
(QA/S-1 Section 5.B.10, Page 8)

This section applies to EPA Organizations only and is not required for QMPs prepared by grant recipients.

11. Organization Competence
(QA/S-1 Section 5.B.11, Page 9)

The QMP must document the *grant recipient*'s process for **ensuring the competence of personnel** to implement the EIO activities described in the QMP. Specifically:

- ✓ Document how the organization determines the minimum requirements (i.e., technical skills, demonstrated knowledge, and documented experience) for personnel described in the QMP conducting environmental information operations.
- ✓ Document how the organization evaluates personnel for competency based on the requirements for the roles to confirm that these persons are competent based on appropriate knowledge, skills, education, training, and experience.

For Subawardees/Contractors, if applicable:

- ✓ The grant recipient shall document how each subawardee/contractor evaluates personnel for competency based on the requirements for the roles to confirm that these persons are competent based on appropriate knowledge, skills, education, training, and experience.

12. Personnel Training
(QA/S-1 Section 5.B.12, Page 9)

Effecting implementation of the QMP requires that training and outreach occur to ensure all personnel involved in the planning, management, and implementation of EIO have the competencies to complete their tasks according to the procedures and processes in the Quality Program.

Training needs within the organization are task- or role-specific and include both technical training and quality-related training.

The QMP must include the following:

- ✓ Describe the process for determining training requirements and training needs for all levels of management and staff involved in EIO, to ensure that QA and QC responsibilities and requirements are understood at every stage of project implementation.
- ✓ Describe the roles of individual(s) responsible for defining, planning, reviewing, and documenting training requirements.
- ✓ Describe the process for identifying, assessing, and supporting subawardees/contractors, if applicable, with QAPP development and other quality-related needs.

For Subawardees/Contractors, if applicable:

- ✓ Include a statement that the training required by the subawardees/contractors must be described within the project-specific QAPPs.

13. Procurement of Items and Services
(QA/S-1 Section 5.B.13, Page 9)

The QMP must describe the grant recipient's procurement processes, including roles, responsibilities, and authorities, pertaining to all procurements and cooperative agreements, for ensuring that subawardees and contractors performing environmental information operations comply with all quality requirements specified in this QMP.

Specifically, the QMP must include the following information:

<u>Purchasing Supplies</u>

- ✓ Describe the process for purchasing supplies.
- ✓ Describe the process for ensuring that purchased supplies are of acceptable quality.

<u>Contracting of Services</u>

- ✓ Describe the process for reviewing and approving procurement and extramural documents (and any changes to these documents) prior to issuing the solicitation to ensure that the documents are accurate, complete, and contain EPA quality requirements.
- ✓ Describe the procedures for verifying how the contractor will conform to the grant recipient's requirements, including the contractor's responsibility for the Quality Program requirements.
- ✓ Describe the process for reviewing all applicable responses to solicitations to ensure that these documents satisfy all technical and quality requirements, including evidence of the contractor's capability to satisfy EPA Quality Program requirements, as defined in the extramural agreement and applicable Federal Regulations.
- ✓ Describe the process for ensuring that contracted services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by contractors, source selection, source inspections, contractor audits, and examination of deliverables.
- ✓ Describe the procedures for reviewing quality-related documentation from contractors.
- ✓ Describe the process for ensuring that EPA quality-related contracting requirements, as defined by the Federal Acquisition Regulations, are satisfied.

<u>Cooperative Agreements with Subawardees, if applicable</u>

- ✓ Describe the subawardee competitive application submission and evaluation process. The process should include a range of submission options, including approaches accessible to communities and community-based organizations without reliable access to internet services.
- ✓ Describe the plans for communicating and conducting outreach activities to reach all disadvantaged and underserved communities, especially urban, rural, and remote

communities. Communications and outreach activities should be focused on making potential subawardees aware of the availability of the EJ Thriving Communities Subgrant funding, deadlines for submitting applications, tutorials to understand the application and subawards process, and opportunities to ask questions.

✓ Describe the procedures for verifying how the subawardee will conform to the grant recipient's requirements, including the subawardees' responsibility for the Quality Program requirements.

✓ Describe the process to make funds available to selected subawardees quickly and how fund expenditures will be monitored.

✓ Describe the procedures for reviewing quality-related documentation prepared by the subawardees.

✓ Describe the process for providing technical support to subawardees to assist in data collection, tracking, evaluation, and reporting of information.

For Subawardees, if applicable:

✓ Describe the process that the subawardee must use if they procure supplies or services.

14. Document and Record Processes
(QA/S-1 Section 5.B.14, Page 11)

The QMP must describe (or provide reference to) the **Document and Record Processes** for all planning documents (e.g., QMPs, QAPPs, SOPs, etc.) that are prepared, reviewed, approved, issued, used, revised, tracked, and verified. The QMP must also describe how record management requirements are met, including the responsibilities and authorities of management and staff.

For the grant recipient, as well as subawardees/contractors, if applicable, the QMP must include the following:

- ✓ Identify all quality-related documents and records requiring management and control, including documents **prepared by the grant recipient and subawardees/contractors**.
- ✓ Reference EPA Record retention schedules.
- ✓ Reference all program regulations, contract, and agreement records requirements for all environmental information operations.
- ✓ Describe the processes for handling quality-related documents and records **prepared by the grant recipient and subawardees/contractors** to ensure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff.
- ✓ Describe the measures for controlling the release, change, and use of grant recipient and subawardee/contractor planning documents and records, including descriptions of how technical guidance and planning documents (e.g., QAPPs, SOPs, etc.) are prepared, reviewed, approved, issued, used, revised, tracked, and verified.
- ✓ Describe the processes and procedures for ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.
- ✓ Describe the procedures for establishing and implementing applicable chain of custody and confidentiality procedures for evidentiary records.
- ✓ Describe how documents and records **prepared by the grant recipient and subawardees/contractors**, including revisions, are reviewed for conformance with new requirements and with the terms and conditions of cooperative agreements, and are approved by authorized personnel before general use.
- ✓ Describe or provide a reference to the management process that ensures that documents and records **prepared by the grant recipient and subawardees/contractors** accurately reflect completed work and/or fulfill statutory and contractual requirements, including any specific record keeping requirements defined in applicable EPA policies, procedures, standards, or regulations. The maintenance of records includes defining requirements and responsibilities for record transmittal, distribution, retention, retention schedules, protection, preservation, traceability, disposition, and retrieval.

✓ Identify or reference the accomplishment for disposing of quality-related records, in accordance with regulatory requirements or schedules.
✓ Describe the process for conducting annual reviews and revisions of the QMP.

- o In accordance with QA/S-1 Section 6, the grant recipient must review its QMP annually for the 5-year life of the QMP to reconfirm the suitability and effectiveness of the approved quality management practices.
- o The grant recipient shall document the review using the Region 8 QMP Crosswalk (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8).
- o QMP review results and/or revisions made must be submitted to the EPA Project Officer and EPA RQAM annually.

15. Plan, Do, Check, Act (PDCA) Quality Model
(QA/S-1 Section 5.B.15, Page 12)

Implement the **Plan, Do, Check, Act (PDCA) Quality Model** described in CIO 2105-S-01.
*Use of a **Systematic Planning** approach based on the scientific method to develop acceptance or performance criteria for all work covered by current versions of <u>CIO 2105, CIO 2105-S-01, and CIO 2105-S-02</u>, where systematic planning and development of QMPs are described. Use of the QA/G-4 (2006), EPA Guidance for the Data Quality Objectives Process is recommended.*

For each of the subsections below (Plan, Do, Check, Act), the QMP must describe how the grant recipient will meet each listed requirement, as well as how the grant recipient will ensure subawardees/contractors, if applicable, also meet each listed requirement.

A. *Plan*

- ✓ Describe (or reference SOPs that describe) the processes for determining systematic planning and the development of acceptance or performance criteria to perform environmental information operations.
- ✓ Document the use of a systematic planning process for environmental information operations that is based on the scientific method. The planning process should be based on a common sense, graded approach to ensure that the level of detail in planning is in accordance with the intended use and the degree of confidence needed in the quality of the results.
- ✓ The following elements of the systematic planning approach must be documented:

  - o identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc.
  - o description of the project goals, objectives, and questions and issues to be addressed
  - o identification of the project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements)
  - o identification of the type of information needed and how the information will be used to support the project's objectives
  - o determination of the quantity of information needed and specification of performance criteria for measuring quality
  - o description of how, when, and where the information will be obtained (including existing information) and identification of any constraints on information collection
  - o specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, sensitivity analysis of models, etc.)

- o description of how the acquired information will be analyzed, evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria

- ✓ Acquired information includes environmental information obtained from sources that used an EPA-approved QAPP, as well as from sources that did not use an EPA-approved QAPP. Project specifics shall be included in the QAPP.
- ✓ Describe the QAPP planning and documentation process, including organization-specific requirements by project-type.
- ✓ Describe the plan, approach, and process for project management, including oversight for funding subawardees/contractors, if applicable, and a system to track all projects.

B. _Do (Implementation)_

- ✓ Include processes for how the grant recipient will implement the work processes to ensure that environmental information is of known and documented quality, scientifically valid, legally defensible, and appropriate for the intended use:

  - o documentation of implementation procedures (e.g., reference methods, SOPs)
  - o testing and evaluation of procedures to confirm their acceptable performance
  - o the work being performed according to approved plans
  - o deviations and waivers from approved procedures
  - o use of measurement and testing equipment and models
  - o use of environmental information obtained from other sources
  - o the integrity of samples and environmental information
  - o performance monitoring

- ✓ Describe how appropriate management controls for the release, change, and use of implementation of quality program documentation.

  - o necessary approvals
  - o specific times
  - o points for implementing changes
  - o removal of obsolete documentation from work areas
  - o verification that the changes are made as prescribed

- ✓ Describe the grant recipient's process for identifying the need for procedures and controlled documents (e.g., SOPs, checklists, templates, forms, etc.), the process for developing SOPs, and the procedures for using SOPs.
- ✓ Describe the process by which SOPs are reviewed for initial and subsequent use, approved, distributed, revised, and rescinded.
- ✓ Describe the process for making EIO determinations based on the work plans submitted by the subawardees, if applicable.

- o If applicable, the grant recipient is responsible for ensuring subawards/contracts involving EIO include appropriate quality requirements for the work. The grant recipient is responsible for ensuring that subawardees/contractors develop and implement project-level planning documents (e.g., QAPPs, SOPs, assessment checklists, etc.).
- o 'Environmental information operations' is a collective term that encompasses the collection, production, evaluation, or use of environmental information and the design, construction, operation, or application of environmental technology.
- o Describe the process for collaborating with EPA, as necessary, to make EIO determinations.

✓ Describe the process for evaluating project and work plans for human subjects research, in compliance with 40 CFR Part 26.

- o 40 CFR Part 26 ensures the rights and welfare of the human subjects are protected.
- o If HSR is suspected for any project proposed by the grant recipient, the EPA Project Officer must be notified.
- o The Project Officer reviews the project and consults with the Region 8 Human Subjects Officer (i.e., the Regional Science Liaison).
- o The Regional Science Liaison requests a review of the project by the Human Subjects Research Review Official (HSRRO) at EPA Headquarters.
- o The HSRRO will provide a letter indicating whether the project is affirmative for HSR applicability.
- o All HSR projects must be approved by the HSRRO before any work involving human subjects can begin.
- o For additional information, visit: https://www.epa.gov/scientific-leadership/human-subjects-research

✓ Describe the process for reviewing QAPPs using the Region 8 QAPP Crosswalk (https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-8).

- o The grant recipient is responsible for ensuring a QAPP(s) is developed that documents the QA, QC, and technical activities that must be implemented to ensure that the project objectives are met.
- o To be approvable, a QAPP must be developed for each project that meets all requirements outlined in EPA QA/S-2: Quality Assurance Project Plan Standard, CIO 2105-S-2 (QA/S-2).
- o For each QAPP, the author must complete the Region 8 QAPP Crosswalk for the QA/S-2 Standard. In the QAPP Crosswalk, the author shall identify the specific section(s) of the QAPP that addresses the corresponding required QAPP element in QA/S-2, including a detailed explanation for any elements considered not applicable to the grant.

- The grant recipient is responsible for reviewing QAPPs prepared by subawardees/contractors, if applicable, using the Region 8 QAPP Crosswalk. The QAPP author is responsible for addressing any issues in the QAPP identified by the grant recipient. Changes made to the QAPP based on the grant recipient's review must be documented in the QAPP Crosswalk.
- Once the grant recipient confirms that the QAPP meets the requirements of QA/S-2, the grant recipient submits the QAPP and completed QAPP Crosswalk to the EPA Project Officer for review and approval.
- The grant recipient is responsible for ensuring no work involving EIO will occur until the QAPP is reviewed and approved by the EPA RQAM or their delegate.
- Each QAPP has a maximum period of performance of 5 years. For multi-year QAPPs, the QAPP author must review the current QAPP(s) annually to reconfirm its suitability and effectiveness. The QAPP author shall document the review using the QAPP Crosswalk. In the QAPP Crosswalk, the author shall identify the specific section(s) of changes to the approved version of the QAPP and include a description of what changed and why in the crosswalk element's comment box. The grant recipient is responsible for submitting the revised QAPP and crosswalks to the EPA Project Officer annually.
- Significant changes to the project require the author to modify the QAPP and submit the updated QAPP as a new document as described above. The grant recipient must submit the updated QAPP and completed QAPP Crosswalk to the EPA Project Officer for review and approval. Only after the revision has been approved by the RQAM can the change be implemented.

C. *Check (Assessment and Oversight)*

✓ Describe management's commitment and approach to assessing its Quality Program.
✓ Describe (or reference SOPs that describe) the process(es) for assessments:

- Assessments shall be planned, conducted, and documented at least annually to provide information on the effectiveness of the Quality Program.
- Assessment/audit tools include, but are not limited to, data quality assessments; quality program assessments; Quality Program Management Reviews; peer, technical, and readiness reviews; performance evaluations; technical system audits; laboratory competency assessments; and surveillances.
- The organization shall base assessment findings on objective evidence and retain the documented information as part of quality records.

✓ Describe the qualifications of assessors:

- Personnel conducting assessments shall be qualified, based on project-specific requirements, to perform the assigned assessment.

o   Management is responsible for choosing the assessors, defining acceptance criteria, approving assessment/audit procedures and checklists, and identifying goals prior to initiation of an assessment/audit.
o   Assessors shall be technically knowledgeable with no real or perceived conflict of interest.
o   If the assessors are chosen from within the organization, they must have no direct involvement or responsibility for the work being assessed, except for self-assessments.

✓ Describe the process for assessing the Quality Program:

o   Assessments of the Quality Program shall be planned, conducted, and documented to assess its effectiveness, institute improvements, and demonstrate senior management's commitment to implementation of the Quality Program in accordance with the procedures described in the QMP.
o   Annually, senior management or as delegated, shall review, assure, and document the organization's Quality Program to confirm its continuing suitability, adequacy, and effectiveness.
o   The QMP shall describe the management review process to include delegation; the status of actions from previous management reviews, changes in external and internal issues that are relevant to the Quality Program; information on Quality Program performance, including trends in nonconformities and corrective actions, assessment results, and opportunities for improvement; and suitability of internal processes and SOPs.

✓ The outputs of the management review shall include decisions related to continual improvement opportunities and any need for changes to the Quality Program. The organization shall retain documented information as evidence of the results of management reviews. This documentation will also serve as evidence that management executed their due diligence responsibilities and have assured the data used in their environmental information operations products and services are of appropriate quality.

The QMP must also describe:

✓ Assessment frequency.
✓ How and by whom assessments of EIO are planned, conducted, evaluated, and documented.
✓ Processes by which management, in conjunction with the QAM, chooses an assessment tool, including performance measures and the expected frequency of their application to environmental information operations.
✓ Routine oversight activities of subawardees/contractors, if applicable.
✓ Processes for the planning, scheduling, response to changes, and implementation of assessments.

- ✓ Responsibilities, levels of participation, and authorities for all personnel and staff participating in the assessment/audit process.
- ✓ How personnel conducting assessments shall have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom to:

  - o identify quality issues
  - o identify and cite noteworthy practices that may be shared with others to improve the quality of their operations products and services
  - o propose recommendations for resolving quality issues
  - o independently confirm implementation and effectiveness of solutions

- ✓ How the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments are determined.
- ✓ How, when, and by whom actions shall be taken in response to the findings of the assessment/audit 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, nonconformance, opportunity for improvement, commendation) that may be used and the appropriate response to each one.

D. *Act (Corrective Actions and Improvements)*

- ✓ Describe or reference how corrective actions and improvements will be performed.
- ✓ Describe or reference how management will respond to the results, non-conformances, findings, corrective actions, recommendations, etc., from assessments in a timely manner.
- ✓ Describe how the appropriate response shall be promptly made when conditions needing corrective action are identified.
- ✓ Describe the corrective action process, including roles and responsibilities, identification of root causes of problems, the determination of whether the problem is unique or has systemic implications, and action(s) to prevent recurrence.
- ✓ Indicate how follow-up actions for corrective actions shall be taken and documented to confirm the implementation and effectiveness of the response action.
- ✓ Describe the processes for identifying and correcting common non-conformances found in different parts of the organization to ensure continual improvement.

16. Dispute Resolution Process
(QA/S-1 Section 5.B.16, Page 16)

The QMP must describe provisions for **Dispute Resolution** to include technical and management program disputes.

- ✓ Describe or reference the grant recipient's dispute resolution process to address issues pertaining to quality, such as QMP requirements, QA and QC procedures, non-conformances, findings, and corrective actions.
- ✓ Describe how disputes, if encountered, because of assessments are addressed and by whom.
- ✓ If applicable, describe the dispute resolution process to address issues that arise between the grant recipient and subawardee(s)/contractor(s) and the grant recipient and EPA.

17.   Continual Improvement
(QA/S-1 Section 5.B.17, Page 16)

The QMP must include the following:

- ✓ Describe how the grant recipient will **Continually Improve** its Quality Program, including how staff at all levels are encouraged to identify and establish communications, identify process improvement opportunities, and identify issues.
- ✓ Identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities, and describe the process to ensure continual improvement, including the roles and responsibilities of management and staff.
- ✓ Describe the continual improvement process to be followed by subawardees, if applicable.

18. Data Review, Validation and Verification, and Data Usability Reporting
(QA/S-1 Section 5.B.18, Page 17)

The QMP must describe or reference general processes on how the grant recipient conducts **reviews, validation, and verification** of environmental information operations for data usability reporting, including the responsibilities and authorities of management and staff.

The QMP must specifically describe the organizational processes for:

- ✓ Review of results involving environmental information to confirm that technical and quality objectives were met, including management and staff roles and responsibilities.
- ✓ Review of environmental information of undocumented quality for potential use.
- ✓ Review of environmental information collected previously for other purposes but being considered for new use.
- ✓ Planning, implementing, and resolving peer review considerations.

For Subawardees/Contractors, if applicable:

- ✓ Indicate that data review, verification, validation, data usability of environmental information collected by subawardees/contractors will be described within each project-specific QAPP (per QA/S-2).

Additional Required QMP Content

<u>References</u>

List all resources used to prepare the QMP. References should include the author, title, document/volume/revision numbers, and date of the referenced document. If a website was used as a reference, include the title of the article or website and the specific URL.

At a minimum, the references should include the following:

U.S. Environmental Protection Agency, *Environmental Information Quality Policy*, CIO 2105

U.S. Environmental Protection Agency, *Quality Management Plan Standard*, CIO 2105-S-01

<u>Revision/Change History</u>

The QMP should include documentation of revisions made to the QMP and the revision number. An example Revision/Change History table is provided below:

Revision Number	Date	History/Change Description

<u>Acronyms and Abbreviations</u>

Include a list of all acronyms and abbreviations used in the QMP text. Note that acronyms and abbreviations should be spelled out the first time they are used in the text with the acronym/abbreviation in parentheses. For example: "Standard operating procedures (SOPs) for field activities are provided in Appendix A." Then the acronym (e.g., SOPs) should be used in the remainder of the text.

<u>Attachments</u>

At a minimum, all SOPs referenced in the QMP must be attached to the QMP.