Quality Assurance Project Plan Guidance

FORWARD

This document, *Quality Assurance Project Plan Guidance*, provides guidance to EPA employees and other organizations involved in developing Quality Assurance (QA) Project Plans that address the requirements in the EPA *Quality Assurance Project Plan Standard*. It replaces all earlier versions of this guidance in their entirety including the version dated December 2002 (EPA/240/R-02/009).

This guidance does not impose legally binding requirements on EPA or the public and may not apply to a particular situation, based on the circumstances. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. Interested parties are free to raise questions about the recommendations in this guidance and the appropriateness of using them in a particular situation, and EPA and other parties should consider whether the recommendations in the guidance are appropriate for the situation. EPA may periodically revise this guidance without public notice.

EPA works every day to produce quality information products. The information used in these products are based on Agency processes to produce quality data, such as the quality program described in this document. Therefore, implementation of the activities described in this document is consistent with *EPA Information Quality Guidelines* and promotes the dissemination of quality technical, scientific, and policy information and decisions.

This guidance is one of the U.S. EPA Quality Program Directives that describe the EPA policies, procedures, standards and guidance for planning, implementing, and assessing the effectiveness of the EPA Quality Program. As described in the *Environmental Information Quality Procedure*, this document is valid for a period of up to five years from the official date of publication, after which it will be reissued without change, revised, or withdrawn from the U.S. EPA Quality Directives. Questions regarding this document or other Quality Directives should be directed to the Quality Team at:

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The most recent versions of all Quality Directives are posted at Quality Program Directives.

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1. PURPOSE

This Quality Assurance Project Plan (QAPP) Guidance supports the implementation of the QAPP Standard.

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

All work performed by or on behalf of EPA involving EIO shall be implemented in accordance with an approved QAPP.

QAPPs are formal planning documents that describe how EIO are planned, implemented, documented, and assessed during the life cycle of a project. QAPPs describe 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 EIO performed will satisfy the stated performance and acceptance criteria.

2. SCOPE

This Guidance provides additional information for addressing the minimum requirements for QAPPs for EPA and non-EPA organizations performing EIO on behalf of the Agency. EIO 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 Guidance is all EPA employees responsible for EIO. This includes EPA Regions, Program Offices, and their sub-organizations hereafter referred to as EPA organization.

The audience also includes non-EPA organizations performing EIO in support of EPA's mission as described in the current version of the EPA organization's Quality Management Plan (QMP) sponsoring the work and 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, 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

The use of this Guidance is optional but should be useful in drafting QAPPs that meet EPA specifications. Please see the QAPP Standard for the minimum requirements for QAPPs for EPA and non-EPA organizations performing environmental information operations.

5. GUIDANCE

General Overview

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.

Because EIO 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 requirements, guidance, tools, and templates specific to the type of project. QAPPs will vary in their level of complexity, based both on the nature of the work being performed (such as the collection of new EIO or the use of previously collected information), available resources, and the intended use of the data. Following the principle of the graded approach, if an element is not applicable to your project, do not omit the element, rather, provide a brief explanation why it is not relevant.

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 Graded Approach and QAPPs

In applying the graded approach, consider the level of detail of complexity for the specific needs and characteristics of each project. This facilitates balancing the scale of the technical work and the QA/Quality Control (QC) activities within the available resources (time, people, financial). For example, a higher level of quality and supporting documentation is appropriate for projects that have greater risk and are subject to challenge, litigation or have higher consequences for decision errors. Small straightforward projects may be simplified to maintain efficiency and remain cost effective.

The QAPP writers, users, and reviewers have flexibility to understand the unique requirements and constraints of a project as well as the credentials and experience of the project team and adjust the detail and review accordingly.

Within a project, the graded approach could allow the level of associated elements that are not critical for overall project outcomes or success, e.g., indicator parameters. Providing thoughtfulness to a graded approach optimizes project success while avoiding costs associated with administrative procedures, delays, and use of resources.

Considerations in applying the Graded Approach may include:

- allowing for the level of detail provided for the required elements in each QAPP to vary accordingly. for example, the quality expectations of fundamental research may be different from that of regulatory compliance because the purpose or intended use of the information is different.
- achieving sufficient detail in the QAPP to satisfy the objectives of the project and ensure adequate quality for the intended use of the information.

- discussing the graded approach during the QAPP development process.
- ensuring the EPA organization sponsoring the work is consistent with the organization's approved QMP and the final decision on the level of detail provided for required elements belongs to the EPA organization.
- developing procedures and include them in their organization's QMP.
- understanding that project or operation context and relative importance, that may range from screening or initial reconnaissance to providing the basis for developing a regulation.
- considering existing information available to include approved QAPPs, QMPs, other programmatic or procedural documentation upon which a project is based.
- considering project complexity including collaboration with multiple organizations or experts.
- knowing the availability of resources for EIO.
- evaluating the overall risk associated with the project including potential for enforcement or litigation.

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

- 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

Table 1. List of QAPP Elements

Group A Project Management and Information/Data Quality Objectives	Group B Implementing Environmental Information Operations
A1 Title	B1 Identification of Project Environmental Information Operations
A2 Approval Page	B2 Methods for Environmental Information Acquisition
A3 Table of Contents, Document Format, and Document Control	B3 Integrity of Environmental Information
A4 Project Purpose, Problem Definition, and Background	B4 Quality Control
A5 Project Task Description	B5 Instruments/Equipment Calibration, Testing Inspection, and Maintenance
A6 Information/Data Quality Objectives and Performance/Acceptance Criteria	B6 Inspection/Acceptance of Supplies and Services
A7 Distribution List	B7 Environmental Information Management
A8 Project Organization	**Group C. Assessment and Oversight**
A9 Project Quality Assurance Manager (QAM) Independence	C1 Assessments and Response Actions
A10 Project Organizational Chart and Communications	C2 Oversight and Reports to Management
A11 Personnel Training/Certifications	**Group D Environmental Information Review and Usability Determination**
A12 Documents and Records	D1 Environmental Information Review
	D2 Useability Determination

It is not necessary to follow the sequence of elements listed herein. However, some organizations may choose to mandate this format.

Group A - Project Management and Information/Data Quality Objective

The elements in Group A (Table 2) 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. Group A elements are applicable to every type of EIO. The requirements for each Group A element are meant to be applied to all projects unless otherwise stated or specified for a specific EIO or organization in the QAPP Standard.

Table 2. Group A Elements

Project Management	
A1	Title
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/Certifications
A12	Documents and Records

A1 - Title

The title of the QAPP should clearly and concisely describe subject of work to be performed under the QAPP. It must include the words “Quality Assurance Project Plan” and not include any acronyms.

The period of applicability for a QAPP may be included as exact dates or statement clearly defining the period of applicability of the QAPP. For example, “Period of Applicability for this QAPP starts on the date of the QAM’s signature and ends five years after that date or until a new version of the QAPP is approved” or “Period of Applicability for this QAPP starts on the date of the QAM’s signature and ends no later than end date of January 22, 2029, for the period of performance for the contract this Task Order was awarded under.” No matter the method used to demonstrate the Period of Applicability for the QAPP, timeline cannot exceed five years after EPA approval and/or if applicable the extramural agreement, contract, memorandum of understanding /agreement, or legal agreement.

For information on the minimum requirements for the Title refer to the most current version of the QAPP Standard.

A2 - Approval Page

The approval information is typically the first page of the QAPP and called an Approval Page. It can also be a separate memorandum depending on the organization's administrative policy.

Approving officials usually include the organization's Operations Manager and QAM, and the EPA (or other funding agency) Project Manager and QAM. Their signatures indicate both their approval of the plan and commitment to follow the procedures noted.

Other key staff who may sign the plan are the laboratory director(s), the field operations manager, and other QAM/QA officer(s).

The EPA QAM signature designates approval of the QAPP, therefore the QAM must sign last confirming all other required signatures are present.

For physical or wet signatures, it is recommended to include the printed name of the signee in the event the signature is difficult to read.

For more information on the minimum requirements of the Approval Page, refer to the most current version of QAPP Standard.

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

The Table of Contents will generally list QAPP standard elements, as well as any tables, figures, references, and appendices necessary to the project. If the QAPP writer is following a different format from the QAPP standard elements, a table can be inserted here or be included appendices to cross-reference where the information for each element may be found. This can simplify its review.

It is recommended to use the built-in features in the document software being used to develop the QAPP to create the Table of Contents. The table of contents should be updated prior to each submission to the EPA project manager or QAM to ensure all elements are properly populating and to identify any potential mislabeled headers.

If Standard Operating Procedures (SOP) are not already available, they should be included in the appendices. Depending on the type of project, sampling methods, analytical research protocols, or environmental information management procedures may be attached. The appendices may also include information concerning previous studies such SOPs/QAPPs not easily accessible by the QAM or Team Members, Lab Bench Sheets, QC Checklists, Chain of Custody Forms, System Interoperability Diagrams, etc.

A document control notation system must be used, starting with the first page of the plan. This notation system is placed on each page to uniquely identify the plan title, version number, date of the version and the page number in relation to the total number of pages. An example format is shown in Figure 1.

For more information on the minimum requirements of the Table of Contents, Document Format, and Document Control, refer to the most current version of QAPP Standard.

QAPP Title: _____
Revision No._____
Date _____
Page ____ of ____

Figure 1. Example Document Control Format

A4 - Project Purpose, Problem Definition, and Background

This element gives the reader an overview of the problem to be solved, along with any pertinent background information for the project. It describes why the project will be done and what needs to be done.

Equally important, the development and documentation of this element ensures that all project personnel clearly understand and agree on the purpose of the project, increasing the likelihood that the project design will address and accomplish that purpose.

For this element, indicate why the project is being performed by first describing the problem and what you want to accomplish, i.e., your goals and objectives. These form the foundation for the entire study. Next, summarize any known information, indicating also what information is not known. Then, identify the intended use of the information and those who need this information.

Problems that are more complex will lead to more extensive information in this section. The reader should be able to understand the importance or context of the project.

For example, for a basic or applied research project, indicate what you are trying to do, such as developing a method. State what other methods are currently being used and describe any problems with those methods. For an enforcement case involving determination of a potential violation or health hazard, specify the statutes to be enforced, appropriate action limits, and how nonconformance will be verified. If a project involves collecting information from previous projects (an existing data usage project), identify the previous QAPPs the original environmental information was collected under and state the new use of this information and how it is relevant for your new study. If this is a questionnaire survey, justify why this survey is needed. For example, “This is to satisfy an Information Collection Request.”

For a modeling project, for example, indicate whether this is a model application project, i.e., evaluating existing models to determine whether they can perform the needed modeling to predict a future environmental condition in useable outputs, or whether this is a project to develop a new model because you know no applicable model exists and whether the model is intended to be used for regulatory purposes. If a model or scientific application is being developed identify the intended user for the software once developed.

Generally, all the sections of the QAPP that follow will contain information consistent with the goals and objectives stated in this section.

For more information on the minimum requirements of the Project Purpose, Problem

Definition and Background, refer to the most current version of QAPP Standard.

A5 - Project Task Description

This element is a management overview or summary the work to be detailed in the remaining sections of the QAPP. It describes the approach taken to address the project's objectives, connecting what is needed to how it will be obtained.

Summarize what work will be done and what information will be newly collected or collected from previous studies. Indicate, for example, the contaminants of concern, chemical compounds expected to be at the site, and sampling locations and concentrations of contaminants from previous investigations. Describe the measurement processes and techniques that will be used to collect the information.

For example, if this were a field project, describe the field operation, including the sample type and numbers to be collected and a general schedule for collecting those samples. For projects using existing data, describe the type of environmental information to be obtained and how it will be identified and used in this project. For modeling projects, identify the model(s) applications to be used or code packages, program language/environment for developing the model, modeling routines that will be developed, calibrated, and tested.

Projects using existing data discuss how the environmental infoamrion can be used to solve the problem, make the decision, or achieve the necessary outcome that was presented previously. Specify the types of existing data that may be used in key components of the project. Include a brief overview (specific details should be included in a later sections of the QAPP):

- how candidate existing data sources would be identified;
- criteria for accepting existing data for use on the study; and any existing data sources that may have already been selected, with their intended uses and any special needs (for example, personnel, hardware/software) associated with accessing and working with these data.

Include maps, diagrams, or tables where appropriate, and provide a work schedule, either in graphical or tabular format. Indicate critical points in the project, such as starting and ending dates, dates for sampling, test runs/trials, and dates by which analyses are to be completed, literature databases researched, reports written, or modeling subroutines completed. When preparing this work schedule, consider potential disruptions or downtime due to such things as vehicle or computer failure, equipment defects, personnel lacking necessary training, user availability for testing, addressing issues identified in testing, and the uncertainty of funding. If an agile development method is being used on the scientific or model application being built, provide approximate timeline for phases to be completed for each module or section to be developed. If the schedule is set by funding or regulatory deadlines, include that information in the plan. For response to emergency situations, a generalized work schedule can be formulated. Table C-2 (Appendix C) can be used to indicate project timelines of critical activities. Existing data schedule presented in this section would include milestones associated with identifying, evaluating, selecting, and obtaining

existing data sources for use on the project.

For more information on the minimum requirements of the Project Task Description, refer to the most current version of QAPP Standard.

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

This element describes quality specifications at two levels: (1) at the level of the decision or study question, and the decision or study question. (2) at the level of the measurements used to support the decision or study question.

The results of the systematic planning process used to plan and design the study that is the subject of the QAPP are documented (or referenced) as part of this element. The outputs from the Agency's recommended system that planning process, the Data Quality Objectives (DQOs) process are ideally suited to addressing the first component of this element. The DQO process results in the full set of specifications needed to support the qualitative and quantitative design of the environmental information collection effort including statements regarding the tolerable limits on the probability of a decision error. DQOs are also used to assess the adequacy of environmental information (new or existing) in relation to their intended use.

In the final step of the DQO process, an optimal design for obtaining environmental information is developed, and it is during this step that alternative sample collection designs are evaluated. During the design process, the document Guidance on Choosing a Sampling Design for Environmental Data Collection (QA/G-5S) will be of great use. This Guidance focuses on how to determine the number of samples needed, and how to allocate these samples across space (within the boundaries of the study) and across time (within the temporal boundaries of the study), to lower uncertainty related to heterogeneity to the greatest extent possible. Associated with each alternative is a set of design assumptions that form the basis for setting quality specifications for the measurement system. These statements comprise the measurement performance criteria (for new studies) or acceptance criteria (for the inclusion of existing data into the project).

Measurement performance criteria for new environmental information collection efforts are stated in terms of the desired (assumed) level of uncertainty in environmental information that will be used to address the study question or support the decision. When possible, it is desirable to state measurement performance criteria in quantitative terms, such as limits on analytical imprecision, bias and method detection limits, and limits on the overall variance of study results (to include spatial and temporal variability). Measurement performance criteria expressed in qualitative terms should be used with care as their interpretation may be subject to observer bias. For example, the concept of a representative sample has different interpretation depending on whether the observer is a field researcher or a laboratory chemist.

When a study is to be based either entirely or in part on existing data (environmental information that was previously collected for a different intended use), acceptance criteria are used in place of measurement performance criteria. In general, these criteria are used to assess environmental information adequacy, and to evaluate uncertainty in the results derived from the use of these environmental information sources. In such

cases, this section of the QAPP is used to explain the criteria for determining which sources of data are sufficient to support the goals of the current project. In addition to existing sources of quantitative analytical measurement data, qualitative terms of acceptance criteria are sometimes used to convey sociological and economic information.

Performance and acceptance criteria are often expressed in terms of Data Quality Indicators (DQIs). The principal indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity. These DQIs are defined for purposes of this document in Table 3, as well as in the method(s) for their determination. (Note that these definitions do not constitute the Agency's official use of the terms for other purposes, including regulatory purposes, and should not be construed to alter or supplant other terms in use.) Measurement Quality Objectives are the acceptance thresholds or goals for this project's data, usually based on the individual DQIs for each matrix and analyte group or analyte.

For some projects, criteria can be presented in a table, such as that illustrated in Table C-3, Appendix C, for typical chemistry data.

Existing data QAPPs for this secion would detail the acceptance criteria that existing data sources would need to satisfy to be used on the project (see Section 3.1). When acceptance criteria are expressed relative to certain data quality indicators (for example, bias, accuracy, representativeness, comparability, completeness, sensitivity), this section would describe how information on these data quality indicators (i.e., metadata) would be obtained for the various existing data sources. To support understanding of the acceptance criteria, this discussion can clarify the intended use of existing data sources, along with the types of existing data sources that would be considered.

If both newly generated data and existing data are being used on the project, this section may focus more on the performance criteria associated with the newly generated data, while details on the acceptance criteria for existing data may appear in Element B2.

For more information on the minimum requirements of the Information/Data Quality Objectives and Performance/Acceptance Criteria, refer to the most current version of QAPP Standard.

Table 3. Data Quality Indicators (DQIs)

DQI	Definition	Example Determination Methodologies
Precision	The measure of agreement among repeated measurements of the same property under identical, or substantially similar conditions; calculated as either the range or as the standard deviation. May also be expressed as a percentage of the mean of the measurements, such as relative	Use the same analytical instrument to make repeated analyses on the same sample. Use the same method to make repeated measurements of the same sample within a single laboratory or have two or more laboratories analyze identical samples with the same method. Split a sample in the field and

	range or relative standard deviation (coefficient of variation).	submit both for sample handling, preservation and storage, and analytical measurements. Collect, process, and analyze collocated samples for information on sample acquisition, handling, shipping, storage, preparation, and analytical processes and measurements.
Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction.	Use reference materials or analyze spiked matrix samples.
Accuracy	A measure of the overall agreement of a measurement to a known value; includes a combination of random error (precision) and systematic error (bias) components of both sampling and analytical operations.	Analyze a reference material or reanalyze a sample to which a material of known concentration or amount of pollutant has been added; usually expressed either as percent recovery or as a percent bias.
Representativeness	A qualitative term that expresses "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." (American National Standards Institute [ANSI]) /American Society for Quality [ASQ] 1995).	Evaluate whether measurements are made, and physical samples collected in such a manner that the resulting data appropriately reflect the environment or condition being measured or studied.
Comparability	A qualitative term that expresses the measure of confidence that one data set can be compared to another and can be combined for the decision(s) to be made.	Compare sample collection and handling methods, sample preparation and analytical procedures, holding times, stability issues, and QA protocols.

Completeness	A measure of the amount of valid data needed to be obtained from a measurement system.	Compare the number of valid measurements completed (samples collected or samples analyzed) with those established by the project's quality criteria (Data Quality Objectives or performance/acceptance criteria).
Sensitivity	The capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest.	Determine the minimum concentration or attribute that can be measured by a method (method detection limit), by an instrument (instrument detection limit), or by a laboratory (quantitation limit).

A7 - Distribution List

This list identifies all individuals who must get a copy of the approved QAPP, either in hard copy or electronic format, as well as any subsequent revisions. The names of key project personnel responsible for project implementation, EIO, and/or funding, are listed here along with their project titles or positions, and organization names. Consider describing how everyone listed will receive a copy or have access to the QAPP and include their contract information necessary for receipt of the QAPP. Key personnel to include Project Operations Manager;

- Project manager;
- Operations manager;
- Laboratory manager;
- Field team leader;
- Data processor or statistician;
- Modeler;
- Programmer/Developer;
- QAM/QA officer;
- Data reviewers; and
- Essential contractor and subcontractor personnel.

Individuals receiving a copy of the plan for informational purposes only, or at their request, should be also identified. A reader then would not expect to see project duties defined for them in the section on project organization

Table C-1 in Appendix C shows an example format for a table that conveniently combines contact information along with the QAPP copy control number.

For more information on the minimum requirements of the Distribution List, refer to the

most current version of QAPP Standard.

A8 - Project Organization

This element allows you to rapidly identify the roles and responsibilities of those individuals involved in the project and their different organizations. It also quickly identifies lines of authority and reporting between these individuals and organizations.

Those individuals involved with the major aspects or phases of the project are listed here, and their project responsibilities are discussed, indicating, for example, who can make changes and who is responsible for maintaining, updating, and distributing the QAPP. These individuals may include those who will use the information or make decisions based on that information, such as:

- Project Operations Manager;
- Principal data user;
- Decision maker;
- Regulator;
- Project QAM other QAMs or QA Officials;
- Field Analysts;
- Laboratory Analysts;
- Database researchers;
- Developer or Programmer;
- Data processors or modelers;
- Senior manager of the organization conducting EIO;
- Contractors and subcontractor's staff; and
- Any essential backup personnel who may be called.

For more information on the minimum requirements of the Project Organization, refer to the most current version of QAPP Standard.

A9 - Project Quality Assurance Manager Independence

Within a small organization, a single individual may have more than one responsibility; however, this information should clearly show that the QAM/QA Officer is independent of those generating project information. For example: The project QAM may be also supporting the Senior Manager role but is not performing EIO such as collecting samples or writing code for the project. The EPA QAM is the Task Order Contracting Officer Representative for the Task Order QAPP.

Additionally, within this section the QAPP writer can refer to the QAM's role and responsibilities described in the element A8 and organizational placement within element A10 of the QAPP if it clearly demonstrates the independent role of the QAM from the generation of project information.

For more information on the minimum requirements of the Project QAM Independence, refer to the most current version of QAPP Standard.

A10 - Project Organizational Chart and Communications

Within a small organization, the organizational chart may not clearly illustrate the QAM/QA Officer independence from those generating project information. Therefore, QAM/QA officer independence needs to be clearly explained within the previous element A9.

The project organizational chart should be helpful illustrating the group hierarchy and communication lines. The type of information found in an organization chart is illustrated in Figure 3. If more than one organization or group is involved in this project, consider creating a separate chart for each. If the project team is large and several individuals share the same roles and responsibilities, consider grouping them together if the organizational structure allows. Be sure to indicate the lines of communication between the different groups. Sometimes it may be helpful to create a legend to accompany the organizational chart to further identify organizations, lines of communication and authorities.

For more information on the minimum requirements of the Project Organizational Chart and Communications, refer to the most current version of QAPP Standard.

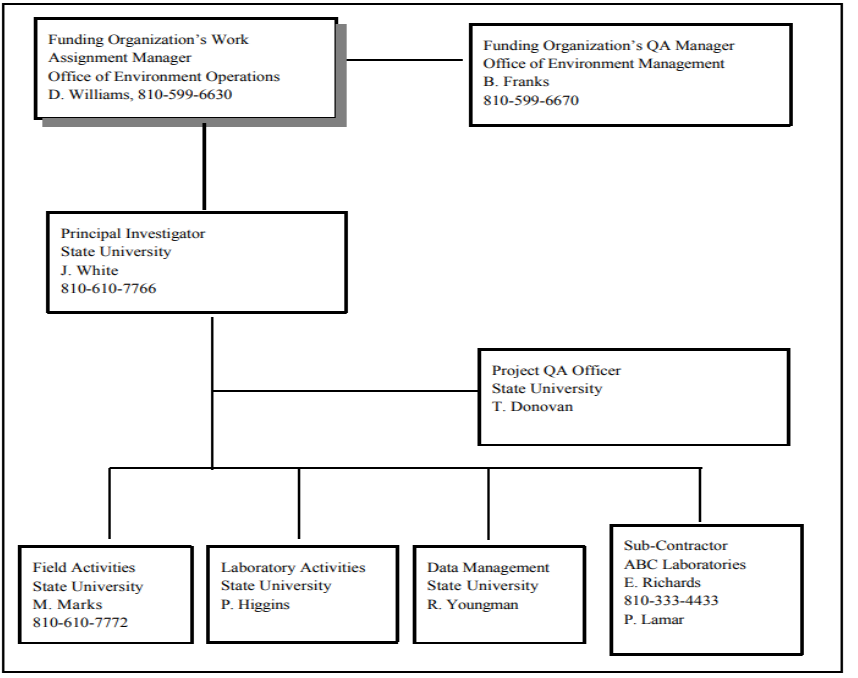

Figure 3. Example Project Organization Chart

A11 - Special Training/Certification

This element identifies any specialized education, training, knowledge, experience, certifications, or qualifications that are necessary for project personnel to successfully perform EIO or particular project task.

This may include such things as having project personnel complete helicopter safety training, being skilled in the collection of samples for trace metal analysis (called the 'clean hands-dirty hands' technique), being trained in global positioning technology, or being certified samplers. Or project personnel may need special security clearances to obtain information from confidential file sources or expertise in code development or performance testing in a special computer language. Laboratory certification for the analysis of certain types of samples may also be necessary.

Specify how this information will be documented and where the records will be kept. For example, training may be documented in personnel files. Indicate who is responsible for ensuring that they are met, and that qualified personnel are available to perform the work.

For exsiting data this section would cite any specialized training or qualifications that

project personnel would need to have or acquire to properly identify, obtain, handle, and analyze existing data sources. For example, use of certain data may specify confidential business information (CBI) clearance or specific mathematical or statistical expertise. Training may be necessary for reviewers of scientific literature to abstract important information for use on the project.

Table C-4 (Appendix C) can be inserted into the QAPP to list special training/certification needs of personnel, and to identify where those records are to be kept.

For more information on the minimum requirements of the Special Training/Certification, refer to the most current version of QAPP Standard.

A12 - Documents and Records

This element includes process and procedures concerning the management of project documents and records, including this QAPP. Management of project environmental information is covered later in Element B7, Environmental Information Management. This section would describe records that would be maintained throughout the project, while Element B7 would describe the process naming, handling, organizing, inputting the environmental information within the file or record.

Describe the process and who is responsible for making sure that project personnel will receive the most recently approved QAPP, SOP(s), and other documents used throughout the project operation. Describe how these documents will be updated and how this information will be communicated. Identify who is responsible for maintaining each record.

Summarize the information to be included in the project's data package and its format. This might include:

- sampling collection and handling records (such as field notebooks or
- analytical logbooks;
- reagent preparation records;
- test method raw environmental information;
- QC sample records;
- Standard Reference Material and/or proficiency test sample data;
- instrument, equipment, and model calibration information;
- model input data;
- output files as results of code and database test procedures;
- test data/runs;
- code/scripts.

Other possible project records that should be mentioned here are:

- inspection or assessment reports and corrective action reports;

- interim progress reports and final reports;
- billing receipts;
- computer system user guides, programmer software and hardware maintenance documents;
- code description documents;
- model evaluation summaries;
- training records;
- QA documentation such as QMPs, QAPPs, and SOPs;
- meeting notes;
- peer review documentation;
- summary file;
- performance Work Statement/technical directive documentation, if applicable;
- deliverables or sub-products; and
- presentations to be made during and after the project, for example, to management or at scientific meetings.

For projects involving collection of information from existing databases and literature files, indicate how those records will be identified, documented, and retained. Describe where all project documents and records will be stored and for how long. Include backup procedures for any environmental information stored electronically and cite the protocols for access to, retrieval from, and photocopying of information archives. Retention and final disposition of some records may be regulated, as well as access to this information.

For more information on the minimum requirements of the Documents and Records, refer to the most current version of QAPP Standard.

Group B - Implementing Environmental Information Operations

The elements in this group (Table 4) address data generation and data acquisition and management activities. Group B elements may not be applicable to every type of EIO. The requirements for most Group B elements in the QAPP Standard are written in a general manner for application to any EIO unless otherwise stated or specified for a specific EIO. Element B5 requirements are only applicable to projects that contain either field or lab activities. Element B6 requirements are only applicable to projects that contain either field or lab activities or involve services provided by a sub-contractor or vendor.

Table 4. Group B Elements

Implementing Environmental Information Operations	
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

B1 - Identification of Project Environmental Information Operations

This element describes the project's data collection or research experimental design. Keys to this element are the assumptions made and how the data will be obtained. This element explains the "how and why" of the project's information collection design to ensure that the appropriate data are collected for this project.

Sampling is the selection of a portion of a larger target population, universe, or body, with the characteristics of that sample being inferred as applicable to the target population. Describe the size of the area, shape, volume, or time that is to be represented by a sample (called the scale of representativeness) as part of the justification for how the sampling sites and durations will be selected. Next, detail the schedule for sampling and analytical activities, test runs, and reviews.

There are two classes of sampling designs to consider: probability-based and judgmental. The former are sometimes called statistical designs, and the latter as directed sampling information. The two classes have very different properties. Strong statistical conclusions are available with probability-based designs but not with judgmental designs. Use of professional expertise and/or historical knowledge about the site can improve development of statistical and judgmental sampling designs. Advice on selecting the appropriate design may be found in Chapter 2 of the Guidance for Choosing a Sampling Design for Environmental Data Collection (QA/G-5S).

Key questions to be considered are:

- is this project to be comparable with previous sampling or analytical efforts, or with a health-based or regulation standard?
- can samples or measurements be taken according to a probability-based design?
- is the objective of the sample to estimate an average or to find a hot spot?
- is there a reference or background population that can be used as a comparison

to the target population?

- will sampling sites be chosen ahead of time or in the field based on visual or other evidence; and, if the latter, what are your criteria for selection?
- will you use a network of sampling sites that will be visited periodically or where sampling will be performed continuously?
- do all the samples need to be taken simultaneously?
- is the target population approximately homogeneous or is it heterogeneous in nature needing stratification or division into approximately homogeneous areas?
- can samples be composited?

The answers to these questions should have been considered during the planning process and help to determine allocation of resources for obtaining samples.

- number of samples,
- how many sampling locations,
- are number of samples at each location,
- number of composites (if any),
- support for the sample (the area or part of the target population that a single sample is supposed to represent),
- number of qc samples (field replicates, etc.); and,
- your plan for obtaining replacement samples essential to the integrity of the project.

As part of the rationale for the study design, explain if any sample types are critical or are secondary to the study. For example, arsenic levels may be critical data in your project while data on lead may be useful for trend analysis; or literature databases may be preferentially reviewed for the last five years and then scanned for the previous ten years.

Indicate how these sampling sites will be located (for example, through use of a randomized grid or by using a global positioning system), and what you would do if any of the sampling locations become inaccessible.

Briefly describe how samples will be obtained and treated before shipping to the laboratory for analysis. This is described in more detail in the other elements. Other important information includes identifying the role of any potential sources of variability which would affect the sampling period, such as tidal cycles, seasonal differences, and rain and wind patterns. Where possible, include detailed diagrams, and use tables to illustrate this information.

Consider including a diagram to illustrate the flow of environmental information for the project. This is helpful in projects that use or develop models or scientific applications, and especially for projects that may utilize more than one model or application.

For projects that involve the development of a model or scientific application identify the how the model or application will be developed (Waterfall, Spiral, Scrum, etc.,). Include how requirements will be gathered ensure the project purpose from element A4 will be met and the DQOs along with the acceptance criteria from element A6 will be satisfied. Be sure to identify here or in element A8 who is responsible for gathering the requirements and who is responsible for providing the requirements or explaining the desired business flow and functionality of the system.

For more information on the minimum requirements of the Identification of Project Environmental Information Operations, refer to the most current version of QAPP Standard.

B2 - Methods for Environmental Information Acquisition

This element details how samples or information will be collected consistently between locations and by all sampling teams, with no contamination being introduced during collection. If a portion of the data collection will be performed without the collection of discrete samples, as *in situ* or remote sensing monitoring, this element details how the instruments will be deployed and operated to ensure that the electronic data will not be corrupted or lost.

For each type of sample, describe what constitutes a sample. Tell how much sample is needed (sample volumes), what types of sample containers are to be used, how samples will be collected, and whether any sample is to be split in the field or subsamples taken. Reference or attach any SOPs and indicate any options to be followed in any standard method. If any evaluations or preparations for these are necessary, for example, triple acid rinsed bottles, note that in the plan. If any of these samples will be homogenized, composited, or split, also indicate how this will be accomplished. For example, “A plastic-lined sediment corer will be used to collect an 18-cm core which will then be sliced into 3-cm sections with a stainless-steel blade.”

For continuous monitoring, indicate what averaging time will be used, and whether the instruments will store and maintain all the raw data or only the data averages over that time. In addition, indicate how the data will be averaged, stored, downloaded, reported (telemetered), etc.

For remote sensing, indicate the area to be imaged and the spatial resolution needed, the degree of overpass, and the film type (black and white, true-color, or false color). For side-scan sonar, note also the resolution needed and the overlap during passes over the area.

Next, identify any limitations and specific performance criteria. If non-standard methods or unusual equipment are to be used, indicate the rationale for their use and describe validation studies to confirm the performance of the method for that particular matrix, and that precision, accuracy, and detection limits will be adequate for the intended use of the data. As for location information, specify the need for accuracy.

List what sampling equipment is appropriate for the project and what support facilities are to be used. Support facilities might include such things as a flat-bottom boat, docking facilities, a plastic/stainless steel bucket, Ponary dredge, submersible pump, or an enclosure on the boat for compositing or weighing samples out of the wind.

Indicate what your backup plans are for when things go wrong. This may be a generic statement about obtaining backup supplies or equipment. Indicate how this information will be communicated to management, identifying who is responsible for corrective action and how corrective action will be documented. For example:

- what happens when someone drops one or more sample bottles or a vehicle, meter, or computer breaks down?
- are replacements going to be borrowed or do they need to be procured?

Indicate whether monitoring equipment, and samplers, will be cleaned and/or decontaminated. Detail how this would be done to ensure that there is no carryover from one sampling location to the next. Remember to include information on how decontamination by-products will be disposed, in accordance with local, state, and federal regulations.

Careful planning, and the use of standardized methods and trained personnel, help to ensure that samples are collected consistently both between sampling locations and teams. Table C-6 in Appendix C can be used to summarize some of this information.

Describe the procedures to analyze samples, and how good these have to be, i.e., their performance criteria required to support any decisions to be made with the data. Specify the analytical procedures to be followed in the field, the fixed laboratory, and/or the office are identified here. These methods can range from chemical analysis of water or soil samples to biological sample processing such as sorting and subsampling, field screening methods using immunological assays, and the analysis of remote sensing data sets and images.

Cite the analytical SOPs if they are already available or include them as appendices to the QAPP. If an EPA standard method is to be followed, then simply cite the number and date. Describe and justify any deviations here.

If the method allows any method options or modifications, such as sub-sampling, preparation, and extraction procedures, explain and detail the modifications to be followed. For example, for analysis of fish tissue with high lipid content, a preparation procedure may be needed to avoid matrix interference. Projects designed to demonstrate conformance to applicable regulations, such as drinking water regulations, will normally follow the methods specified in those regulations, or an explanation will be needed here.

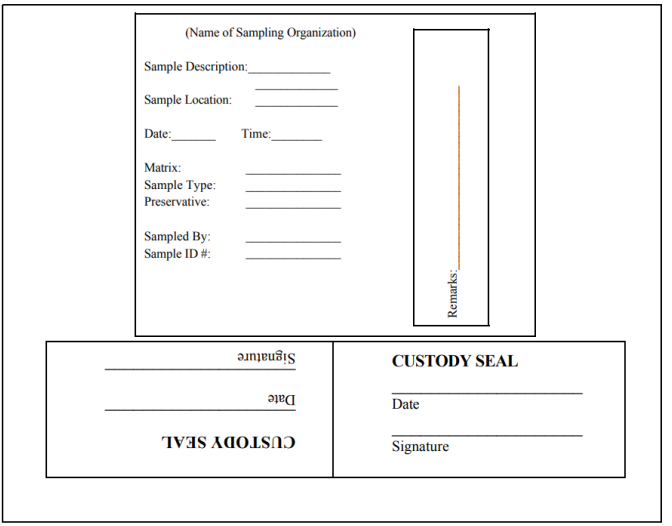

Figure 2. Examples of a Sample Label and a Custody Seal

If the laboratory is using a non-standard or unapproved method, as might occur when unusual matrices are being analyzed, provide method validation data to confirm that it will be adequate for the intended use of the data. This includes information such as determination of detection limits, quantitation limits, typical recoveries, and analytical precision and bias. Ultimately, the data will indicate the laboratory's ability to demonstrate control of the method and document the quality of the data obtained. With a performance-based measurement system (known as PBMS), the data quality needs, mandates, or limitations of a program or project are specified. These serve as criteria for selecting measurement processes which will meet those needs in a cost-effective manner, rather than the use of a specific method.

In this element, also include any specific method performance specifications. If no method currently exists, as might occur in some research projects, method performance criteria will be discussed here. Consider, for example, if the project involves a decision focused on an action level identified in Element A5. Review Table C-8 in Appendix C as one means to concisely record some of this information, for example, action level, method detection level, and achievable laboratory limits.

Identify the activities to be followed when problems arise.

In Appendix C, Table C-9 summarizes analytical services information, such as identifying which laboratory or laboratories will analyze the different types of samples and indicating time limits for reporting analytical results.

Include obtained from existing data sources, that were not directly measured or generated in project. In addition to listing the information to be discuss here your intended use of that information, for example, whether it is central ancillary to the

project, and your criteria for accepting and limiting use of that information. For a complete the data discussion of existing data, see Projects Using Existing Data section in this Guidance.

Environmental Information to be identified may be qualitative or quantitative in nature, for example:

- existing sampling and analytical data and files from a previous effort (current project and/or related project);
- photographs or topographical maps produced outside this project;
- information from the published literature;
- background information from facility or state files;
- measurements that are ancillary to addressing the project's objectives (for example, meteorological data, primarily used to better predict or explain dispersion and concentration of airborne toxic compounds in a localized area).

If you have not yet decided upon the sources of these data (outside of knowing that sources exist), document the process you will use to identify these sources and select the data. Along with specifying these types of data, specify how you will acquire (or did acquire) these data (for example, describe the literature search method).

Next, address how the types of data mentioned in the previous paragraph will be used, either exclusively or in combination with newly collected data, in certain phases of project implementation (for example, project scoping, design) or in decision-making. Element A5, mentions that such data would be used, but Element B2 documents the intended use. You would have identified this through the project's systematic planning process. For example, when following the Guidance for the Data Quality Objectives Process (QA/G-4), the third step is "Identify the Inputs to the Decision."

Document the measures of data quality that you will use to judge whether the environmental information is acceptable for their intended use, i.e., performance/acceptance criteria or DQO. The criteria may be qualitative or quantitative, such as:

- scientific literature, from which candidate data may be selected, originating from peer reviewed studies (qualitative),
- specific DQIs (Table 3) (qualitative and quantitative),
- measurement process limits, for example, method detection and quantitation limits (quantitative).

Note that the quality objectives and performance criteria documented in the Element A6, apply to measurements taken as part of the project while the criteria in Element B2 apply to existing data.

Projects Using Existing Data section illustrates a process to determine whether existing data meet a project's acceptance criteria. It uses some of the features of the data quality assessment process, which is addressed in the Element D1 and is performed at the end of

the project to determine whether the data achieved their purpose. For example, were the data collected from a population sufficiently similar to the population of interest for this project? Were the site locations and the sampling and analytical methods used to generate the original data satisfactory for the current needs? Just because a set of data has been collected according to some documented, peer reviewed, quality protocol does not mean that it is "acceptable" for your study.

Document programmatic, legal, or any other constraints on the use of existing data and their impact on the project. Note that limitations may result from the specific objectives of the project and, therefore, may not have been associated with the data in any previous use. Here are some examples of constraints:

- only staff with the necessary clearance have access to proprietary or confidential data (for example, confidential business information).
- you must use data that do not meet acceptance criteria (they are the only data available, and you need to proceed with the project).
- you may be unable to evaluate data due to a lack of background information (for example, information on target population, sampling and analysis methods, associated QA and QC measures, etc.)

For projects that involve the use of a model or scientific software application describe the procedures for using the model or scientific application or identify any SOPs or guidebooks that will be followed for the use the application.

For projects developing a Model or Scientific Software describe the procedures or process or identify the SOPs for development, testing, deployment, and maintenance.

For more information on the minimum requirements of Methods for Environmental Information Acquisition, refer to the most current version of the QAPP Standard.

B3 - Integrity of Environmental Information

This element describes your efforts to ensuring and maintaining the original integrity of EIO describe in Element B1. Element B3 has additional expectations for how integrity of environmental information is ensured by addressing specifics requirement directed towards field and laboratory activities.

Describe what steps will be taken to ensure each collected sample retain its original physical form and chemical composition through collection to final disposal. It also identifies maintenance of custody, i.e., possession, of the sample. For *in situ* and remote sensing measurements, the same issues apply to the records of these measurements.

Describe conditions that will be necessary for these samples to keep their original condition during sample collection, transportation, and storage. This may include the use of preservatives such as the addition of acid to the sample bottle before transportation and ice to the transport container, appropriate packing material, and a freezer for long-term storage.

Give maximum holding times for each type of sample. Holding times will vary with the analyte/matrix and are designed to ensure stability of the analyte/sample.

Tell who will maintain the field notebooks and who is responsible for sample custody in the field and sample receipt, custody, and ultimate disposal in the laboratory. For example, does the laboratory have a sample receipt department, or will the sample be given directly to the analyst? Will the analyses use the entire sample? For in-situ or remote sensing measurements, whether discrete or continuous, the same issues apply to the measurement records.

Explain the project's sample tracking system to identify where and when samples were obtained. A unique project numbering system helps to track each sample through the entire process to ensure samples are not switched accidentally.

The term "chain-of-custody" is often used to designate legal custody procedures that enable tracing the possession and handling of a "sample" (for example, a physical environmental sample, a confidential document, or critical maps) during transfer, i.e., from sample collection through laboratory analysis, so that its physical possession is known at all points of the project. This may include sample custody tags and written documentation to be signed by each person who handles the samples, and the use of a container sealed with custody tape. If such a procedure will be followed, describe it fully so that it can be done. Chain-of-custody procedures may be specified for projects where the data may be used in court as evidence.

Indicate the types of sample tags, labels, custody seals, and forms to be used to the QAPP so that the samplers know what label to use and how it is to be filled out. Figure 2 is an example of a sample label and custody seal. See Table C-7 in Appendix C as an example of how some of this information can be summarized.

For more information on the minimum requirements of Integrity of Environmental Information, refer to the most current version of the QAPP Standard.

B4 - Quality Control

Quality Control is a vital step in any quality program and project regardless of the type of EIO. The results from QC help determine whether results and outputs are accurate representations and can be trusted. This means QC is a contributing factor to determining if the data or environmental information produced will be useable (Refer to Group D).

There is potential variability in any sample collection, analysis, or measurement activity, with field variability generally contributing more than laboratory variability. In an environmental monitoring project, total study error can be divided into between-sampling-unit variability (influenced by sampling design error and inherent spatial variability) and within-sampling-unit variability (due to small-scale within unit variability, and variability due to sampling, analytical, and data manipulations). This section lists those checks that can be performed to estimate that variability. For a more detailed discussion of sampling unit variability, review the Guidance for Choosing a Sampling Design for Environmental Data Collection (QA/G-5S).

QC activities are those technical activities routinely performed, not to eliminate or minimize errors, but to measure or estimate their effect. The actual QC data needs are based on the decision to be made and the data quality specifications for the project. Here you should list all the checks you are going to follow to assess/demonstrate reliability and

confidence in your information.

For example, contamination occurs when the analyte of interest, or another compound, is introduced through any one of several project activities or sources, such as contaminated equipment, containers, and reagents. Blanks are “clean” samples used to measure the sources of contamination at different collection and measurement stages.

Bias is systematic error. A variety of QC samples can be used to determine the degree of bias, such as analysis of samples with a known concentration of the contaminant of concern. These are known as standards, matrix spike samples, and matrix-specific QC samples. For example, calibration drift is a nonrandom change in a measurement system over time and is often detectable by periodic re-measurement of calibration check standards or samples.

Imprecision is random error, observed as different results from repeated measurements of the same or identical samples. Replicate samples and split samples are commonly used to denote the level of precision in the measurement or collection system. For example, a sample split in the field and sent to two different laboratories can be used to detect interlaboratory precision. A sample split in a laboratory and then analyzed separately can indicate analytical precision, while a sample repetitively measured with one instrument can determine instrumental precision.

For each measurement activity, identify those QC checks that will be followed in this project, and indicate at what frequency each will occur. This can include items such as field collocated, duplicate, and matrix spike samples and laboratory duplicate, matrix spike, and control samples. The QAPP may identify and describe the documentation procedures for QC activities such as:

- one in ten field samples or one per batch will be a replicate sample, with a batch being defined as twenty or fewer samples per preparation test method;
- the spike compound will be analyzed at a concentration of five to seven times the suspected concentration level;
- a proficiency test (PT) sample will be evaluated once per quarter.

Table 5 lists some QC check samples often included in QAPPs and details the information each provides. Note that these QC samples may be also described in other elements, such as Element B3 Integrity of Environmental Information, and Element B4 Quality Control, and may not necessarily be repeated here.

Table 5. Project Quality Control Checks

QC Check	Information Provided
Blank Bottle Blank Field Blank Reagent Bank Reinstate or Equipment Blank Method Blank	Cleanliness of Sample Bottles Transport, Storage, And Field Handling Bias Contaminated Reagent Contaminated Equipment Response of an Entire Laboratory Analytical System

Spikes Matrix Spike Matrix Spike Replicate Analysis Matrix Spike Surrogate Spike	Analytical (Preparation + Analysis) Bias Analytical Bias and Precision Instrument Bias Analytical Bias
Calibration Check Samples Zero Check Span Check Mid-Range Check	Calibration Drift and Memory Effect Calibration Drift and Memory Effect Calibration Drift and Memory Effect
Replicates, splits, etc. Field Collocated Samples Field Replicates Field Splits Laboratory Splits Laboratory Replicates Analysis Replicates	Sampling + Measurement Precision Precision of All Steps After Acquisition Shipping + Interlaboratory Precision Interlaboratory Precision Analytical Precision Instrument Precision

When you identify the QC activity control limits, tell what is to be done when these are exceeded. For example, what will happen when the "blank" sample comes out positive for the contaminant-of-concern? Cited methods usually do not provide this information or it may be insufficient for the needs of your project.

State how the effectiveness of control actions will be determined and documented. For example, if the senior taxonomist determines that the junior taxonomist has misidentified x% of macro invertebrate samples, retraining may be specified until accuracy, i.e., correct identification has improved, and the retraining is recorded in the project files. For these QC samples, identify also the procedures, formulae, or references for calculating applicable statistics, such as estimating sample bias and precision.

It is useful to summarize QC activities depending on the EIO, when the project involves other types of EIO. This way, appropriate personnel can quickly identify the QC samples that apply to their activities. Tables C-10 and C-11 in Appendix C are examples of tables that can be used to denote sampling and analytical QC activities.

Remember that QC activities vary considerably between environmental monitoring programs and between different agencies. They do incur a cost to the project, which should be included during project planning by management and/or decision makers. In other words, the x% of samples to be analyzed as blanks should be considered to be an inherent part of the analytical process, not as an expendable add-on.

If the project involves existing data describe the process or procedures as applicable for systematic review and independent secondary review of studies in the open literature. If files are downloaded from a database what steps are taken to ensure the files were downloaded correctly and there are no gaps in data, misaligned fields, missing units of measure, or loss characters. Describe what checks are done to ensure there are no transcription errors, accidental entries, units conversion errors, formula or calculation errors, and other types of verification checks for constructed databases or spreadsheets.

Models in development and existing models used in new conditions will also need to be "calibrated" to assure the model's equations represent the environmental conditions being modeled. Test performance criteria usually provide the acceptable difference between the model output and values measured in the field or laboratory to be used in statistical tests for goodness-of-fit. Describe the process if the model involves the parametrization to be performed. Describe if the model application or code package has test data to use and the frequency it was used for determining the model is operating correctly and what is the acceptance criteria. This element should answer the question for most modeling projects, how do you know the model was operating optimally to determine if the output data can be used.

If the project involves the development of a model or scientific application what steps and types of tests (code review, unit testing, integration testing, parallel testing, etc.,) will be performed during the development and deployment phase of the model or scientific application. What will be the frequency for each test to be conducted and the acceptance criteria performed. Models in development will also need to be "calibrated." Test criteria for models in development might involve statistical methods such as regression analyses and goodness-of-fit methods where model output is compared to actual measurement data.

For more information on the minimum requirements of Quality Control, refer to the most current version of the QAPP Standard.

B5 - Instruments/Equipment Calibration, Testing Inspection, and Maintenance

This element is only applicable to EIO that that use instruments and equipment to perform the EIO (This does not include Information Technology, any special software or hardware requirements are addressed in B7). It describes how project personnel will know that the equipment will work properly when needed.

In this element list any equipment or systems that will be used during the project that should be inspected or tested before use, or what maintenance is conducted on a routine basis. Describe what will be done to test, inspect, and maintain the project's instruments and equipment, and identify where critical spare parts will be located. Indicate also, how often this will be done and who is responsible for doing it. For example:

- the dissolved oxygen membrane probe will be checked for holes daily before each use by the first individual using the meter;
- the analytical balance is to be checked out by an instrument specialist annually;
- the mercury column in a thermometer will be examined for breaks before each use; and
- the field team leader will supply the fresh batteries before leaving.

SOPs that contain this information may be referenced or attached. In addition, much of this information may be summarized in a table, such as Table C-12 in Appendix C.

Ensure the continual quality performance of all equipment and instruments by listing those requiring calibration, whether in the field, a fixed laboratory, or in the office.

Identify any applicable criteria and measurement and testing equipment that will be used.

For example, field equipment to be calibrated might include items such as pumps, flow meters, gauges, pH meters, and temperature sensing devices. Laboratory equipment might include items such as pH meters, dissolved oxygen probes, balances, and spectrophotometers.
Test methods should be discussed, or referenced as SOPs, as appropriate. Test criteria and standards or certified equipment to be used might include statements such as the following:

- accuracy is to be ± 0.05 ml or ± 0.2° C;
- a NIST-traceable thermometer is to be used annually for calibrating all temperature sensing devices;
- balances are to be calibrated with Class One weights before each use.

Tell how frequently these activities are to be done to ensure the quality of the results. For example, sensitive or critical equipment may need to be calibrated before each use and performed by the analyst. Describe also how the data calibration or information will be recorded and analyzed. Then indicate how the records will be maintained to be traceable to the instrument or equipment in question, and to the standards to be used, for example, lot number and expiration date. For a large laboratory with several pieces of similar equipment with exchangeable components, this tracking system takes considerable effort. Cite or attach any SOPs that document this information. This information can be recorded in a table, such as is shown in Table C-13.

For more information on the minimum requirements of Instruments/Equipment Calibration, Testing Inspection, and Maintenance, refer to the most current version of the QAPP Standard.

B6 - Inspection/Acceptance of Supplies and Services

Not all projects will need supplies or services to conduct EIO. For those projects that do, this element documents your system for having field and laboratory supplies and services available.

Here you should identify what project supplies are necessary to perform the planned EIO to meet the identified DQOs in element A6. Identify who is responsible to make sure the supplies and services are available and are acceptable for use. Where applicable, document the following information so that these supplies can be located, and similar items purchased when the listed items are exhausted:
supply source (vendor);

- procedures for identifying, tracking, storing, and retrieving these supplies;
- identification of those responsible for maintaining these supplies; and
- any acceptance criteria for these items, for example, certificates of cleanliness, testing, health, or taxonomic identification

Examples of supplies and consumables that may be used in a project are:

- filters or cartridges for air monitoring;
- reference toxicant chemicals for toxicity testing;
- test organisms for toxicity testing;
- Agar or media for organism recovery;
- Sterile bottles;
- film and photographic paper for geospatial projects;
- bottles of known cleanliness for specialized chemical analyses, such as for trace metals analysis;
- reagent water or reagent-grade quality; and
- reference standards for calibrating instrumentation.

Describe your acceptance criteria for these items, such as the minimum percent organism viability.

Table C-14 in Appendix C can be used to list inspection or acceptance testing activities and to indicate who is responsible for such testing, as well as where and how this material will be stored. Alternatively, Table C-15 can be used to list critical consumables and supplies, tracking numbers, dates of receipt and expiration, and to indicate whether they meet the inspection criteria.

Not For more information on the minimum requirements of Inspection/Acceptance of Supplies and Services, refer to the most current version of the QAPP Standard.

B7 - Environmental Information Management

In Element A12, you described managing project documents, such as this QAPP and records from the project. This element gives an overview of the management of the data generated throughout the project.

Identify the process and hardware and software equipment for data/information handling and storage throughout the life cycle of the project, i.e., from the field notes and laboratory results or from existing data sources to the office's data or model system This includes:

- recording, transcribing, digitizing, and downloading,
- transformation and reduction (mathematical operations),
- transmittal,
- management,
- storage, and
- retrieval

In doing so, indicate the project organization's standard record-keeping practices and document control system for both hard-copy and electronic media. Next, identify where the information can be found and for how long.

Describe here control mechanisms for detecting and correcting errors, such as manual calculations on a spot-check basis and review of field data sheets before transmittal to the office, backup procedures. Also, identify who is responsible for these separate activities. For example, the technician performing the analysis is to review the data before handing the information to the laboratory's QA officer. If there are any forms or checklists to be used, attach them to the plan. If there is a flowchart that diagrams any part of this process, include it.

Indicate how the computerized information systems such as code repositories will be maintained. For example, indicate what hardware and software items are necessary, how they will be routinely tested, and upgraded when software changes occur.

For EPA personnel writing a QAPP, identify also how all applicable EPA information management specifications will be met. For projects involving data processing or modeling and computer data storage, discuss EPA software/hardware configuration specifications, such as identifying project coding standards; design configurations; users and maintenance manuals, and indicate how these will satisfy EPA specifications. For projects requiring sampling, address how EPA's locational or geospatial data specifications will be satisfied. Where any of this information is already incorporated in an organization's QMP, simply refer to that document and section.

For existing data projects this section documents how existing data (as well as newly generated data) would be incorporated and managed into the project's data management system. Example topics include how existing data will be obtained from its source in a given format, how and what data will be entered and verified if obtained in hard copy format, and how certain security or confidentiality specifications will be incorporated into the project's data management system.

For more information on the minimum requirements of Environmental Information Management, refer to the most current version of the QAPP Standard.

Group C - Assessment, Response Actions and Oversight

An assessment is the evaluation of the 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. Certain types of assessments are designed to determine whether the QAPP is being implemented as approved (conformance/nonconformance), to increase confidence in the information obtained, and ultimately to determine whether the information may be used for their intended purpose. The elements in this group (Table 6) detail what assessments will occur both during and after the project. Data assessments, such as data verification and validation, are discussed in the Group D elements. Group C elements are applicable to every type of EIO. The requirements for each Group C element are meant to be applied to all projects unless otherwise specified for a specific organization in the QAPP Standard.

Table 6. Group C Elements

Assessment and Oversight	
C1	Assessments and Response Action
C2	Oversight and Reports to Management

C1 - Assessments and Response Actions

This element gives information concerning how a project's activities will be assessed during the project to ensure that the QAPP is being implemented as approved.

A wide variety of internal (self) and external (independent) assessments can be conducted during a project. The types of assessments to be conducted, and the frequency for conducting these assessments, will depend on the intended use of the information and the confidence needed and expected in the quality of the results. For example, a high-profile or a long-term project is more likely to have assessments conducted on its activities (and they are more likely to be unannounced assessments) than a project such as development of an analytical method, a basic research project, or a project in which only a few samples will be collected.

Assessments are best done throughout the project to identify potential problems early in the project and allow for timely corrective action. This reduces the impact of non-conformance such as occurrences of questionable data and faulty conclusions. Assessments should be considered as a routine part of the project, rather than being conducted on an "as-needed" basis. Cost, influenced by the type of audit to be conducted, supplies needed, and the availability of technical personnel, should be balanced with the potential savings such as not having to repeat measurements having deficiencies.

Assessments may consist of:

- audits such as:
    - readiness reviews;
    - surveillance;
    - proficiency testing; and
    - Audits of Data Quality
    - technical systems audit of field, laboratory, or environmental information management activities.
- management reviews;
- peer reviews;
- inspections;
- surveillances;
- peer consultations; and

- products and deliverable reviews.

Definitions of each of these assessments may be found in Section 9, with a full discussion in the Guidance on Technical Audits and Related Assessments (G-7), which is available on the EPA quality website.

For existing data use projects, data may be assessed to determine suitability for their intended use and to identify whether project specifications were met. For model performance evaluations, assessments may be made to qualitatively and quantitatively assess model performance, for example, uncertainty analyses, model verification tests, and internal and external peer reviews. Model assessments may also involve peer review on the mathematical basis for the model, algorithm checks, code verification, model evaluation, data quality assessment of input data, user acceptance testing (UAT), and evaluation of model output uncertainty and variability.

In this element, supply information for each type of assessment, such as what type of assessment will be conducted, when and how often. Discuss when assessments results will be reported, so that these evaluations can affect changes in the project as it progresses. When identifying who will conduct these assessments, indicate also their position within the project's organization or from another organization, and the scope of their authority, for example, issuing stop work orders.

Attach any checklists to be used. For an example of a project assessment table to summarize this information, review Table C-16 in Appendix C.

List assessments that involve the use of existing data, for example, assessments that:

- existing data meet basic project specifications (for example, are of the proper type) and are appropriately relevant and suitable for their targeted use (for example, have an acceptable target population);
- the quality of existing data meets the acceptance criteria specified and that a sufficient quantity of existing data is available to allow the project to meet criteria on data quality;
- proper procedures and protocols were used in obtaining or abstracting existing data from their sources;
- sufficient quality control information was obtained on the data; and, the quality assurance techniques documented in the QA Project Plan have been followed in the use of the existing data.

Assessments involving existing data generally address the process of acquiring, evaluating, selecting, and obtaining existing data for use on the project. A graded approach is used to determine the overall scope and level of detail in which the assessments are performed. Include the following information (as it would be for any type of assessment:

- the role that these assessments play in the project's total set of assessments;
- the schedule of assessments;
- the organizations and individuals expected to participate in the assessments;
- information expected from the assessment;

- documentation needed for the assessment; and,
- possible types of corrective action and levels of authority that would determine corrective action (for example, collect additional data, investigate other data sources, loosen acceptance criteria).

For more information on the minimum requirements of Assessments and Response Actions, refer to the most current version of the QAPP Standard.

C2 - Oversight and Reports to Management

This element documents how management will be kept informed of project oversight and assessment activities and findings.

Identify here what project status reports will be written during the project. These might include:

- assessment reports;
- results of proficiency test samples;
- calibration reports; and
- model evaluation report

In addition, indicate those responsible for writing these reports, when, and how often these reports will be written, and identify who will be notified of audit findings. Table C-17 in Appendix C contains a sample table that could be used to summarize this information. Projects of short duration may only have a final report which includes assessment results, along with project results and conclusions.

For more information on the minimum requirements of Oversight and Reports to Management, refer to the most current version of the QAPP Standard.

Group D - Environmental Information Review and Usability Determination

The elements in this group (Table 7) address the final project checks to see if the data or product obtained will conform to the project's objectives, and to estimate the potential impact(s) of any deviations. For projects that use existing data, these elements focus on evaluating how data values from these acquired data sets will be used to determine the quality objectives for the new data use. For a modeling project, the focus is on confirming that the steps in the modeling process were followed correctly to produce the model outputs and that the results meet project objectives. Group D elements are applicable to every type of EIO. The requirements for each Group D element in the QAPP Standard are meant to be applied to all projects.

Table 7. Group D Element

Data Validation and Usability	
D1	Data Environmental Information Review
D2	Reconciliation with User Requirements

D1 - Environmental Information Review

This element lists your criteria for deciding to accept, reject, or qualify project information to be obtained. In a sense, this lists the final critical checks that will be done on the information obtained to decide whether they satisfy the quality criteria listed previously, for example, Element A6, and whether that information can be used.

Data review is the in-house examination to ensure that the data have been recorded, transmitted, and processed correctly. That includes, for example, checking for data entry, transcription, calculation, reduction, and transformation errors. It may also mean ensuring that there is a complete list of sample information available, such as sample matrixes, blanks, duplicates, shipping dates, preservatives, holding times, etc., and ensuring that there are no programming errors. It is also a completeness check to determine if there are any deficiencies, such as missing data or integrity issues (for example, due to corruption or loss in storage or processing). This includes the review of records for code review and verification testing (e.g., unit testing, integration testing, etc.) performed, and determining the sufficient level of commits or other supporting code development documentation for the code developed in projects involving the development of models and scientific applications.

Data verification is the process for evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual specifications. It essentially evaluates performance against pre-determined specifications, for example, in an analytical method, or a software or hardware operations system.

Data validation, however, addresses how individual data values and information (including analyte and sample-specific information, and existing data sources) are determined to be acceptable for use or otherwise need to be qualified, when the procedures would be performed, and by whom. This process extends the evaluation of data beyond method, procedure, or contractual compliance (i.e., data verification) to determine the quality of a specific data set relative to the end use. It focuses on the project's specifications or needs, designed to meet the needs of the decision makers/data users and should note potentially unacceptable departures from the QAPP. The potential effects of the deviation will be evaluated during the data quality assessment. How are the results from validation testing (e.g., UAT, parallel testing, etc.) for development of models and scientific applications going to be evaluated to determine if the model or scientific application is acceptable for use.

Data verification is generally done first, internally by those generating the data or by an organization external to that group. Data validation is generally performed on the verified data later in the process and by someone independent or external to the data generator and the data user. These processes may occur both during and at the end of the project.

The criteria for deciding whether the data meet the project's quality specifications are listed here for review, verification, and validation. Therefore, each component of the project for which criteria were listed previously in the QAPP (in the data generation and acquisition elements) should be identified here. For example, discuss the criteria for sample collection procedures, such as precision for location data. Indicate what

tolerances are allowed for deviations from sampling locations, pH values, blank contaminations, satellite imagery (coverage and quality), etc. If data are to be flagged, state the criteria. For a modeling project, describe the criteria for code verification and/or indicate whether the model will be evaluated by comparing model predications with data used during model development.

The level of detail and frequency for performing data review, verification, and validation activities will depend on the complexity of the project, and the importance of the decision to be made based on it

Describe the methods or processes for verifying and then validating project information. Much of the information previously listed in other elements will be discussed here for the series of final checks on the data that will be conducted. The data may be reviewed to verify how it was:

- recorded or formatted;
- transformed (for example, log values, calculations of replicate measurements, dry weight to wet weight values);
- reduced (for example, calculation of sample concentrations from peak areas), transferred (for example, software);
- analyzed (for example, using the organization's Laboratory Information Management System); and
- qualified.

The methods to be used or processes to be followed can be identified as SOPs, if available, or described in the text. For example, indicate what data validation software will be used, if any. Those responsible for performing these functions should have been identified earlier in the plan Element A8, if not, then identify them here. Describe the process to show how errors will be handled and this information given to the data users. Attach any necessary forms and checklists to the QAPP. Table C-18 can be used to summarize some of this information.

Describe the process to show how errors will be handled and this information given to the data users. Attach any necessary forms and checklists to the QAPP. Table C-18 can be used to summarize some of this information.

For a more detailed description of the data verification and validation process, review the Guidance on Environmental Data Verification and Data Validation (QA/G-8).

For more information on the minimum requirements of Environmental Information Review, refer to the most current version of the QAPP Standard.

Existing data projects would document how the ability to use existing data to achieve the project's needs will be evaluated. While the assessments in Element C1 may have been performed initially on existing data, this section discusses the final set of assessments of how the data can be used to address project objectives. Although previous sections of the QA Project Plan address how an entire existing data source is determined to be acceptable for use on the project, this section would address how individual data values and

information within the existing data source are determined to be acceptable for use or otherwise need to be qualified, when the procedures would be performed, and by whom.

D2 - Useability Determination

The purpose of this element is to describe how you will evaluate the validated data to see if it answers the original questions asked, i.e., the measurement quality objectives or data quality objectives. This is the final assessment of the data quality and the culmination of the entire QA process for the project.

Describe in this element what statistical analyses or error estimates will be made based on total error, i.e., the cumulative error from field, laboratory, and data handling. This may involve some statistical analyses such as tests for outliers, trends, dispersion, etc., or a scientific evaluation of the information (for example, for content or reasonableness). Describe how data will be presented, e.g., tables or charts, to illustrate trends, relationships, and anomalies.

If a systematic planning was employed when developing the project technical and quality goals, use the Data Quality Assessment (DQA) process to evaluate how well the validated data can support their intended use. The DQA process is a five-step process described in the Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9). This document is specifically written for non-statisticians and provides many graphical and statistical tools.

If the project will collect data without using a statistically based (probability based) design, analysis and inference becomes limited to simple descriptions of the data with no extrapolation to more general cases. Qualitative statements about the data are valid, but quantitative estimates are highly suspect.

Discuss how limitations on the use of the data will be handled and reported to the decision makers. For example, what will be done if data quality indicators do not meet performance criteria?

For exisitng data, include a disscussion of any mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified before any statistical analysis. In addition, if existing data need to be entered into a project database, detail the features of the data management system that verify the accurate entry of values for important data parameters into this database, along with any data reduction procedures (for example, averages of replicate measurements). Include when these activities will be done.

The ultimate “adequacy” of the existing data used on the project relative to the data users’ needs is determined by methods detailed in this section. This is done by describing statistical tools and other methods used to evaluate whether the existing data can be used to achieve their intended uses and are therefore justified to be used in addressing project objectives. Discuss strategies in place to resolve or account for any issues that arise from investigating the data. These issues may include the impact of data limitations that were encountered, the need for new data collection or re-analysis, or the need to use data with caveats.

For more information on the minimum requirements of Useability Determination, refer to the most current version of the QAPP Standard.

Appendix A: Projects Using Existing Data

When Existing Data Are Used on An Environmental Project

What does "existing data" mean?

Data or information that you plan to use but that have not been newly generated by your project are called "existing data." They may also be known as "secondary" data or non-direct measurements.

Why should I consider using existing data on a project?

When working on an environmental task or project, some project objectives (for example, to answer a given question or to gain more knowledge in a given area) may be met by using data previously generated, but which are still relevant to your current needs. It is less expensive, easier, and sometimes solves sampling access problems. Existing data may have certain characteristics that may be advantageous. For example, existing data may provide more detailed and exhaustive information than your project would be able to generate (such as data covering a longer time span), thereby allowing decision makers to have a greater understanding of the situation and providing a greater statistical basis for any decision to be made.

What are some examples of typical sources of existing information for environmental projects?

Examples of the many types and sources of existing information include the following:

- data from publicly available databases, such as data from the Census Bureau, data represented within EPA's Environmental Information Management System, and data cataloged in EPA's Environmental Data Registry;
- data from published literature, reports, and handbooks;
- data generated and submitted by third parties, including compliance data when used for purposes other than its primary purpose (i.e., to assess compliance);
- data from state and local monitoring programs;
- results from unpublished research;
- output generated by executing existing models;
- data obtained from previously performed pilot studies; and
- existing maps, Geographical Information System (GIS) layers, plots, photographs, or land surveys.

What are considerations when using existing data?

Data collection is designed to meet a project's performance criteria. Existing data from other projects may not have been generated to meet the specific quality criteria established for your project, i.e., you did not get to choose the processes for collecting these data that are appropriate for your intended use. Even though some existing data sources may be well-respected, and their data handling may be appropriate for its original

use, such data still should be evaluated for the appropriateness of their specific use on your project.

When planning to use existing data, evaluate the data relative to your project's own acceptance criteria by obtaining and reviewing available metadata. Metadata is information that describes the data and their quality criteria.

Because certain existing data sets, such as major regulatory databases, are frequently used on other environmental projects, EPA has developed tools to make it easier for a user to obtain the metadata and to standardize the information in the metadata. EPA's scientific environmental information management system (EIMS) is one of these tools. It is a repository of scientific documentation, such as data sets, databases, documents, models, multimedia, projects and spatial information, and its accompanying metadata. The descriptive information stored within EIMS is also consistent with the Federal Geographic Data Committee metadata content standards for spatial data, available at www.fgdc.gov.

When using existing data, you should assess any limitations associated with the data and how these may impact their use relative to your project's objectives. For example, the data may represent a target population that differs from the population targeted in your project or may have been generated from analytical methods that yield measurement errors or used detection limits that are higher than are acceptable for your project. Lack of sufficient or adequate metadata for an existing data source may be a reason not to use it. Conversely, previously documented limitations on a data set may or may not prove to be limitations relative to your specific project's needs.

How do I determine whether to use existing data?

Once possible existing data sources are identified, you should evaluate each source relative to the quality needs (i.e., acceptance criteria) of your project. The rigor of this evaluation is determined by the overall role and importance of those data relative to your intended use. Do not use any data without assessing whether they can meet your needs.

The following sections outline planning guidance for projects using existing data. Please also visit Resources for Planning Projects that Use Existing Data for additional helpful information on planning and implementing projects using existing data.

Determine Your Data Needs

First define the problem to be investigated or the decision to be made, identify a need for data and the types of data necessary to address this problem, and then determine criteria for the level of quality that these data will need to satisfy. Identify how you intend to use the data that you will generate or acquire on your project.

Your goal is to establish project data performance or acceptance criteria (or Data Quality Objectives) for projects involving formal decision-making. Different data elements may have different acceptance criteria, depending on their importance to the project.

Identify Existing Data Sources That May Meet Project Needs

Find out whether the data you need already exist in adequate quality to meet your project needs. Some data may be used to help scope the project and define project objectives,

while other data may be used to validate model-generated predictions, to contribute to data collection, or to help interpret results. Certain phases of the project may have less stringent criteria for data quality than others (as addressed below). If getting the most appropriate data is critical, for example, in a risk assessment, then documenting the search is important.

Any programmatic, legal, or security specifications for the use of the data should be identified and evaluated. Verify the extent to which the data are consistent relative to any other data sources, thus allowing for comparisons between the data sources or to ensure that all important data fields are present. If some fields are missing, additional data sets may be needed to fill in data gaps. If data sources lack sufficient metadata, they will not be acceptable for use and should not be used.

If you continue with further evaluation, despite using data not meeting all of these basic project specifications, document the potential ramifications that using the data may have on your ability to ultimately meet your project needs. For example, a data set may complete a study of monitored concentrations that vary over time. The analytical method for one parameter may be unknown, but the user could note a potential bias based on that uncertainty and still use the data.

Evaluate Existing Data Relative to Your Project's Data Quality Specifications

Examples of questions that may be posed in this evaluation (preferably to be answered by the organization who collected the data) are given in Table 8. Metadata would be used to obtain answers to these questions. These answers would then be documented in the project's planning document (such as the QAPP) or in the final report. If collecting and reviewing data sources will be done after the QAPP is written, the QAPP should indicate the types of metadata that will be used in the evaluation. The QAPP would then be amended to give the results of the evaluation.

Table 8. Examples of Potential Data Sources and Related Question

Potential Data Sources	Example Questions*
Data from handbooks or the scientific literature	How did you ensure that these data are the most up-to-date available? What are the assumptions implicit in the data? What are the limitations of the data?
Model outputs	What are the assumptions that these estimates are based upon? Has the quality of the modeling effort been evaluated? What are the limitations of the data?
Public-use data sets	Are the data correct for the problem, or can they be transformed so that they are? What are the limitations of the data (for example, uncertainty, representativeness, QC flags)?

*** It is recommended that you involve the use of an expert on the potential data "type" if you are unfamiliar with the method or techniques for collection and/or use.**

If you continue with further evaluation, despite using data not meeting all of these basic project specifications, document the potential ramifications that using the data may have on your ability to ultimately meet your project needs. For example, a data set may complete a study of monitored concentrations that vary over time. The analytical method for one parameter may be unknown, but the user could note a potential bias based on that uncertainty and still use the data.

The possible outcomes of this evaluation on a given existing data source include the following:

- Documentation that the data meet the needs of this project and therefore can be used,
- A finding that the data do not meet the needs of the project and therefore will not be used, or
- Documentation that the data can be used in the project with some caveats on the confidence or significance of the findings based on these data, after some other action is taken (for example, supplemental data collection), or after some relaxation of the acceptance criteria.

The second outcome implies that some level of new data collection should be done. In the third outcome, reasons for accepting the data, and the associated caveats and revised acceptance criteria should be documented. Certain existing data sources might be acceptable for use, but conditional on new data collection to supplement the existing data.

Document Quality Issues in Planning Documents or the Final Report

Document in the QAPP (or equivalent planning document) the needed confidence in the information that you obtain, along with the specific acceptance criteria associated with

selecting existing data sources for the project. If the scope of your project is only to identify and evaluate existing data sources for some use on a future project, the outcome of this investigation would be documented in a final report. Provide enough detail to allow the reader to understand the process you followed and the criteria you developed to determine whether certain existing data sources are acceptable for your intended use. Existing data sets with high data quality information (i.e., metadata) and known data limitations are preferred. Include this information when the QAPP is being prepared. However, if such information is not yet known, include a description of the process that will be used to locate the data (for example, literature searches, contacting state agencies, on-line searches) and obtain the needed information.

Issues On Preparing A QAPP For Projects Using Existing Data

Why should I prepare a quality assurance planning document (such as a QA Project Plan) if my project uses only existing data?

The QAPP shall describe the purpose of the project's EIO (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. See the QAPP Standard for more details.

How is the graded approach applied to writing a QAPP?

Your project's planning team may apply the graded approach to writing a QAPP and specify how the acquisition and use of existing data are to be addressed in the plan. Adequate documentation of all data sources to be used for decision making should be noted in the QAPP. However, a QAPP may not necessarily include incidental use of existing data or widely accepted parameter values from sources such as chemical handbooks. The level of detail associated with the documentation of a specific data source is ultimately determined by the project's planning team.

What issues on the consideration and use of existing data should be addressed when preparing a QAPP?

Available sources of data of sufficient quality for their intended use on the project.

Table 9. QAPP Elements That May Address Existing Data Issues

Group A: Project Management and Information/Data Quality Objectives	
QA Project Plan Element	**Consideration for the Use of Existing Data**
A1 - Title	No special considerations likely.
A2 - Approval Page	No special considerations likely.
A3 - Table of Contents, Document Format, and Document Control	Cite any appendices containing detailed information that may be relevant in assessing existing data relative to its intended use on this project (for example, QA Project Plan for the operation used to collect the data, audit reports, final reports). (Note that in most cases, these materials may be cited as references rather than included as appendices.)
A4 - Project Purpose, Problem Definition and Background	Identify why these data are relevant for consideration for the current project and, where relevant, include background information on how existing data were collected and are maintained.
A5 - Project Task Description	Discuss how existing data can be used to solve the problem, make the decision, or achieve the necessary outcome that was presented previously. Specify the types of existing data that may be used in key components of the project. Include: • an overview of how candidate existing data sources would be identified; • an overview of the criteria for accepting existing data for use on the study; and, any existing data sources that may have already been selected, with their intended uses and any special needs (for example, personnel, hardware/software) associated with accessing and working with these data. Details on these items would be provided in later sections of the QA Project Plan. The project schedule presented in this section would include milestones associated with identifying, evaluating, selecting, and obtaining existing data sources for use on the project
A6 - Information/Data Quality Objectives and Performance/Acceptance Criteria	This section would detail the acceptance criteria that existing data sources would need to satisfy to be used on the project (see Section 3.1). When acceptance criteria are expressed relative to certain data quality indicators (for example, bias, accuracy, representativeness, comparability, completeness, sensitivity), this section would describe how information on these data quality indicators (i.e., metadata) would be obtained for the various existing data sources. To support understanding of the acceptance criteria, this

	discussion can clarify the intended use of existing data sources, along with the types of existing data sources that would be considered. If both newly generated data and existing data are being used on the project, this section may focus more on the performance criteria associated with the newly generated data, while details on the acceptance criteria for existing data may appear in Element B2.
A7 - Distribution List	Identify those who will evaluate and assess existing data relative to the project's acceptance criteria and, where necessary, include representatives of operations that collected or maintain existing data sets.
A8 - Project Organization	Clearly state the roles and responsibilities of each group.
A9 - Project QAM Independence	Include those responsible for identifying candidate existing data, and representatives of the sources of the existing data.
A10 - Project Organizational Chart and Communications	Include in the Project Organizational Chart those evaluating existing data relative to use on the project.
A11 - Personnel Training/Certifications	This section would cite any specialized training or qualifications that project personnel would need to have or acquire to properly identify, obtain, handle, and analyze existing data sources. For example, use of certain data may specify confidential business information (CBI) clearance or specific mathematical or statistical expertise. Training may be necessary for reviewers of scientific literature to abstract important information for use on the project.
A12 - Documents and Records	Information on existing data that need to be included within the project's data report package would be discussed in this section. This section would also discuss how the approach to identifying, selecting, and obtaining existing information for use on the project, along with the approach to determining that candidate data sources achieve the needs associated

	with their intended use on the project and the outcome of these processes, would be properly documented.
Group B: Implementing Environmental Information Operations	
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	These elements address various quality aspects of the design and procedures for collecting, handling, and analyzing environmental field samples and are relevant when collecting new data for purposes of addressing the project's objectives. Thus, these elements generally do not address issues regarding existing data sources. This is the primary element of the QA Project Plan within which information on existing data, their intended uses, and their limitations is presented. This section also presents the acceptance criteria for specific data sources that were introduced in Element A6 of this guidance for details on what should be presented in this section. In some cases (for example, on projects using exclusively existing data), the project's principal investigator may decide to present certain procedures associated with the generation and use of existing data within these QA Project Plan elements rather than all appearing in Element B2. However, it is often more informative to have these elements focus only on newly generated data and to have the element "Methods for Environmental Information" focus on existing data
B7 - Environmental Information Management	This section documents how existing data (as well as newly generated data) would be incorporated and managed into the project's data management system. Example topics include how existing data will be obtained from its source in a given format, how and what data will be entered and verified if obtained in hard copy format, and how certain security or confidentiality specifications will be incorporated into the project's data management system.
Group C: Assessment, Response Actions and Oversight	
C1 - Assessments and Response Actions	List assessments that involve the use of existing data, for example, assessments that: • existing data meet basic project specifications (for example, are of the proper type) and are

	appropriately relevant and suitable for their targeted use (for example, have an acceptable target population); • the quality of existing data meet the acceptance criteria specified and that a sufficient quantity of existing data is available to allow the project to meet criteria on data quality; • proper procedures and protocols were used in obtaining or abstracting existing data from their sources; • sufficient quality control information was obtained on the data; and, • the quality assurance techniques documented in the QA Project Plan have been followed in the use of the existing data. Assessments involving existing data generally address the process of acquiring, evaluating, selecting, and obtaining existing data for use on the project. A graded approach is used to determine the overall scope and level of detail in which the assessments are performed. Include the following information (as it would be for any type of assessment): • the role that these assessments play in the project's total set of assessments; • the schedule of assessments; • the organizations and individuals expected to participate in the assessments; • information expected from the assessment; • documentation needed for the assessment; and, possible types of corrective action and levels of authority that would determine corrective action (for example, collect additional data, investigate other data sources, loosen acceptance criteria)
C2 - Oversight and Reports to Management	Reports to Management cite any reports that need to be brought to the attention of management that may affect the extent to which the project relies on existing data.
Group D: Environmental Information Review and Usability Determination	
D1 - Environmental Information Review	Document how the ability to use existing data to achieve the project's needs will be evaluated. While the assessments in Element C1 may have been performed initially on existing data, this section discusses the final set of assessments of how the data can be used to address project objectives.

	Although previous sections of the QA Project Plan address how an entire existing data source is determined to be acceptable for use on the project, this section would address how individual data values and information within the existing data source are determined to be acceptable for use or otherwise need to be qualified, when the procedures would be performed, and by whom.
D2 - Useability Determination	Discuss any mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified before any statistical analysis. In addition, if existing data need to be entered into a project database, detail the features of the data management system that verify the accurate entry of values for important data parameters into this database, along with any data reduction procedures (for example, averages of replicate measurements). Mention when these activities will be done. The ultimate "adequacy" of the existing data used on this project User Requirements relative to the data users' needs is determined by methods detailed in this section. This is done by describing statistical tools and other methods used to evaluate whether the existing data can be used to achieve their intended uses and are therefore justified to be used in addressing project objectives. Such statistical tools are documented in the Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9). Discuss strategies in place to resolve or account for any issues that arise from investigating the data. These issues may include the impact of data limitations that were encountered, the need for new data collection or re-analysis, or the need to use data with caveats.

6. ROLES AND RESPONSIBILITIES

EPA Administrator: Promotes and ensures quality is an integral part of the Agency's mission by assuring that EIO 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 the QAPP Standard to Assistant Administrators (AA) and Regional Administrators (RA).

Assistant Administrators (AA) and Regional Administrators (RA): Each AA and RA is responsible for implementing the QAPP 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 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 the Administration (AO), Chief Information Officer (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 EIO encompassed by the QAPP Standard.

Chief Information Officer's (CIO) Strategic Advisory Council (SAC): Consisting of Senior Information Officials (SIOs) and other senior managers, the SAC advises and reports to the 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 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 (MSDDs): Manage issues related to 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 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 Chief Procurement Officer 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 the Chief Grants Officer: 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.

Data & Enterprise Programs Division (DEPD), Data & Quality Branch (DQB), Chief Quality Officer (CQO): Responsible for oversight of the Agency's Quality Program. Execute actions on behalf of the 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 EIO 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 Quality Team 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 EIO 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 QAM to refer to the individual designated as the QAM for project defined in the QAPP.

Agency Personnel: Perform work associated with EIO as identified in their organization's QMP.

Recipients of Extramural Agreements: Perform all EIO 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 Guidance. Since these documents are subject to periodic review, users of this Guidance should refer to the most recent version:

- ASQ/ANSI E4: 2014 (R2019) Quality management systems for environmental information and technology programs—Requirements with guidance for use
- Environmental Information Policy, Procedures and Standards
- 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
- Enterprise Data Management Policy
- 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)
- EPA Guidance for the Data Quality Objectives Process (QA/G-4)
- EPA Guidance for Geospatial Data Quality Assurance Project Plans (QA/G-5G)
- EPA Guidance for Choosing a Sampling Design for Environmental Data Collection (QA/G-5S)
- EPA Guidance for Quality Assurance Project Plans for Modeling (QA/G-5M)
- EPA Guidance for Preparing Standard Operating Procedures (QA/G-6)
- EPA Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7)
- EPA Guidance on Environmental Data Verification and Data Validation (QA/G-8)
- EPA Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)
- EPA Data Quality Assessment: Statistical Tools for Practitioners (QA/G-9S)
- EPA Guidance on Quality Assurance for Environmental Technology Design, Construction and Operation (QA/G-11)

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— systematic and independent examination to determine whether quality activi ties 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 wit h procedures used by the International Organization for Standardization or organizations accredited by the ANSI.

Data— quantitative or qualitative representation of values, facts, observations, or ide as 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, l ocates, 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 (EIO)— 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 a nd/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 the most current version of the 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 t hat 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 EIO products and services.

9. WAIVERS

Waivers to this Guidance are non-applicable. This Guidance does not include mandatory requirements and is a tool to assistance with implementation of the QAPP Standard.

10. GUIDANCE SUPERSEDED

EPA Guidance for Quality Assurance Project Plans (EPA QA/G-5, December 2002)

11. CONTACTS

For information about this Guidance or the EPA Quality Program, contact the Data & Enterprise Programs Division, Data & Quality Branch, or email quality@epa.gov.

Appendix B: Acronyms & Abbreviations

AA	Assistant Administrator
ANSI	American National Standards Institute
ASQ	American Society for Quality
CIO	Chief Information Officer
DAA	Deputy Assistant Administrator
DEPD	Data & Enterprise Programs Division
DQI	Data Quality Indicator
EPA	Environmental Protection Agency
EQMD	Enterprise Quality Management Division
IM	Information Management
IT	Information Technology
LSASDD	Laboratory Services and Applied Science Division Director
MSDD	Mission Support Division Director
NPO	National Program Office
OCIO	Office of Chief Information 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
SAC	Strategic Advisory Council
SIO	Senior Information Official
SOP	Standard Operating Procedure
STPC	Science and Technology Policy Council
UFP	Uniformed Federal Policy

Appendix C: Sample QAPP Tables

This appendix contains several tables for summarizing QAPPs information. Since the content and level of detail in a specific QAPPs will vary by program, by the work being performed, and by the intended use of the data, specific tables may not be applicable to all projects. These tables illustrate possible formats that can be used; columns may be deleted, rows expanded, or items added as needed.

Table C-1. Project Organizational Contact and QAPP Distribution List

Name	Organizational Affiliation	Title	Contact Information[1]	QAPP Receipt/Control #

[1]Telephone number, fax number, email address.

Table C-2. Project Schedule Timeline

Activity	Date (MM/DD/YY)		Deliverable	Deliverable Due Date
	Anticipated Date of Initiation	Anticipated Date of Completion		

Table C-3. Measurement Performance Criteria

Matrix	
Analytical Parameter	
Concentration Level	
Sampling Procedure	
Analytical Method #	

Data Quality Indicators (DQIs)[1]	Measurement Performance Criteria	QC Sample and/or Activity Used to Assess Measurement Performance	QC Sample to Assess Error for Sampling (S), Analytical (A) or both (S&A)

Table C-4. Special Personnel Training or Certification

Specialized Training Course Title or Description	Training Provider	Training Date	Personnel Receiving Training/ Organizational Affiliation	Location of Records & Certificates*

***If training records and/or certificates are on file elsewhere, then document their location in this column. If these training records and/or certificates do not exist or are not available, note this.**

Table C-5. Document and Record Retention, Archival, and Disposition Information

	Identify Type Needed*	Retention	Archival	Disposition
Sample Collection Records				
Field Records				
Analytical Records				
Data Records				
Assessment Records				
Field Records				

*** Consider confidential business information (CBI).**

Table C-6. Sampling Locations and Sampling Method/SOPs

Sampling Location[1,2]	Location ID Number	Matrix	Depth (Units)	Analytical Parameter	# Samples (include field duplicates)	Sampling SOP	Sample Volume	Containers #, size, type	Preservation (Chemical, temperature, light protected)	Maximum Holding Time Preparation/ Analysis

[1]Indicate critical field sampling locations with "[1]".
[2]Indicate background sampling locations with "[2]".

Table C-7. Sample Handling System

Sample Collection, Packaging and Shipment
Sample Collection:
Sample Packing:
Coordination of Shipment:
Type of Shipment (Courier):
Sample Receipt and Analysis
Responsible Organization:
Sample Receipt:*
Sample Custody and Storage:*
Sample Preparation:*
Sample Determinative Analysis:*
Sample Archival
Field Sample Storage (# days from sample collection):
Sample Extract/Digestate Storage (# days from extraction/digestion):
Sample Disposal
Responsible Organization:
Responsible Personnel:

*** Identify primary responsible laboratory group or individual.**

Table C-8. Contaminants of Concern and Other Target Analytes

Analyte	Matrix	Project Action Limit (units, wet or dry weight)	Project Quantitation Limit (units, wet or dry weight)	Analytical Method		Achievable Laboratory Limits	
				MDLs[1]	Method[1]	MDLs[2]	QLs[2]

[1]Analytical Method Detection Limits (MDLs) and Quantitation Limits (QLs) documented in validated methods. QLs can be 3-10 times higher than the MDLs, depending on the specifications from the Data Quality Objectives established for the project.
[2]Achievable MDLs and QLs are limits that an individual laboratory can achieve when performing a specific analytical method.

Table C-9. Analytical Services

Analytical Parameter	Matrix	Analytical Method/SOP	Modified for Method yes/no	Data Package Turnaround Time	Laboratory/Organization (Name, Address, Contact Person, Telephone Number)	Backup Laboratory/Organization (Name, Address, Contact Person, Telephone Number)

Table C-10. Sampling QC

Matrix
Sampling SOP
Analytical Parameter
Analytical Method/ SOP Reference
Sample Locations

Field QC:	Frequency/ Number	Method/SOP QC Acceptance Limits	Corrective Action (CA)	Person(s) Responsible for CA	Data Quality Indicator (DQI)	Measurement Quality Objectives
Equipment Blanks						
Field Blanks						
Trip Blanks						
Cooler Temperature						
Field Duplicate Pairs						
Collocated Samples						
Field Splits						
Field Matrix Spikes						
Other:						

Table C-11. Analytical QC

Matrix
Sampling SOP
Analytical Parameter
Analytical Method/ SOP Reference
Sample Locations

Laboratory QC:	Frequency/ Number	Method/SOP QC Acceptance Limits	Corrective Action (CA)	Person(s) Responsible for CA	Data Quality Indicator (DQI)	Measurement Quality Objectives
Method Blank						
Reagent Blank						
Storage Blank						
Instrument Blank						
Lab. Duplicate						
Lab. Matrix Spike						
Matrix Spike Dup.						
Lab. Control Sample						
Surrogates						
Internal Standards						
Others						

Table C-12. Testing, Inspection and Maintenance of Sampling Equipment and Analytical Instruments

Equipment/ Instrument	Maintenance Activity	Testing Activity	Inspection Activity	Responsible Person	Frequency	Acceptance Criteria	Corrective Action	SOP Reference

Table C-13. Equipment and Instrumentation Calibration

Equipment/ Instrument	Procedure	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	SOP Reference

Table C-14. Inspection/Acceptance Testing Requirements for Consumables and Supplies

Critical Supplies/ Consumables	Inspection/ Acceptance Specifications	Acceptance Criteria	Testing Method	Frequency	Responsible Individual	Handling/ Storage Conditions

Table C-15. Critical Supplies and Consumables Tracking Log

Critical Supplies/ Consumables	Tracking Number	Date Received	Meets Inspection/ Acceptance Criteria (Y/N, if yes include date)	Retesting Needed (Y/N, if yes include date)	Expiration Date	Initials/Date

Table C-16. Assessments

Assessment Type	Matrix	Frequency	Internal or External	Organization Performing Assessment	Person, Title, Organizational Affiliation Responsible For:			
					Performing Assessment	Responding to Assessment Findings	Identifying and Implementing Corrective Actions	Monitoring Effectiveness of Corrective Actions

Table C-17. QA Management Reports

Type of Report	Frequency (daily, weekly monthly, quarterly, annually, etc.)	Projected Delivery Date(s)	Person(s) Responsible for Report Preparation	Report Recipients

Table C-18. Data Validation

Medium/ Matrix	Analytical Parameter	Concentration Level	Validation Criteria	Validation Criteria Modified	Data Validator (Name, Title, and Organizational Affiliation)

Example of a QAPP Review Checklist

This is a checklist based on the elements in *Environmental Protection Agency (EPA) Quality Assurance Project Plan (QAPP) Standard*. It is intended as an example only, as each organization may develop checklists specific to their needs.

Title: _____
Operation Manager: _____
Extramural (Yes/No): _____
Quality Assurance (QA) Manager: _____
Reviewer: _____

Revision/Version Number: _____
EPA Organization: _____
Extramural Vehicle (EV): _____
Date Submitted for Review: _____
Date of Review: _____

Element	Acceptable (Yes/No/ Partially)	Page/Section	Comments
Group A: Project Management and Project/Data Quality Objective Elements **A1: Title Page**			
The EPA Organization responsible for the QA is listed on the title page. e.g., (EPA/[NPO]/[Center]/[Division]/[Branch]) (**A1:** The QAPP Standard)			
There is a Title that meets the following criteria: a. It is descriptive of the project; b. Acronyms are spelled out; and c. contains the word "Quality Assurance Project Plan". (**A1:** The QAPP Standard)			
Version or Preparation Date of the QAPP is provided. (**A1:** The QAPP Standard)			
Revision or Version Number is on the title page. (**A1:** The QAPP Standard)			
The QAPP is identified as being intramurally or extramurally developed.			

(**A1:** The QAPP Standard)			
There is a period of applicability listed that is not greater than 5 years from date of approval or extends past the Period of Performance (POP) whichever is lesser. (**A1**: The QAPP Standard)			
Non-EPA Organizations Only: Lists the Vehicle # (Grant, Cooperative Agreement, Contract, Task Order, or IA Number) or the title and date of the Memoranda of Understanding/Agreement. (**A1:** The QAPP Standard)			
Non-EPA Organization Only: Includes the name of the non-EPA organization: (**A1:** The QAPP Standard)			
Non-EPA Organizations Only: POP is provided for the agreement or contract. (**A1:** The QAPP Standard)			
Non-EPA Organizations Only: Citation of the regulatory requirement, if applicable. (**A1:** QAPP Standard)			
Non-EPA Organizations Only: Title and date of the enforcement or legal agreement, if applicable. (**A1:** QAPP Standard)			
A2: Approval Page			
There is a Signature Block for the EPA Operation Manager, Project Officer, and/or Contracting Officer Representative. (**A2:** The QAPP Standard)			
There is a Signature Block for the EPA QA Manager (QAM). (**A2:** The QAPP Standard)			
Non-EPA Organizations Only: Includes the external entity's Signature Block for their Program Lead.			

(**A2:** The QAPP Standard)			
Non-EPA Organizations Only: Includes the external entity's Signature Block for their QA personnel. (**A2:** The QAPP Standard)			
Headers/Footers of every page other than Title			
Every page has a Header or Footer that contains the revision/version number as the title page. (**A3:** The QAPP Standard)			
Every page has a Header or Footer that contains the same Version Date as the title page. (**A3:** The QAPP Standard)			
Every page has a Header or Footer with a page number in relation to the total number of pages (e.g., Page X of Y). (**A3:** The QAPP Standard)			
Every page has a Header or Footer that contains the same Title of the QAPP as the title page (abbreviations are acceptable) (**A3:** The QAPP Standard)			
A3: Table of Contents, Document Format, and Document Control			
There is a Table of Contents. (**A3:** The QAPP Standard)			
The Table of Contents lists all of the QAPP Standard Elements of the QAPP with the correct page numbers. (**A3:** The QAPP Standard)			
The Table of Contents lists all of the Figures in the QAPP with the correct page numbers. (**A3:** The QAPP Standard)			
The Table of Contents lists all of the Tables in the QAPP with the correct page numbers. (**A3:** The QAPP Standard)			

The Table of Contents lists all of the Appendices in the QAPP with the correct page numbers. (**A3:** The QAPP Standard)			
The Table of Contents lists all of the identified worksheets within the QAPP with the correct page numbers. (**A3:** The QAPP Standard)			
Revision History Page/Table (Required for re-submission/approval of previously approved QAPPs)			
There is a Revision History or Versioning Table. (**Section 6:** The QAPP Standard)			
The Revision History lists all the approved versions of the QAPP by revision or version number. (**Section 6:** The QAPP Standard)			
The Version Date of each QAPP listed is provided in the Revision History table. (**Section 6:** The QAPP Standard)			
The Version Date of each QAPP listed is provided in the Revision History table. (**Section 6:** The QAPP Standard)			
The author of the QAPP is listed in the Revision History table for each version listed. (Not an actual requirement-Best Practice)			
The Revision History table (history page) describes the updates and changes made to each revision with sufficient detail. (**Section 6:** The QAPP Standard)			
Abbreviation/Acronyms List			
There is a list or table of all abbreviations and acronyms used in the document. (Not an actual requirement-Best Practice)			
A4: Project Purpose, Problem Definition, and Systematic Planning			

Identifies relevant QA Documentation to the project, such as related QAPPs, QMPs, etc. (**A4:** The QAPP Standard)			
Clearly explains the reason (site background or historical context) for initiating this project. (**A4:** The QAPP Standard)			
Includes information and sources about previous work as it relates to the current project (if applicable) (**A4:** The QAPP Standard)			
Clearly describes the purpose of the project's EIO. (**A4:** The QAPP Standard)			
Defines Problems to be addressed. (**A4:** The QAPP Standard)			
Describes any research questions or hypothesis the project will address. (**A4:** The QAPP Standard)			
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained. (**A4:** The QAPP Standard)			
Identifies the type, quantity of environmental information/data needed for the intended use. (**A4** The QAPP Standard)			
Describe the acceptance and performance criteria for the environmental information. (**A4** The QAPP Standard)			
Identifies applicable regulatory programs and standards. (**A4:** The QAPP Standard)			
Identifies applicable Conceptual site model(s) (**A4:** The QAPP Standard)			
Provides a discussion that directly links the results of the EIO to possible actions, if applicable.			

(**A4:** The QAPP Standard)			
Identifies the intended audience for this project. (Not an actual requirement-Best Practice)			
Identify who would most likely use the environmental information generated from this project. (Not an actual requirement-Best Practice)			
A5: Project Task Description			
The description of tasks to be performed during the project is provided. (**A5:** The QAPP Standard)			
Has a schedule of all tasks to be performed under the Project/QAPP (e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and products). (**A5:** The QAPP Standard)			
Project Tasks are identified by schedule and include: • Collection of Environmental Information • Data Reviews • Analysis • External Peer Review (if required) • Final Product (Not an actual requirement-Best Practice)			
Project Tasks are identified by schedule and include: • Collection of Environmental Information • Data Reviews • Analysis • External Peer Review (if required) • Final Product (Not an actual requirement-Best Practice)			
There is a description of the responsibilities of each individual participating in the project. **(A8:** The QAPP Standard)			

Identifies who has approval authority for the QAPP (EPA QAM) **(A8:** The QAPP Standard)			
Identifies who is the senior manager having executive leadership authority for the organization conducting the EIO. One responsibility of the senior manager is providing resources. Resources are knowledgeable personnel, funding, materials, supplies, and time. **(A8:** The QAPP Standard)			
Identifies who is the Operations Manager for the organization conducting the EIO. **(A8:** The QAPP Standard)			
Identifies who is the project QAM for the organization conducting the environmental operations. **(A8:** The QAPP Standard)			
Describes the Project QAM's oversight authority and responsibilities for planning, documenting, coordinating. and assessing effectiveness of the QAPP. **(A8:** The QAPP Standard)			
Describes 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. **(A8:** The QAPP Standard)			
Identifies who is responsible for maintaining and annually reviewing the QAPP. **(A8:** The QAPP Standard)			
A9: Project Quality Assurance Manager Independence			
Describes how Project QAM is independent from the EIO and the QAM independence is ensured during the project. **(A9:** The QAPP Standard)			
A10: Project Organization Chart and Communications			
There is an organizational Chart.			

(**A10:** The QAPP Standard)			
The organizational chart includes everyone's name that has an active role identified in Section A8. (**A10:** The QAPP Standard)			
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. (**A10:** The QAPP Standard)			
The organizational chart identifies everyone's role or title in the organizational chart. (**A10:** The QAPP Standard)			
All individuals in the organization chart are identified by their organizational info. (Example: EPA/[NPO]/[Center]/[Division]/[Branch], Contract Inc., A University) (**A10:** The QAPP Standard)			
The Operations Manager is listed in the Organizational Chart (**A10:** The QAPP Standard)			
The Senior Manager is listed in the organizational chart. (**A10:** The QAPP Standard)			
The organizational chart clearly identifies the reporting relationship between the Operations Manager and Senior Manager. (**A10:** The QAPP Standard)			
The EPA Project QAM is identified in the organizational chart. (**A10:** The QAPP Standard)			
The organizational chart demonstrates the independence of the QAM from the EIOs. (**A10:** The QAPP Standard)			

The organizational chart demonstrates the project QAM's reporting relationship to the Senior Manager of the organization conducting EIO. 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. (**A10:** The QAPP Standard)			
The organizational chart uses dotted lines for communication between individuals and solid lines for lines of authority. (**A10:** The QAPP Standard)			
Communications procedures and timing of communication are outlined in the QAPP, including roles and responsibilities associated with communication. (**A10:** The QAPP Standard)			
Describes procedures for elevating discrepancies and QAPP non-conformance; process for improvements and seeking concurrence and approvals between EPA personnel and/or contractors responsible for conducting EIO. (**A10:** The QAPP Standard)			
Non-EPA Organizations Only: Describes the communication procedures to EPA to include elevating discrepancies and QAPP non-conformances. (**A10:** The QAPP Standard)			
Identifies and describes any specialized education, training, knowledge or certifications needed by personnel in order to successfully complete the project or task. (**A11:** The QAPP Standard)			
Discusses how this training will be provided, and the necessary skills are assured.			

(**A11:** The QAPP Standard)			
Describes the procedure that will document the training records and skill evaluation. (**A11:** The QAPP Standard)			
Indicates personnel responsible for documenting personnel training. (**A11:** The QAPP Standard)			
Identifies the individual is responsible for ensuring personnel conducting EIO are qualified, trained and experienced. (**A11:** The QAPP Standard)			
A12: Documents and Records			
Lists all project documents, records, and electronic files that currently exist and will be produced. (**A12:** The QAPP Standard)			
References all applicable requirements for the final disposition, storage location and length of retention. (Or identifies the record schedule for all project records and documents; i.e.,1035a for Category A 1035b for Category B). (**A12:** The QAPP Standard)			
Identifies the system in place by the organization conducting EIO for the control of all documents including preparation, review, approval, issuance, revision, and archiving documents. (**A12:** The QAPP Standard)			
Identifies who is responsible for managing each of the records or documents. (**A12:** The QAPP Standard)			
Includes the file location (file path for electronic records) for all project documents, records and electronic records that exist or will be produced for this project. (Not an actual requirement-Best Practice)			

Identifies the format of the record (csv, docx, jpeg, html, PDF, xlsx, shp, txt, etc...). (Not an actual requirement-Best Practice)			
Identify which records contain Confidential Business Information (CBI) or Personally Identifiable Information (PII) or proprietary information or intellectual property. (Not an actual requirement-Best Practice)			
Identify who has access to the listed project documents, records and electronic records. (Not an actual requirement-Best Practice)			
For Field Activities only: Includes all Document Control and Records Management requirements identified in the EPA QA Field Activities Procedure (QAFAP). (**A12:** The QAPP Standard)			
Group B: Implementing Environmental Information Operations			
Any Section B Element that is not applicable to the project type/discipline states that the specific element “Does Not Apply” and provides in detail why it does not apply or reference the project specific requirements provided by the EPA sponsoring organization. (**Group B:** The QAPP Standard)			
Describes all guidance, tools, and templates used to develop the QAPP. (**Group B:** The QAPP Standard)			
For Field Activities conducted by EPA only: Field EIO activities, include all of the requirements identified in the EPA QAFAP. (**Group B:** The QAPP Standard)			
B1: Identification of Project Environmental Information Operations			

Describes in detail how the EIO will be conducted for the project. (**B1:** The QAPP Standard)			
Describes in detail how the project purpose (from A4) will be satisfied based on the described EIO. (**B1:** The QAPP Standard)			
Describes in detail how the DQOs and performance and acceptance Criteria (from A6) will be satisfied based on the described EIO. (**B1:** The QAPP Standard)			
B2: Methods for Environmental Information Acquisition			
Identifies and describes the methods and procedures for how environmental information/data will be acquired throughout the project including any implementation requirements. (Acquisition of environmental information is defined as collection, production, evaluation, use, design, construction, operation or application of environmental technology). (**B2:** The QAPP Standard)			
Any methods are identified by the following: • Number/identifier, • Version/revision date, • method option selected or to be u (if are options in the method cited), and • Regulatory citation (if applicable). (**B2:** The QAPP Standard)			
Identifies and describes any Standard Operating Procedures (SOPs) used for the acquisition of environmental information including the: • Version/revision date of the SOP, • Responsible Party for maintaining and updating the SOP (SOP Contact/Author/Mentor),			

• Any planned SOP updates/modifications for the course of the project, • Exact procedures to be used if there is more than one option of procedure within the SOP, and • The equipment to be used if there is more than one option for equipment to be used within the SOP. (**B2:** The QAPP Standard)			
Describe how the identified SOP(s) will be available to the personnel conducting the EIO. (**B2:** The QAPP Standard)			
For Field Activities only: 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. (**B2:** The QAPP Standard)			
For Field Activities only: Describe or reference maximum holding times for sample extraction and/or analysis, selection and preparation of sample containers, sample volumes, preservation methods, and sample handling and custody. (**B2:** The QAPP Standard)			
For Laboratory using analytical methods only: Identifies the analytical methods by number/identifier, version/revision date and regulatory citation (if applicable) (**B2:** The QAPP Standard)			

For Laboratory Activities only: 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. (**B2:** The QAPP Standard)			
For Laboratory Activities only: Specifies laboratory data package turnaround time needed, if important to the project schedule (**B2:** The QAPP Standard)			
For Laboratory Activities only: For non-standard method applications, such as for unusual sample matrices and situations, appropriate method performance study information is described to confirm the performance of the method for the matrix. If previous performance studies are not available, the QAPP shall describe how performance studies will be developed during the project and included as part of the project results. (**B2:** The QAPP Standard)			
For Existing Data only: Describes the existing environmental information (data) to be obtained/collected. (**B2:** The QAPP Standard)			
For Existing Data only: Describes how the existing environmental information is to be collected. (**B2:** The QAPP Standard)			
For Existing Data only: Describes the intended use of the existing environmental information is to be collected. (**B2:** The QAPP Standard)			

For Existing Data only: Describes the criteria for acceptance and evaluation of the existing environmental information for suitability for the current project. If the information is to be combined with new environmental information, describes the criteria to ensure compatibility. (**B2:** The QAPP Standard)			
For Environmental Technology only: Identifies whether the technology is primarily for pollution prevention, contamination containment, storage, or remediation. (**B2:** The QAPP Standard)			
For Environmental Technology only: Describes 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. (**B2:** The QAPP Standard)			
B3: Integrity of Environmental Information			
Describes or cites the procedures for ensuring the integrity of EIO. (**B3:** The QAPP Standard)			
For Field Activities only: Describe or cites 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. (**B3:** The QAPP Standard)			
For Field Activities only: Contain examples of the following:			

• sample labels, and • chain of custody forms/sample custody logs. (**B3:** The QAPP Standard)			
For Laboratory only: Identifies 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). (**B3:** The QAPP Standard)			
For Laboratory only: Describes the processes for ensuring the laboratory maintains current accreditation and/or certification for applicable analytes and matrices. (**B3:** The QAPP Standard)			
B4: Quality Control			
Identifies and describes the Quality Control (QC) activities needed for each EIO activity to meet project DQOs and performance/acceptance criteria. (**B4:** The QAPP Standard)			
Describes or cites the frequency of each type of QC activity, corrective actions, and how the effectiveness of the corrective action shall be determined and documented. (**B4:** The QAPP Standard)			
Describes or references the procedures to be used to calculate applicable statistics (e.g., precision and bias). (**B4:** The QAPP Standard)			
For Field Activities and Laboratory only: Describe how the following QC activities will be used: • blanks, • duplicates, • matrix spikes,			

• laboratory control samples, and • surrogates. (**B4:** The QAPP Standard)			
For Existing Data Only: Describe how the following QC practices will be applied: • the use of systematic review, • independent secondary review of studies in the open literature, and • QC of constructed databases or spreadsheets. (**B4:** The QAPP Standard)			
For Modeling Use Only: Describe how the following QC practices will be applied: • model calibration, and • model validation (sensitivity analyses). (**B4:** The QAPP Standard)			
B5: Instrument/Equipment Calibration, Testing, Inspection, and Maintenance			
Identifies instruments/equipment, to include, but not limited to for use during the project: • tools, • gauges, and • pumps (**B5:** The QAPP Standard)			
Describes all procedures and documentation activities that will be performed to ensure that the instruments and/or equipment are available and in working order when needed. (**B5:** The QAPP Standard)			
Describes or reference how calibration will be conducted, documented, and be traceable to the instrument. (**B5:** The QAPP Standard)			

Describes or references procedures and documentation activities on how instruments and equipment will be tested, inspected, and maintained. (**B5:** The QAPP Standard)			
Describes the availability of critical spare parts, identified in the operating guidance and/or design specifications of the instruments/equipment. (**B5:** The QAPP Standard)			
B6: Inspection/Acceptance of Supplies and Services			
Describes or reference the procedures for how supplies are inspected and accepted. 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. (**B6:** The QAPP Standard)			
Describes or reference the procedures for services are inspected and accepted. Services provided by vendors to include, but not limited to contractors, subcontractors, and sub-grantees may include: • document development and • performing EIO. (**B6:** The QAPP Standard)			
Identifies the individual(s) responsible for inspection and acceptance of services and supplies.			

(**B6:** The QAPP Standard)			
Specifies the elements of the Standard for which the vendor is responsible and how their adherence to the QAPP requirements will be verified. (**B6:** The QAPP Standard)			
Describes how acceptance of supplies will be documented either on the items themselves or in documented environmental information traceable to the items. (**B6:** The QAPP Standard)			
B7: Environmental Information Management			
Describes the environmental information management process for the project, tracing the path of the environmental information from its generation to its final use or storage. (**B7:** The QAPP Standard)			
Describes or references standard record-keeping procedures. (**B7:** The QAPP Standard)			
Describes how working documents and files will be generated, maintained, and stored (including file/folder naming conventions) (**B7:** The QAPP Standard)			
Identifies and describe environmental information/data handling and procedures to process, compile, and analyze the environmental information/data. (Includes generated data as well as existing data) (**B7:** The QAPP Standard)			
Describes the control mechanism for detecting and correcting errors and for preventing loss of data during data entry (to forms, spreadsheets, reports and/or databases), data reduction, data reporting, and data storage (including back-up frequency). (**B7:** The QAPP Standard)			
References the appendices that include the examples of any forms or checklists to be used (as applicable).			

(**B7:** The QAPP Standard)			
Documents the hardware, software (including collaboration tools), and performance requirements for managing data generation and incorporating existing data into the project. (**B7**: The QAPP Standard)			
Describes or references the procedures to demonstrate acceptability of the hardware/software configuration required for assuring that applicable information resource management requirements are satisfied. (**B7:** The QAPP Standard)			
Describes if data contains CBI or PII and addresses special agreements, special access certifications and storage requirements that apply. (Not an actual requirement-Best Practice)			
Describes data security measures for protecting scientific data including any extra security measures that are deemed necessary to protect intellectual property, any legal issues, and any level of protection for CUI. (Not an actual requirement-Best Practice)			
Group C: Assessment, Response Actions and Oversight **C1: Assessments and Response Actions** **C1.1 Assessments**			
Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates if known, the following are examples of assessment activities as defined by the QAPP Standard: • audits, • performance evaluations, • management reviews, • peer reviews, • inspections,			

• surveillances, • readiness reviews (competency assessment, pre-award assessment of proposal, technical assessment), • peer consultations, and/or • product reviews (data inspection, software testing, pre-dissemination reviews or reviews of contractor deliverables), (**C1:** The QAPP Standard)			
Identifies individual(s) responsible for conducting assessments. (**C1:** The QAPP Standard)			
Individuals identified as Assessors are free of conflicts of interest and are not involved in the EIOs being assessed. (**C1:** The QAPP Standard)			
Describes how assessment findings, non-conformance and corrective actions will be documented for assessments. (**C1:** The QAPP Standard)			
C1.2: Response Actions			
Describes how response actions associated with assessment findings, non-conformances, and corrective actions will be developed, documented and tracked to ensure completion. (**C1:** The QAPP Standard)			
Identifies the individual(s) responsible for response actions and how the response actions will be reported. (**C1:** The QAPP Standard)			
C2: Oversight and Reports to Management			
Describes 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. (**C2:** The QAPP Standard)			
Identifies individual(s) responsible for oversight activities.			

(**C2:** The QAPP Standard)			
Identifies all reports to management (Audit Report is an example of a report to management) including the following information: • description of content of the management reports, • who is responsible for transmitting the report; • how the report will be transmitted, and • who is the recipient for the report. Note: Distribution shall include the Project Operations Manager, the Project QAM of the organization conducting the work. Non-EPA organizations must include their EPA Project Officer/Contracting Officer Representative and/or EPA Operation Manager. It is the EPA Operation Manager's responsibility to determine if the report relates to QA and if they must notify the EPA QAM. (**C2:** The QAPP Standard)			
Group D: Environmental Information Review and Usability Determination **D1: Environmental Information Review**			
Describes or cites the procedures for the environmental information/data verification and information/data validation activities. (**D1:** The QAPP Standard)			
If applicable, describes or cite the data quality assessment activities that will occur after the EIO phase of the project is completed. (Data Quality Assessment is the scientific and statistical evaluation of data to determine if the data obtained from EIO are of the right type, quality, and quantity to support their intended use.) (**D1:** The QAPP Standard)			

Identifies who will conduct information/data verification and information/data validation activities, and how the activities will be documented and communicated. **(D1:** The QAPP Standard)			
Describes or references how performance criteria and/or acceptance criteria, and DQOs identified in A6 will be incorporated in the environmental information/data review process. **(D1:** The QAPP Standard)			
D2: Useability Determination			
Describes or references the process that will be used to determine whether the environmental information is useable. **(D2:** The QAPP Standard)			
Describes how the determination for useability will be documented and all individuals responsible for the documentation. **(D2:** The QAPP Standard)			
Describes how any known or anticipated limitations on the use of the environmental information will be communicated and to whom. **(D2:** The QAPP Standard)			