US EPA REGION 1 QUALITY PROGRAM

EPA REGION 1 QUALITY ASSURANCE PROJECT PLAN (QAPP) PROGRAM GUIDANCE

PREPARED BY: EPA REGION 1 QUALITY ASSURANCE BRANCH MAY 2024

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Document Revision Page

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R1/LSASD/QAB

Introduction

Background and Purpose:

All EPA and non-EPA organizations performing environmental information (EI) operations on behalf of EPA are required to participate in the EPA Agency-wide Quality Program. Each EPA Region, National Program Office, and Office of Research and Development plans, documents, and implements their processes and procedures for meeting the Agency's EI Quality Policy and quality directives (such as the Quality Assurance Project Plan Standard). To ensure that the Agency's environmental decisions are supported by information of known and documented quality, all work performed by or on behalf of EPA involving EI operations must be implemented in accordance with an EPA-approved Quality Assurance Project Plan (QAPP).

A QAPP is a planning document that describes in comprehensive detail the necessary quality assurance and quality control (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. QAPPs must be reviewed and approved by the EPA Region 1 Quality Assurance Manager or designee and EPA Region 1 Operations Manager (i.e., Project Officer, Project Manager, Contract Officer's Representative) prior to any environmental data/information collection, use, or evaluation except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

EPA Region 1 implements a QAPP Program in accordance with the Agency-wide Quality Directives. This document does not supersede Agency-wide quality program directives, but rather serves as guidance for EPA and non-EPA organizations conducting environmental information operations in Region 1 which require QAPPs to document and describe project activities. This Guidance document:

- Describes components of the EPA Region 1 QAPP Program, including roles and responsibilities, QAPP submission and approval process, and updates/revisions to QAPPs
- Provides an overview of the 23 QAPP Standard elements including specific considerations for projects implemented in EPA Region 1
- Includes references, examples, and other resources to assist with project planning and QAPP development

EPA QAPP Standard and EPA QA/R-5 Comparison

In July 2023, the Agency issued the Quality Program Directive CIO 2105-S-02 *Quality Assurance Project Plan Standard* (QAPP Standard) to define minimum requirements for QAPPs prepared by and for EPA. This Standard replaces the longstanding *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5). Much of the Standard's content and requirements for QAPPs remain

the same, or similar to, those defined in EPA QA/R-5. The categories below describe some of the notable differences between the two documents. For more information and the most up-to-date versions of the Agency-wide QA Directives (including the QAPP Standard), please visit www.epa.gov/quality.

Terminology

The QAPP Standard adopts new terminology consistent with the EPA *Environmental Information Quality Policy*. Most notable among these terms is "environmental information" and "environmental information operations", detailed in **Table 1**. Throughout this guidance, "environmental information" is used interchangeably with "environmental data", and "environmental information operations" with "data collection activities" or "environmental operations".

Another new term used throughout the QAPP Standard is "Operations Manager". This project role is described in detail in the QAPP Standard, but essentially the Operations Manager is the individual responsible for the project's environmental tasks. In many organizations, this individual is often referred to as the "Project Manager" or "Program Manager." For EPA Region 1 officials, this person may be considered the project manager, project officer, on-scene coordinator, or contract officer's representative.

| TABLE 1: TERMINOLOGY AND DEFINITIONS FROM EPA QAPP STANDARD | | |
|---|---------------------------|--|
| Terminology in QAPP Standard | Terminology in EPA QA/R-5 | |
| "Environmental information" | "Environmental Data" | |

Definition: 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)
- 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
- Design, construction, and operation or application of environmental technology

| "Environmental information operations" " collections" |
|---|
|---|

Definition: A collective term for work performed to collect, produce, evaluate, or use environmental information and the design, construction, operation, or application of environmental technology

QAPP Standard Elements

Like EPA QA/R-5, the QAPP Standard identifies elements that are required for a project and groups them into four categories. The QAPP Standard elements have been revised consistent with the terminology changes, and in some instances, parsed or consolidated from EPA QA/R-5 elements.

QAPP elements may be reordered and/or combined during document development provided that all applicable components of the QAPP element are addressed. In these instances, it's recommended to include a table or crosswalk showing how the document's sections link to the OAPP Standard elements.

See **Appendix A** for a crosswalk comparison of QAPP Groups and Elements from the QAPP Standard and QA/R-5, along with EPA Region 1's suggested grouping of QAPP Elements.

Roles and Responsibilities

The development, review, and approval of QAPPs is a cooperative process between the Lead Organization, QAPP preparing organization (if different from the Lead Organization), the EPA Regional Program Office, and the EPA Region 1 Quality Assurance Branch.

Lead Organization

The Lead Organization is responsible and accountable for all phases of the project. The Lead Organization may prepare the QAPP and implement the project directly or contract/award tasks for QAPP preparation, field sampling, analytical work, data validation, data usability assessment, and/or assessment and oversight.

The Lead Organization is responsible for ensuring that there is an EPA-approved QAPP in place prior to beginning environmental operations, and that all project personnel, including subcontractors/subgrantees, perform project work as prescribed in the QAPP. Prior to submitting the QAPP to EPA Region 1 for approval, the Lead Organization should review the QAPP internally and ensure that all project personnel, contractors, and subcontractors review applicable sections of the QAPP for technical accuracy.

Lead Organizations may include the following:

- EPA Region 1 Program Offices
- Federal agencies under interagency agreements, federal facility agreements, or memoranda of understanding (MOUs) with EPA Region 1
- States, Tribal Nations, and local governments under financial assistance agreements with EPA Region 1
- External organizations performing environmental operations under grants, cooperative agreements, or contract with EPA Region 1

EPA Region 1 Program Office

All environmental operations in the Region are performed by or in support of a Region 1 Program Office. In both cases, an EPA Region 1 Project Manager or equivalent ensures QAPPs are prepared according to regional QA policies and the extramural agreement (e.g., grant, contract, MOU) terms, as applicable.

QAPPs are often received concurrently by the EPA Region 1 Project Manager and the EPA Region 1 Quality Assurance Branch (QAB). The Project Manager verifies that the QAPP accurately reflects the project workplan or scope-of-work and addresses any program-specific requirements. The Project Manager may also provide technical comments or feedback. The Project Manager ensures that their comments and the QAB's comments have been addressed and the QAPP revised, if necessary, prior to the start of environmental operations. The Project Manager is the last to sign off on the QAPP after it has been finalized, and the Project Manager maintains the official record of the QAPP.

EPA Region 1 Quality Assurance Branch

The EPA Region 1 QAB is responsible for implementing the Region 1 Quality Program, which includes the Region's QAPP Program. The QAB is a team of quality assurance specialists who have delegated QAPP approval authority by the Regional Quality Assurance Manager (RQAM).

When QAPPs are received by the QAB, a QAPP reviewer is assigned. The QAPP Reviewer reviews the document against Agency QAPP requirements and prepares comments, if necessary, to address any missing or deficient QAPP elements. The QAPP Reviewer provides feedback and comments to the Region 1 Project Manager and Lead Organization and signs off on the QAPP once all comments have been addressed and QAPP finalized.

EPA Region 1 QAPP Submission, Review, and Approval Process

QAPPs should be submitted to EPA Region 1 at least 60 days prior to the planned start of environmental operations. This allows adequate time for review, response to comments and QAPP revision if needed, and QAPP approval. When a QAPP has been prepared and is ready for EPA Review, it is submitted to both the EPA R1 Project Manager and the QAB.

The QAB receives QAPPs via a centralized email inbox (R1QAPPS@epa.gov). The EPA Project Manager should be copied on all correspondence with R1QAPPS@epa.gov. The inbox is managed by the QAB Manager who assigns a QAPP Reviewer to each QAPP within 1-3 business days of receipt. QAPPs are reviewed within 30-days of receipt. QAPP Reviewer feedback and/or comments are provided to the Lead Organization, QAPP Preparer (if different from the Lead Organization), and the Region 1 Project Manager. The Region 1 Project Manager may add comments in addition to those provided by QAB. Once the response-to-comments and revised

QAPP are received, the QAPP Reviewer performs another review to ensure comments have been addressed and revisions incorporated. If the EPA QAPP Reviewer and Project Manager have no additional comments, the QAPP is finalized by the QAPP Preparer, and signed by all external parties, and submitted to the EPA QAPP Reviewer and Project Manager for signature. The EPA Project Manager signs last.

The QAPP submission, review, and approval process is illustrated in Figure 1:

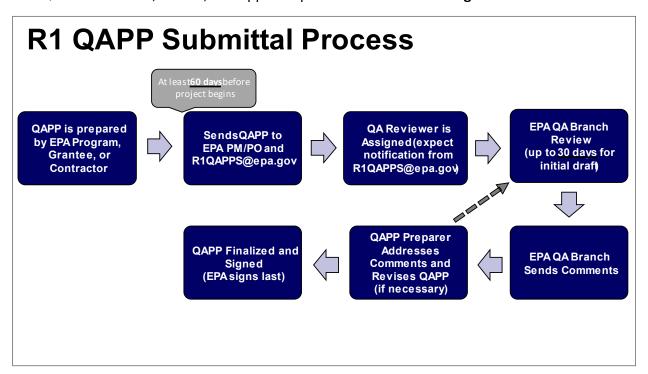


FIGURE 1: EPA REGION 1 QAPP SUBMITTAL FLOW CHART

Review of EPA-Approved QAPPs and QAPP Revision Process

A QAPP must remain current and accurate for the project it describes. However, it is not uncommon for project conditions, tasks, or objectives to change throughout the lifecycle of a project.

QAPP Modifications

When a QAPP needs to be modified to reflect changes to project objectives, data quality objectives, sampling design or methods, assessment, or data review procedures, the QAPP must be amended. This amendment should be reviewed and approved in the same manner as the original QAPP. The amendment should contain complete identifying information, as presented on the original QAPP title and approval pages, with updated signatures and dates. Amendments should be approved before changes are implemented.

Verbal or e-mail approval of modifications may be obtained to expedite project work. Descriptions of modifications and verbal approvals must be documented in email or memoranda which are retained in the project file. Subsequently, this verbally approved modification must be documented in an amendment to the QAPP and submitted to EPA Region 1 on a mutually agreed date for formal signature approval.

When minor changes are needed (e.g., updating organization contact information), formal approval is not required. Instead, the EPA Region 1 Project Manager and QAPP Reviewer should be notified by email or memorandum of all changes and the corresponding page(s)/section(s) of the QAPP. **Note**: The EPA Project Manager and QAPP Reviewer must agree that the modifications constitute a minor change.

Annual Review and Five-year Period of Applicability

The QAPP Standard requires QAPPs for multi-year projects to be reviewed annually to ensure they remain current and accurate. Documentation of the annual review and any revisions should be documented by the Lead Organization and made available to EPA upon request.

For multi-year projects greater than five-years in length, or for projects and programs of indefinite length, QAPPs are valid for a period of five-years. If the project or program remains active beyond five-years, QAPPs must be reviewed, revised as necessary, and resubmitted for EPA review and approval.

Program and Generic QAPPs

The most common type of QAPP received by the EPA Region 1 QAB is the project-specific QAPP. Project-specific QAPPs provide the organizational information, objectives, tasks, and QA/QC processes specific to one project.

For some environmental programs, a Generic or Program QAPP may be better suited. Both Generic and Program QAPPs provide an overarching plan that describes organizational information and quality objectives, along with a comprehensive set of sampling, analysis, QA/QC, data review, and assessment procedures specific to one program or long-term project. In Region 1, Generic QAPPs are supported with site-specific Sampling and Analysis Plans (SAPs) or, in the case of Brownfields, site-specific QAPP addenda. Program QAPPs, such as those prepared for the Pesticide Program or State Air Toxics Program, function as an umbrella document that supports the implementation of the program. The Region 1 Quality Assurance Manager may authorize the lead organization of a Generic or Program QAPP to approve site-specific workplans or addenda contingent upon a review and approval process that is fully documented in the Program QAPP.

EPA Region 1 QAPP Template and Additional Resources

EPA Region 1 QAB has developed quality program documents, tools, and resources available at https://www.epa.gov/quality/region-1-quality-systems-documents to assist EPA and non-EPA organizations meet EPA quality program requirements.

Among these resources are a fillable QAPP template (see also **Appendix B**), QAPP Completion Checklist (see also **Appendix C**), and additional program or project-specific QAPP guidance documents, such as the EPA New England Brownfields Program QAPP Guidance and Existing (Secondary) Data QAPP Guidance. Please note, the QAB is working to update these additional guidance and resource documents to refer to the most current quality program directives and information. For additional information or assistance, please contact the RQAM.

QAPP Standard Elements

The QAPP is divided into four basic element groups: A) Project Management & Quality Objectives; B) Implementing EI Operations; C) Assessments and Response Actions; and D) Data Review and Usability Determination. Each group consists of standard elements that pertain to various aspects of the project. If an element is not applicable, the QAPP should indicate why it is not relevant.

A QAPP that addresses the basic elements will define and describe the following:

- Who will use the data;
- What the project's goals/objectives/questions or issues are;
- What decision(s) will be made from the information obtained;
- How, when, and where project information will be acquired or generated;
- What problems may arise and what actions can be taken to mitigate their impact on the project;
- The type, quantity, and quality of data needed;
- How "good" those data have to be to support the decision to be made; and
- How the data will be analyzed, assessed, and reported.

The sections below provide the QAPP Element's purpose and offer guidance for addressing each of the 23 QAPP Elements, including any EPA Region 1 additional considerations.

A: Project Management and Information/Data Quality Objectives

A1: Title Page

Purpose: The QAPP Title Page presents the administrative information of the project.

Guidance for completing Section A1:

Include the name of the project, the date of preparation, version control information (e.g., revision number), name of organization responsible for QAPP preparation, the extramural agreement identifier (e.g., EPA Grant Number or Contract and Task Order Number), if applicable, and period of applicability of the QAPP.

The period of applicability is specific to the project. Generally, it begins with the proposed start date of environmental information operations and ends with the reporting and documentation of environmental information operations. For most QAPPs, these dates are approximated.

For Program and Generic QAPPs or QAPPs of indefinite length, the period of applicability begins with date of EPA approval and end five-years after that date of approval.

Because the date of EPA approval is not known upon submission of the initial draft QAPP, the period of applicability start date can be left blank until the QAPP is finalized for EPA approval.

EPA Region 1 Considerations: Include the EPA Region 1 QA Tracking Number (QA#), which you will receive after submitting your QAPP to the Region 1 QA Branch.

A2: Approval Page

Purpose: The approval page identifies the key project officials and documents their approval of the QAPP. The last recorded date of signature marks the earliest date when the project's operations can begin.

Guidance for completing Section A2:

Who needs to be included on the approval page?

EPA Region 1

- Operations Manager (i.e., Project Officer, Project Manager, Contracting Officer's Representative)
- QA Manager or designee (i.e., QA Branch staff)

External Organizations

Operations Manager for the organization performing environmental operations

 <u>Project QA Manager</u> (or individual with overall QA responsibilities for the project, such as oversight, assessing compliance or effectiveness of the QAPP, and authority to report independently to senior management, if necessary).

EPA Region 1 Considerations: Additional project staff or stakeholders, such as State or Tribal partnering organizations, Field or Laboratory Task Leaders, or subcontractors and subgrantees, may be added to the approval page to document their approval and/or commitment to follow the procedures of the QAPP.

A3: Table of Contents, Document Format and Document Control

Purpose: This section ensures all QAPP readers are reading or reviewing the most current version of the document with all applicable appendices, figures, and references.

Guidance for completing Section A3:

In the table of contents, list QAPP elements, tables, figures, and appendices for the project.

Add document control information on each page. Include the QAPP title (or abbreviated title), version number, version date, and page number relative to total pages.

A4: Project Purpose, Problem Definition and Background

Purpose: The Project Purpose, Problem Definition, and Background provides an overview of the problem to be solved or task(s) to be performed, along with any pertinent background information for the project.

Guidance for completing Section A4:

Describe the goals and objectives that form the foundation for your project. Summarize background information from a historic, scientific, and/or regulatory perspective to establish the current understanding of the project, site, or location (e.g., Conceptual Site Model). Then, identify the intended use and audience for the information to be collected or evaluated.

EPA Region 1 Considerations: When applicable, identify any additional QA planning documents and address their association to the current QAPP. In EPA Region 1, this will primarily apply to programs with EPA-approved Program or Generic QAPPs (e.g., Region 1 Brownfields Program).

A5: Project Task Description

Purpose: The Project Task Description provides an overview of the work to be completed in subsequent sections of the QAPP (Groups B, C, and D), along with an estimated timeline for these tasks. It summarizes the approach to address the project's objectives and connects what is needed to how it will be obtained.

Guidance for completing Section A5:

Provide a summary of work to be performed and products to be produced. It's recommended to separate out work by tasks and include this information in a table, such as the example in **Table 2**.

EPA Region 1 Considerations: When drafting the project task schedule, incorporate time for QAPP preparation, review, and approval prior to environmental operations.

| TABLE 2. EXAMPLE PROJECT SCHEDULE | | | | | | | |
|---|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Project Task Schedule | Jul 2023 | Aug 2023 | Sep 2023 | Oct 2023 | Nov 2023 | Dec 2023 | Jan 2024 |
| QAPP Preparation and Approval | | | | | | | |
| Field mobilization (Soil borings and MW installation; soil and GW sampling) | | | | | | | |
| Indoor Air Sampling | | | | | | | |
| Laboratory Analysis | | | | | | | |
| Data Validation and Review | | | | | | | |
| Final Report | | | | | | | |

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

Purpose: The purpose of systematic planning is to ensure data of known and documented quality that are suitable for their intended use are used to support project outcomes and decisions. Element A6 ensures that the quality needs of the project are clearly defined and documented.

Systematic Planning and the Data Quality Objectives Process

Systematic planning is a process based on the scientific method and includes concepts such as objectivity of approach and acceptability of results. ¹ EPA's recommended application of systematic planning is the Data Quality Objectives (DQO) Process, particularly when information

¹ EPA *Guidance on Systematic Planning Using the Data Quality Objectives Process* (EPA QA/G-4), https://www.epa.gov/quality/guidance-systematic-planning-using-data-quality-objectives-process-epa-qag-4

is used to make some type of decision (e.g., compliance with a standard) or estimation (e.g., determining mean concentration of a contaminant). The DQO Process is an iterative, seven-step process used to establish performance or acceptance criteria. **Appendix D** illustrates these steps.

Systematic planning begins before QAPP development when project team-members and stakeholders start to plan their project. The QAPP is *the documentation* of that planning process. Element A6 plays an important role by defining quality specifications at two levels: 1) the level of decision or study question, and 2) the level of the measurement(s) used to support the decision or study question.

Guidance for completing Section A6:

Describe the project's data quality needs at the level of decision or study question. For example, if an overall project objective is to assess whether a potentially contaminated site is suitable for residential use, you need to ensure the type and quality of data can support this decision.

Next, describe the project's data quality needs at the measurement level by defining data quality indicators (DQIs) and the performance or acceptance criteria that they will be measured against. DQIs are qualitative or quantitative descriptors used to assess data quality.

PARCCS Parameters

Precision, Accuracy, Representativeness, Comparability, Completeness, and Sensitivity are principal DQIs, particularly for environmental operations generating primary data. Together, these are referred to as "PARCCS parameters." **Table 3** provides definitions of the parameters, along with example activities and criteria to assess data quality.

| TABLE 3: DATA QUALIT | TY INDICATORS (PARCCS PARAM | ETERS) DEFINITIONS AND | EXAMPLE ACTIVITIES AND CRITERIA | |
|---------------------------|---|---|--|--|
| Data Quality Indicator | Definition | QC Activities* | DQI Criteria* | |
| Precision | measure of agreement among repeated measurements of the same property under identical, or substantially similar, conditions. | Field and laboratory replicates | 30 percent RPD (relative percent difference) | |
| Accuracy (Bias) | measure of the overall agreement of a measurement to a known value. | Calibration standards, blanks | No blanks contaminated and all calibrations within acceptable limits | |
| Representativeness | measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variation at a sampling point, | Evaluate whether the data accurately represents the system, population, | Data collected represent the system characterized or exposure experienced and are not biased | |

| | a process condition, or an environmental condition. | place, time and/or situation of interest | |
|---------------|--|---|---|
| Comparability | measure of confidence that two or more data sets can contribute to a common analysis. | Compare to existing data or datasets. | Data collected are sufficiently similar in methodology to permit a meaningful analysis |
| Completeness | measure of the amount of valid data obtained from a measurement system, expressed as a percentage of the number of valid measurements that should have been collected. | Compare to intended sampling goals to meet the project purpose. | Could be stated as the total number of samples or a percentage (e.g., 90%) of samples collected, or an identification of the critical samples needed for the project purpose |
| Sensitivity | capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest. | Compare to reporting or detection limits from existing data or for decision-making. | State the sensitivity needed for the instruments, methods or processes used for the project to obtain meaningful data. This depends on analytical method but generally the reporting or detection limits should be 3 to 5 times lower than an action level. |

^{*}QC Activities and Criteria are provided for illustrative purposes. QC activities and criteria should be determined on a project-specific basis.

Existing (Secondary) Data Projects

For projects using only existing (secondary) data, the PARCCS parameters may only partially apply. Another way to assess information quality is with general assessment factors (GAFs). Five GAFs, summarized in **Table 4**, were developed by the EPA Science Policy Council to evaluate scientific and technical information.² When identifying potential existing data and information to be used in a project, provide project-specific criteria that will be used to rank and select the information or information sources acceptable to meet the project's needs.

| TABLE 4: GENERAL ASSESSMENT FACTORS, GUIDANCE ON SYSTEMATIC PLANNING USING THE DATA QUALITY | | | | |
|---|--|--|--|--|
| OBJECTIVES PROCESS (E | PA QA/G-4), US EPA (FEBRUARY 2006) | | | |
| General | Description | | | |
| Assessment Factor | Description | | | |
| Soundness | The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application | | | |
| Applicability and Utility | The extent to which the information is relevant for the Agency's intended use | | | |

² EPA QA/G-4

.

| Clarity and Completeness | The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented |
|--------------------------------|--|
| Uncertainty and Variability | The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized |
| Evaluation and | The extent of independent verification, validation, and peer review of the information or |
| Review | of the procedures, measures, methods, or models |

A7: Distribution List

Purpose: The distribution list identifies all individuals who should receive a copy of the QAPP and any subsequent revisions. It also designates who is responsible for maintaining and distributing the QAPP.

Guidance for completing Section A7:

List all individuals (and their organizations and contact information) who will receive a copy of the QAPP and any subsequent revisions. At a minimum, include the officials identified on the approval page, but it's recommended to include project personnel involved in environmental operations (e.g., Field Team Leader, Laboratory Manager).

Identify who is responsible for maintaining and distributing the official version of the QAPP and any subsequent revisions.

A8: Project Organization

Purpose: The Project Organization quickly identifies those involved with the project and describes their roles and responsibilities.

Guidance for completing Section A8:

List individuals and their organizations involved in major aspects of the project and describe their roles and responsibilities.

Identify the individuals who will fulfill the roles of Senior Manager, Operations Manager, and Project QA Manager.

Note: the individuals identified as Senior Manager, Operations Manager, and Project QA Manager may not formally hold these titles, but will fulfill the responsibilities of these roles.

Senior Manager, Operations Manager, Project QA Manager

The "Senior Manager" is the individual with overall responsibility for the project. For example, this individual may be the grant program manager or principal-in-charge for a contract.

The "Operations Manager" is the individual responsible for conducting or managing the environmental operations of a project.

The "Project QA Manager" is the individual with oversight authority of the Project and responsible for assessing compliance or effectiveness of the QAPP. The Project QA Manager may or may not be the organization's overall QA Manager.

A9: Project Quality Assurance Manager Independence

Purpose: Element A9 clearly documents the independence of the Project QA Manager from the Operations Manager and unit generating data.

Guidance for completing Section A9:

Identify the individual that will serve as the Project QA Manager. This individual is independent of project operations, has oversight authority of the project, and assesses project compliance with the QAPP.

QA Manager Independence in Small Organizations

For small organizations, the QA role may be shared by more than one individual. The key is to separate the QA activities from direct environmental information functions for that person. For example, a field manager may serve in a QAM capacity for laboratory tasks, and a laboratory manager may serve in a QAM capacity for field tasks. An individual should still be identified as overall Project QAM and sign the QAPP in that role.

A10: Project Organization Chart and Communications

Purpose: The Project Organization and Communications chart allows readers to quickly identify the organizations and roles of key project members and documents lines of communication and authority.

Guidance for completing Section A10:

Include an organization chart that clearly demonstrates lines of authority and communication among key project members (i.e., those identified in Element A8). Indicate that the Project QAM has an independent line of communication to the Senior Manager. This is often illustrated by a "dashed line" connecting the Project QAM to the Senior Manager.

An example project organization chart is included as **Figure 2**.

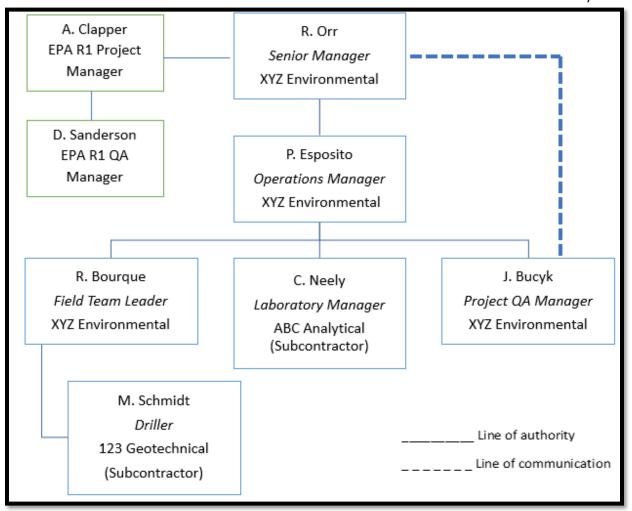


FIGURE 2: EXAMPLE PROJECT ORGANIZATION CHART

A11: Personnel Training/Certification

Purpose: This element identifies any special or non-routine training or certifications that are necessary for project personnel to successfully complete the project, and how such training/certifications will be ensured and documented.

Guidance for completing Section A11:

Identify any specialized education, experience, training, or certification requirements for project personnel (including subcontractors/subgrantees) to successfully complete the project or task(s). Discuss how these requirements will be provided and documented.

EPA Region 1 Considerations: <u>EPA only</u>: When EPA Region 1 personnel are conducting environmental operations, provide reference to the <u>EPA Region 1 Field Personnel Training SOP</u> to comply with the Agency's QA Field Activities Procedure (QAFAP).

A12: Documents and Records

Purpose: Element A12 describes the management of project documents and records, including the QAPP. Management of project data is covered later in Element B7 (Environmental Information Management).

Guidance for completing Section A12:

Describe how the finalized QAPP will be maintained and distributed to project staff and stakeholders. For updates or revisions, describe how documents will be updated and the changes communicated.

Identify any other project documents or records that will be generated and maintained throughout the project lifecycle (e.g., assessment and corrective action reports, interim and final reports, presentation materials, and environmental software, such as models and applications).

EPA Region 1 Considerations: <u>EPA only</u>: When EPA Region 1 personnel are conducting environmental operations, in addition to the above guidance, provide reference to the <u>EPA Region 1 Document Control and Field Documentation and Records Management SOPs</u> to comply with the Agency's QAFAP.

B: Implementing Environmental Information Operations B1: Identification of Project Environmental Information Operations

Purpose: Element B1 describes the design of the project's planned environmental operations. It describes in detail the specific tasks to be completed and the rationale associated with these tasks (i.e., "how" and "why" specific project tasks are conducted).

Guidance for completing Section B1:

Describe in detail the specific project tasks to be performed and describe how these tasks will satisfy the overall project objectives and data quality objectives. Ensure that the project scope is clear and identify any data gaps that will not be investigated in the study.

Primary Data Collection

When primary data collection (i.e., direct measurement and/or sampling of environmental media) is planned, identify the following components:

Environmental media to be sampled;

- Number and type of samples (specify minimum number or a range of min./max. number of samples);
- Description of sampling locations (include figures as appropriate); and
- Parameters to be measured or analyzed, including field measurements and laboratory analyses.

Existing Data Projects

For project tasks involving existing data and information, describe how information sources are identified and selected, how the information will be collected or compiled from these sources or databases, how information will be used or evaluated for project decisions or outcomes, and any known limitations (e.g., age of existing dataset) to the existing data or information source. If there is a preferred hierarchy of sources, this should be described in the QAPP. See **Table 5** for example of existing data types, sources, and limitations.

| | | | ASED ON <i>OPTIMIZED UFP-QAPP WORKSHEETS,</i> TERGOVERNMENTAL DATA QUALITY TASK FORCE |
|---|--|--|---|
| Data type | Source | Data uses relative to current project | Factors affecting the reliability of data and limitations on data use |
| Meteorological | National Weather Service | Estimations of seasonal fluctuations in storm water runoff. | Published data are available for past 20 years. No known limitations. |
| Topographic | USGS | Surface water drainage pathways. | Topography in area X has been altered by grading activities between 2008 and 2009. |
| Background concentrations of metals in soil | Phase II Site Assessment Report, 2006 | Comparison to metals concentrations in surface and subsurface soils in area X. | Substantial excavation has taken place since 1996 in areas from which background samples were collected. Depth of subsurface samples is unknown. Supplemental background samples will be collected. |
| Past site uses | Plant operating records and personnel interviews | Potential locations of burn pits. | Records for operations prior to 1966 lost in fire. Information prior to 1966 based solely on interviews. |

B2: Methods for Environmental Information Acquisition

Purpose: Element B2 documents how project data and information will be collected, analyzed, and/or evaluated consistently throughout the project.

Guidance for completing Section B2:

Describe or reference the procedures used to collect, analyze, and/or evaluate project data and information. If SOPs are available, provide an SOP reference table with complete titles and dates for all applicable components of the project (e.g., field sampling, laboratory preparation and analysis methods). Please ensure all SOPs are readily available by attaching them to the QAPP or verifying that referenced hyperlinks are accessible.

If SOPs allow multiple options to be followed, specify the project or site-specific procedures that will be followed.

Additional Considerations by Project Type:

Field Activities

- Describe or reference procedures for all sample collection methods. Include, as necessary, procedures for:
 - Operating tools, instruments, and equipment
 - Sample handling and chain-of-custody
 - o Installation of test pits, soil borings, monitoring wells, etc.
 - Sample collection
 - Decontamination

Laboratory Analysis

- Include, as applicable, all laboratory SOPs for preparation, extraction, and analysis of environmental samples
- Include SOPs for all parameters/compounds of interest
- Identify methods version/revision date and regulatory citation when applicable

B3: Integrity of Environmental Information

Purpose: Element B3 describes how the integrity of environmental samples and environmental information will be retained throughout the project lifecycle.

Guidance for completing Section B3:

Describe or reference procedures to ensure the physical and chemical integrity of environmental samples from collection through final disposal. Include container, preservation, and holding time requirements as appropriate. See **Table 6** for example of a Sample and Preservation Requirements Table.

Identify or reference chain-of-custody procedures, forms, and sample labels.

For existing data and information, describe or reference procedures for safeguarding the integrity of environmental data and information. Include, for example, measures to ensure appropriate access to information and databases and to prevent loss or manipulation of data.

| TABLE 6: EXAMPLE SAMPLING AND PRESERVATION REQUIREMENTS TABLE, OPTIMIZED UFP-QAPP WORKSHEETS, |
|--|
| UNIFORM FEDERAL POLICY-QUALITY ASSURANCE PROJECT PLAN, INTERGOVERNMENTAL DATA QUALITY TASK FORCE |
| (MARCH 2012). |

| Analyte/ Analyte Group | Matrix | Method/ SOP | Containers (number, size & type per sample) | Preservation | Preparation Holding Time | Analytical Holding Time | Data Package Turnaround |
|----------------------------------|------------------|----------------|---|--------------|--------------------------------|-------------------------------|-------------------------------|
| Volatile Organic Compounds | Ground- water | 5035/8260C | 2, 40-ml VOA vials w/ PTFE-faced silicone | 4 ± 2°C | 14 days | 14 days | 28 days |
| Chlorinated Herbicides | Ground- water | 8151A | 1 L amber glass | 4 ± 2°C | 7 days | 40 days | 28 days |

B4: Quality Control

Purpose: Element B4 identifies and describes the quality control activities designed to assess the potential variability inherent to any sample collection, analysis, or measurement.

Guidance for completing Section B4:

Identify the type and frequency of QC samples and activities planned for all components of the project (e.g., field sample collection, laboratory analysis, modeling, etc.). Results of QC activities are often compared against the performance and acceptance criteria specified in Element A6. Describe any corrective actions or validation that will occur when QC results exceed these performance/acceptance criteria.

Tables 7-9 illustrate several ways that QC information may be presented in a QAPP. **Table 7** identifies several common QC activities for field sampling and laboratory analysis. **Table 8** provides a Field QC Summary to quickly identify the number and type of QC samples. And **Table 9** lists the QC activity and its associated DQI and performance criteria.

| TABLE 7: QUALITY CONTROL CHECKS, ADAPTED FROM GUIDANCE FOR QUALITY ASSURANCE PROJECT PLANS (EPA | | | | |
|---|--|--|--|--|
| <i>QA/G-5)</i> , US EPA (DECEMBER 2002). | | | | |
| QC Check Information Provided | | | | |
| Blanks | | | | |
| Field blank Transport, storage, and field handling bias | | | | |

| Reagent blank | Contaminated reagent |
|--|--|
| Rinsate or equipment blank | Contaminated equipment |
| Method blank | Response of an entire laboratory analytical system |
| Spikes | |
| Matrix spike | Analytical (preparation and analysis) bias |
| Matrix spike duplicate | Analytical bias and precision |
| Surrogate spike | Analytical bias |
| Calibration Check Samples | |
| Zero check | Calibration drift and memory effect |
| Span check | Calibration drift and memory effect |
| Replicates and Splits | |
| Field collocated samples | Sampling and measurement precision |
| Field replicates | Precision of all steps after acquisition |
| Field splits | Shipping and interlaboratory precision |
| Laboratory splits | Interlaboratory precision |
| Laboratory replicates | Analytical precision |

| TABLE 8: EXAM | TABLE 8: EXAMPLE FIELD QC SUMMARY TABLE, ADAPTED FROM OPTIMIZED UFP-QAPP WORKSHEETS, UNIFORM FEDERAL | | | | | | | | |
|---------------|--|--------------------|------------|----------|-------------|----------|--------------|--------|----------|
| POLICY-QUALIT | Y Assurance Projec | <i>T PLAN,</i> INT | ERGOVERNME | NTAL DAT | A QUALITY T | ASK FORC | E (MARCH 201 | L2). | |
| Matrix | Analyte/Analytical | Field | Field | Matrix | Matrix | Field | Equipment | Trip | Total # |
| | Group | Samples | Duplicates | Spikes | Spike | Blanks | Blanks | Blanks | analyses |
| | | | | | Duplicates | | | | |
| Soil | VOCs (low conc.) | 40 | 2 | 2 | 2 | 0 | 0 | 1 | 47 |
| Soil | RCRA Metals | 60 | 3 | 2 | 2 | 0 | 1 | 0 | 68 |
| Groundwater | VOCs (low conc.) | 20 | 1 | 1 | 1 | 0 | 0 | 1 | 24 |

| TABLE 9: EXAMPLE QC ACTIVITIES AND DATA QUALITY INDICATORS TABLE, ADAPTED FROM OPTIMIZED UFP-QAPP WORKSHEETS, UNIFORM FEDERAL POLICY-QUALITY ASSURANCE PROJECT PLAN, INTERGOVERNMENTAL DATA | | | | | | | |
|---|---|--|--|--|--|--|--|
| QUALITY TASK FORCE (MARCH 2012). Data Quality Indicator (DQI) QC Activity Measurement Performance Criteria | | | | | | | |
| Overall Precision | Field Duplicates | RPD ≤ 30% when VOCs are detected in both samples ≥ sample-specific LOQ | | | | | |
| Analytical Precision (laboratory) | Laboratory Control Sample Duplicates | RPD ≤ 25% | | | | | |
| Analytical Accuracy/Bias (laboratory) | Laboratory Control Samples | Analyte-specific criteria (Attach list) | | | | | |
| Analytical Accuracy/Bias (matrix interference) | Matrix Spike Duplicates | Analyte-specific criteria (Attach list) | | | | | |
| Overall accuracy/bias (contamination) | Equipment Blanks | No target analyte concentrations ≥ 1/2 LOQ | | | | | |

| Sensitivity | LOQ verification sample (spiked at LOQ) | Recovery within ±25% of LOQ |
|--------------|---|---|
| Completeness | Compare valid samples per total number of samples | 90% valid samples per total samples collected |

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

Purpose: This element describes how project personnel will know that the equipment will work properly when needed, and how it will be ensured that instrumentation and equipment operate at a known performance quality.

Guidance for completing Section B5:

Identify instruments and equipment used to complete project tasks for all components of the project (e.g., field screening, laboratory analysis, etc.) Describe or reference procedures for calibrating, testing, inspecting, and maintaining project equipment and instrumentation. Ensure calibration documentation is traceable to the particular instrument.

Table 10 illustrates how this information may be presented for field instrumentation.

| Table 10: Example Field Instrument Calibration Table, Adapted from <i>Optimized UFP-QAPP Worksheets, Uniform Federal Policy-Quality Assurance Project Plan,</i> Intergovernmental Data Quality Task Force (March 2012). | | | | | | |
|---|---------------------------|---------------------|--|--|---|---|
| Field Instrument | Activity | SOP Reference | Title or position of responsible person | Frequency | Acceptance Criteria | Corrective Action |
| pH meter | Calibration | Tech 001 | Field Crew Chief | 1/day (prior to samples) | <10% Difference using NIST Standard Solutions of pH 4, 7, 10 | Re-calibrate or replace probe |
| pH meter | Maintenance (cleaning) | Operators Manual | Equipment Coordinator | 1/day (end of day) | Instrument is free of debris and contamination; operates normally | Consult with vendor or replace instrument |
| pH meter | Testing | Tech 001 | Field Crew Chief | Calibration check performed 1x per 20 | <10% Difference using NIST Standard Solutions of pH 4, 7, 10 | Re-calibrate or replace probe |

| | | | | samples and end of | | |
|----------|------------|----------|---------------------|---------------------------------------|---------------------------------|--|
| | | | | day | | |
| pH meter | Inspection | Tech 001 | Field Crew Chief | 2/day (start and end of day) | Instrument operates as designed | Consult vendor or replace instrument |

B6: Inspection/Acceptance of Supplies and Services

Purpose: This element describes how the quality of supplies and services is addressed and documented to meet the quality needs of the project.

Guidance for completing Section B6:

Identify any extramural supplies and services, such as those provided by vendors, subcontractors, or subgrantees, and identify who in the project team is responsible for inspection and acceptance.

B7: Environmental Information Management

Purpose: Element B7 describes how the data and information used, generated, or evaluated during the project will be managed. It describes the management process from generation to final use of the data, including any specific handling or storage requirements.

Guidance for completing Section B7:

Describe or reference the processes for handling, processing, compiling, and analyzing environmental data. Identify any record-keeping and storage requirements for project data, including hardware or software requirements for data management and storage. Describe control mechanisms for detecting and preventing errors and unintended loss or manipulation of data.

C: Assessments and Response Actions and Oversight

C1: Assessment, Response Actions

Purpose: Element C1 describes how a project's activities will be assessed during the project to ensure that the QAPP is being implemented as approved.

Guidance for completing Section C1:

Identify the type, frequency, and anticipated schedule of assessments planned during the project lifecycle. Types of assessments include, but are not limited to,

- Field or laboratory audits
- Inspections or surveillance
- Performance evaluations
- Product Reviews

Identify who is responsible for conducting assessments and ensure that individuals designated as assessors are free from conflicts of interest. Describe how assessment findings are documented and communicated.

Identify who is responsible for responding to corrective actions. Describe how corrective actions are documented and tracked to ensure completion.

C2: Oversight and Reports to Management

Purpose: Element C2 describes oversight procedures and documents how project management and other stakeholders are kept informed of oversight and assessment activities.

Guidance for completing Section C2:

Describe oversight activities to record project status and any QA/QC issues that arise during project implementation. Identify the type, frequency, and recipients of project reports pertaining to assessments and oversight, and who is responsible for preparing and communicating these reports.

D: Environmental Information Review and Usability Determination

D1: Environmental Information Review

Purpose: Element D1 describes the review procedures for determining whether project data and information meet the project's stated data quality objectives and intended use(s).

Guidance for completing Section D1:

Describe or reference procedures for data review (e.g., verification and validation) and data quality assessment, and who is responsible for conducting and communicating these tasks. The data quality assessment will incorporate the data quality objectives and performance/acceptance criteria identified in Element A6.

EPA Region 1 Considerations: Consult the <u>EPA New England Environmental Data Review</u>

<u>Program Guidance</u> and <u>EPA New England Data Review Supplement</u> for regional and programspecific guidance for environmental data review.

D2: Useability Determination

Purpose: Section D2 describes how you will determine if the project data and information is of the right type, quality, and quantity to support the intended use and are suitable for the decisions that will be made. This section involves retrospective evaluation of the planning process using the outputs of data verification, validation, and data quality assessment.

Guidance for completing Section D2:

Identify the individuals responsible for conducting and documenting data usability and describe or reference the procedures for performing data usability assessment. Describe how any known or anticipated limitations on the use of environmental data will be documented and communicated.

References

Intergovernmental Data Quality Task Force, Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), (March 2005)

Intergovernmental Data Quality Task Force, Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), Optimized UFP-QAPP Worksheets (March 2012)

- U.S. EPA Environmental Information Quality Policy (EPA CIO 2105.4, March 2024)
- U.S. EPA Environmental Information Quality Procedure (EPA CIO 2105-p-01.4, March 2024)
- U.S. EPA Guidance for Quality Assurance Project Plans (EPA QA/G-5, December 2002)
- U.S. EPA Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4, February 2006)
- U.S. EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5, March 2001); *superseded in July 2023*
- U.S. EPA Quality Assurance Project Plan Standard (EPA CIO 2105-S-02.1, April 2024)

Appendix A: Crosswalk of QAPP Groups and Elements, QAPP Standard vs EPA QA/R-5, and Region 1 Suggested Grouping of Elements

| EPA QA/R-5 | QAPP Standard (CIO 2105-S-02.1) | *Elements may be reordered and/or combined if all applicable requirements are met |
|--|--|---|
| Group A Project Management Elements | Group A Project Management and Information/Data Quality Objectives | Group A Project Management and Data Quality Objectives |
| A1 Title and Approval Sheet | A1 Title Page | Project Identification and Approval |
| A1 Title and Approval Sheet | A2 Approval Page | A1 Title Page and A2 Approval Page |
| A2 Table of Contents | A3 Table of Contents, Document Format, and | Document Information and Control |
| | Document Control | A3 Table of Contents, Document Format, and Document Control |
| A5 Problem Definition and | A4 Project Purpose, Problem Definition and | Project Organization and Personnel |
| Background | Background | A7 Distribution List |
| A6 Project/Task Description | A5 Project Task Description | A8 Project Organization, A9 Project QAM Independence, A10 |
| A7 Quality Objectives and Criteria | A6 Information/Data Quality Objectives and | Project Organizational Chart and Communications |
| | Performance/Acceptance Criteria | A11 Personnel Training/Certifications |
| A3 Distribution List | A7 Distribution List | Problem Definition, Task Description, and Data Quality Objectives |
| A4 Project/Task Organization | A8 Project Organization | A4 Project Purpose, Problem Definition, and Background |
| A4 Project/Task Organization | A9 Project QAM Independence | A5 Project Task Description |
| A4 Project/Task Organization | A10 Project Organizational Chart and | A6 Information/Data Quality Objectives and |
| | Communications | Performance/Acceptance Criteria |
| A8 Special Training/Certifications | A11 Personnel Training/Certifications | Documentation and Records Management |
| A9 Documents and Records | A12 Documents and Records | A12 Documents and Records |
| Group B Data Generation and | Group B Implementing Environmental | Group B Environmental Information Operations |
| Acquisition Elements | Information Operations | |
| B1 Sampling Process Design | B1 Identification of Project Environmental | Project/Sampling Design and Rationale |
| (Experimental Design) | Information Operations | B1 Identification of Project EI Operations and Sampling Process |
| B2 Sampling Methods | B2 Methods for Environmental Information | Design (from QA/R-5) |
| B4 Analytical Methods | Acquisition | B2 Methods for Environmental Information Acquisition |
| B9 Non-Direct Measurements | | |

| B3 Sample Handling and Custody | B3 Integrity of Environmental Information | o Field Methods |
|---|---|--|
| B5 Quality Control | B4 Quality Control | Analytical Methods |
| B6 Instrument/Equipment Testing, Inspection and Maintenance B7 Instrument/Equipment Calibration and Frequency B8 Inspection/Acceptance of | B5 Instruments/Equipment Calibration, Testing Inspection, and Maintenance B6 Inspection/Acceptance of Supplies and | Existing Data, Modeling, or other methods as applicable Quality Control Activities B3 Integrity of Environmental Information B4 Quality Control B5 Instruments/Equipment Calibration, Testing, Inspection, and |
| Supplies and Consumables | Services | Maintenance |
| B10 Data Management | B7 Environmental Information Management | B6 Inspection/Acceptance of Supplies and Services Data Management B7 Environmental Information Management |
| Group C Assessment and Oversight | Group C Assessment, Response Actions and Oversight | Group C Assessment, Response Actions, and Oversight |
| C1 Assessments and Response Actions | C1 Assessments and Response Actions | Assessment, Oversight, and Response Actions • C1 Assessments and Response Actions |
| C2 Reports to Management | C2 Oversight and Reports to Management | C2 Oversight Reports to Management C2 Reports to Management |
| Group D Data Validation and Useability | Group D Environmental Information Review and Usability Determination | Group D Data Review and Usability |
| D1 Data Review, Verification, and Validation D2 Verification and Validation Methods | D1 Environmental Information Review | Data Review D1 Environmental Information Review Project Evaluation D2 Useability Determination |
| D3 Reconciliation with User Requirements | D2 Useability Determination | |

Appendix B: EPA Region 1 QAPP Template Instructions

For Fillable QAPP Template, visit: https://www.epa.gov/quality/region-1-quality-systems-documents

Instructions Updated: January 2024

Region 1 Optional QAPP Template Instructions

Introduction

Congratulations, your project is receiving funding from EPA! The Word document accompanying these instructions (Region 1 Optional QAPP Template) was developed as an optional tool to meet the quality assurance requirements of funding for environmental information operations, which are defined in the EPA Quality Assurance Project Plan Standard. Before you start your work collecting environmental data/information, you will need to complete a quality assurance project plan (QAPP) and have it approved by EPA. You should work with your EPA Project Officer (PO) to ensure you address all other funding requirements.

This document presents the instructions for each section of the Region 1 Optional QAPP Template, a Word document that can be found here. When using the template document, do the following:

- Replace the highlighted text and headers with the specific information for your project by clicking the highlighted text. Asterisks are also used to indicate the start and stop of text to be replaced.
- For each section of the QAPP, add the appropriate details for your project under each header. For each section, this instruction document provides:
 - o a brief description of the content;
 - o any specific required elements;
 - o questions/comments about details you should include if they pertain to your project;
 - o sections of the funding proposal or work plan that you submitted that could be relevant; and
 - o where to go for more information.
- The QAPP element(s) addressed in each section are indicated in parentheses in the header.
- Tables are helpful, but not required. The example tables provided can be modified or removed as appropriate.
- If there are sections of the template that do not apply to your project, please indicate so and explain why the section is not relevant.
- Before you submit your QAPP, update the entire table of contents using the "Update Table" button and delete the Comment with resources located on the first page of the template.
- Review, save, and submit the final version of your QAPP to your EPA Project Officer and R1QAPPS@epa.gov 60 days before the scheduled start of data collection. Remember, the QAPP must be approved before you can collect data, analyze secondary/existing data, start modeling, etc.

Next steps:

- → EPA Quality Assurance (QA) Reviewer and EPA Project Officer review the submitted QAPP within 30 days and provide comments.
- → You respond to any comments and submit the updated QAPP for approval.
- → EPA QA Reviewer and EPA PO review and accept the updated QAPP.
- → Signatures are collected on the approval page EPA PO signs last.

→ Your project is officially approved, and environmental information operations/data collection can start!

Additional resources

The controlled copy of the template is located on the <u>EPA Region 1 Quality Systems Documents</u> webpage. For questions related to this document or the template, please contact <u>R1QAPPS@epa.gov</u> for assistance. You may also find the following documents useful:

- EPA Quality Assurance Project Plan Standard
- EPA Region 1 Quality Assurance Project Plan Guidance
- EPA Guidance for Quality Assurance Project Plans (G-5)
- EPA Quality Assurance Project Plan Development Tool

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Title and Approval Pages (A1 & A2)

| Title Page (A1) | | | |
|--|--|--|--|
| Field | Instructions | | |
| Project Title | Enter a descriptive project title | | |
| Prepared by | Name and address of the organization preparing the QAPP | | |
| Prepared for | Identify who the QAPP was prepared for. Add any organizations aside from US EPA Region 1 if applicable. | | |
| Version Date | Date of this version of the QAPP | | |
| Revision | Revision number for this version of the QAPP | | |
| Estimated Project Start and End Dates | Include the month and year for the estimated project start and end; for Program and Generic QAPPs the end date will be five years after EPA approval. Note: These dates are also referred to as the "Period of Applicability". The start date of the project should not be before EPA approval. | | |
| EPA Grant/Contract/Task Order | If applicable, include the number or identifier for this project's funding. | | |
| EPA QA Tracking # | Placeholder for the QA Tracking number that will be assigned when the QAPP is submitted for EPA QA review. | | |

| Approval Page (A2) | |
|--------------------|--|
| Field | Instructions |
| Project Name | Name of the project, can be the same as the project title |
| Version Date | Date of this version of the QAPP |
| Plan Prepared by | Name(s) and affiliation(s) of QAPP writer(s) |
| Signature Lines | Include the name, title, and organization for individuals fulfilling each role. Copy and paste additional lines as needed. |

Table of Contents (A3)

Include QAPP elements, tables, figures, and appendices in the Table of Contents. The Tables and Figures tables of contents in the template were created using the Captions group on the References tab.

A. Project Management and Data Quality Objectives

1. Project Organization and Personnel (A7 - A10)

Identify the roles and responsibilities and lines of reporting and communication for project personnel. Clearly state who is responsible for maintaining and distributing the QAPP.

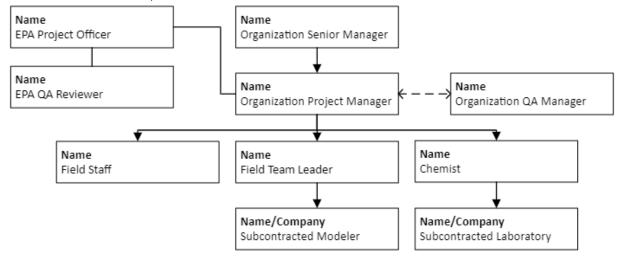
- 1. Provide a distribution list of key individuals involved in the project and their contact information for QAPP distribution (suggest creating a table). At minimum, the list should include the individuals on the approval page and contact info for laboratories. If the project is small, this can be merged with the project organization chart.
- 2. Include a project organization chart that identifies all key personnel and organizations/subcontractors involved in the project, including data users. This includes the individuals' names, titles, organizations, responsibilities (e.g., project tasks), and lines of reporting and communication. See an example organization chart below.
- 3. Clearly identify the individuals who will fulfill the roles of Senior Manager, Operations Manager, and Project QA Manager (Project QAM). Note: The Project QAM should have an independent line of communication to the Senior Manager.
- 4. Clearly document the independence of the Project QAM from project operations (e.g., data collection).

See Proposal/Work Plan sections:

- EPA Key Contacts Form
- Project Linkages and Partnerships
- List of Project Partners

- EPA QAPP Standard Element A7-A10
- EPA Region 1 QAPP Program Guidance A7-A10
- EPA G-5 Section 2.1.4

Figure 1. Example organization chart made with Microsoft Visio (dashed line indicates line of communication).



2. Personnel Training and Certifications (A11)

State any required training, certifications, or experience, including refreshers, that are necessary for project personnel to successfully complete the project. Can be in narrative or table format.

Required elements:

- Describe the specialized training or certifications for personnel or laboratories.
- Indicate how training/experience will be provided and documented.

See Proposal/Work Plan section:

- Programmatic capability
- Past performance

For more information see:

- EPA QAPP Standard Element A11
- EPA Region 1 QAPP Program Guidance A11
- EPA QA G-5 Section 2.1.8

3. Project Purpose, Problem Definition, and Background (A4)

Define the environmental problem(s), question(s), and/or threat(s) your project will address. Include the relevant historical information, previous studies, and data that have been collected.

Required elements:

- Describe the goals and objectives that form the foundation for your project
- Provide relevant background information (may include figures, tables, and narrative)
- Provide relevant regulatory criteria
- Define the data gap(s) that this project will address
- When applicable, identify any additional QA planning documents and address their association to the current QAPP (e.g., EPA-approved Program or Generic QAPPs)

See Proposal/Work Plan sections:

- Environmental and Public Health Information of the Underserved Community
- Program objectives
- Project activities
- Target investment area
- Target program area

- EPA QAPP Standard Element A4
- EPA Region 1 QAPP Program Guidance A4

4. Project Task Description and Schedule (A5)

Provide a summary of the work that will be done and the products that will be created to address the project's objectives and give an estimated project timeline.

Required elements:

- Summarize the work to be completed and the information to be collected. Include project objectives, study area, and data users.
- Provide the rationale for site/secondary data/model selection and the minimum number (or range) of samples to be collected.
- Provide a project schedule that includes critical project points for field, laboratory, analysis, and reporting (can be graphical or tabular; see example Table 1 in template)

Things to think about:

- What media need to be sampled? What contaminants of concern or other chemical compounds are expected to be present at the site?
- Where will samples be collected? Provide the rationale for site/sample selection and a map of the study area.
- For secondary data/modelling projects, how will datasets be identified, what temporal range will be evaluated? How will models be evaluated?
- What techniques/methods will be used to collect information? Include both field and laboratory components (more method detail required in section B).
- Are there any action levels or standards that the data should be compared to?

See Proposal/Work Plan section:

- Project Activities/Milestone Schedule
- Project Deliverables

For more information see:

- EPA QAPP Standard Element A5
- EPA Region 1 QAPP Program Guidance A5
- EPA QA G-5 Section 2.1.6

5. Data Quality Objectives (A6)

Describe the quality specifications for your project at two levels:

1) Data quality objectives (DQOs): What are the data needs? How 'good' do data need to be to support the project objectives?

2) Data quality indicators (DQIs): How will you measure the quality of the data and determine if you have enough data to meet project objectives?

Required elements:

- Data quality objectives: provide a qualitative or quantitative DQO statement for the project. DQOs should relate back to the project objectives.
- Data quality indicators: specify what methods you will use to verify data precision, accuracy, representativeness, completeness, comparability, and sensitivity (PARCCS parameters) for the field, laboratory, and existing data. We suggest using a table format (see Table B below).
- Existing/secondary data projects may use general assessment factors instead of PARCCS parameters (see Table C below).

Things to think about:

• Are action levels included in the DQO clearly stated and appropriate?

See Proposal/Work Plan section:

Project Activities

For more information see:

- EPA QAPP Standard Element A6
- EPA Region 1 QAPP Program Guidance A6
- EPA QA G-5 Section 2.1.7

Table 2. Project data quality indicators.

| Data quality indicator | Quality control activities and checks | Example Goal |
|------------------------|---|---|
| Precision | Field and laboratory replicates | 20 % relative percent difference |
| | (include the number of replicates) | between replicates |
| Bias | Pre- and post-calibration, blanks | Data are not biased in a particular |
| | (include the number and type of blanks) | direction |
| Accuracy | Calibration standards, blanks | No blanks contaminated and all |
| | (include number of standards and | calibrations within acceptable limits |
| | blanks) | |
| Representativeness | Evaluate whether the data | Data collected represent the site |
| | accurately represents the system, | |
| | population, place, time and/or | |
| | situation of interest | |
| Comparability | Compare to existing data or | Data collected are sufficiently similar |
| | datasets | in methodology to permit a |
| | | meaningful analysis |
| Completeness | Compare to intended sampling | 90 % of samples collected and |
| | goals to meet the project purpose | analyzed |
| Sensitivity | Compare to reporting or detection | Reporting limits 3-5 times lower than |
| | limits from existing data or for | action levels |
| | decision-making | |

Table 3. General assessment factors (<u>GUIDANCE ON SYSTEMATIC PLANNING USING THE DATA QUALITY</u> <u>OBJECTIVES PROCESS (EPA QA/G-4</u>).

| General | Description |
|--------------------------------|--|
| Assessment | |
| Factor | |
| Soundness | The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application |
| Applicability and Utility | The extent to which the information is relevant for the Agency's intended use |
| Clarity and Completeness | The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented |
| Uncertainty and Variability | The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized |
| Evaluation and Review | The extent of independent verification, validation, and peer review of the information or of the procedures, measures, methods, or models |

6. Documentation and Records Management (A12)

Describe the management of project documents and records. Management of data is covered later.

Required elements:

- Describe how the finalized QAPP will be maintained and how updates or revisions will be communicated.
- Identify any other project documents or records that will be generated and maintained (e.g., assessment and corrective action reports, presentation materials, and environmental software).
- Provide information on final disposition of records and documents, including storage location and retention schedule.

Things to think about:

- How frequently will data be backed up? Who will be responsible for backing up data?
- How will project staff receive the most up to date QAPP?
- How will quality assessments be documented?
- What reports will the project produce?

For more information see:

- EPA QAPP Standard Element A12
- EPA Region 1 QAPP Program Guidance A12
- EPA QA G-5 Section 2.1.9

B. Environmental Information Operations

1. Project/Sampling Design and Rationale (B1)

Describe and provide the rationale for the project/sampling design.

Required elements:

- Clearly define the project scope and identify data gaps that will not be investigated.
- Provide details about the project tasks to be completed.
- Provide the sampling locations or study area, include maps (maps should have scales, a north arrow, legend, and groundwater flow direction if relevant). See example figure in Appendix below.
- Provide details about sampling frequency and quality control samples.
- If using existing data, provide criteria that will be used to rank and select the information or information sources acceptable to meet the project's needs (see Figure 1 below).

Things to think about:

- Primary data collection:
 - Include the environmental media to be sampled and the number and types of samples.
 - Specify sample depths where appropriate.
 - o Include parameters to be measured in the field and analyzed in the lab.
- Existing data projects:
 - Describe selection of data sources and evaluation of secondary data (e.g., data resolution).
 - o Include any known limitations to existing data.
 - Specify how scientifically sound and transparent data will be compiled and analyzed to meet project objectives.
- Modeling projects:
 - Describe model inputs and outputs
 - o Include known limitations to models and how models will be evaluated
- Are there any sources of variability that might affect the sampling period (e.g., tides, seasons)?

For more information see:

- EPA QAPP Standard Element B1
- EPA Region 1 QAPP Program Guidance B1
- EPA QA G-5 Section 2.2.1

Figure 2. Example existing data selection steps.

- 1. Select the most reliable data source
- 2. Determine if data meet quality requirements.
 - a. If "Yes", use the data with full references.
 - b. If "No", move to step 3.
- 3. Determine if there are other data sources available.
 - a. If "Yes", evaluate the alternate data source starting at step 2.
 - b. If "No", move to step 4.
- 4. Evaluate if the data are crucial.
 - a. If "Yes", move to step 5.
 - b. If "No", do not use the data.
- 5. Evaluate if data can provide relevant, if limited, information.
- a. If "Yes", use the data and fully describe its limitations and document the need for better data.
 - b. If "No", do not use the data and note the need for data collection.

2. Methods (B2)

Describe or reference the methods to collect, analyze, and evaluate project data. This section should include enough detail for the project to be replicated.

- Provide standard procedures for all technical elements of the project (i.e., field and laboratory standard operating procedures). Standard operating procedures (SOPs) can be included as appendices. If SOPs have options, specify which options will be followed. Document any modifications to published Federal, State, Tribal, etc. or previously submitted SOPs.
- Include details about parameters and media to be sampled/measured, including volumes and sampling containers, averaging time for continuous monitoring, spatial resolution for remote sensing, etc.
- Identify any limitations and performance requirements.
- Describe corrective actions to be taken should problems arise.

Things to think about:

- Consider including a full list of SOP references in a table (see Tables D & E in template).
- How will equipment be cleaned/decontaminated and how will by-products be disposed?

For more information see:

- EPA QAPP Standard Element B2
- EPA Region 1 QAPP Program Guidance B2
- EPA QA G-5 Section 2.2.2

3. Integrity of Environmental Information (B3)

Describe the approach for sample handling and custody for the project. How will you ensure sample integrity?

Required elements:

- Describe sample preservation requirements and maximum holding times (see example Table F in template).
- Identify who is responsible for sample custody throughout the project and provide a chain of custody form (Example form provided in template Appendix).

Things to think about:

- How will samples be identified?
- How will samples be transported? Will temperature blanks be required?
- How will samples be disposed and who is responsible for disposal?

- EPA QAPP Standard Element B3
- EPA Region 1 QAPP Program Guidance B3
- EPA QA G-5 Section 2.2.3

4. Environmental Information Management (B7)

Describe how the data or information used, generated or evaluated during the project will be managed.

Required elements:

- Describe or reference procedures for handling, processing, compiling and analyzing data (including secondary data).
- Indicate record-keeping and storage requirements for project data (e.g., hardware or software requirements)

Things to think about:

- How will you identify and prevent data loss or manipulation?
- How will you ensure access to appropriate parties at various stages of data processing (e.g., raw, under QA review, final)?

For more information see:

- EPA QAPP Standard Element B7
- EPA Region 1 QAPP Program Guidance B7
- EPA QA G-5 Section 2.2.10

5. Quality Control (B4)

Describe the project's quality control activities for sampling, analytical, and measurement techniques. Include corrective actions and identify any applicable statistics.

Required elements:

- Identify the frequency and types of quality control samples for all components of the project (e.g., field sampling, laboratory analysis, modeling, etc.; see Table G in template)
- Describe corrective actions or validation that will occur should problems arise (e.g., inspect instruments, recalibrate, flag the samples)

Things to think about:

- Do you expect different levels (trace, low, medium, high) of an analyte in your sample? If so, specify the quality control samples for each concentration level.
- What kinds of blanks, replicates, matrix spikes, or calibration checks will you use?
- How will you calibrate your model and assess collinearity?

- EPA QAPP Standard Element B4
- EPA Region 1 QAPP Program Guidance B4
- EPA QA G-5 Section 2.2.5
- 6. Equipment/Instrument Calibration, Testing, Inspection, and Maintenance (B5)

 Describe the maintenance and calibration requirements for the field and laboratory equipment that will be used during the project. These details may be in SOPs.

- Identify instruments and equipment used to complete project tasks.
- Describe or reference procedures for calibrating, testing, inspecting and maintaining instruments and equipment (see Table H in template).
- Provide acceptance criteria for equipment and corrective actions.
- Identify who is responsible for inspections.
- Indicate how documentation of calibrations, maintenance, etc. will be traceable to the particular instrument.

Things to think about:

• What corrective actions will you take and how will you determine their effectiveness?

For more information see:

- EPA QAPP Standard Element B5
- EPA Region 1 QAPP Program Guidance B5
- EPA QA G-5 Section 2.2.7 & 2.2.8
- 7. Inspection/Acceptance of Supplies and Services (B6)

Describe how the quality of supplies and services is addressed and documented to meet project quality needs.

Required elements:

 Identify supplies and services needed and who on the project team is responsible for inspecting and accepting them.

Things to think about:

- Will the project be using any services provided by vendors, subcontractors or subgrantees? If so, how will they be/were they selected?
- How was the laboratory selected (e.g., accredited lab)?
- How will you ensure the sampling bottles are clean?

- Will certified standards be used? Who will ensure standards are not expired?
- How will you document inspection of supplies?

For more information see:

- EPA QAPP Standard Element B6
- EPA Region 1 QAPP Program Guidance B6
- EPA QA G-5 Section 2.2.3

C. Assessment, Response Actions, and Oversight

1. Assessments, Oversight, and Response Actions (C1 & C2)

Describe project oversight procedures and how you will assess the project activities to ensure this QAPP is being implemented as approved.

Required elements:

- Identify the type, frequency, and anticipated schedule of assessments.
- Identify potential participants in any self-assessments and any independent assessments. Note: Assessors should be free from conflicts of interest.
- Describe oversight activities to record project status and QA/QC issues that arise during project implementation.
- Provide details regarding how assessment findings and corrective actions are documented and communicated.
- Indicate who is responsible for responding to corrective actions and how corrective actions will be tracked to ensure completion.

Things to think about:

- Will your assessments consist of readiness reviews, surveillance, proficiency testing, and/or field, laboratory or data management technical systems audits?
- Will you use any checklists for your assessments? If so, provide them.

For more information see:

- EPA QAPP Standard Element C1 & C2
- EPA Region 1 QAPP Program Guidance C1 & C2
- EPA QA G-5 Section 2.3.1

2. Reports to Management (C2)

Describe how project management and other stakeholders are informed of oversight and assessment activities.

- Identify the type, frequency, and recipients of project reports.
- Indicate who is responsible for preparing and communicating these reports.

For more information see:

- EPA QAPP Standard Element C2
- EPA Region 1 QAPP Program Guidance C2
- EPA QA G-5 Section 2.3.2

D. Data Review and Usability

1. Data Review (D1)

State the criteria for determining if project data meet the stated data quality objectives and intended use(s).

Required elements:

- Describe procedures for data review (e.g., verification and validation)
- Identify the individual(s) responsible for reviewing data and communicating results
- Describe how any issues will be resolved and who has the authority to resolve them
- Ensure the data quality assessment incorporates the data quality objectives and performance/acceptance criteria identified in Section A above.

Things to think about:

- Will data verification and validation be done by internal or external parties?
- When during the process will these processes be performed?
- If quality control issues are found, who will resolve them and communicate the results and data limitations?
- Are there any forms or checklists that will be used? If so, include them.

- EPA QAPP Standard Element D1
- EPA Region 1 QAPP Program Guidance D1
- EPA QA G-5 Section 2.4.1 & 2.4.2
- EPA New England Environmental Data Review Program Guidance
- EPA New England Data Review Supplement

2. Project Evaluation – Usability Determination (D2)

Describe how you will use the outputs of data review to determine if the data are the right type, quality, and quantity to support the intended use(s) and are suitable for the decision(s) to be made.

Required elements:

- Outline methods to analyze the data and identify any departures from assumptions made when the project was planned
- Describe how you will reconcile your data with your project data quality objectives
- Describe how you will document and communicate any limitations on the use of the data
- Indicate who is responsible for conducting and documenting data usability

For more information see:

- EPA QAPP Standard Element D2
- EPA Region 1 QAPP Program Guidance D2
- EPA QA G-5 Section 2.4.3

References

Include full citations for all references in the QAPP. There is no specific format required for references. Website citations should include the date the information/site was accessed.

Appendices

Attach all relevant quality assurance or other project-specific documents and forms.

Suggested elements:

- All Standard Operating Procedures attached sequentially, if not included in an associated Generic or Program QAPP.
- Site figures with proposed and historic sampling locations.

Example appendix structure:

APPENDIX A. Field Documentation

- A-1. Equipment/Instrument Manual
- A-2. Standard Operating Procedures
- A-3. Field Data Forms

APPENDIX B. Laboratory Documentation

• B-1. Chain-of-custody form

- B-2. Standard Operating Procedures
- B-3. Data Report Format

APPENDIX C. Data Evaluation

• C-1. Data Evaluation/Documentation Form

Figure A1. Example map of sampling stations with water depth, sample number, and sample depths.

Appendix C: QAPP Completion Checklist

| Quality | Assurance | Project | Plan Title | : |
|---------|-----------|---------|------------|---|
|---------|-----------|---------|------------|---|

Grant, Contract/Task Order, or Interagency Agreement Number (if applicable):

EPA Project Officer/Project Manager:

QAPP Lead Organization:

QAPP Preparing Organization (if different from Lead Org.):

| Element | Purpose | Included | Not included | If element is not included, explain why: Additional comments: |
|---|--|----------|--------------|---|
| A1 Title Page | Presents the administrative information of the project. | | | |
| A2 Approval Page | Identifies the key project officials and documents their approval of the QAPP. The last recorded date of signature marks the earliest date when the project's operations can begin (i.e., its effective date). | | | |
| A3 Table of Contents, Document Format, and Document Control | Ensures all QAPP readers are reading or reviewing the most current version of the document with all applicable appendices, figures, and references. | | | |
| A4 Project Purpose, Problem Definition, and Background | Provides an overview of the problem to be solved or task(s) to be performed, along with any pertinent background information for the project. | | | |
| A5 Project Task Description | Provides an overview of the work to be completed in subsequent sections of the QAPP (Groups B, C, and D), along with an | | | |

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| | estimated timeline for these tasks. It summarizes the approach to address the project's objectives and connects what is needed to how it will be obtained. | | |
| A6 Information/Data Quality Objectives and Performance/ Acceptance Criteria | Ensures that the quality needs of the project are clearly defined and documented. | | |
| A7 Distribution List | Identifies all individuals who should receive a copy of the QAPP and any subsequent revisions. It also designates who is responsible for maintaining and distributing the QAPP. | | |
| A8 Project Organization | Identifies those involved with the project and describes their roles and responsibilities. | | |
| A9 Project QAM Independence | Documents the independence of the Project QA Manager from the Operations Manager and unit generating data. | | |
| A10 Project Organization Chart and Communications | Identifies the organizations and roles of key project members and documents lines of communication and authority. | | |
| A11 Personnel Trainings/ Certifications | Identifies any special or non-routine training or certifications that are necessary for project personnel to successfully complete the project, and how such training/certifications will be ensured and documented. | | |
| A12 Documents and Records | Describes the management of project documents and records, including the QAPP. Management of project data is covered later in Element B7 (Environmental Information Management). | | |
| B1 Identification of Project Environmental Information Operations | Describes the experimental design of the project's planned environmental operations. It describes in detail the specific tasks to be | | |

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| | completed and the rationale associated with | | |
| | these tasks (i.e., "how" and "why" specific | | |
| | project tasks are conducted). | | |
| B2 Methods for | Documents how project data and information | | |
| Environmental | will be collected, analyzed, and/or evaluated | | |
| Information Acquisition | consistently throughout the project. | | |
| B3 Integrity of | Describes how the integrity of environmental | | |
| Environmental | samples and environmental information will | | |
| Information | be retained throughout the project lifecycle. | | |
| B4 Quality Control | Identifies and describes the quality control | | |
| | activities designed to assess the potential | | |
| | variability inherent to any sample collection, | | |
| | analysis, or measure. | | |
| B5 Instruments/ | Describes how project personnel will know | | |
| Equipment Calibration, | that the equipment will work properly when | | |
| Testing, Inspection, and | needed, and how it will be ensured that | | |
| Maintenance | instrumentation and equipment operate at a | | |
| | known performance quality. | | |
| B6 Inspection/ | Describes how the quality of supplies and | | |
| Acceptance of Supplies | services is addressed and documented to | | |
| and Services | meet the quality needs of the project. | | |
| B7 Environmental | Describes how the data and information used, | | |
| Information | generated, or evaluated during the project | | |
| Management | will be managed. It describes the | П | |
| | management process from generation to final | | |
| | use of the data, including any specific handling | | |
| | or storage requirements. | | |
| C1 Assessments and | Describes how a project's activities will be | | |
| Response Actions | assessed during the project to ensure that the | | |
| | QAPP is being implemented as approved. | | |
| C2 Oversight and Reports | Identifies oversight procedures and | | |
| to Management | documents how project management and | | |

| | other stakeholders are kept informed of oversight and assessment activities. | | |
|--|--|--|--|
| D1 Environmental Information Review | Describes the review procedures for determining whether project data and information meet the project's stated data quality objectives and intended use(s). | | |
| D2 Useability Determination | Describes how you will determine if the project data and information is of the right type, quality, and quantity to support the intended use and are suitable for the decisions that will be made. This section involves retrospective evaluation of the planning process using the outputs of data verification, validation, and data quality assessment. | | |

Additional Comments:

Appendix D: Data Quality Objectives (DQO) Process

The Data Quality Objectives (DQO) Process, from EPA QA/G-4

Step 1: State the Problem

Define the problem that necessitates the study; identify the planning team, examine budget, schedule



Step 2: Identify the Goal of the Study

State how environmental data will be used in meeting objectives and solving the problem, identify study questions, define alternative outcomes



Step 3: Identify Information Inputs

Identify data & information needed to answer study questions



Step 4: Define the Boundaries of the Study

Specify the target population & characteristics of interest, define spatial & temporal limits, scale of inference

Step 5: Develop the Analytic Approach

Define the parameter of interest, specify the type of inference, and develop the logic for drawing conclusions from findings



Step 6: Specify Performance Criteria

Decision-making (hypothesis testing): Specify probability limits for false rejection and false acceptance decision errors

Estimation and other analytical approaches: Develop performance criteria for new data collection or acceptable criteria for existing data being considered



Step 7: Develop the Plan for Obtaining Data

Select the resource-effective sampling and analysis plan that meets the performance criteria