Instructions for the

Preparation of Quality Assurance Project Plans

For EPA Brownfields Projects in the Southeast

July 2020

U.S. Environmental Protection Agency
Region 4
Land, Chemicals, and Redevelopment Division
Redevelopment and Brownfields Branch
Brownfields & Redevelopment Section
61 Forsyth St. S.W.
Atlanta, GA 30303

FORWARD

The Instructions were prepared by the Environmental Protection Agency (EPA) Region 4 Brownfields Program to provide Brownfield Cooperative Agreement Recipients (CARs) and their consultants and EPA contractors the instructions needed to develop a Generic Quality Assurance Project Plan (QAPP) and Site-Specific QAPP Addendum for environmental projects involving the collection and use of environmental data. This version of the Instructions replaces any previous versions. When environmental data is collected using federal funds, the CAR shall comply with 2 Code of Federal Register (CFR) 1500.11 requirements to develop and implement quality assurance practices sufficient to produce data adequate to meet project objectives and to minimize data loss. State law may impose additional Quality Assurance requirements. Once the Generic QAPP is approved by EPA, then a Site-Specific QAPP Addendum can be prepared and approved by EPA Region 4 before sampling begins.

This document should not be considered a substitute for EPA policy, regulations and guidance.

Table of Contents

Figures

Tables

This Page Intentionally left Blank

1.0 Introduction

The Environmental Protection Agency (EPA) requires that a Quality Assurance Project Plan (QAPP) be prepared to support all federally funded environmental projects involving the collection of environmental data. For EPA's Brownfields Program, this requirement means that whenever environmental samples are being collected as part of a site assessment or cleanup project, a QAPP must be prepared and **approved** by EPA **before** samples are collected.

The EPA Region 4 Brownfields Program is providing these instructions to provide anyone that is planning to collect samples with EPA Brownfields funding in Region 4 an overview of the information that should be in a Generic QAPP and Site-Specific QAPP Addendum.

These instructions briefly explain each of the elements that are required in the QAPP. The Checklist and QAPP Example Template files contained in Appendices A through C ensure the plans contain all the required information.

This document is consistent with the following documents: "EPA Requirements for Quality Assurance Project Plans," (EPA QA/R-5), EPA/240/B-01/003 (March 2001) Reissue Notice May 2006; and "EPA Guidance for Quality Assurance Project Plans" (EPA QA/G-5), EPA/240/R-02/009, (December 2002). EPA has additional tools that can be found online, such as the Quality Assurance Project Plan Development Tool contains information designed to assist in developing a QAPP that meets EPA requirements for projects that involve surface or groundwater monitoring and/or the collection and analysis of water samples. The online structure of the tool is intended to guide one through the thought process of planning a project, as well as to provide a framework for documenting the plan. The tool is divided into modules and can be found at https://www.epa.gov/quality/quality-assurance-project-plan-development-tool. Additional reference documents are listed in Section 6, References.

1.1 What is a QAPP?

A QAPP is a formal document describing, in detail, the necessary quality assurance (QA), quality control (QC), and other technical activities needed to ensure that the results of the work performed will satisfy the stated performance criteria. Furthermore, a QAPP outlines how and why a project involving the collection of analytical data will be conducted, and assures the quality of the data for making environmental decisions.

When developing a QAPP, consideration is to be given as to what potential contamination will be encountered, and to what extent, and what site decisions need to be supported by the data. When planning environmental assessments, consideration is to be given as to potential cleanup alternatives that could be compatible with redevelopment of the site.

The QAPP also describes the site or project background, the environmental problem (or the Recognized Environmental Conditions (RECs) as defined in ASTM E1527-13), the objectives for the project, the tasks to be performed, and the sampling design. The use of a Generic QAPP and Site Specific QAPP Addendum will eliminate duplication of tasks that are consistently conducted for all site assessment projects during the grant project period. Once EPA has approved the Generic QAPP, the Site Specific QAPP Addendums can be prepared and approved for each site assessment.

1.2 What is the purpose of this document?

The purpose of these instructions is to reduce the time required for QAPP development, review, and approval. By providing a Checklist, EPA anticipates the review and approval process will be streamlined. Two templates, one for a Generic QAPP and one for a Site-Specific QAPP, are included in Appendices B and C to aid in the development process. The July 2020 instructions for the Preparation of Quality Assurance Project Plans for EPA Brownfields Projects in the Southeast replaces all previous versions.

The purpose of a QAPP is to communicate the specifications for implementation of the project design and to help ensure that the data quality objectives are achieved for the project. QA planning and implementation increases efficiency and provides for early detection of problems, either in the field or in the laboratory. This can help ensure that federal funds are not wasted on sampling that is not necessary and that the data collected can be used to make meaningful site decisions.

1.3 General Overview

EPA Region 4 requires that a Generic QAPP must be developed by all community-wide assessment CARs. The Generic QAPP contains the information and processes that will be the same for each site sampling event. These activities can include field sampling methods and field measurement procedures, laboratory analysis and methodology, and comparison levels that will be used for results, such as EPA screening levels or state criteria. If a CAR has only one site to assess, for example those with a Site-Specific Assessment Grant or Cleanup Grant, there need only be one QAPP prepared for the project.

The checklist, presented as a separate document, should be completed and submitted with the Generic QAPP to the EPA Region 4 Project Officer. Provide the page number and paragraph where each of the elements can be found on the second column of the checklist. This process helps the EPA Region 4 Project Officer and Designated Approving Official (DAO) conduct the QAPP review. It also helps the QAPP developer/writer ensure accuracy and ensure the necessary content is in the Generic QAPP. The Generic QAPP should be organized similarly to the contents in these instructions and the checklist (e.g. A1. Title and Approval Page, A2. Table of Contents, etc.).

The EPA-approved Generic QAPP has a 5-year shelf life and it must be reviewed and updated annually.

The Site-Specific QAPP Addendums can be developed after EPA approves the Generic QAPP, and after the Project Officer has signed a Site Eligibility Form indicating the property is indeed a brownfield property. The same checklist can be used for the Site-Specific QAPP. The Site-Specific QAPP Addendum is the project sampling plan prepared for each site assessment. When a site is identified and approved by EPA for assessment, a Site-Specific QAPP is developed as an addendum to the approved Generic QAPP.

When additional sampling is necessary after the first sampling event, another Site-Specific QAPP or update can be prepared for the additional sampling. The initial Site-Specific QAPP Addendum for a site will be 1.A and the subsequent Site-Specific QAPP Addenda for the same site would continue the sequence with 1.B, 1.C, etc. As additional sites are proposed for sampling, the second site would start with 2.A and so forth (see Figure 1).

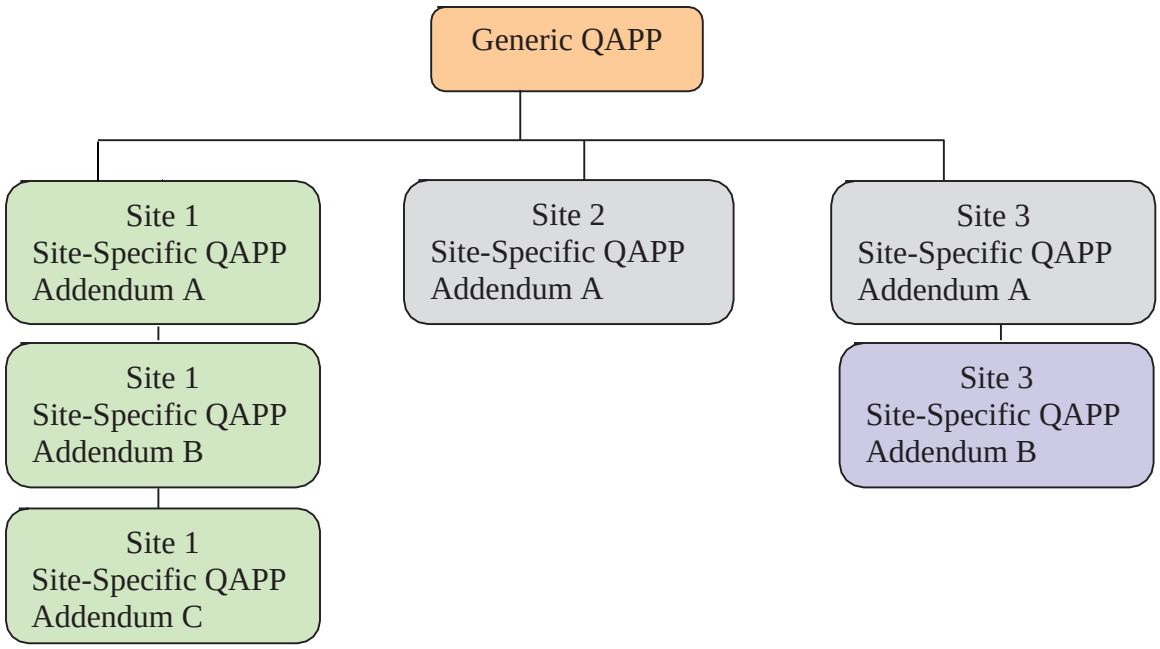

Figure 1 - Generic QAPP and Site-Specific Addendum Process for Multiple Sites

EPA has up to 30 calendar days to review a QAPP. In time sensitive situations, contact with the Project Officer/Designated Approving Official should be as soon as possible to inform him/her of the expedited need.

1.4 QAPP Contents and Elements

The Generic QAPP and Site-Specific QAPP Addendum have four parts:

A) Project Management - how you will organize and run the project;
B) Measurement and Data Acquisition - how you will collect and report data;
C) Assessment and Oversight - how you will check that all activities are completed correctly;
D) Data Evaluation - how you will review and interpret the data.

Table 1 shows the four components and breakdown of all the QAPP elements that need to be covered in a Generic QAPP and Site-Specific QAPP Addendum.

Table 1 - Components and Subsections of a QAPP

PROJECT MANAGEMENT		
A1, 2, 3	Title and Approval Page / Table of Contents/ Distribution List	In Generic and Site-Specific
A4	Project / Task Organization	In Generic
A5	Problem Definition / Background	In Site-Specific
A6	Project/ Task Description	In Site-Specific
A7	Quality Objectives and Criteria for Measurement Data	In Generic
A8	Special Training/ Certification	In Generic
A9	Documentation and Records	In Generic
MEASUREMENT DATA ACQUISITION		
B1	Sampling Design and Site Figures	In Site-Specific
B2	Sampling and Analytical Procedures	In Site-Specific
B3	Sample Handling & Custody	In Generic
B4	Analytical Methods and Requirements	In Generic
B5	Field Quality Control Requirements	In Generic
B6	Laboratory Quality Control Requirements	In Generic
B7	Field Equipment Calibration and Corrective Action	In Generic
B8	Laboratory Equipment Calibration and Corrective Action	In Generic
B9	Analytical Sensitivity and Project Criteria	In Generic
B10	Data Management and Documentation	In Generic
ASSESSMENT/OVERSIGHT		
C1	Assessments and Corrective Actions	In Generic
C2	Project Reports	In Generic
DATA EVALUATION		
D1	Field Data Evaluation	In Generic
D2	Laboratory Data Evaluation	In Generic
D3	Evaluating Data in Terms of User Needs	In Generic

2.0 QAPP – Section A. Project Management

This section of the QAPP answers who will be involved with the project, what is the environmental problem, background of the problem, how will the data be used, and what decisions will be made with the data.

The information that goes into the elements of this section includes:

A1. Title and Approval Page: (In Generic and Site-Specific)

A Title and Approval Page is required for every Generic QAPP and every Site-Specific QAPP Addendum. Essential items for the title page include the title of the project, the Brownfield Cooperative Agreement number, date prepared, the CAR's full name, the name of person or organization that prepared the QAPP, and the effective date of the QAPP and revision number. The approval page is required to include the names, titles, and dated signatures of all approving officials. These include your organization's Project Manager, your organization's QA/QC Manager/Officer, EPA Project Officer, EPA DAO, and the Brownfields' State Coordinators/Managers, if applicable. Add additional approving officials as appropriate to your organization or circumstance. In many cases, the EPA Project Officer and DAO will be the same person. If the Project Officer and DAO are the same individual, one signature line will suffice if both titles are specified for the EPA Project Officer/DAO. Your Project Officer will be able to let you know the situation for your project.

EPA's definition of a QA/QC Manager/Officer is the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

A2. Table of Contents and Page Header: (In Generic and Site-Specific)

The Table of Contents lists the sections, figures, photographs, maps, tables, and appendices contained in the QAPP with corresponding page numbers.

A3. Distribution List: (In Generic and Site-Specific)

The purpose of the distribution list is to ensure that all key project personnel and people mentioned in the document and/or have interest in the project get a copy of the approved QAPP including subsequent QAPP revisions, addenda, and amendments. If it is easier, create a bulleted line item for each or a table that includes the name of the recipient, their title, organization, and contact information including telephone number, address, and email address. Include a sentence in this section that indicates all the personnel will receive and follow applicable sections of the QAPP and subsequent revisions.

The key personnel may include: EPA project officer/DAO, contractors, laboratory director, field team leader, QA/QC officer, data reviewers, subcontractors, and other major individuals mentioned in the document, including those that need to review and approve the Generic and Site-Specific Addendum.

A4. Project/Task Organization: (In Generic)

List key project personnel (managers, laboratory personnel, QA personnel) and describe their roles and responsibilities for the project, identify who is of the lead manager for the entire project, and identify who is in charge of each activity (sampling, laboratory analysis, data reporting, etc.). Describe critical instructions that will need to be communicated and the person responsible (e.g. who will initiate soil sampling?).

Attach an organizational chart (see Figure 2) and indicate lines of communication and authority for all of the above. The organizational chart shows the group hierarchy and reporting structure within the organization. Everyone involved in this project needs to know who reports to whom.

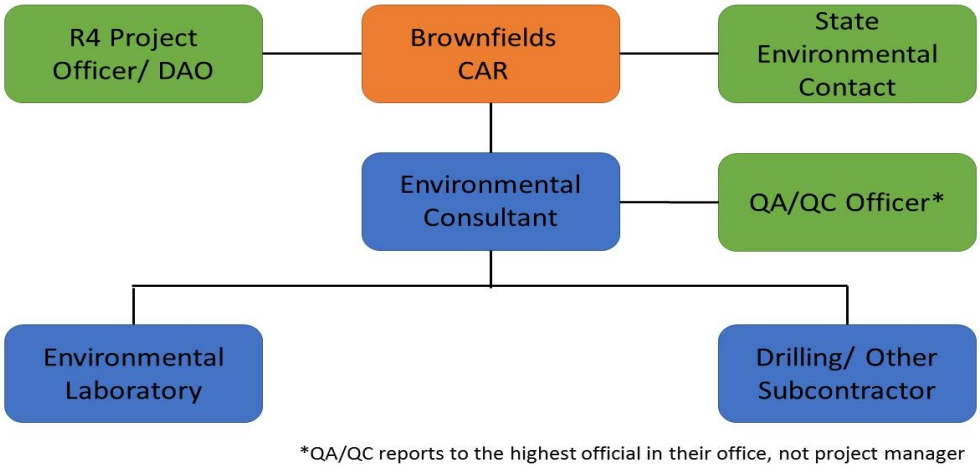

Figure 2 - Typical Brownfields Project Organization Layout

The chart should indicate a separation of responsibilities that could create real or perceived conflicts of interest. For example, the person who is responsible for checking the quality of the data will be separate from those who generate the data. The QA/QC officer should therefore report to the highest official in their office and not to the project manager. In other words, the QA/QC officer should be independent or must have an "arm's length" distance from other groups to ensure that they can make objective determinations on quality assurance issues.

Use the following language when describing the EPA Project Officer:

> EPA Project Officer has the responsibility to oversee and monitor the grant. As part of that responsibility he/she must ensure the activities conducted by the CAR are consistent with those described in the work plan.

When the Project Officer and the DAO are the same person, this person need only be listed once with dual titles.

Use the following language when describing the EPA Brownfields Region 4 quality assurance manager's DAO:

> The Brownfields Region 4 Designated Approving Official (DAO) provides a technical assistance role to some Region 4 Project Officers. The DAOs role is to provide technical reviews of the QAPPs.

The state environmental regulatory agency or its delegate has the lead regulatory role in any Brownfields site assessment or cleanup. The site assessment and cleanup of a Brownfields property must comply with state procedures, rules, and regulations. Be sure to have early involvement by the

state.

A5. Problem Definition/Background: (In Site-Specific)

The purpose of this section is to describe the reason for the data collection activity. The environmental problem can be the RECs as determined from a current and ASTM E1527-13 compliant Phase I Environmental Site Assessment (ESA). Appropriate items to include are a description of the environmental problem to be studied, background information from a historic, scientific, and/or regulatory perspective, a summary of the known information/data including environmental parameters of concern and magnitude of contamination, and a clearly stated definition of the objectives of the project.

Describe how data will be used (exploratory, delineation of contamination, compliance with regulatory criteria, etc.) and who will use the data. Identify what decisions will be made with the data. Cite any regulatory standards or criteria that data will be compared against. Identify information/data that are needed and questions that must be answered during the study. Include (or reference) historic maps, diagrams, and summary of the data that comprise secondary data.

List the types of secondary data (data generated for another purpose) that that will be used for your project, such as historical data or studies, compliance data, information from public databases, photographs, Sanborn Fire Insurance Maps, and literature files.

Describe the intended use of the secondary data and discuss any limitations on the use of the data. Discuss whether there are any QC data associated with the secondary data to characterize its quality.

Previously collected data should be used in planning subsequent sampling events. Sources of previously collected data that may be used should be identified and discussed, along with available sampling maps and results.

A6. Project/Task Description: (In Site-Specific)

This section summarizes the tasks that will be performed, the data that will be collected, and the reports that will be generated. Provide maps and/or tables to identify geographic locations of field tasks and provide a timeline, either in a graphical or tabular format, for scheduled activities and deliverables.

A7. Quality Objectives and Criteria for Measurement Data (Site-Specific)

This Section states the project objectives and limits, both qualitatively and quantitatively. It also states and characterizes measurement quality objectives as to applicable action levels or criteria.

The data quality objectives (DQO) process will be used to establish performance or acceptance criteria and helps set the minimum quality/quantity of data needed to address the previously stated problem in A6. The DQO process entails seven steps:

Step 1. State the problem(s)
Step 2. Identify the goals of the study

Step 3. Identify information inputs
Step 4. Define the boundaries of the study
Step 5. Develop the analytic approach
Step 6. Specify performance or acceptance criteria
Step 7. Develop the plan for obtaining data

For a detailed explanation of the DQO process, additional information can be found in the following document: "Guidance on Systematic Planning Using the Data Quality Objectives Process," (QA/G-4), February 2006.
Website https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf

A8. Special Training/Certification: (In Generic)

List the training(s) of personnel, including any special or non-routine training or certifications needed by personnel to conduct project activities. These include: the project activity, specialized training course title (or description), from whom the training was provided, the date of training, and expiration date of training credentials. Also describe how and by whom this training will be provided and documented, and where the records will be maintained.

A9. Documents and Records: (In Generic)

The purpose of this element is to describe the documents and records that will be generated for the project and how they will be retained. For some projects, where results and conclusions may be challenged, raw data records and documents should be retained for a specified length of time.

List all the records and documents that will be created during the project and describe which ones will be kept, how long they will be kept, and where they will be kept.

Itemize the contents of the laboratory report package. It should include: field sample results, QC samples results (blanks, duplicates, etc.), description of data qualifiers that laboratory applies to sample results, narrative describing issues and problem, resolution during analysis, chain-of-custody records raw data, and copies of logbook information. Include additional information as appropriate. A table may be a used to list the documents and records process. Records maintenance requirements are described in the Cooperative Agreement Programmatic Terms and Conditions.

2.1 QAPP – Section B. Measurement/Data Acquisition

The elements in this group answer the following questions:

- What are the sampling design and the rationale behind it?
- What sample collection methods will be used?
- What quality control will be used to assure that representative samples are collected?
- What measurement procedures, field techniques, and laboratories will be used, and what quality control measures will be used to ensure accurate, precise, and sensitive data are collected?
- How will sample data be managed?

Field measurements, sampling procedures, quality system procedures, and guidance documents that can

be used as a reference for this section can be found at the EPA Region 4 Science and Ecosystem Support Division's SESD's "Field Branches Quality System and Technical Procedures." Website http://www.epa.gov/region4/sesd/fbqstp/index.html. These are also called Standard Operating Procedures (SOPs) and are often referenced in Sections B2 through B9 of the QAPP. The EPA R4 Brownfields Program requires the use of SOPs because they present procedures that have been reviewed and approved by EPA, the State environmental agency, or a qualified environmental professional, and ensure the reproducibility or quality of data. Any SOPs that are referenced or used must comply with applicable state or federal requirements for the activity to be performed.

Referencing SOPs, QC criteria, state standards/criteria or other documents in the Generic QAPP and/or Site-Specific QAPP Addendum is acceptable, but the portion of the document that is referenced must be included within the QAPP or as an appendix to the QAPP. SOP references must include the organization that wrote the SOP, the version number, and date. When a SOP provides an option, the option must be specified in the site-specific QAPP.

B1. Sampling Design and Site Figures: (In Site-Specific)

This element should describe how you plan to collect representative samples. For guidance on selecting the appropriate design refer to: "Guidance for Choosing a Sampling Design for Environmental Data Collection" (QA/G-5S), December 2002.
Website https://www.epa.gov/sites/production/files/2015-06/documents/g5s-final.pdf

Explain why the sampling locations, environmental parameters and matrices were chosen. Describe the sampling design for the project including: sampling locations and directions to them, frequency of sampling at each location, matrices to be sampled, environmental parameters of interest in each matrix, and any design assumptions (e.g. storm event defined as "X" inches of rain after "Y" number of dry days). Include maps that detail sample locations.

It is recommended to create a table that includes:

- Sample matrix,
- Environmental parameters,
- Sampling collection method,
- Analytical method reference,
- Number of field samples, and
- Type and number of field QC samples for each matrix and parameter

Some things to consider in developing your sampling design: What are the standards or action levels against which the data will be compared? Do you need to determine whether water quality criteria are exceeded? Do you care about average contamination levels, hot spots, or the proportion of site contaminated? Will composite samples or grab samples be collected? Are you looking for trends over time? Are you using a statistical or judgmental sampling design? Will there be a reference site? Are you collecting background samples?

Judgmental sampling is a non-statistical approach for selecting sampling locations. Non-statistical approaches are useful in characterizing a relatively small population and in finding average values over time. Although there is a large degree of bias associated with judgmental sampling, judgmental samples

can provide useful information when sample locations are chosen based on prior history, visual assessment, and/or technical judgment.

Statistical sampling/grid sampling is a probability-based approach to selecting sample locations. It is useful in locating areas of contamination at a study site. The approach provides a uniform coverage of the area and is the best design for locating "hot spots" when limited data are available. Generally, a larger number of samples are collected and data are more representative of the sampling area than when a judgmental sampling approach is used. However, this may be more expensive than judgmental sampling. If needed, this approach may be more conducive to field screening approaches.

B2. Sampling and Analytical Procedures: (In Site-Specific)

Describe in detail each step of the sampling procedure, the equipment, materials, supplies, sample preservation techniques, sample holding times, decontamination procedures, disposal of decontamination by-products, sample containers and volumes, quality control acceptance limits, and corrective actions that will be used. Describe how problems (lost samples, broken equipment, inaccessible sampling locations, etc.) will be resolved and documented.

EPA SOPs are commonly used for this section. If multiple SOPs are referenced, include a table listing all field sampling SOPs that will be used.

Provide another table that includes: parameters, sample container, sample volume, preservation method, holding times for each parameter and matrix. You must describe any modifications to the SOPs that are necessary for your project. Also, if there are any method or equipment options within the SOP, indicate which will be used. Indicate how these modifications and option choices will be relayed to the samplers.

Describe how Investigation-derived Waste or IDW will be handled and managed.

B3. Sample Handling and Custody: (In Generic)

This element describes how you will maintain sample integrity (how samples will not get corrupted or mixed up). Indicate how samples will be handled, transported, and then held in the laboratory.

Describe how samples will be handled in the field, during transport, and in the lab. Identify responsible persons. Specify chain-of-custody (COC) procedures that will be used to ensure samples do not get lost, mixed up, or compromised by tampering. Provide examples of a sample label, COC forms, and other documentation. Describe the sample numbering/identification systems that will be used for field samples and the laboratory.

B4. Analytical Methods and Requirements: (In Generic)

This element identifies the analytical methods that will be used in the field and in the laboratory. These methods need to be sensitive enough to characterize the environmental conditions. Identify the extraction, digestion, and analytical methodologies (provide the actual method numbers) to be followed. This information is often in the laboratory SOPs or Laboratory Quality Assurance Manual (QAM).

Describe sample preparation and analytical procedures for field techniques and laboratory methods.

Detail any project-specific modifications to analytical methods and SOPs. List laboratory quantitation limits (reporting limits) to ensure project sensitivity requirements will be met. Describe how problems (lost samples, quantitation limits, holding time exceedances, etc.) will be resolved and documented.

B5. & B6. Field and Lab Quality Control Requirements: (In Generic)

This element should list all the QC checks you are going to perform to characterize the quality of the data and, as above, these procedures are often in SOPs.

Quality Control-Field: This element should list all the QC checks you are going to perform to characterize the quality of the data. Provide a table listing the QC samples for each sampling matrix (e.g., water, soil) and environmental parameter (pH, phosphorus, etc.). The table should include: type of QC sample (field duplicates, split samples, Performance Evaluation Samples, and trip, equipment and cooler temperature blanks), frequency, and acceptance criteria (controls and formulas for calculating QC data).

Quality Control-Laboratory: Provide a table listing the QC samples for each analytical method, for each matrix, and for each measurement parameter. The table should include:

- Types of QC sample (lab duplicates, matrix spikes, method blanks, etc.)
- Frequency of QC samples
- Acceptance criteria (control limits)
- Corrective actions that will be done when acceptance criteria are exceeded
- Description of procedures and formulas for calculating QC data

Data should also be considered in terms of accuracy, precision, and completeness. Accuracy is assessed through quality control samples and is expressed as the percent recovery of a known concentration of an analyte. Precision is determined by field duplicates, matrix spikes, and duplicate quality control samples. The relative percent difference between the two results is an indication of the precision of the analysis performed. Completeness is a measure of the amount of valid data obtained compared to what was expected to be obtained under normal conditions. Completeness is expressed as a percentage of valid data obtained from the measurement system. For data to be valid it must meet acceptability criteria of accuracy, precision, and any other criteria required by the prescribed analytical method.

When reviewing QC sample results consider the following: What will you do if contaminants are found in a "blank" sample? What will you do with sample results that do not compare with previously collected data and appear to be incorrect? What will you do with sample results if the instrument was not calibrated correctly? What will you do when duplicate sample results are not comparable? What will you consider as the range of comparable results? What will you do with sample results when a spiked compound is not recovered or the results of a performance evaluation sample are inaccurate?

The answers to these questions should be addressed in the discussion of how your QA/QC officer or the laboratory will review and qualify your data. For example, if the calibration check was not acceptable, will you estimate the sample results associated with the calibration. Will you apply a flag to the data, such as a J flag? Remember, QC data are only worth generating if they are used to review and evaluate your data.

B7. & B8. Field Equipment Calibration and Corrective Action & Laboratory Equipment Calibration and Corrective Action: (In Generic)

The information in this element should describe how you will keep instruments and equipment properly operational during the project. Identify equipment and instrumentation (both field and laboratory) requiring calibration and periodic maintenance, inspection, and testing. Describe how often the instrument needs to be calibrated and maintained, who will perform tasks, and who will document tasks. Describe the calibration and testing procedures and acceptance criteria (control limits) for operation. List the spare parts needed to be kept on hand to keep the instrument operational. Describe how problems (e.g. instrument does not hold calibration) will be resolved and documented.

B9. Analytical Sensitivity & Project Criteria: (In Generic and Site-Specific)

Provide an analytical method sensitivity and project criteria table for the analytical methods that will be routinely performed in Brownfields projects. If data from multiple laboratories is presented, the site-specific QAPP Addendum needs to clearly identify the laboratory being used on the project. As new methods and/or new laboratories are added on, this table is to be updated accordingly.

This is an important table for both planning the project and evaluating the resulting data. Initially, the table helps evaluate potential concerns with the sensitivity of an analytical method in relation to the project criteria, particularly for primary contaminants of concern. The table helps evaluate potential concerns with the sensitivity of an analytical method in relation to the project criteria. Additionally, the table is critical for understanding the usability of a data point when a sample result is near the project criteria, which is in turn near the quantitation limits and/or detection limits of the method (i.e. is the data point usable, or is more data needed to support a decision or trend in site contamination).

The table should include:

-Laboratory providing the data
-Analytical methods referenced (e.g. VOCs 8260B)
-Matrix (soil, groundwater, air, etc.)
-Analyte/compound list
-Method detection limit (MDL)
-Quantitation/reporting limit (QL/RL)
-Relevant state/federal criteria or standard that is associated with each analyte/compound and each matrix

EPA expects the laboratory reporting limit to be based on the low calibration standard for the value to be less than the appropriate action limit. The QAPP should include how data will be handled if the routine reporting limit is greater than the associated action limit. If the analyte is a primary contaminant of concern, the environmental professional should request an alternate method with a lower limit of detection to verify the absence of the analyte.

Ensure the appropriate units are specified and that the analytical method and project criteria are the same.

B10. Data Management and Documentation: (In Generic)

The information contained in this element describes managing project data. It also describes procedures for maintaining data so that it will not be lost or corrupted. Data can be lost during data reduction, reporting, and entry into forms, reports, databases, and even in storage. Indicate how computerized information will be maintained and stored. Any forms or checklists to be used can be attached. Describe how data (both hard copy and electronic) will be managed from the time they are generated in the field to final report and archival. Discuss methods and equipment for detecting/correcting errors, and preventing data loss. Describe how computer outputs will be checked. Identify who is responsible for these tasks.

2.2 QAPP – Section C. Assessment and Oversight

The elements in this group answer the following questions: How will you check to make sure that the project is being conducted as described in the QAPP? For example: Are field personnel collecting samples at the correct locations? Is the laboratory generating accurate data? What interim and final reports will be generated? Assessment findings should be documented in a report with recommendations for corrective actions, if applicable.

C1. Assessments and Corrective Actions: (In Generic)

Discuss how you plan to ensure that the project will be conducted as described in the QAPP. Describe any oversight activities and/or assessments that will be performed, approximate timeframe, and person(s) responsible. Identify who will receive a report of the findings, and who will be responsible for corrective actions and follow up. At a minimum, the project manager should schedule one review of field activities at the beginning of the project to ensure that all personnel are trained and that the appropriate equipment is in place. A Corrective Action Flow Chart is extremely useful for illustrating the decision-making process, particularly as state roles vary within Region 4 (see Figure 3).

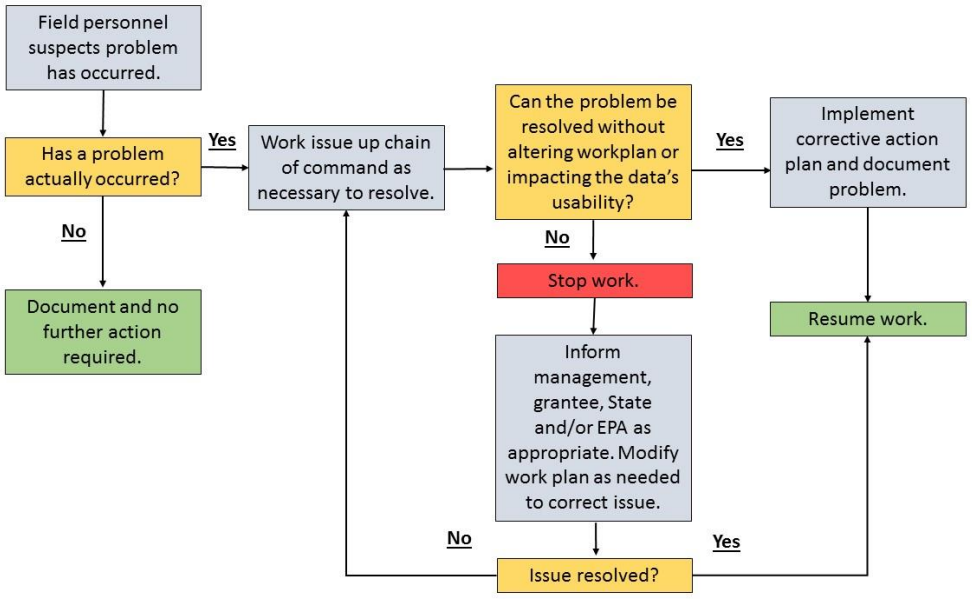

Figure 3 - Hypothetical Corrective Action Flow Chart

For additional information refer to "Guidance on Technical Audits and Related Assessments for Environmental Data Operations" (QA/G-7), January 2000.
Website: https://www.epa.gov/sites/production/files/2015-07/documents/g7-final.pdf

C2. Project Reports: (In Generic)

The QAPP should clearly state the type of information that will be included in the site assessment or sampling report. Describe the type and number of reports that will be generated for the project. Identify who is responsible for preparing the reports and the recipients for each report. This report should analyze and interpret data, present observations, compare results to the appropriate criteria or cleanup levels, draw conclusions, recommend next actions, identify data gaps, and describe any limitations in the way the data should be used.

2.3 QAPP – Section D. Data Evaluation

D1. Field Data Evaluation, D2. Laboratory Data Evaluation and D3. Evaluating Data in Terms of User Needs: (In Generic)

This section describes how the data will be evaluated to determine if they meet the requirements necessary to address the environmental issue in question. This group of elements answers the following questions: How will you check that individual data collection tasks were completed correctly? How will you determine that individual sample results are acceptable or unacceptable based on QC data? How will you assess the entire set of project data to determine whether the data are "good" enough to use in making project decisions and conclusions?

These elements are simplified into 3 steps for the purpose of this section.

Step 1: Verification

Describe how data will be checked to ensure that they are complete and were generated according to the methods and procedures specified in the QAPP. Describe steps taken by the laboratory to qualify sample results. Include qualifiers that the laboratory will apply when data do not meet laboratory QC acceptance limits. Discuss how issues will be resolved, documented and reported, and the personnel responsible for these tasks.

Attach any forms and checklists used to perform completeness checks. For example, is there a procedure to check that the samples were correctly preserved? Is there a procedure to check that laboratory data packages are complete (contain all required information)?

Laboratories generally apply flags to reported sample results that do not meet lab QC limits. For example, if a lab contaminant is present in a method blank, that contaminant would be flagged on the sample report form. Other items to check include: incubation temperatures, media preparation, and sample holding times.

Step 2: Validation Procedures

Describe how sample results will be accepted, rejected, or estimated based on quality control acceptance criteria. Define the data qualifiers that will be applied to the data (e.g. U=not detected, J=estimated, R=rejected). Attach or refer to written data validation procedures, if used.

Identify the individuals who will review data, and resolve and document data quality problems.

Validation is a review of sample results by an individual who is independent of the generation of the data. That means that the laboratory reporting the data would not perform data validation. Instead, the laboratory generally performs an internal verification (QC check) of the data that it generates. Data validators use mathematical and/or statistical procedures to review measurement data and generate data validation reports to describe the acceptability of the data. See Table 2 for examples of common data validation activities.

Table 2 – Examples of Data Validation Activities

	Activity
Data Deliverables and QAPP	Ensure that all required information on sampling and analysis was provided (including planning documents).
Analytes	Ensure that required lists of analytes were reported as specified.
Chain-of-Custody	Examine the traceability of the data from time of sample collection until reporting of data. Examine chain-of-custody records against contract, method, or procedural requirements.
Holding Times	Identify holding time criteria, and either confirm that they were met or document any deviations. Ensure that samples were analyzed within holding times specified in method, procedure, or contract requirements. If holding times were not met, confirm that deviations were documented, that appropriate notifications were made (consistent with procedural requirements), and that approval to proceed was received prior to analysis.
Sample Handling	Ensure that required sample handling, receipt, and storage procedures were followed, and that any deviations were documented.
Sampling Methods and Procedures	Establish that required sampling methods were used and that any deviations were noted. Ensure that the sampling procedures and field measurements met performance criteria and that any deviations were documented.
Analytical Methods and Procedures	Establish that required analytical methods were used and that any deviations were noted. Ensure that the QC samples met performance criteria and that any deviations were documented.
Data Qualifiers	Determine that the laboratory data qualifiers were defined and applied as specified in methods, procedures, or contracts.
Deviations	Determine the impacts of any deviations from sampling or analytical methods and SOPs. Consider the effectiveness and appropriateness of any corrective action.
Sampling Plan	Determine whether the sampling plan was executed as specified (i.e., the number, location, and type of field samples were collected and analyzed as specified in the QAPP).
Sampling Procedures	Evaluate whether sampling procedures were followed with respect to equipment and proper sampling support (e.g., techniques, equipment, decontamination, volume, temperature, preservatives, etc.).
Co-located Field Duplicates	Compare results of collocated field duplicates with criteria established in the QAPP.
Project Quantitation Limits	Determine that quantitation limits were achieved, as outlined in the QAPP and that the laboratory successfully analyzed a standard at the QL.
Confirmatory Analyses	Evaluate agreement of laboratory results.
Performance Criteria	Evaluate QC data against project-specific performance criteria in the QAPP (i.e., evaluate quality parameters beyond those outlined in the methods).
Data Qualifiers	Determine that the data qualifiers applied were those specified in the QAPP and that any deviations from specifications were justified.
Validation Report	Summarize deviations from methods, procedures, or contracts. Include qualified data and explanation of all data qualifiers.

Step 3: Evaluating Data in Terms of User Needs

This step describes how you intend to objectively decide whether the data you collected are good enough for the data user to use. Describe how the results of the study will be analyzed and evaluated to determine whether the needs of your project were met and then reported. Include mathematical and statistical formulae that will be used to calculate precision, accuracy/bias, completeness, and comparability of the project data. Describe what will happen if data is unusable. Remember, anything that compromises data representativeness ultimately impacts data quality. Table 3 details common items that can affect data usability and should be reviewed to ensure the data can be used for its intended purpose.

Table 3 - Examples of Consideration for Usability Assessment

Item	Assessment Activity
Data Deliverables and QAPP	Ensure that all necessary information was provided, including but not limited to validation results.
Deviations	Determine the impact of deviations on the usability of data.
Sampling Locations, Deviation	Determine if alterations to sample locations continue to satisfy the project objectives.
Chain-of-Custody, Deviation	Establish that any problems with documentation or custody procedures do not prevent the data from being used for the intended purpose.
Holding Times, Deviation	Determine the acceptability of data where holding times were exceeded.
Damaged Samples, Deviation	Determine whether the data from damaged samples are usable. If the data cannot be used, determine whether resampling is necessary.
PT Sample Results, Deviation	Determine the implications of any unacceptable analytes (as identified by the PT sample results) on the usability of the analytical results. Describe any limitations on the data.
SOPs and Methods, Deviation	Evaluate the impact of deviations from SOPs and specified methods on data quality.
QC Samples	Evaluate the implications of unacceptable QC sample results on the data usability for the associated samples. For example, consider the effects of observed blank contamination.
Matrix	Evaluate matrix effects (interference or bias).
Meteorological Data and Site Conditions	Evaluate the possible effects of meteorological (e.g., wind, rain, temperature) and site conditions on sample results. Review field reports to identify whether any unusual conditions were present and how the sampling plan was executed.
Comparability	Ensure that results from different data collection activities achieve an acceptable level of agreement.
Completeness	Evaluate the impact of missing information. Ensure that enough information was obtained for the data to be usable (completeness as defined in PQOs documented in the QAPP).
Background	Determine if background levels have been adequately established (if appropriate).
Critical Samples	Establish that critical samples and critical target analytes/COCs, as defined in the QAPP, were collected and analyzed. Determine if the results meet criteria specified in the QAPP.
Data Restrictions	Describe the exact process for handling data that do not meet PQOs (i.e., when measurement performance criteria are not met). Depending on how those data will be used, specify the restrictions on use of those data for environmental decision-making.
Usability Decision	Determine if the data can be used to make a specific decision considering the implications of all deviations and corrective actions
Usability Report	Discuss and compare overall precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity for each matrix, analytical group, and concentration level. Describe limitations on the use of project data if criteria for data quality indicators are not met.

Note: For additional guidance in data usability assessment refer to these EPA Documents: "Data Quality Assessment: A Reviewer's Guide", QA/G-9R, and the companion document "Data

Quality Assessment: Statistical Tools for Practitioners" (QA/G-9S).
Website https://www.epa.gov/quality/guidance-data-quality-assessment

3.0 Review, Approval and Distribution

Once you are ready to submit your QAPP to EPA for review, include the completed appropriate checklist to your EPA R4 Brownfields Project Officer. The Project Officer will specify whether a hard or electronic copy is required. EPA review time is approximately 30 days. However, if a faster turnaround time is necessary, as in the case with some Site-Specific QAPP Addendum, contact the EPA Project Officer to discuss. The EPA Region 4 Brownfields Program will work with the CAR and its consultant to try and meet a faster turnaround when necessary.

If EPA has comments, the plan must be revised and resubmitted. If necessary, make any revisions to the checklist and resubmit to EPA. The EPA Project Officer/DAO will sign the appropriate place on the signature page once the comments have been addressed successfully. EPA's signature of the project specific QAPP provides approval to begin the sampling. Once all signatures have been obtained on the signature page, the completed final document should be provided to all those on the Distribution list. Figure 4 shows a flowchart diagram of the review, approval, and distribution process.

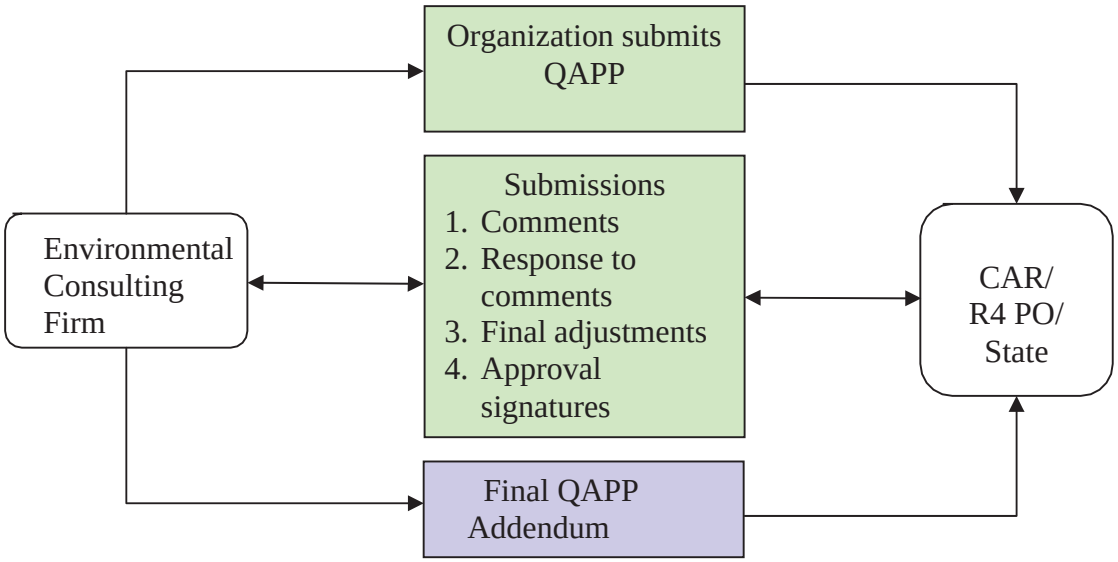

Figure 4 - QAPP Review, Approval and Distributions

4.0 QAPP Modifications, Revisions and Updates

Modifications can be made to QAPPs if necessary. Discuss the modifications that are needed to either the Generic or Site-Specific QAPP Addendum with your EPA R4 Brownfields Project Officer. Then submit the revision for review and approval prior to implementing the modifications (e.g. change in scope of sampling design and analytical methods). Revisions for minor changes may not be required, but your Project Officer must be made aware of such changes.

5.0 Generic QAPP Updates, Revisions and Resubmittals

Generic QAPPs are valid for five years or for as long as the cooperative agreement is active (whichever is shorter) starting from the signed approval date. The consultant that prepared the QAPP should review the plan annually for updates. The annual update can capture the accumulated changes over the past year.

If a cooperative agreement project period extends beyond five years, another Generic QAPP should be resubmitted to the EPA Project Officer for review and approval. It is important to keep the Generic QAPP updated to account for any relevant information that became known after the start of the cooperative agreement. At a minimum, personnel and SESD SOP changes are likely to have occurred.

6.0 References

US EPA Region 4, SESD, Field Branches Quality System and Technical Procedures, February 2008. These procedures supersede the US EPA Region 4 "Environmental Investigations Standard Operating Procedures and Quality Assurance Manual" (EISOPQAM) November 2001 and the "Ecological Assessment Standard Operating Procedures and Quality Assurance Manual" (EASOPQAM) January 2002. https://www.epa.gov/quality/quality-system-and-technical-procedures-sesd-field-branches

U.S. Environmental Protection Agency, 2002. Guidance for Quality Assurance Project Plans (EPA QA/G-5). Final. December 2002. EPA/240/R-02/009, Office of Environmental Information. https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf

U.S. Environmental Protection Agency, 2001. EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5). (March 2001), Reissue Notice May 2006. EPA/240/8-01/003, Office of Environmental Information. https://www.epa.gov/sites/production/files/2016-06/documents/r5-final_0.pdf

The updated EPA Region 9 Preliminary Remediation Goals (PRGS) are now called Regional Screening Level (RSL). Several states have adopted these values for use in screening analytical results. QAPP preparers should confirm that their state is using these values or find out what their state recommends. https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables-may-2016

U.S. Environmental Protection Agency, "Guidance for Choosing a Sampling Design for Environmental Data Collection" (QA/G-5S) https://www.epa.gov/sites/production/files/2015-06/documents/g5s-final.pdf

U.S. Environmental Protection Agency, "Guidance for Preparing Standard Operating Procedures (SOPs)", EPA QA-G/6 http://www.epa.gov/quality/qa_docs.html

U.S. Environmental Protection Agency, "Guidance on Technical Audits and Related Assessments for Environmental Data Operations", G-7 https://www.epa.gov/sites/production/files/2015-07/documents/g7-final.pdf

U.S. Environmental Protection Agency, "Data Quality Assessment: A Reviewer's Guide, (QA/G-9R)"and the companion document "Data Quality Assessment: Statistical Tools for Practitioners, (QA/G-9S). https://www.epa.gov/quality/guidance-data-quality-assessment

Quality Assurance Project Plan Development Tool:
https://www.epa.gov/quality/quality-assurance-project-plan-development-tool

EPA's Quality Assurance Website:
https://www.epa.gov/quality

7.0 EPA Region 4 State Web Links:

Alabama:	http://www.adem.state.al.us/
Georgia:	http://www.gaepd.org/
Florida:	http://www.dep.state.fl.us/
Kentucky:	http://dep.ky.gov/Pages/default.aspx
Mississippi:	http://www.deq.state.ms.us/
South Carolina:	http://www.scdhec.net/
North Carolina:	https://deq.nc.gov/
Tennessee:	http://www.tennessee.gov/environment/