Instructions Updated: May 3, 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. 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 components;
 - 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 Standard 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, renumber figures and tables as appropriate, update the table of contents using the "Update Table" button, and remove all highlighted text.
- Review, save, and submit the final version of your QAPP to your EPA Project Officer 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 after QAPP submission to EPA Region 1:

- → 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)

Field	Instructions		
Project Title	Enter a descriptive project title. The title must include "QAPP".		
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	Include the month and year for the estimated project start and		
Dates	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	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 Region 1 QA review.		
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.

Required elements:

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).

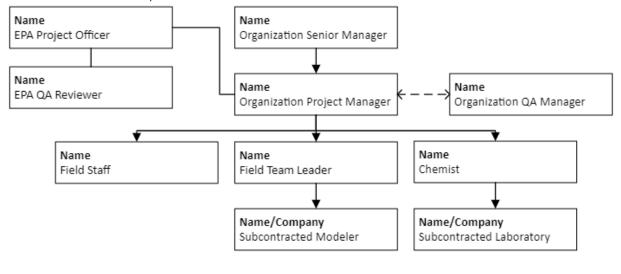
See Proposal/Work Plan sections:

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

For more information see:

- 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

For more information see:

- EPA QAPP Standard Element A4
- EPA Region 1 QAPP Program Guidance A4
- EPA QA G-5 Section 2.1.5

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 tThe 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 2 below).
- Existing/secondary data projects may use general assessment factors instead of PARCCS parameters (see Table 3 below).

Things to think about:

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

See Proposal/Work Plan section:

Project Activities

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

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?

- EPA QAPP Standard Element A12
- EPA Region 1 QAPP Program Guidance A12

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)?

- 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.

Required elements:

- 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 4 & 5 in template).
- How will equipment be cleaned/decontaminated and how will by-products be disposed?

- EPA OAPP 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 6 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?

For more information see:

- 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)?

- 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 7 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?

For more information see:

- 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.

Required elements:

- Identify instruments and equipment used to complete project tasks.
- Describe or reference procedures for calibrating, testing, inspecting and maintaining instruments and equipment (see Table 8 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?

- 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.

Required elements:

- 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.

For more information see:

- 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.

