**Quality Management Plan Standard**

Directive No: CIO 2105-S-01.0

*Issued by the EPA Chief Information Officer,*
*Pursuant to Delegation 1-19*

# Quality Management Plan Standard

## 1. PURPOSE

This Standard supports the implementation of EPA's Environmental Information Quality Policy and Environmental Information Quality Procedure[1].

All EPA organizations performing environmental information operations and non-EPA organizations performing environmental information operations on behalf of EPA are required to participate in the EPA Agency-wide Quality Program. EPA's Quality Program supports EPA's mission to protect human health and the environment and to ensure environmental information operations products and services are of known and documented quality for their intended use(s).

The Quality Management Plan (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 (QAPP) into all its environmental information operations.

The requirements described in this Standard are consistent with the principles in the American Society for Quality (ASQ)/American National Standards Institute (ANSI) E4:2014 (R2019), *Quality management systems for environmental information and technology programs—Requirements with guidance for use*.

## 2. SCOPE

This Standard defines the minimum requirements for QMPs for all EPA and non-EPA organizations performing environmental information operations. Environmental information operations is a collective term that encompasses the collection, production, evaluation, or use of environmental information by or for EPA and the design, construction, operation, or application of environmental technology by EPA.

## 3. AUDIENCE

The audience for this Standard is all Agency employees responsible for environmental information operations. This includes EPA Program Offices, Regions, and their sub-organizations hereafter referred to as EPA organizations.

[1] *The current versions of these directives are located at IT/IM Directives.*

This Standard also applies to non-EPA organizations performing environmental information operations in support of EPA's mission or national program priorities as defined by and in accordance with:

- federal laws and legal requirements including administrative orders/enforcement actions,
- regulations,
- extramural agreements, or
- performing work on a voluntary basis under agreement with EPA.

Non-EPA organizations include but are not limited to:

- contractors,
- regulated parties,
- cooperative agreement holders,
- grantees,
- states, tribes, localities, intergovernmental agencies,
- educational institutions, hospitals, non-profits,
- other federal governmental agencies, and parties to Memoranda of Agreement or Understanding,
- volunteer organizations, and
- other environmental information providers.

Since non-EPA organizations may participate in more than one extramural agreement with EPA, the organization's QMP may contain common management information that may be applied to more than one agreement.

## 4. BACKGROUND

Since 1979, it has been an Agency requirement for all EPA organizations performing environmental information operations and non-EPA organizations performing environmental information operations on behalf of EPA to participate in an Agency-wide Quality Program.

In March 2001, the Agency issued *EPA Requirements for Quality Management Plans EPA QA/R-2,* and in May 2006, the Agency reissued *EPA QA/R-2.*

In March 2021, the Agency revised EPA's quality policy and procedure and reissued as EPA's Environmental Information Quality Policy and Environmental Information Quality Procedure[2]. Together we refer to these as the Agency's Quality Policy and Procedure.

## 5. AUTHORITY

These citations are valid at the time of issuance of this Standard. Since these documents are subject to periodic review, users of this Standard should refer to the most recent version.

- U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086 (Reorganization Plan No. 3 of 1970)

[2] *The current versions of these directives are located at IT/IM Directives.*

- Information Quality Act, Section 515 of Treasury and Government Appropriations Act, 2001 (PL 106-554, 31 USC 3516) (Refer to Page 114 STAT.2763A-154)
- 2 CFR 1500.12: Uniform Administration Requirements, Cost Principles and Audit Requirements for Federal Awards, Quality Assurance
- 40 CFR Part 35: State and Local Assistance
- 48 CFR Part 46: Quality Assurance
- 40 CFR Appendix A to Part 58 – Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards

## 6. STANDARD

### A. QMP Overview

#### 1. General Content

The QMP describes and documents an organization's Quality Program consistent with the Agency's Quality Policy and Procedure. Specific QMP content requirements are described in Section B. Each organization should evaluate these requirements for applicability to their Quality Program. Where a particular requirement is not relevant, an explanation of why it is not relevant shall be provided in the QMP. Also, if the QMP preparer or EPA organization sponsoring the work determines that additional quality requirements are useful or necessary for an adequate Quality Program, these requirements shall also be described in the QMP. Examples of additional requirements that may be useful or necessary to include may be found in Section 8. RELATED INFORMATION.

#### 2. Level of Detail: The Graded Approach and QMPs

A QMP is unique to its organization. Implementation of the Agency's Quality Policy and Procedure allows for the principle of the graded approach to be applied to the systematic planning, development, and approval of QMPs.

The graded approach establishes the QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization or the customer (for contracts). The process of determining the level of detail for management controls to be applied to activities listed in the QMP can be developed according to the intended use and the degree of confidence needed in the quality of the results.

#### 3. QMP Preparation Responsibility

**EPA Organizations**

The EPA organization's senior manager having executive leadership authority for the organization is responsible for assuring the preparation and approval of the QMP to cover all environmental information operations to be performed under the Quality Program.

The actual preparation of the QMP may be assigned to the organization's QA Manager (QAM) and/or designee.

**Non-EPA Organizations**

The senior manager of the non-EPA organization is responsible for assuring the preparation and approval of a QMP that covers all environmental information

operations specified by the applicable extramural agreement(s) and for which the organization's management is accountable.

The actual preparation of the QMP may be assigned to the organization's QAM and/or designee.

4. **QMP Submittal and Approval**

**EPA Organizations**

EPA Program Offices and Regions shall have one overarching QMP for their organization. This QMP shall be submitted to EPA Office of Mission Support (OMS), Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (EQMD) for review and approval by the Chief Information Officer (CIO) and Deputy Assistant Administrator (DAA) for Environmental Information (CIO/DAA) All submittals to EQMD shall also include a completed QMP Checklist to ensure that the QMP contains all requirements.

The EPA organization's QMP approval signatures shall include the QAM, the organization's Assistant Administrator (AA) or Regional Administrator (RA), and management between the RA/AA and the QAM. Program Offices shall also include the Senior Information Officer (SIO). Regions shall also include the Laboratory Services and Applied Sciences (LSAS) Division Director.

The Office of Mission Support approval signatures shall include the OMS-EI CIO/DAA for all Program Office and Regional QMPs.

All signatures shall be dated.

**Non-EPA Organizations**

When a QMP is required either by regulation, contractual requirement, assistance agreement condition, etc., the QMP shall be submitted for review and approval to the EPA official responsible for the work, who will then follow the approval procedures listed in the sponsoring organization's QMP. The EPA official may include the contracting officer's representative (COR), the grant project officer (PO), and the EPA QAM in accordance with their organization's overall approved QMP. All signatures shall be dated.

States, Tribes, and Territories: If stated in the EPA sponsoring organization's QMP, approval of the state, tribal, or territory QMP may include delegated QA activities such as the approval of Quality Assurance Project Plans (QAPPs), training, etc.

Non-EPA Organizations shall consult with the EPA organization sponsoring the work for additional requirements for document submittal and approval.

5. **Period of Applicability of an Approved QMP**

- **EPA Organizations**
  For EPA organizations, QMPs approved under this standard shall be valid for no more than five years from the date approved.
- **States, Tribes, Territories, and Other Federal Agencies**
  For states, tribes, territories, and other Federal Agencies, QMPs approved under this standard shall be valid for no more than the lesser of five years or shorter duration as may be defined in the extramural agreement.

**All other non-EPA organizations**

For all other non-EPA organizations, QMPs approved under this standard shall be valid for no more than five years or shorter duration as may be defined in the extramural agreement, contract; memorandum of understanding (MOU)/agreement (MOA), or legal agreement.

If a QMP no longer meets the requirements of this standard, approving officials may rescind their approval prior to the period of applicability listed.

**6. QMP Annual Reviews and Revisions**

All EPA and non-EPA organizations required to have a QMP shall review their QMP at least annually to confirm its suitability and evaluate the effectiveness of the approved quality management practices. These documented reviews shall be made available to the sponsoring EPA organization if requested.

When necessary, the organization shall revise its QMP to incorporate minor changes and notify the EPA approving authority of the changes. If significant changes have been made to the Quality Program that affect the performance of environmental information operations, it may be necessary to re-submit the entire QMP for re-approval. In general, a copy of any QMP revision(s) made during the year should be submitted to the EPA approving authority in writing when such changes occur.

Conditions requiring the revision and resubmittal of an approved QMP include:

- expiration of the QMP,
- significant changes in the organization's mission or structure, such as in the delegation status of a program,
- re-organization of existing functions that affect programs covered in the QMP,
- change in the scope (i.e., statement of work or workplan) in the extramural agreement, or
- corrective actions that significantly change the organization's quality program

All personnel in the organization performing environmental information operations covered by the scope of the QMP shall be notified of changes to the Quality Program and the QMP to keep them informed of the current requirements. This practice may also include contractors, sub-contractors, and grantees, in accordance with the organization's overall approved QMP.

**B. QMP Requirements**

QMPs for both EPA organizations and non-EPA organizations, as defined in the Agency's Quality Policy and Procedure*,* shall address all requirements of this Standard for environmental information operations. QMPs shall also describe the management commitment and approach to assessing its Quality Program.

Tribal Primary Quality Assurance Organizations (PQAOs) conducting regulatory and/or informational monitoring shall also consult with the EPA organization sponsoring the work for additional information on QMPs supporting 40 CFR Appendix A to Part 58: Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards.

The QMP shall include at a minimum:

1. **Title Page**

   The title page shall contain the name of the document to include "Quality Management Plan"**;** date of QMP preparation; name of the organization; title or identification reference number of the extramural agreement if applicable; period of performance; and version control information.

2. **Approval Page**

   The approval page is for the signatures of the QAM, senior manager, and managers between the senior manager and the QAM.

   **EPA Organizations**

   For EPA Organization QMPs, the approval page shall contain the signatures of the organization's QAM, senior manager having executive leadership authority (AA/RA), managers between the QAM and senior manager, and the OMS DAA/CIO.

   **Non-EPA Organizations**

   For Non-EPA Organization QMPs, the approval page shall contain signatures of the organization's QAM, senior manager, and managers organizationally between the QAM and senior manager.

   The approval page shall include a section for EPA signatures. QMPs shall include EPA signatures from both operations (COR, PO, etc.) and the EPA QAM or designee. For specific signatures to include, contact the EPA organization sponsoring the work.

3. **Organization's Quality Statement**

   The statement shall include at a minimum the importance of quality in its environmental information operations; the general objectives and goals of the QMP; a description of management and staff responsibilities for implementing the QMP; the organization's commitment to quality management principles, practices, and resource allocation for the organization's QA Program.

   The difference between the mission and quality statements is in their orientation. The mission statement addresses goals for the entire organization; the 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. **Organizational Chart**

   The organizational chart shall identify all components of the organization including the organizational position; lines of communication and authority; and lines of reporting for the QAM and QA staff, and the areas of the organization conducting environmental information operations. The title of the QAM position may vary by organizational structure (e.g., Quality Manager, QA Officer, Regional QAM). For this Standard, this position will be referred to as the QAM.

The organizational chart shall establish and document the independence of the QAM and quality staff from groups conducting direct environmental information operations.

**5. Roles, Responsibilities and Authorities**

In context of the overall organizational structure, the QMP shall describe the responsibilities and authority of the QAM and the Operations Manager:

**QA MANAGER**

QAMs are individuals within the organization who are assigned specific quality management duties and are delegated authority for quality management as defined in the organization's QMP. The delegation of authority to the QAM for management of the Quality Program shall be documented in the QMP.

Redelegation of procedures/processes from the QAM to others within their organization, or to states, tribes, and territories if applicable, shall also be documented in the QMP.

The QMP must state that the QAM has the authority to conduct independent oversight of the organization's Quality Program. The QAM must also function independently of direct environmental information operations.

If the QAM is not conducting routine QA activities on a full-time basis, this shall be noted in the QMP. A part-time QAM shall remain independent of environmental information operations covered in the QMP and remain objective regarding the Quality Program, particularly during internal assessments of the Quality Program.

The QAM shall report to senior managers having executive leadership for the organization. If the senior manager does not directly supervise the QAM, the QAM must have authority to access and discuss quality-related issues with their organization's senior manager outside of their direct supervisory chain as necessary. The latter is demonstrated by a dotted line on the organizational chart and the QMP shall describe the processes in place to ensure this access.

**OPERATIONS MANAGER (Program Manager)**

The Operations Manager is independent of the QAM. In some organizations this individual may also be referred to as the Program Manager or person responsible for the activity. Some organizations may have multiple operations managers. The Operations Manager will not have authority to sign QA documentation for the QAM, nor will the QAM have authority to sign documentation for operations unless specified in the organization's QMP.

The QMP shall also describe the roles and responsibilities of the senior manager having executive authority for the organization, managers, QA staff, technical staff, and others involved with environmental information operations and implementing the QMP.

**6. Technical Activities and Programs Supported by the QMP**

The QMP shall document all technical activities and/or programs supported by the QMP.

Specifically, the QMP shall:

- identify and describe all parts of the organization (by name) to which the QMP applies. (This description shall correlate to the organizational chart.),
- identify and describe all programs and technical activities involving environmental information operations, and
- describe how the programs will integrate QA/QC procedures and QAPPs into all its environmental information operations as specified in their extramural agreements and described in their implementation.

**7. Conformance with Policies, Procedures, Standards, and Regulations**

The QMP shall identify EPA policies, procedures, standards, and regulations; and internal organization procedures, processes, and standard operation procedures (SOPs) pertinent to the environmental information operations included in the Quality Program.

For non-EPA organizations, the QMP shall document all quality-related terms and conditions and requirements specified in extramural agreement(s) such as contracts, grant agreements, interagency agreements, MOUs, and describe their implementation.

**8. QA Field Activities**

**EPA Organizations**

EPA's QA Field Activities Procedure (QAFAP), CIO 2105-P-02.0[3] describes how the Agency's Quality Program shall be applied consistently to sampling and non-sampling field activities. The QAFAP provides a comprehensive, coordinated approach for consistent implementation for field activities.

EPA organizations shall include a section in the QMP that describes implementation of and conformance to the requirements in QAFAP.

**Non-EPA Organizations**

Non-EPA organizations shall include a section in their QMP for field procedures, if applicable, that cover environmental information operations. The QMP shall describe, reference, and confirm this information in this section.

**9. Computer Hardware and Software**

**EPA and Non-EPA Organizations**

To ensure the information produced from or collected by computers meet applicable requirements and standards, the QMP shall 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*[3]
- *EPA CIO 2104.1 IT/IM Directive Policy Software Management and Piracy Policy*[4]

[3] *The current version of this directive is located at IT/IM Directives.*
[4] *The current version of this directive is located at IT/IM Directives.*

- *EPA CIO 2104-P-01-0 Software Management and Piracy Procedure*[5]

**10. Information Quality Guidelines (Pre-Dissemination Review)**

**EPA Organizations only**

The QMP shall describe organizational procedures for assessing environmental information prior to dissemination. Procedures shall ensure implementation of the current version of *EPA Guidelines for Ensuring and Maximizing the Quality, Objectivity. Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*[6], referred to as the Information Quality Guidelines.

Agency reports shall be reviewed in accordance with the process described in the organization's QMP before publication to ensure that an adequate discussion of QA and QC activities is enclosed.

Documentation of pre-dissemination reviews performed on disseminated information products shall be retained.

**11. Organization Competence**

The QMP shall document the organization's process for ensuring the competence of personnel to implement the environmental information operations described in the QMP.

Specifically, the organization's QMP shall:

- 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; and
- 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/or experience.

**12. Personnel Training**

The QMP shall contain a section on training. The section shall describe the process for determining training requirements, and training needs. The section shall also describe the roles of individual(s) responsible for defining, planning, reviewing, and documenting the training requirements.

Effective implementation of the QMP requires that training and outreach occur to ensure all personnel involved in the planning, management, and implementation of environmental information operations have the competencies to complete their tasks according to the procedures and processes in their organization's Quality Program.

Training needs within the organization are task or role specific and include both technical training and quality-related training. Managers can benefit from training or briefings to help understand the structure, concepts, and operating principles of

[5] *The current version of this directive is located at IT/IM Directives.*
[6] *The current version of this document is available at https://www.epa.gov/sites/default/files/2019-08/documents/epa-info-quality-guidelines_1.pdf*

the Quality Program. Technical personnel can benefit from training to help understand the organization's quality program and the QA and QC tools and techniques necessary to fulfill the requirements of the program.

Organizations often have Human Resource Training Coordinators that can be consulted when developing training programs.

**13. Procurement of Items and Services**

The QMP shall describe the organization's processes including roles and responsibilities, and authorities pertaining to all procurements and extramural agreements for ensuring that appropriate quality requirements are included and implemented. Procurement and extramural agreements can include contracts, assistance agreements, interagency agreements, and other cooperative agreements.

This description shall also include:

- 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 Agency quality requirements,
- ensuring that the agreement(s) clearly document how the supplier will address technical and quality requirements,
- ensuring that the agreement(s) clearly document the supplier's responsibility for the Quality Program requirements,
- providing procedures for verifying how the supplier will conform to the customer's requirements,
- reviewing all applicable responses to solicitations to ensure that these documents satisfy all technical and quality requirements,
- providing evidence of the supplier's capability to satisfy EPA quality program requirements as defined in the extramural agreement or applicable Federal Regulations,
- ensuring that procured items and services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by suppliers and subcontractors, source selection, source inspections, supplier audits, and examination of deliverables,
- reviewing procedures for quality-related documentation, QMPs or QAPPs from contractors,
- reviewing and approving QMP and QAPP procedures and criteria for delegations of EPA authority, and
- ensuring that EPA quality-related contracting requirements, as defined by the Federal Acquisition Regulations are satisfied.

**EPA Organizations** EPA organizations shall describe or reference the process including roles and responsibilities for reviewing and approving QA Review Forms (QARF) and accompanying statements of work/performance work statements. The QA Review Form is used to ensure that quality requirements of 48 CFR Part 46.202 and clause 52.246-11 are communicated to the EPA contract officer, and

to ensure that EPA-specific requirements (defined in the Agency's Quality Policy and Procedure) are met.

If an EPA organization is using a customized QARF and not the QARF in the EPA Acquisition Guide (EPAAG) 7.1.1.5.5.L.3, Appendix 46.2.1-D, the customized form shall be included in the organization's QMP and approved as per 6.A.4. of this standard.

**Non-EPA Organizations**

Non-EPA organizations shall describe or reference their procurement processes including roles and responsibilities for ensuring that sub-contractors assigned to perform environmental information operations by the responsible non-EPA organization comply with all quality requirements as specified in the EPA extramural agreements.

**14. Document and Record Processes**

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

Specifically:

- quality-related documents and records requiring management and control shall be identified,
- EPA Record retention schedules shall be referenced,
- program regulations, contract and agreement records requirements shall be referenced for all environmental information operations,
- processes for handling quality-related documents and records to ensure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff,
- measures for controlling the release, change, and use of planning documents and records including descriptions of how technical guidance and planning documents (e.g., QAPPs, QMPs, SOPs, etc.) are prepared, reviewed, approved, issued, used, revised, tracked, and verified,
- processes and procedures 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, and
- procedures for establishing and implementing applicable chain of custody and confidentiality procedures for evidentiary records.

The QMP shall describe how documents and records, including revisions, are reviewed for conformance with new requirements and with the terms and conditions of extramural agreements, and are approved by authorized personnel before general use.

The QMP shall describe or provide a reference to the management process that ensures that documents and records 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.

The QMP shall identify or reference the accomplishment for disposing of quality-related records, in accordance with regulatory requirements or schedules.

**15. Plan, Do, Check, Act (PDCA) Quality Model**

The PDCA Quality Model is an iterative four-step approach for managing, planning, implementing, and administering continual improvement over the lifecycle of environmental information operations.

**a. *Plan***

The QMP shall 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.

Organizations shall document the use of a systematic planning process for environmental information operations that is based on the scientific method. The planning process shall 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.

Elements of the systematic planning approach that shall be documented include: identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc.; description of the project goal, objectives, and questions and issues to be addressed; identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements); identification of the type of information needed and how the information will be used to support the project's objectives; determination of the quantity of information needed and specification of performance criteria for measuring quality; description of how, when, and where the information will be obtained (including existing information) and identification of any constraints on information collection; 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.); and a 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.

The QMP shall describe the QAPP planning and documentation process including organization-specific requirements by project-type.

**b.** ***Do (Implementation)***

The QMP shall address and include processes for how the organization 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.

This description shall address and include general processes for:

- documentation of implementation procedures (e.g., reference methods, SOPs).
- testing and evaluation of procedures to confirm their acceptable performance.
- the work being performed according to approved plans.
- deviations and waivers from 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; and
- performance monitoring.

The QMP shall describe how appropriate management controls for the release, change, and use of implementation of quality program documentation. Such management controls provide for the necessary approvals, specific times, and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

The QMP shall contain the organization'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. The QMP shall also describe the process by which SOPs are reviewed for initial and subsequent use, approved, distributed, revised, and rescinded.

**c.** ***Check (Assessment and Oversight)***

The QMP shall describe the management commitment and approach to assessing its Quality Program. The process(es) for assessments may be in the QMP and/or in referenced SOPs that are readily available. 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 shall retain the documented information as part of quality records.

Personnel conducting assessments shall be qualified, based on project-specific requirements, to perform the assigned assessment. 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. Assessors shall be technically knowledgeable with no real or perceived conflict of interest. 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.

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 organization's QMP. Annually, senior management or as delegated, shall review, assure, and document the organization's Quality Program to confirm its continuing suitability, adequacy, and effectiveness. 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.

**EPA Organizations**

The QMP shall describe:

- oversight activities of QMPs approved by their organization (e.g., state, tribal, contractor, federal partner, etc.).
- conditions under which a "stop work" order may be needed and when and how authority for such decisions shall be made.
- frequency of assessments.
- how and by whom assessments of environmental information operations programs are planned, conducted, evaluated, and documented.
- processes by which management in conjunction with the QAM chooses an assessment tool for use and performance including performance measures, and the expected frequency of their application to environmental information operations.
- processes for the planning, scheduling, response to changes, and implementation of assessments.
- responsibilities, levels of participation, and authorities for all personnel 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:
    - identify quality issues,
    - identify and cite noteworthy practices that may be shared with others improve the quality of their operations products and services,
    - propose recommendations for resolving quality issues, and
    - 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 how the effectiveness of the response shall be determined.
- 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.

**Non-EPA Organizations**

The QMP shall describe:

- assessment frequency.
- how and by whom assessments of environmental information operations 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 sub-organization QMPs, 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:
    - identify quality issues.
    - identify and cite noteworthy practices that may be shared with others to improve the quality of their operations products and services.

- propose recommendations for resolving quality issues.
- 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)***

The QMP shall:

- Describe or reference how corrective actions and improvements will be performed.
- Describe or reference how management shall 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. Corrective actions shall include the 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. In addition, processes for identifying and correcting common non-conformances found in different parts of the organization will be described to ensure continual improvement.

**16. Dispute Resolution Process**

The QMP shall describe provisions for dispute resolution to include technical and management program disputes. The QMP shall describe or reference the organization's dispute resolution process to address issues pertaining to quality such as QMP requirements, QA and QC procedures, non-conformances, findings, and corrective actions. The QMP shall also describe how disputes, if encountered, because of assessments are addressed and by whom.

**17. Continual Improvement**

The QMP shall describe how the organization 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.

The QMP shall 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.

**18. Data Review, Validation and Verification, and Data Usability Reporting**

The QMP shall describe or reference general processes on how the organization conducts reviews, validation, and verification of environmental information operations and for data usability reporting, including the responsibilities and authorities of management and staff. Specific project information shall be included in the QAPP.

This general description shall address 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; and
- planning, implementing, and resolving peer review considerations.

## 7. ROLES AND RESPONSIBILITIES

**EPA Administrator:** Promotes and ensures quality is an integral part of the Agency's mission by assuring that environmental information operations supporting EPA's programs and activities are of known and documented quality, scientifically valid, legally defensible, and appropriate for the intended use. The Administrator may re-delegate the responsibilities for this Standard to AA and RAs.

**Assistant Administrators (AA) and Regional Administrators (RA):** Each AA and RA is responsible for the following QA activities:

- Implementing this Standard in the context of the organization's specific mission;
- Ensuring that adequate resources are devoted to QA activities to ensure compliance with EPA's QA directives, to support the organization's mission and to fully implement the organization's approved QMP;
- Ensuring that the organization's QMP includes activities that will help assure the quality of the information the organization collects, manages, or uses in carrying out its mission;
- Providing reasonable assurance and certifying annually to the CIO/DAA that their organization has implemented the Quality Policy and have internal controls in place to ensure that environmental information produced and utilized is of known and documented quality for the intended use. Provide this certification along with the organization's QA annual report to the EQMD. The AA/RA may re-delegate the responsibilities for certification to the appropriate manager or supervisor; and
- Promoting continual improvement in QA activities across the organization.

**Office of Mission Support (OMS), Chief information Officer (CIO) and Deputy Assistant Administrator for Environmental Information):** Acts as the EPA Senior Management Official for quality management and leads Agency-wide implementation of this Standard and EPA's Quality Program. Informs AAs, RAs, and the CIO Strategic Advisory Council (SAC) of any issues related to the quality of Agency environmental information and environmental information operations encompassed by this Standard.

**Chief Information Officer's (CIO's) Strategic Advisory Council (SAC):** Consisting of Senior Information Officials (SIOs) and other senior managers, the SAC advises and reports to the DAA/CIO on Agency-wide environmental information operations. The SAC serves as a forum to discuss coordination of cross-cutting Agency quality-related issues.

**Senior Information Officials (SIOs):** Oversee effective implementation, coordination, and management of the organization's Quality Program for environmental information operations. Located in each Program Office and Region, SIOs report to the Agency DAA/CIO on quality-related issues.

**National Program Office Directors:** Provide Program direction to the Regional Program Office Directors on National Program Office QA guidance.

**Mission Support Division Directors:** Manage issues related to information technology and information management (IT/IM). Support the Region's Quality Program and coordinate with Laboratory Services and Applied Science Division Directors (LSASDDs).

**Laboratory Services and Applied Science Division Directors (LSASDDs):**

Serve as Director of a Regional Division with oversight of the Regional Quality Program through direct management oversight of the Regional QA personnel including the Regional QAM. Through this oversight the LSASDD ensures conformance with this Standard and Regional QMPs.

**Science and Technology Policy Council (STPC):** Serves as a mechanism for addressing EPA's science policy issues that go beyond regional and program boundaries, with a goal of integrating policies that guide Agency decision-makers on their use of scientific and technical information. The STPC is an executive level council that is chaired by the Agency Science Advisor, and provides a venue for identifying, coordinating, and, when appropriate, establishing consensus for high priority, cross-agency science and technology policy issues to assist Programs and Regions. It focuses on issues that require high-level action and are relevant to the Programs Offices and Regions (such as: Peer Review, Public Access, and Risk Assessment).

**Office of General Counsel and Offices of Regional Counsel:** Provide legal advice on issues related to environmental information operations.

**OMS, Environmental Information Office of Enterprise Information Programs (OEIP) and Enterprise Quality Management Division (EQMD) Directors:** Serve as Office and Division Directors respectively and are responsible for oversight of the Agency's Quality Program. Execute actions on behalf of the DAA/CIO according to Delegation 1-41. Mandatory Quality Program.

**EPA Quality Assurance Managers (QAMs) or designee:** Have delegated authority for the management of the Quality Program as described in their organization's QMP. The QAM roles and responsibilities serve as a reference to assist the QAM in identifying activities and best practices. These activities and best practices are applicable to their organizations and may assist in continual improvement. These activities are not provided

as performance measures for the organization but may be used to guide the QAM in discussion with management on their roles and expectations for implementing this Standard. These roles and responsibilities focus on managing quality for environmental information and technology programs.

**Agency Personnel:** Perform work associated with environmental information operations as identified in their organization's QMP.

**Recipients of Extramural Agreements:** Perform all environmental information operations in accordance with this Standard's requirements as defined by federal laws, regulations, and as defined in their extramural agreements. The agreement terms and conditions may also specify applicability of the EPA lead organization's QMP.

## 8. RELATED INFORMATION

This section provides references to standards, directives, policies, and guidance that are integral to establishing procedures and processes for a Quality Program. Within the QMP, if applicable, describe implementation of these references as part of a Quality Program, see Section 6.A.1. GENERAL CONTENT. These citations are valid at the time of issuance of this Standard. Since these documents are subject to periodic review, users of this Standard should refer to the most recent version. These references can also be located at www.epa.gov/quality.

- ASQ/ANSI E4: 2014 (R2019) *Quality management systems for environmental information and technology programs—Requirements with guidance for use*
- Environmental Information Quality Policy
- Environmental Information Quality Procedure
- EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans
- CIO 2105-P-02.0 *EPA QA Field Activities Procedure*
- CIO 2105-P-03.0 *CIO Notification Procedure for Environmental Data Quality Issues*
- Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency
- U.S. EPA Scientific Integrity Policy
- U.S. EPA Peer Review Handbook
- Enterprise Architecture Policy
- Data Standards Policy
- CIO 2137.1 *Unmanned Aircraft Systems (UAS) Policy*
- EPA CIO 2122-P-03.1 Enterprise Architecture IT Standards Procedure
- EPA CIO 2104.3 *IT/IM Directive Policy Software Management and Piracy Policy*
- EPA CIO 2104-P-01.2 *Software Management and Piracy Procedure*
- National Technology Transfer and Advancement Act, (PL 104-113)
- Clinger-Cohen Act of 1996 (PL 104-106)
- 1-41. Mandatory Quality Program Delegation 1200 TN 496 1-41
- Office of Management and Budget Circular A-130, Managing Information as a Strategic Resource
- 40 CFR Part 49: Tribal Authority Rule

## 9. DEFINITIONS

While this Standard uses multiple sources as the foundation for the terms defined, ASQ/ANSI E4 (R2019), and the Quality Policy and Procedure served as primary references. The intent of this Standard is to ensure consistency with these primary references and modifications are made where necessary to be applicable to the Agency.
**Assessment**—The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, surveillance, or readiness review (including competency assessment, pre-award assessment of proposal, or technical assessment), peer consultation, product review (e.g., data inspection, software testing, pre-dissemination review, or review of contractor deliverables).

**Audit**—A systematic and independent examination to determine whether quality activities and related results comply with documented planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Consensus Standards**—Standards that are developed and adopted by achieving agreement with all affected parties. These standards are developed in accordance with procedures used by the International Organization for Standardization or organizations accredited by the ANSI.

**Data—**A quantitative or qualitative representation of values, facts, observations, or ideas in a formalized manner capable of being transmitted, processed, stored, analyzed, interpreted, and/or communicated by some process, whether on paper or in electronic form.

- **Qualitative data**—is descriptive.
- **Quantitative data**—is numerical.
- **Primary data**—are data observed, collected, stored, or generated directly for a specific purpose.
- **Existing data**—are data that have been collected, derived, stored, or reported in the past or by other parties (for a different purpose and/or using different methods and quality criteria). Sometimes referred to as data from other sources.
- **Metadata**— Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information resource.

**Data Standard**—Documented consensus-based agreement on the format and definition of common data.

**Environmental Information**—Includes data and information that describe environmental processes or conditions which support EPA's mission of protecting human health and the environment. Examples include but are not limited to:

- direct measurements of environmental parameters or processes.
- analytical testing results of environmental conditions (e.g., geophysical, or hydrological conditions).
- information on physical parameters or processes collected using environmental technologies.
- calculations or analyses of environmental information.

- information provided by models.
- information compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources.
- development of environmental software, tools, models, methods, and applications; and
- design, construction, and operation or application of environmental technology.

**Environmental Information Operations**—A collective term for work performed to collect, produce, evaluate, or use environmental information and the design, construction, operation or application of environmental technology.

**Environmental Measurement**—A subgroup of Environmental Information that includes or produces values derived from tools, instruments, observational results, laboratory operations on environmental samples, or other sampling and testing equipment. It is any data collection activity or investigation involving the assessment of chemical, physical, or biological factors in the environment which affect human health and the environment.

**Environmental Processes**—Manufactured or natural processes that produce discharges or that impact human health and the environment.

**Environmental Programs**—Work or activities involving the environment, including but not limited to, characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, operation, or application of environmental technologies; and laboratory operations on environmental samples.

**Environmental Technology**—An all-inclusive term for systems, devices, and their components applicable to both hardware and methods or techniques that measure and/or remove pollutants or contaminants and/or prevent them from entering the environment.

Examples include but are not limited to:

- Pollution prevention: measurement, monitoring, reduction, control, and/or treatment processes; such as wet scrubbers (air), granulated activated carbon unit(water), filtration (air, water).
- Contamination: containment to prevent further movement of the contaminants, such as capping, and solidification or vitrification, and biological treatment.
- Storage containers, methods, or facilities, such as drums, tanks, and pond or lagoon.
- Remediation processes and their components, and/or technologies; such as contaminant removal and replacement with backfill, soil washing (soil), pump and treatment, soil vapor extraction (soil), land farming and other bioremediation processes.

For the purpose of this procedure, Environmental Technology does not include or incorporate QA associated with the development and design of IT systems.

**Extramural Agreement**—A legal agreement between EPA and a non-EPA organization. Such agreements include but are not limited to contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements and as negotiated in other agreements not funded

by EPA. Refer to the Quality Procedure, for additional details related to QA documentation associated with extramural agreements.

**Graded Approach**—The process of determining the level of detail for management controls to be applied to an activity according to the intended use and the degree of confidence needed in the quality of the results. This approach establishes the QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization.

**Intergovernmental**—Between the EPA and international, other federal, state, tribal, territorial, area-wide, regional, or local governments and agencies.

**Management System**—A management system may describe the polices, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization.

**Organization**—An EPA organization is an office, region, national center, or laboratory. An external organization is a state, tribe, agency or other government entity, academia, company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public, or private, that has its own functions and administration.

**Primary Quality Assurance Organization (PQAO) –** A monitoring organization, a group of monitoring organizations or other organization that is responsible for a set of stations that monitor the same pollutant and for which data quality assessments can be pooled. Each criteria pollutant sampler/monitor at a monitoring station must be associated with only one PQAO.

**Process**—A set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

**Product**—The intended result or final output of an activity or process that is disseminated or distributed among EPA organizations or outside of EPA.

**Quality**—The totality of processes, procedures, features, and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

**Quality Assurance (QA)**—Management of an integrated system of activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the organization.

**Quality Assurance Manager (QAM)**—The individual designated as the principal manager within the organization having oversight authority and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the Quality Program for the organization.

**Quality Assurance Project Plan (QAPP)**—A planning document related to a project that describes in comprehensive detail the necessary QA/QC requirements and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance and acceptance criteria.

**Quality Assurance Review Form (QARF)**— An internal EPA form that describes QA requirements for contracts and documents the review and approval by the QAM. This document must be included with all contract packages involving either new work or a

significant change. Actions that do not affect the work performed by the contractor (e.g., incremental funding or time extensions, do not require a QA Review Form). Exceptions to the requirement for use of this form are described in EPA contracting guidance and are subject to approval by the organization authorized to execute actions on behalf of the DAA/CIO according to Delegation 1-41. Mandatory Quality Program.

**Quality Control (QC**)—The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements; operational techniques and activities that are used to fulfill requirements for quality.

**Quality Management**—The aspects of the organization's overall management system that drive the implementation of an organization's Quality Program. Quality Management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to an organization's Quality Program.

**Quality Management Plan (QMP)** — A formal document that describes a Quality Program in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

**Quality Program**—The totality of management controls, processes, and documentation in EPA's planning, implementation, and assessment for ensuring the quality of Agency environmental information operations products and services.

## 10. WAIVERS

Statutory requirements for quality may supersede the specifications in this Standard or be more rigorous. In such cases, affected programs shall be exempt from the requirements of this Standard. EPA organizations conducting exempted activities shall comply with the Quality Policy and Procedure in all other respects. The following exemptions from these requirements apply:

- The collection of environmental data under the authority of Good Laboratory Practices as defined by 40 CFR 792, for the Toxic Substances Control Act.
- The collection of environmental data under the authority of Good Laboratory Practices as defined by 40 CFR 160, for the Federal Insecticide, Fungicide, and Rodenticide Act.

## 11. MATERIAL SUPERSEDED

- *EPA Requirements for Quality Management Plans (EPA QA/R-2, March 2001)*
- *Guidance for Developing Quality Systems for Environmental Programs (EPA QA/G-1, November 2002)*
- *Guidance for Developing a Training Program for Quality Systems (EPA QA/G-10 December 2000)*

## 12. CONTACTS

For information about this Standard or the Quality Program, please contact the Office of Mission Support, Environmental Information, Office of Enterprise Information Programs, Enterprise Quality Management Division, or email quality@epa.gov.

VAUGHN NOGA

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***Vaughn Noga***
***Deputy Assistant Administrator for Environmental Information and Chief Information Officer***
***U.S. Environmental Protection Agency***

## APPENDIX A: ACRONYMS & ABBREVIATIONS

| | |
|---|---|
| AA | Assistant Administrator |
| ANSI | American National Standards Institute |
| ASQ | American Society for Quality |
| CFR | Code of Federal Regulations |
| CIO | Chief Information Officer |
| DAA | Deputy Assistant Administrator |
| EPA | Environmental Protection Agency |
| EPAAG | EPA Acquisition Guide |
| EQMD | Enterprise Quality Management Division |
| FY | Fiscal Year |
| IM | Information Management |
| IT | Information Technology |
| LSASDD | Laboratory Services and Applied Science Division Director |
| MOU | Memorandum of Understanding |
| OEIP | Office of Enterprise Information Programs |
| OMS | Office of Mission Support |
| PL | Public Law |
| PQAO | Primary Quality Assurance Organization |
| QA | Quality Assurance |
| QAFAP | Quality Assurance Field Activities Procedure |
| QAM | Quality Assurance Manager |
| QAPP | Quality Assurance Project Plan |
| QARF | Quality Assurance Review Form |
| QC | Quality Control |
| QMP | Quality Management Plan |
| RA | Regional Administrator |
| SAC | Strategic Advisory Council |
| SIO | Senior Information Official |
| SOP | Standard Operating Procedure |
| STPC | Science and Technology Policy Council |
| USC | United States Code |