Directive No: CIO 2105-S-02.1

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

Quality Assurance Project Plan Standard

1. PURPOSE

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

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).

All work performed by or on behalf of EPA involving environmental information operations shall be implemented in accordance with an approved Quality Assurance Project Plan (QAPP).

The QAPP is a formal planning document which describes how environmental information operations are planned, implemented, documented, and assessed during the life cycle of a project. The QAPP describes in comprehensive detail the necessary Quality Assurance (QA) and Quality Control (QC) requirements and other technical activities that must be implemented to ensure that the results of the environmental information operations performed will satisfy the stated performance and acceptance criteria.

QAPPs must be approved in accordance with this Standard. EPA QA Managers (QAM), as defined by the organization's Quality Management Plan (QMP), review and approve QAPPs for all environmental information operations projects prior to any information gathering work, or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

2. SCOPE

This Standard defines the minimum requirements for QAPPs for 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.

3. AUDIENCE

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

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.

This Standard will be applied to non-EPA organizations as described in the current version of the EPA organizations' QMP that is sponsoring the work.

Non-EPA organizations include but are not limited to:

- contractors,
- regulated parties,
- cooperative agreement holders,
- grantees,
- states, tribes, territories, 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.

4. 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)
- 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

5. STANDARD

A. QAPP OVERVIEW

1. GENERAL CONTENT

All work performed by or on behalf of EPA involving the collection, production, evaluation, or use of environmental information including the design, construction, operation, or application of environmental technology must be documented in a QAPP.

The QAPP shall be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment, and final data use and reporting. Section 5.B QAPP REQUIREMENTS of this document describes requirements for QAPPs.

The EPA organization sponsoring the work has the authority to define any special requirements beyond those listed in this Standard. Each EPA organization shall define their organization-specific requirements for QAPP documentation in their QMP. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

2. LEVEL OF DETAIL: THE GRADED APPROACH AND QAPPs

A QAPP is unique to its specific project. Implementation of the Quality Policy and Procedure allows for the principle of the graded approach to be applied to the systematic planning, development, and approval of QAPPs.

The graded approach establishes the QA and QC requirements commensurate with the complexity and type of work, how the results will be used, , the available resources, and the unique needs of the organization or the customer (for contracts). The level of detail to be applied to activities listed in the QAPP are developed and then documented according to the intended use and the degree of confidence needed in the quality of the results.

The Graded Approach is not a mechanism to waive requirements. If an element is not applicable, an explanation as to why it is not applicable shall be provided in the QAPP.

3. QAPP PREPARATION RESPONSIBILITY

The QAPP is prepared by EPA and the organizations listed in Section 3. In most instances, the preparation of the QAPP is the responsibility of the organization performing the environmental information operations.

- **EPA Organizations**
  The EPA organization's senior manager having executive leadership authority for the organization is responsible for assuring the preparation and approval of QAPPs as per the organization's approved QMP to cover

all environmental information operations to be performed under the Quality Program.

The actual preparation of the QAPP may be assigned to managers of the environmental information operations (Operations Managers) and/or designees within the organization.

- **Non-EPA Organizations**
  The senior manager of the non-EPA organization is responsible for assuring the preparation and appropriate approval of QAPPs that cover 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 QAPP may be assigned to Operations Managers and/or designees within the organization.

4. QAPP SUBMITTAL AND APPROVAL

QAPPs must be approved prior to the collection, production, evaluation, or use of environmental information including the design, construction, operation, or application of environmental technology except under circumstances requiring immediate emergency response action to protect human health and the environment or operations conducted under police powers.

- **EPA Organizations**
  QAPPs shall be submitted to the QAM or designee as specified in the organization's QMP and follow internal processes for review and approval.

  The EPA organization's QAM or designee has authority to review and approve QAPPs within their organization as stated in the organization's approved QMP.

  In emergency response cases, QAPPs shall be approved during the environmental information operations in accordance with the sponsoring organization's QMP and other applicable EPA-approved QMPs (such as the contractor's QMP).

- **Non-EPA Organizations:**
  The QAPP 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.

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

- **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 to include, but not limited to QAPP approvals and training. In these cases, states, tribes, or territories with delegated approval for QAPPs, shall follow the QAPP approval processes as stated in their EPA-approved QMP.

5. PERIOD OF APPLICABILITY OF AN APPROVED QAPP

- **EPA Organizations:** QAPPs approved under this Standard shall be valid for no more than the lesser of five years or shorter duration as may be defined for the project.

- **States, Tribes, Territories, and Other Federal Agencies:** QAPPs 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:** QAPPs 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 /agreement, or legal agreement.

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

6. QAPP ANNUAL REVIEWS AND REVISIONS

Annual Reviews

All EPA and non-EPA organizations required to have a QAPP shall review their QAPP at least annually to confirm its suitability and evaluate its effectiveness for the project. Projects less than one year in duration will not be required to have an annual review.

The review shall be documented and made available to the QAM of the sponsoring organization if requested.

Non-EPA organizations shall contact the EPA organization sponsoring the work for additional requirements for QAPP annual reviews.

Revisions

Although the approved QAPP should be implemented as approved, it is a flexible, living document. Because of the complex and diverse nature of environmental

information operations, changes to original plans may be needed.
When necessary, the organization shall revise its QAPP to incorporate minor changes and notify the approving authority of the changes. In general, a copy of any QAPP revision(s) made during the year should be submitted to the approving authority (QAM or designee) in writing when such changes occur.

If significant changes have been made to the project, it may be necessary to re-submit the entire QAPP for re-approval. When significant changes occur, the approving authority (QAM or designee) shall determine if the change significantly impacts the technical and/or quality objectives of the project. The QAM may consult with the Operations Manager for this determination.

If it is determined that the QAPP must be revised and submitted for re-approval, the originator of the QAPP shall submit the revision for approval to the same organization with approving authority that performed the original review. The submission shall include a revision history page that briefly summarizes the changes made. No work under the changed condition shall be performed until the QAPP is reviewed and approved.

Significant changes that may require the revision and resubmittal of an approved QAPP include: change in the scope of the project resulting in new or revised project objectives; changes in implementation such as how information will be collected, produced, evaluated or used; changes in the design, construction, operation, or application of environmental technology; change in the statement of work or workplan for extramural agreements; expiration of the QAPP; changes in the organization's mission or structure, such as in the delegation status of QAPPs; or changes in performance criteria as to how results will be assessed for acceptance.

All personnel in the organization performing environmental information operations covered by the scope of the QAPP shall be notified of the changes. This practice shall also include contractors, sub-contractors, and grantees associated with the environmental information operations described in the QAPP.

B. QAPP REQUIREMENTS

QAPPs are required for all work performed by or on behalf of EPA involving the collection, production, evaluation, or use of environmental information and the design, construction, operation, or application of environmental technology.

Environmental Information includes data and information that describe environmental processes or conditions. 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, applications; and
- design, construction, and operation or application of environmental technology.

Environmental Technology includes 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 ponds or lagoons.
- Remediation processes and their components, and/or technologies, such as soil washing (soil), pump and treatment, soil vapor extraction (soil), land farming and other bioremediation processes.

Because environmental information operations can encompass many different types of projects, the EPA organization sponsoring the work has authority to define their organization-specific content requirements for QAPPs by project type. QAPP preparers shall contact the EPA organization sponsoring the work for additional QAPP guidance, tools, and templates specific to the type of project.

The QAPP shall be composed of standardized, recognizable elements covering the entire project. Elements of a QAPP may be described or cited. If the designated references are well documented and are readily available to all key personnel, citations may be adequate; however, because weblinks and web addresses may change over time, one official, controlled version (such as pdf) of the referenced documents should be placed on file with the appropriate EPA office and available for routine referencing when needed.

The required QAPP elements have been arranged into four general groups. The four groups of elements are:

- GROUP A - Project Management and Information/Data Quality Objectives
- GROUP B - Implementing Environmental Information Operations
- GROUP C - Assessment and Oversight
- GROUP D - Environmental Information Review and Usability Determination

1. GROUP A ELEMENTS: PROJECT MANAGEMENT AND INFORMATION/DATA QUALITY OBJECTIVES

The elements in Group A (Table 1) address project management including project history and roles and responsibilities of the personnel involved in the project. These elements document that the project has defined information/data quality objectives, that strategies are in place to help personnel understand the approach to be used, and that the planning has occurred. QAPPs should contain all of the Group A elements.

Group A: Project Management and Information/Data Quality Objectives

Element	Description
A1	Title Page
A2	Approval Page
A3	Table of Contents, Document Format, and Document Control
A4	Project Purpose, Problem Definition, and Background
A5	Project Task Description
A6	Information/Data Quality Objectives and Performance/Acceptance Criteria
A7	Distribution List
A8	Project Organization
A9	Project QAM Independence
A10	Project Organizational Chart and Communications
A11	Personnel Training/Certification
A12	Documents and Records

Table 1

A1 – Title Page

The Title Page shall contain the name of the document to include “Quality Assurance Project Plan”; date of QAPP preparation; organization conducting the environmental information operations; name of organization that developed the QAPP (if different from organization conducting the work); period of applicability; and revision/version control information.

Non-EPA Organizations shall also specify:

- Grant or cooperative agreement number if the work is performed under an EPA assistance agreement
- Contract number and Task Order number (if applicable) if the work is performed under an EPA contract acquisition
- Interagency Agreement number if the work is performed under an Interagency Agreement

- Title and date of the Memoranda of Understanding/Agreement if applicable
- Citation of the regulatory requirement if applicable, or
- Title and date of the enforcement or legal agreement if applicable

A2 – Approval Page

QAPPs shall include signatures from the Operations Manager or designee and QAM or designee. Electronic signatures and equivalent electronic approval systems are acceptable. At a minimum, signatures shall include:

- **EPA Organizations:**
  - Operations Manager or designee, and
  - EPA QAM or designee as specified in the organization's QMP.

- **Non-EPA Organizations:**
  - Operations Manager or designee for the project,
  - Project QAM or individual with QAM responsibilities for the project
  - QAPPs requiring EPA approval shall also include:

    - EPA signature from operations (COR or PO) and
    - EPA QAM or designee.

  For specific signatures to include, contact the EPA organization sponsoring the work.

A3 – Table of Contents, Document Format, and Document Control

Table of Contents

The Table of Contents shall include location of sections, tables, diagrams, charts, worksheets (if used), and other deliverables.

Document Format

In general, the organization developing the QAPP should follow the format and section headings of this QAPP Standard to expedite review and approval.

QAPP preparers shall contact the EPA organization sponsoring the work for additional format requirements. The Environmental Information Quality Procedure authorizes the EPA organization sponsoring the work to determine guidance or tools suitable for QAPPs where projects do not readily fit in the structure or described contents of this Standard. National Program Offices may also provide program direction to the Regional Program Offices on National Program QA guidance and requirements.

Document Control

Document Control is used to identify the most current version of the QAPP and shall be included on every page.

Document control for the QAPP shall include at a minimum:

- The title of the document (abbreviations are acceptable),
- The version number of the document (original or revision number),
- The date of the version, and
- The page number in relation to the total number of pages.

A4 – Project Purpose, Problem Definition, and Background

The QAPP shall identify and address other QA planning documents that have relevant requirements such as QMPs.

The QAPP is the output or result of systematic planning. Its purpose is to document the purpose of the project, the environmental information operations needed to meet those goals, and the application of quality management strategies to those goals.

For additional guidance on systematic planning, refer to the current version of EPA G*uidance for the Data Quality Objectives Process*.

Project Purpose and Problem Definition
The QAPP shall describe the purpose of the project's environmental information operations (to include, but not limited to research, monitoring, environmental technology for clean-up, and use of existing data from other sources) and define the problem(s) to be addressed and question(s) to be answered.

The QAPP shall also document the environmental decision(s) that need to be made and the level of information quality needed to ensure that those decisions are based on sound environmental information.

The QAPP shall identify the type, quantity, and quality of information needed for its intended use and describe the acceptance and performance criteria.

The QAPP shall include the following as applicable:

- Identification of the applicable regulatory programs and standards,
- conceptual site model(s), and
- a discussion that directly links the results of the environmental information operations to possible actions.

Project Background
The QAPP shall describe and/or cite background information, plans, and/or reports to provide the historical, scientific, and regulatory perspective for the project as well as identify the sources for existing information for the project.

A5 – Project Task Description

The QAPP shall include all project tasks and the schedule for accomplishing the tasks. The QAPP shall also include the following:

- description of work to be performed, and
- products to be produced.

A6 – Information/Data Quality Objectives and Performance/Acceptance Criteria

The QAPP shall describe the project's information/data quality objectives, the performance and/or acceptance criteria to achieve those objectives, and the information/data quality indicators.

Performance criteria address the adequacy of information that is to be collected for the project. These criteria often apply to new information collected for a specific use.

Acceptance criteria address the adequacy of existing information proposed for inclusion in the project. These criteria often apply to information drawn from existing sources. Identifying the information/data quality objectives ensures that the quality goals of the project are clearly defined and communicated, guiding the conduct of environmental information operations to provide information of known and documented quality. For example, the QAPP shall describe performance and acceptance criteria for laboratory analytical methods (each matrix, each analyte or analyte group, and concentration level). Information/Data Quality Indicators (DQI) are qualitative and quantitative measures of information/data quality attributes associated with the environmental information.

The principal DQIs for environmental information projects are precision, accuracy (bias), representativeness, comparability, completeness, and sensitivity. However, depending on the type of project, other DQIs may be more appropriate. DQIs are typically applied to the laboratory measurement processes, but DQIs can be identified to capture the effects of other important processes and procedures on the overall quality of environmental Information.

The six standard DQIs are also referred to by the acronym PARCCS:

- *Precision* is the measure of agreement among repeated measurements of the same property under identical, or substantially similar, conditions.

- *Accuracy (Bias)* is a measure of the overall agreement of a measurement to a known value.

- *Representativeness* is defined as the measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

- *Comparability* is the qualitative term that expresses the measure of confidence that two or more data sets can contribute to a common analysis. Before pooling data, the comparability of data sets generated at different times or different organizations must be evaluated in order to establish whether two data sets can be considered equivalent in regard to the measurement of a specific variable or groups of variables.

- *Completeness* is a measure of the amount of valid data obtained from a measurement system, expressed as a percentage of the number of valid measurements that should have been collected (i.e., measurements that were planned to be collected).

- *Sensitivity* is the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest. The term "detection limit" is closely related to sensitivity and is often used synonymously.

Please contact the EPA organization sponsoring the work for additional information and requirements for performance and/or acceptance criteria, and information/data quality indicators.

A7 – Distribution List

The QAPP distribution list shall include all individuals and their organizations who shall receive copies of the approved QAPP and any subsequent revisions. Also, a complete copy of the original version and all revisions of the QAPP shall be maintained on file by the organization responsible for conducting the environmental information operations and made available to approval authorities upon request.

The distribution list shall include the following:

- Operations Manager
- QAM
- Other operations and quality personnel involved in environmental information operations for the project to include those working for the organization responsible for conducting the environmental information operations as well as contractors, subcontractors and grantees in key operations and quality roles.

A8 – Project Organization

The QAPP shall identify the individuals and organizations participating in the project or the environmental information operations and describe their roles and responsibilities. Specifically, the QAPP shall identify individuals with the following roles and describe their responsibilities:

- The approval authority for the QAPP.

- The senior manager having executive leadership authority for the organization conducting the environmental information operations One responsibility of the senior manager is providing resources. Resources are knowledgeable personnel, funding, materials, supplies, and time.
- The project Operations Manager for the organization conducting the environmental information operations.
- The Project QAM for the organization conducting the environmental operations. The QAPP shall describe the Project QAM's oversight authority and responsibilities for planning, documenting, coordinating. and assessing effectiveness of the QAPP. The QAPP shall also describe the QAM's authority to access and discuss quality-related issues with their organization's senior manager outside of their direct supervisory chain as necessary.
- The individual responsible for maintaining the QAPP.
- Titles, roles, and names (if determined during planning) of operations and quality individuals within the organization conducting or supporting environmental information operations and their reporting relationships.
- Identification of all contractors, subcontractors, sub-grantees, supporting environmental information operations and their project role and responsibilities.
- Principal environmental information or data users within the organization conducting the environmental information operations as well as outside of this organization.

A9 – Project Quality Assurance Manager Independence

The Project QAM shall be independent of environmental information operations. The QAPP shall describe how the Project QAM's independence is ensured. The Project QAM is not required to be independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in environmental information operations. The Operations Manager or designee will not have authority to sign QAPPs for the QAM or designee, nor will the QAM or designee have authority to sign QAPPs for the Operations Manager or designee.

The two functions, QA and operations, must remain independent; however, in small organizations outside of EPA and EPA contractors (e.g., small tribal departments), these two functions may be combined with approval from the EPA QAM.

A10 – Project Organization Chart and Communications

The Project Organization Chart

The Project Organization Chart shows both the lines of authority to include the reporting relationships and the lines of communication both within the organization

responsible for the environmental operations and between the organization responsible for the work and all organizations involved in the project.

The Project Organization Chart shall also include the following:

- The name of the organization responsible for conducting the environmental information operations.
- Identification of all contractors, subcontractors, and sub-grantees and their reporting relationships to the organization responsible for conducting the environmental information operations.
- The individual in the senior manager role.
- The individual in the Project Operations Manager role for the organization conducting the environmental information operations and their reporting relationship to the senior manager.
- The individual in the Project QAM role for the organization conducting the environmental information operations, their independence from environmental information operations, and their reporting relationship to the senior manager. If the senior manager does not directly supervise the QAM, the QAM must have authority to access and discuss quality-related issues with the senior manager outside of their direct supervisory chain as necessary. The latter is demonstrated by a dotted line on the organizational chart.
- Titles, roles, and names (if determined during planning) of operations and quality individuals within the organization conducting or supporting environmental information operations and their reporting relationships.

Lines of communication, communication pathways and communication mechanisms shall be determined during planning and documented in the QAPP.

Communication procedures including timing of communication shall be outlined in sufficient detail to ensure that users of the QAPP understand the processes and the roles and responsibilities associated with those processes when communication is necessary.

The QAPP shall describe or cite the standard procedures for communications to include elevating discrepancies and QAPP non-conformances; process improvements; and seeking concurrence and approvals between project personnel, and/or between contractors within the organization responsible for conducting environmental information operations.

Non-EPA Organizations - Shall also describe communication procedures to EPA to include elevating discrepancies and QAPP non-conformances.

A11 – Personnel Training/Certification

Personnel responsible for conducting environmental information operations identified in the QAPP shall have appropriate qualifications, education, training, experience, and knowledge of the requirements of the work activities to be performed.

The QAPP shall identify the individual responsible for ensuring personnel conducting environmental information operations are qualified, trained, and experienced.

The QAPP shall identify the individual responsible for documenting personnel training.

The QAPP shall identify and describe any specialized training or certifications needed by personnel to successfully participate in the environmental information operations. Training may include on-the-job training as well as training on internal procedures. Additionally, the QAPP shall describe how the training will be provided, how the necessary skills will be assured, and the procedure or system that will document training records and skill evaluation.

EPA Organizations - QAPPs for EPA Organizations conducting environmental information operations involving field activities shall also include or reference all Personnel and Training requirements identified in the current version of the EPA Quality Assurance Field Activities Procedure (QAFAP).

A12 – Documents and Records

The QAPP shall identify documents and records that will be produced for projects that involve environmental information operations. The QAPP shall also describe or reference the management of the documents and records, including the QAPP. Management of project information is covered in the Group B Elements, Implementing Environmental Information Operations, B7 Environmental Information Management.

The QAPP shall include or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period. The organization responsible for conducting the environmental information operations shall maintain a system for the control of all documents including preparation, review, approval, issuance, revision, and archiving documents.

EPA Organizations - QAPPs for EPA Organizations conducting environmental information operations involving field activities shall also include all Document Control and Records Management requirements identified in the EPA QAFAP.

2. GROUP B ELEMENTS: IMPLEMENTING ENVIRONMENTAL INFORMATION OPERATIONS

Group B Elements identify and address all aspects of environmental information operations to help to ensure products and services are of known and documented quality and to evaluate the products and services delivered under the project.

This section of the QAPP describes in comprehensive detail the implementation of necessary QA and QC requirements and other technical activities to ensure that the results of the environmental information operations performed will satisfy the

intended purpose, and the information/data quality objectives and performance/acceptance criteria in the Group A4 and A6 Elements.

The Group B elements in Table 2 shall be addressed in the QAPP. Most of the Group B Elements are unique to the type of environmental information operations in the project. The EPA sponsoring organization may have organization or project specific requirements for QAPP documentation in their QMP. If so, these elements also must be addressed.

If a Group B element is not applicable to the project based on the type of project, the QAPP shall 1.) state that the specific element "Does Not Apply" and why, or 2.) reference the project specific requirements provided by the EPA sponsoring organization that shall be used.

The QAPP shall describe all guidance, tools, and templates used to develop the QAPP.

EPA Organizations only - Conducting environmental information operations involving field activities shall also include all requirements identified in the EPA QAFAP.

Group B: Implementing Environmental Information Operations

Element	Description
B1	Identification of Project Environmental Information Operations
B2	Methods for Environmental Information Acquisition
B3	Integrity of Environmental Information
B4	Quality Control
B5	Instruments/Equipment Calibration, Testing, Inspection, and Maintenance
B6	Inspection/Acceptance of Supplies and Services
B7	Environmental Information Management

Table 2

In the Group B Section, if the Standard Operating Procedures (SOPs) and/or referenced materials are well documented and readily available to all key personnel, citations may be adequate; however, because weblinks and web addresses may change over time, one current, controlled version of the referenced documents (such as pdf) should be placed on file with the appropriate EPA office and made available for routine referencing when needed.

B1 – Identification of Project Environmental Information Operations

The QAPP shall describe in detail the environmental information operations to be

conducted for the project and state how they will satisfy the project purpose, and the information/data quality objectives and performance and acceptance criteria in the Group A4 and A6 Elements.

B2 – Methods for Environmental Information Acquisition

The QAPP shall identify and describe the methods and procedures for how environmental information will be acquired throughout the project including any implementation requirements. The acquisition of environmental information includes collection, production, evaluation and/or use as well as design, construction, operation, or application of environmental technology.

Methods shall be identified by number/identifier, version/revision date, and regulatory citation (if applicable). If a method allows the user to select from various options, then the method citations shall state exactly which option(s) are being selected.

The QAPP shall identify, describe or reference SOPs used for the acquisition of environmental information including the version/revision date of the SOP. If a SOP provides more than one procedure or option (for example, one SOP covers the use of several different types of field equipment for the same procedure) the QAPP shall note the specific option or equipment being used.

SOPs shall be available to personnel conducting the environmental information operations. The QAPP shall identify the individual responsible for updating and maintaining the SOPs. The QAPP shall describe any planned modifications to SOPs expected to occur during the project.

For additional information on SOPs, refer to the current version of *EPA Guidance for Preparing Standard Operating Procedures*.

Field Activities Environmental Measurements

If the environmental information operations include field activities such as environmental measurements of parameters or processes, the QAPP shall also describe or reference detailed descriptions of procedures for all field activities, including, but not limited to information derived from tools, instruments, observational results, investigations, and sample collection. The QAPP shall also describe or reference maximum holding times for sample extraction and/or analysis; selection and preparation of sample containers; sample volumes; preservation methods; sample handling and custody. For field activities involving emergency responses, QAPPs shall be approved during the environmental information operations as per the timelines specified in the EPA sponsoring organization's QMP and other applicable EPA-approved QMPs (such as the contractor's QMP).

Tribal Primary Quality Assurance Organizations (PQAO) conducting air monitoring should contact the EPA regional office sponsoring the work for additional information on B Elements.

Laboratory Analyses

If the environmental information operations involve laboratory analyses, the QAPP shall identify the analytical methods by number/identifier, version/revision date and regulatory citation (if applicable). Also, the QAPP shall describe or reference SOPs that address procedures to be conducted when a non-compliance or failure in the analytical system occurs, who is responsible for corrective action, and how to determine and document the effectiveness of the corrective action. The QAPP shall specify the laboratory data package turnaround time needed, if important to the project schedule. If a laboratory method allows the user to select from various options, then the method citations should state exactly the selection of option(s).

For non-standard method applications, such as for unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the matrix. If previous performance studies are not available, they shall be developed during the project and included as part of the project results.

Existing Information

For environmental information compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources, the QAPP shall describe the information to be obtained, the collection process, and the intended use of that information together with criteria for acceptance and evaluation for suitability for the current project. If the information is to be combined with new environmental information, the criteria to ensure compatibility shall be described.

Environmental Technology

For environmental information operations involving environmental technology, the QAPP shall identify whether the technology is primarily for pollution prevention, contamination containment, storage, or remediation. The QAPP shall also describe the physical parameters or processes collected using environmental technologies as well as the specific 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. For additional advice on QAPPs for design, construction, and operation or application of environmental technology refer to the current version of *EPA Guidance on Quality Assurance for Environmental Technology Design, Construction and Operation*.

B3 – Integrity of Environmental Information

The QAPP shall describe or cite the procedures for ensuring the integrity of the environmental information operations.

If the environmental information operations include field sampling, the QAPP shall describe or cite procedures and requirements for sample handling and custody to include but not limited to field logs, packaging, transport and/or shipment from the

site, and storage at the laboratory. The QAPP shall also contain examples of sample labels, and chain of custody forms/sample custody logs.

If the environmental information operations include laboratory analyses, the QAPP shall identify each laboratory to be used as well as a back-up laboratory if identified as required in systematic planning, contract statements of work, or workplans. The QAPP shall also describe the processes for ensuring the laboratory maintains current accreditation and/or certification for applicable analytes and matrices.

B4 – Quality Control

The QAPP shall identify and describe the QC activities needed for each environmental information operation to meet project environmental information/data quality objectives and performance/acceptance criteria.

The QAPP shall describe or cite the frequency of each type of QC activity, corrective actions, and how the effectiveness of the corrective action shall be determined and documented. The QAPP shall describe or reference the procedures to be used to calculate applicable statistics (e.g., precision and bias).

For environmental information operations involving field sampling, measurements, and laboratory analysis, QC activities include, but are not limited to, the use of blanks, duplicates, matrix spikes, laboratory control samples, and surrogates.

For environmental information operations using existing data, QC activities include, but are not limited to, the use of systematic review, independent secondary review of studies in the open literature, and QC of constructed databases or spreadsheets.

For environmental information operations using models or modeling, QC activities include, but are not limited to model calibration and model validation (sensitivity analyses).

B5 – Instrument/Equipment Calibration, Testing, Inspection, and Maintenance

The QAPP shall identify instruments/equipment, to include, but not limited to tools, gauges, and pumps used for environmental information operations. The QAPP shall describe all procedures and documentation activities that will be performed to ensure that the instruments/equipment are available and in working order when needed. The QAPP shall describe or reference how calibration will be conducted, documented, and be traceable to the instrument.

The QAPP shall describe or reference procedures and documentation activities on how instruments and equipment will be tested, inspected, and maintained. The QAPP shall also discuss the availability of critical spare parts, identified in the operating guidance and/or design specifications of the instruments/equipment.

B6 – Inspection/Acceptance of Supplies and Services

The QAPP shall describe or reference the procedures for how supplies and services are inspected and accepted. The QAPP shall identify the individual(s) responsible for inspection and acceptance. This description shall specify the elements of this Standard for which the vendor is responsible and how their adherence to the QAPP requirements will be verified. Acceptance shall be identified on the items themselves or in documented information traceable to the items.

Supplies may include but are not limited to spare parts for instruments/equipment, standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, and electronic data storage media. Services provided by vendors to include, but not limited to contractors, sub-contractors, and sub-grantees may include document development, performing environmental information operations.

B7 – Environmental Information Management

The QAPP shall describe or cite the environmental information management process for the project, tracing the path of the environmental information from its generation to its final use or storage (e.g., the field, the laboratory. the office, the database).

The QAPP shall describe or reference the standard record-keeping procedures, the document control system, and the approach used for information storage and retrieval on electronic media. The QAPP shall describe or reference the control mechanism for detecting and correcting errors and for preventing loss of information during data entry, reduction, and reporting, and data entry to databases, forms, and reports, and databases. The QAPP shall provide or reference examples of any forms or checklists to be used in these processes.

The QAPP shall describe or reference all procedures to process, compile, and analyze the information. This includes procedures for addressing environmental information generated as part of the project as well as environmental information from other sources.

Also, the QAPP shall describe or reference any required computer hardware/software and address any specific performance requirements for the hardware/software configuration used. The QAPP shall describe or reference the procedures to demonstrate acceptability of the hardware/software configuration required and for assuring that applicable information resource management requirements are satisfied.

3. GROUP C ELEMENTS FOR ASSESSMENT, RESPONSE ACTIONS, AND OVERSIGHT

The elements in this group (Table 3) address assessment, response actions and oversight activities. Assessments ensure that the planned project activities in the

QAPP are implemented as approved. Assessments can be internal and/or external and should be conducted throughout the project to ensure that usable environmental information are obtained. Response actions address findings, corrective actions and non-conformances identified from the assessments.

Oversight activities ensure that response actions and reporting mechanisms are in place to capture the project status and any QA issues that arise during implementation and through assessments.

The elements in this group, identified in Table 3, address the activities for assessing the effectiveness of project implementation and associated QA and QC activities.

Refer to the current version of *EPA Guidance on Technical Audits and Related Assessments for Environmental Data Operations* for additional information.

Group C: Assessment, Response Actions and Oversight

Element	Description
C1	Assessments and Response Actions
C2	Oversight and Reports to Management

Table 3

C1 – Assessments and Response Actions

This element addresses the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of an assessment is to ensure that the QAPP is implemented as approved. Assessments are conducted both during and after the environmental information operations identified in the Group B Elements.

Assessments
Assessment is the evaluation process used to measure the performance or effectiveness of a system and its elements. Assessments may also be used as an investigative tool where problems may be suspected.

The QAPP shall include assessment activities. The QAPP shall identify the assessments for the project to include the number, frequency, and types of planned assessments that will be performed. The QAPP shall also identify who will be performing the assessments. Assessment activities may include audits, performance evaluations, management reviews, peer reviews, inspections, surveillances, or readiness reviews (including competency assessment, pre-award assessment of proposal, or technical assessment), peer consultations, product reviews (e.g., data inspection, software testing, pre-dissemination reviews, or

review of contractor deliverables). The EPA organization sponsoring the work may also specify additional assessment requirements.

The QAPP shall address how assessment findings, non-conformances, and corrective actions will be documented. One objective of this documentation is to communicate assessment results to management and to the EPA organization sponsoring the work as specified in Section C2 Oversight and Reports to Management. Documentation may include reports, memos, and/or other formal communication as specified by the EPA organization sponsoring the work. The assessment documentation shall also indicate the timeframe for response actions.

Audits are a type of assessment. Audits are systematic and independent examinations to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Peer review is a type of assessment. Contact the EPA organization sponsoring the work to determine peer review activities for the project.

The QAPP should be the basis for planning and conducting assessments, although other planning documentation to include, but not limited to SOPs, workplans, statements of work may also be used.

Assessors should be free of any conflicts of interest, such as might occur by close association with the environmental information operations being assessed. Independence from the environmental information operations helps to ensure that the assessor has no stake in the outcome of the assessment, other than an interest that the environmental information operations are conducted objectively and in accordance with the approved QAPP.

Response Actions
The QAPP shall describe how response actions associated with assessment findings, non-conformances, and corrective actions will be developed, documented and tracked to ensure completion. The QAPP shall also identify the individual(s) responsible for response actions and how the response actions will be reported.

Response actions may include formal memos and notifications addressing findings, corrective actions, or non-conformances; and timelines for follow-up assessments.

C2 – Oversight and Reports to Management

The QAPP shall identify the individual(s) responsible for oversight activities. The QAPP shall describe the oversight activities that ensure that response actions and reporting mechanisms are in place to capture the project status and any QA issues that arise during implementation and through assessments.

The QAPP shall identify all reports to management. The QAPP shall describe the content of the management reports; and who is responsible for transmitting the

report, how the report will be transmitted, and to whom. Distribution shall include the Project Operations Manager, the Project QAM of the organization conducting the work, and the EPA organization sponsoring the work. An assessment report would be an example of management report.

QAPP preparers shall also contact the EPA organization sponsoring the work for additional QA reporting requirement.

4. GROUP D ELEMENTS FOR ENVIRONMENTAL INFORMATION REVIEW AND USABILITY DETERMINATION

The elements in this group (Table 4) address the activities associated with environmental information review for the purpose of determining whether the environmental information meets the established environmental/data quality objectives, the performance/acceptance criteria, and are useable for its intended purpose. Information review activities ensure that products and services resulting from the environmental information operations are of known and documented quality for their intended use(s) and that any limitations concerning its intended use is documented and communicated.

Although environmental information review takes place after the environmental information operations have been conducted, determination of the type of information/data verification, information/data validation, and information/data quality assessment activities needed to determine whether the project's environmental information/data quality objectives are met begins during the planning phase of the project and are documented in the QAPP.

Additional information can also be found in the current versions of the following:

- EPA Guidance on Environmental Data Verification and Data Validation
- EPA Guidance for Data Quality Assessment Practical Methods for Data Analysis
- EPA Data Quality Assessment: A Reviewer's Guide
- EPA Data Quality Assessment: Statistical Tools for Practitioners

Group D: Environmental Information Review and Usability Determination

Element	Description
D1	Environmental Information Review
D2	Useability Determination

Table 4

D1 – Environmental Information Review

The QAPP shall describe or cite the procedures for the information/data

verification and information/data validation activities.

The QAPP shall also describe or cite the data quality assessment activities that will occur after the environmental information operations phase of the project is completed, if applicable. Information/data verification and information/data validation activities are conducted prior to and may serve to inform information/data quality assessment activities.

The QAPP shall also describe or reference how performance criteria and/or acceptance criteria, and information/data quality indicators identified in A6 will be incorporated in the environmental information/data review process.

The QAPP shall also describe who will conduct these activities, and how the activities will be documented and communicated.

For additional environmental information review requirements including requirements for performance and/or acceptance criteria, and information/data quality indicators, contact the EPA organization sponsoring the work.

In general, verification is confirmation, through provision of objective evidence, that specified requirements have been fulfilled; and validation is confirmation, through provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

The following activity descriptions are from the EPA Quality Guidance documents listed above:

Data Verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements.

Data Validation is an analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set.

Data Quality Assessment is the scientific and statistical evaluation of data to determine if the data obtained from environmental information operations are of the right type, quality, and quantity to support their intended use.

D2 – Useability Determination

Determining useability of the environmental information is the culmination of the entire QA process for the project and involves a retrospective evaluation of the planning process. Not all environmental information may be useable for its intended purpose. The useability of the environmental information is performed at the conclusion of the environmental information operations using the outputs of the environmental information/data verification, the environmental information/data validation, and the environmental information/data quality assessment activities. This reconciliation phase involves a qualitative and quantitative evaluation of

environmental information to determine if the project information is of the right type, quality, and quantity to support its intended use and are suitable for the decisions that will be made.

The QAPP shall describe or reference the process that will be used to determine whether the environmental information is useable. The QAPP shall describe how this determination will be documented and the individual(s) responsible. The QAPP shall describe how any known or anticipated limitations on the use of the environmental information will be communicated and to whom.

6. 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 Assistant Administrators (AA) and Regional Administrators (RA).

Assistant Administrators (AA) and Regional Administrators (RA): Each AA and RA is responsible for 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 DAA for IT/IM/CIO that their organization has implemented the Quality Policy and Procedure 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. Promoting continuous improvement in QA activities across the organization.

Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for Information Technology/Information Management (IT/IM)/Chief Information Officer (CIO) (DAA for IT/IM/CIO): Acts as the EPA Senior Management Official for quality management and leads Agency-wide implementation of the Quality Policy and Procedure 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 for IT/IM/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 for IT/IM/CIO on quality-related issues.

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

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Mission Support Division Directors (MSDDs): 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 (RQAM). Through this oversight the LSASDD ensures conformance with this Policy 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 Regions and Program Offices (such as: Peer Review, Public Access, and Risk Assessment).

Office of Acquisition Solutions: Responsible for planning, awarding and administering contracts for the Agency, including issuing and interpreting acquisition regulations; administering training for contracting and program acquisition personnel; providing advice and oversight to regional procurement offices; and providing information technology improvements for acquisition.

Office of Grants and Debarment: Provides cradle-to-grave administrative management of all Headquarters-administered grants, loans, cooperative agreements, fellowships, interagency agreements (IAs) and for the management of the Agency's Suspension and Debarment program.

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

OMS, Office of Records, Administrative Systems and eDiscovery (ORASE) 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 for IT/IM)/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 below 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 continuous 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 the Quality Directives.

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. Organizations may re-delegate the QAM's responsibilities as described in their QMP. The functions of the QAM or designee may be totally related to Quality Program activities or may be in conjunction with other functions and responsibilities within the organization. If these personnel have other functions to perform, there should be no conflict of interest. It is the QAM's responsibility to determine whether a conflict of interest exists.

Specific duties and responsibilities shall include:

- Facilitating QMP development and approval by the organization and preparing updates to the approved QMP.
- Representing the organization on matters pertaining to quality management and QA and QC activities.
- Providing expert assistance to the staff in the organization on QA and QC policies, requirements, programs and procedures applicable to procurement and technical activities.
- Reviewing QAPPs and, if applicable, QMPs for all projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements involving environmental information operations that are performed by or on behalf of EPA.
- Approving all QAPPs for implementation in all applicable projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements performed on behalf of EPA.
- Coordinating the correction of deficient QAPPs with the author(s) and their management including, as applicable, EPA authors, the COR, or the PO.
- Identifying QA and QC training needs for the organization.
- Providing oversight of QA and QC implementation in the environmental programs conducted by or for the organization.
- Performing assessments of environmental programs and confirming the effectiveness of corrective actions.
- Managing the day-to-day implementation of the mandatory Quality Program.

- Acting as liaison between the organization and EQMD on matters of QA requirements.
- Coordinating with senior management regarding changes to the Quality Program as needed to assure its continued effectiveness and assisting in reporting the results to EQMD.
- Managing organization resources designated for the Quality Program.
- Maintaining records of pertinent Quality Program activities performed by the organization.
- Reviewing environmental information products (i.e., project reports containing environmental information or reporting the results of environmental information activities), independently (i.e., by others than those who produced the information or the reports) to confirm that the information is presented correctly; and
- Preparing reports approved by management prior to release, publication, or distribution.

The QAM or designee roles and responsibilities reflect the activities that support systematic planning and life cycle management of EPA's environmental information operations products and services. Criteria for success are the organization executive management endorsement of quality, sufficiency of quality resources, and empowerment/authority of the QAM to oversee the organization's Quality Program. The list above does not prescribe the roles of management, but instead presents them from the perspective of the QAM. Executive management actions and support are needed for success. The QAM is to be aware of the support needed by the organization and can communicate those needs to management. Note: The QAPP Standard also uses the term Project Quality Assurance Manager to refer to the individual designated as the QAM for project defined in the QAPP.

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 Policy'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.

7. RELATED INFORMATION

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.

OMS Links:

- Environmental Information Quality Policy
- Environmental Information Quality Procedure
- EPA QA Field Activities Procedure
- 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

- Enterprise Architecture Policy
- Data Standards Policy
- Enterprise Data Management Policy
- EPA Guidance for Quality Assurance Project Plans
- EPA Guidance for Geospatial Data Quality Assurance Project Plans
- EPA Guidance for Quality Assurance Project Plans for Modeling
- EPA Guidance for Preparing Standard Operating Procedures
- EPA Guidance on Technical Audits and Related Assessments for Environmental Data Operations
- EPA Guidance on Environmental Data Verification and Data Validation
- EPA Data Quality Assessment: Statistical Tools for Practitioners
- EPA Guidance on Quality Assurance for Environmental Technology Design, Construction and Operation

Other EPA/External Links:

- ASQ/ANSI E4: 2014 (R2019) Quality management systems for environmental information and technology programs—Requirements with guidance for use
- U.S. EPA Scientific Integrity Policy
- U.S. EPA Peer Review Handbook
- A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information EPA 100/B-03/001
- 40 CFR Part 49: Tribal Authority Rule
- Uniform Federal Policy (UFP) for Quality Assurance Project Plans
- Uniform Federal Policy for Quality Assurance Project Plans: Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs - Part 1: UFP-QAPP Manual
- Workbook for Uniform Federal Policy for Quality Assurance Project Plans: Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs
- Uniform Federal Policy for Quality Assurance Project Plans - Part 2B: Quality Assurance/Quality Control Compendium (Minimum QA/QC Activities)

8. DEFINITIONS

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 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 data compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources: 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, and operation 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).
- 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 ponds or lagoons.
- Remediation processes and their components, and/or technologies, such as soil washing (soil), pump and treatment, soil vapor extraction (soil), land farming and other bioremediation processes.

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 *Environmental Information 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.

Operations 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.

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.

Project—A unique process consisting of a set of coordinated, defined, and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements including constraints of time, cost, and resources.

Project Quality Assurance Manager (Project QAM)—The individual designated as the quality assurance manager for project defined in the QAPP. Note: The QAPP Standard also uses the term Quality Assurance Manager for the individual designated in the organization's QMP 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—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 in the organization's QMP 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. Note: The QAPP Standard also uses the term

Project Quality Assurance Manager to refer to the individual designated as the QAM for project defined in the QAPP.

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 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.

9. WAIVERS

Statutory requirements for quality may supersede the specifications in this Directive or be more rigorous. In such cases, affected programs shall be exempt from the requirements of this Directive. EPA organizations conducting exempted activities shall comply with EPA CIO 2105.1 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.

10. DIRECTIVE(S) SUPERSEDED

- *EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5, March 2001)*
- *EPA Systematic Planning: A Case Study for Hazardous Waste Site Investigations (QA/CS-1, February 2006)*

- *EPA Systematic Planning: A Case Study of Particulate Matter Ambient Air Monitoring (QA/CS-2, EPA QA/CS-2)*

11. CONTACTS

For information about this Standard or the Quality Program, contact the OMS, ORASE, EQMD, or email quality@epa.gov.

VAUGHN NOGA

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Vaughn Noga, Chief Information Officer and Deputy Assistant Administrator for Information Technology and Information Management

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
COR	Contracting Officer Representative
DAA	Deputy Assistant Administrator
EPA	Environmental Protection Agency
EQMD	Enterprise Quality Management Division
FMFIA	Federal Managers Financial Integrity Act
FY	Fiscal Year
IM	Information Management
IQA	Information Quality Act
IQG	Information Quality Guidelines
IT	Information Technology
LSASDD	Laboratory Services and Applied Science Division Director
MSDD	Mission Support Division Director
NTTA	National Technology Transfer and Advancement Act
OMB	Office of Management and Budget
OMS	Office of Mission Support
ORASE	Office of Records, Administrative Systems and eDiscovery
PL	Public Law
PO	Project Officer
PQAO	Primary Quality Assurance Organization
QA	Quality Assurance
QAFAP	Quality Assurance Field Activities Procedure
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
RA	Regional Administrator
RQAM	Regional Quality Assurance Manager
SAC	Strategic Advisory Council
SIO	Senior Information Official
SOP	Standard Operating Procedure
STPC	Science and Technology Policy Council
UFP	Uniformed Federal Policy
USC	United States Code