

US EPA Region 2  
Guidance for the Development of  
**Quality Assurance Project Plans**  
for Environmental Monitoring Projects  
April 12, 2004

Prepared by: Donna Ringel 4/12/04 Carol Lynes 04/12/04  
Donna Ringel and Carol Lynes, Date

Air and Water Quality Assurance Team  
Monitoring and Assessment Branch  
Division of Environmental Science and Assessment

Approved by: Marcus E. Kantz 04/12/04  
Marcus E. Kantz, Air and Water QA Team Leader, date

Approved by: Randy Braun 4/12/04  
Randy Braun, Monitoring and Assessment Branch Chief, date

Approved by: Kevin W. Kubik 4/12/04  
Kevin Kubik, Regional QA Manager, date

## Table of Contents

<u>Title</u>	<u>Page</u>
I. Introduction.....	03
II. QAPP Elements.....	04
1.0 Title and Approval Sheet.....	04
2.0 Table of Contents.....	04
3.0 Distribution List.....	04
4.0 Project/Task Organization.....	04
5.0 Special Training Needs/Certification.....	05
6.0 Problem Definition/Background.....	05
6.1 Problem Definition	
6.2 Background	
7.0 Project/Task Description.....	05
8.0 Quality Objectives and Criteria for Measurement Data.....	06
8.1 Precision	
8.2 Bias	
8.3 Representativeness	
8.4 Comparability	
8.5 Completeness	
8.6 Sensitivity	
9.0 Non-Direct Measurement (Secondary Data).....	08
10.0 Field Monitoring Requirements.....	09
10.1 Monitoring Process Design	
10.2 Monitoring Methods	
10.3 Field Quality Control	
11.0 Analytical Requirements.....	11
11.1 Analytical Methods	
11.2 Analytical Quality Control	
12.0 Sample Handling and Custody Requirements.....	12
13.0 Testing, Inspection, Maintenance and Calibration Requirements....	12
13.1 Instrument/Equipment Testing, Inspection and Maintenance	
13.2 Instrument/Equipment Calibration and Frequency	
13.3 Inspection/Acceptance of Supplies and Consumables	
14.0 Data Management.....	13
15.0 Assessments/Oversight.....	13
16.0 Data Review, Verification, Validation and Usability.....	13
16.1 Data Review, Verification, and Validation	
16.2 Reconciliation with User Requirements	
17.0 Reporting, Documents and Records.....	17

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2**

**Guidance for the Development of Quality Assurance Project Plans  
for Environmental Monitoring Projects**

**I. Introduction**

This document presents guidance for the development of a Quality Assurance Project Plan (QAPP) for **non-Superfund** environmental monitoring projects to be conducted by or for EPA Region 2. It is based on, and is consistent with, "EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/003" and "EPA Guidance for Quality Assurance Project Plans, EPA QA/G-5, EPA/240/R-02-009."<sup>1</sup>

It is important to remember during the QAPP development process that data quality is an issue because of the possibility of both variability and error. The natural environment is inherently variable; nothing stays exactly the same from time to time or from place to place. In addition, all of our measurement processes are flawed to some degree, imposing error on top of the inherent variability. One of the main purposes in developing and implementing a QAPP is to face up to these potential variabilities and errors and to make sure that they do not compromise the usefulness of the data resulting from the project.

While making sure to cover all of the elements described here, the QAPP development team should not let this guidance in any way limit the inclusion of thought process and/or material that might be useful for understanding the substance or rationale for the project. Also, this guidance is most applicable to environmental monitoring projects that do not involve extensive modeling or research components (See national G-5M for modeling.).

The QAPP must be prepared by the project manager or designee in cooperation with representatives from all groups expected to be involved in the project or users of the project's information. The QAPP should be submitted for review at least 30 days prior to the scheduled project start date. It **must** be approved before environmental data collection or use activities begin. When changes in the project will significantly impact either the technical or data quality objectives of the project, the QAPP will need to be amended, requiring re-approval and notification of all project participants. QAPPs for multi-year projects should be reviewed annually and revised when necessary.

---

<sup>1</sup> These EPA documents are available on EPA's website at: [www.epa.gov/quality](http://www.epa.gov/quality). The QAPP development team may choose to base their QAPP directly on R-5 and G-5. This Region 2 guidance is offered only as a potentially more user-friendly approach for developing an approvable QAPP.

## **II. QAPP Elements**

The notations in parenthesis listed after each QAPP section heading reference the QAPP elements as listed in EPA's R-5 and G-5 documents.

### **1.0 Title and Approval Sheet (A1)**

Information to be included here is as follows:

- Project title
- Organization name
- Effective date of plan
- Names, titles, signatures and signature dates of approving officials.

Approving officials include the organization's technical project manager and QA manager and the EPA project manager and QA officer. If more than one agency or organization is involved, additional lines should be added for each organization. The managers of the field and laboratory groups should be included as signatories. An individual's signature indicates review and approval of the plan.

### **2.0 Table of Contents (A2)**

A table of contents is recommended for all projects and is required if the document being submitted is longer than ten pages. The table of contents should include sections, lists of figures, tables, references and appendices.

### **3.0 Distribution List (A3)**

A distribution list is required to help insure that all individuals involved with the implementation of the project receive a copy of the QAPP and any future revisions. The distribution list should provide the names, positions, and contact information for all individuals listed.

### **4.0 Project/Task Organization (A4)**

- Describe the responsibilities (relative to the project) of each key individual and/or organization.
- Document the relationship between the QA manager and the unit generating the data. The QA manager for the project should be independent from the project manager(s), allowing for frank discussion of relevant QA/QC issues.
- Provide an organizational chart identifying key personnel and/or organizations, showing their relationships and lines of communications.

If names are not known because contract or grant arrangements are not finalized, they must be supplied prior to the start of work.

## **5.0 Special Training Needs/Certification (A8)**

Identify any special training and certification requirements needed by any project personnel for field or laboratory activities and how this information will be provided, documented and assured. Describe any laboratory certification requirements.

## **6.0 Problem Definition/Background (A5)**

This section should be written such that a technical person, unfamiliar with the project, will understand what is intended. State the specific problem to be addressed and the decision to be made. Include background/historic information supporting the need for the project. This represents the justification for all that follows in the document.

### **6.1 Problem Definition**

State the overall project goals and objectives.

- Describe why the project is being undertaken and what you intend to accomplish.
- State the intended use of the data by describing the decisions to be made along with any action levels or standards that will be used.
- Identify the data users for the project.

### **6.2 Background**

This background information will provide a historical perspective for the project.

- Describe the problem as it is understood and its importance to the specific program (enforcement, permitting, standard setting, trend or risk analysis, research, etc.).
- Provide information indicating and supporting the need for this work.
- Discuss any previous work or data collected as they relate to the project.

## **7.0 Project/Task Description (A6)**

This section should provide a management summary of the work that will be conducted and a schedule for implementation. Specific technical details about the work will be provided in later sections of the QAPP.

- Describe the approach taken to address the project's objectives, connecting what is needed to how it will be obtained.
- Include maps, as appropriate.
- Identify what data will be collected directly via the project and what data will be obtained from other sources.
- Delineate the project schedule from initiation to final report submission, listing all intervening major events or actions. This may be prepared in tabular form.
- Identify any special personnel and/or equipment requirements.
- Include appropriate technical, regulatory or program specific quality standards.

## 8.0 Quality Objectives and Criteria for Measurement Data (A7)

The chosen monitoring design and the sampling and analytical procedures can greatly affect the usability of the data for a specific purpose. Remember that both variability and error will affect data quality. In order to estimate and report these effects, the QAPP must describe the quality criteria for the data to be produced. The establishment of quality criteria for a project should be developed jointly, and in a systematic manner, by technical staff and project managers. The process should combine management's need for confidence in their decision-making with the practical difficulties and expense of collecting "better" data.

Development of the data quality criteria can be accomplished via the formal DQO process described in the EPA document "Guidance for the Data Quality Objectives (DQO) Process", EPA/600/R-96/055. This DQO process will result in qualitative and quantitative outputs that define the acceptance criteria for the data. For most projects, a less iterative process is normally used to develop the project's data quality criteria. In either case, the systematic planning process that is used to develop the project needs to be described here, and attached, if DQOs.

Performance acceptance criteria are sometimes expressed as data quality indicators, (DQIs). The principal DQIs are: precision, bias, representativeness, comparability, completeness and sensitivity. These DQIs are discussed below in items 8.1 - 8.6. In each case, when possible, acceptance criteria are specified in the QAPP, delineating "how good" the data will need to be for use, and as an early warning system to allow corrective action to be taken before the entire project is completed. Include the acceptance criteria, etc. with the explanation of each DQI in the text in items 8.3 - 8.5. For each method and parameter, specify the precision, bias, and sensitivity (detection limits) in items 10.3 and 11.2 for the field and laboratory operations, respectively, assigning the acceptance criterion for each (note that the table formats suggested in those sections and in section 11.1 may need modification, as for in situ field methods that have detection limits).

### 8.1 Precision

Precision is the measure of agreement among repeated measurements. State how you will determine the precision of your data. This might include the following:

- Use the same analytical instrument to make repeated analyses on the same sample
- Use the same method to make repeated measurements of the same sample within a single laboratory
- Use two or more laboratories to analyze identical samples with the same method
- Split a sample in the field and submit both for sample handling, preservation and storage and analytical measurements

Precision for laboratory and field measurements can be expressed as the relative percent difference between two duplicate determinations. Acceptance criteria for laboratory precision are usually those specified in the method. Acceptance criteria for field precision will usually need to be developed based on the needs of the project.

## **8.2 Bias**

Bias is the systematic or persistent distortion of a measurement process causing errors in one direction. State how you will determine any bias in your data. This might include analysis of certified/standard reference materials and/or of matrix spike samples.

Acceptance criteria for matrix spike measurements are usually expressed as a percent recovery and are usually specified in the analytical method. Various blank samples (laboratory or field) may also be used to assess contamination of samples that may bias results high. Acceptance criteria for field bias are much more difficult to define and will usually need to be developed based on the needs of the project.

## **8.3 Representativeness**

Representativeness is the extent to which measurements represent the true system. In almost every project you will not be able to measure the whole system, process or situation of interest. You can't know the composition of a whole river, or all the air over a city. Instead, you will normally need to sample or monitor a small fraction of it, and then assume that your results present a sufficiently reasonable picture of what is going on in the whole system, process or situation. The key to designing the sampling scheme or monitoring network is to capture a sufficiently broad and/or weighted view of the situation to tell you what you need to know. For example, do you need to know the average concentration in a huge river, or the range of concentrations, or the concentration near the bottom, or near the banks, or after a rain, or during a drought? The only concentrations you will know will be the ones in the bottles you fill. Deciding how many to fill, and when and where to fill them, is both an art and a science. EPA's document, "Guidance on Choosing a Sampling Design for Environmental Data Collection (QA/G-5S) EPA/240/R-02/005," provides some assistance with the design of your monitoring/sampling effort. One thing is certain, if the samples you collect do not appropriately represent what you are interested in, any decisions you make based on your results will be close to guess-work and you won't know it.

In this Section of the QAPP, describe how the collected data will accurately represent the population, place, time or situation of interest, and the logical process that supports it. It is appropriate to refer to Section 10.1 of the QAPP in which the monitoring process design is described and justified. You may even find it convenient to combine this section on representativeness with that section on monitoring design. If determining a representative monitoring scheme is particularly difficult, consider collecting preliminary data to help develop an appropriate scheme.

## **8.4 Comparability**

Comparability is defined as the extent to which data from one data set can be compared directly to similar or related data sets and/or decision making standards. State the goals for achieving data comparability and how they will be attained. Discuss comparisons of sample collection and handling methods, sample preparation and analytical procedures, holding times, stability issues and QA protocol.

## **8.5 Completeness**

Completeness is the fraction of planned data that must be collected in order to be sufficient for the intended use of the data. State the level of completeness required. For example, of the 20 samples planned to be collected, 80% or 16 are required for a valid determination of compliance. It is very important to define completeness requirements for statistically designed studies. It may be less important in other projects.

## **8.6 Sensitivity**

Sensitivity is essentially the lowest detection limit of the method or instruments for each of the measurement parameters of interest. Technically, it is the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest.

Determine the minimum concentration or attribute that can be measured, (i.e., method detection limit, instrument detection limit, quantitation limit) and discuss the appropriateness of this for your project. If available or affordable methods cannot achieve specified quality, the project is not likely to succeed. Perhaps restructuring or delay is needed.

## **9.0 Non-Direct Measurement (Secondary Data) (B9)**

In many projects it may be valuable or even necessary to use existing data (e.g., historic environmental trends data, geographic/location data, census data, socio-economic data...). When existing data, also known as secondary data, will be used for a current environmental project, an assessment of the secondary data must be performed to determine if the quality of the data is sufficient for the current project objective(s) and intended use.

It is not enough that the secondary data proposed to be used for the project may have been produced by a reliable source, such as a peer reviewed publication, or a known environmental monitoring project with an approved QAPP. As with any environmental monitoring project, the user(s) of the secondary data must establish data quality acceptance/rejection criteria and perform a data quality assessment. In other words, perform this assessment as if you collected the data yourself. If your project will utilize extensive secondary data, it will be best to consider the secondary data all the way through the QAPP, not just in this section.

State the potential sources of the data and define the data quality acceptance and rejection criteria that will be used when performing the quality assessment of the secondary data. Describe the assessment process and discuss any limitations on the use of the data (e.g., geographic limitations, different sampling and/or analytical methods used, availability of the QA/QC records). Be sure to include how you intend to utilize any available DQI for the existing data. Based on the established acceptance/rejection criteria, explain how data will be qualified and how deficiencies and data gaps will be resolved.

If your project is intended to collect environmental data primarily to be used as secondary data by others, a precautionary statement must be prominent in the QAPP and in any subsequent project reports. It should indicate that the users of your data must evaluate the data using quality criteria appropriate for their new use or decision-making process.

Also, Please note that Chapter 3 in EPA QA/G-5 contains valuable information on developing a QAPP for a secondary data project.

## 10.0 Field Monitoring Requirements

In this section you will describe your monitoring design, field methods, and field QC activities. It explains how and why you are monitoring to ensure that the appropriate data are collected for the project. (Note: Laboratory requirements will be included in Section 11.0). Please note that we have used the term “monitoring” to refer to both sampling and monitoring activities.

### 10.1 Monitoring Process Design (B1)

Describe and **justify** the monitoring design of the project. State the area of interest, what you are testing for, and how often. State the number of anticipated monitoring points and how and why they will be selected. If appropriate, attach a map showing the site(s) and each monitoring point. Discuss how locational information will be obtained, such as the use of Geographical Positioning System (GPS) instrumentation. Identify the potential sources of spatial and temporal variability and how the monitoring design will account for them. (Potential variability might be seasonal, diurnal, upstream vs. downstream, tidal, soil profile changes, weather related and process variation within the source.) Some questions to be answered in this section include, but are not limited to:

- Is the monitoring design probability or judgment based?<sup>2</sup>
- What are you comparing your results against, (previous data, a standard, a reference population)?
- How many samples/data points are needed?
- Where do you need to monitor?
- What is the required frequency of monitoring?
- How are monitoring locations determined?
- Is the target population homogeneous or heterogeneous?
- Are composite samples appropriate?
- What QC samples are needed?

---

<sup>2</sup> Probability based designs involve the random selection of sampling units. Judgmental designs involve the selection of sampling units based on expert knowledge or professional judgment (such as sampling stained soil).

## 10.2 Monitoring Methods (B2)

- All monitoring methods should be fully described, referenced, or attached to the QAPP in the form of approved Standard Operating Procedures (SOPs). (Specify all selected options and describe deviations from standard protocol). If the complete method descriptions, with all specified options, are readily available, cite the method and where it can be obtained. If these complete method descriptions are not readily available, they must be attached to the QAPP.
- List all needed monitoring equipment and supplies
- Identify what to do when problems arise
- If flow is to be determined, state how
- If samples are to be homogenized or split, state how
- For continuous monitoring, indicate what averaging time will be used and how the data will be averaged, stored, downloaded, and reported (telemetered)
- List all data acquisition and handling equipment and software. If software is to be developed or modified for the project, indicate how it will be tested and verified.
- For remote sensing, indicate the area to be imaged, the spatial resolution needed and the degree of overpass
- Describe any field equipment cleaning procedures used to prevent cross-contamination, and how they will be verified

## 10.3 Field Quality Control (QC) (B5)

Identify the field QC activities that will be conducted along with their frequency. Field and laboratory QC activities are designed to confirm and document that the actual measurement process is achieving its specified level of quality (the acceptance criteria). Each QC activity addresses one of the data quality indicators specified above, (i.e., precision, bias). Describe which data quality indicator each addresses, the acceptance criteria for each of the QC activities (i.e.,  $RPD \leq 20\%$  ), and the corrective actions to be taken if the defined acceptance criteria are not met. Be sure to include all of your potential QC checks for each type of sample, each matrix, each method and each analyte, as appropriate, including, for example, the following: Equipment Blanks, Field Blanks, Trip Blanks, Cooler Temperature, Field Duplicate Pairs, Collocated Samples, Field Splits, Field Matrix Spikes.

Much of this information can be summarized in tabular form as suggested below.

Analyte(s)	DQI	Field QC Check	Frequency of Collection	Acceptance Criteria	Corrective Action(s)

## 11.0 Analytical Requirements

In this section identify the analytical methods to be used along with the analytical QC activities.

### 11.1 Analytical Methods (B4)

Identify the analytical methods to be used. This would include the use of any field instruments to analyze samples. Fully specify all selected options and describe any deviations from published and/or required methodology, along with the procedures for and/or results of validation of the modified method. Unless the complete method descriptions, with all specified options, are readily available, attach them to the QAPP.

The methods and instruments to be used must be capable of measuring each analyte at the desired detection level. Different methods have different levels of accuracy and certain methodologies may be required by program regulations. If the project requires analytical performance criteria which are different from those specified in the analytical method, this must be highlighted. In addition, the laboratory must be able to quantify results at a level appropriate for the project.

Much of this information can be summarized in tabular form as suggested below.

Analyte	Sample Matrix	Project Action Level	Analytical Method	Method Detection Limit	Laboratory Reporting Limit

### 11.2 Analytical Quality Control (B5)

Identify all required laboratory QC checks, their required frequency, the established control limits and the actions to be taken if the control limits are exceeded. Be sure to include all of your potential QC checks for each type of sample, each matrix, each method, and each analyte, as appropriate, including, for example, the following: Method Blank, Reagent Blank, Storage Blank, Instrument Blank, Lab. Duplicate, Lab. Matrix Spike, Matrix Spike Dup., Lab. Control Sample, Surrogates, and Internal Standards.

Much of this information can be summarized, for each analytical method, in tabular form as suggested below.

Method/SOP	DQI	Lab QC Check	Frequency	Acceptance Criteria	Corrective Action

## 12.0 Sample Handling and Custody Requirements (B3)

Describe the logistics of sample handling from point of collection through disposal. Include a discussion of holding times, preservation requirements, (including temperature requirements), sample tracking and management procedures, and any chain-of-custody requirements. State any special handling requirements. (For in-situ or remote sensing, the procedures for handling the measurement records should be discussed.) Attach any forms to be used, such as sample identification labels and custody forms. Identify what sample containers will be used, where they will be obtained and any special cleaning procedures. State requirements for sample archiving and disposal. Some of this information can be presented in tabular form, as suggested below. Identify and include all field QC samples in the total number of samples.

Sample Matrix	Analyte(s)/ Parameter(s)	Total # Samples	Sample Volume	Type Container	Sample Preservation	Maximum Allowable Holding Time

## 13.0 Testing, Inspection, Maintenance and Calibration Requirements

### 13.1 Instrument/Equipment Testing, Inspection and Maintenance (B6)

- List the equipment (field, laboratory and data management) that will require periodic maintenance, testing or inspection and provide the schedule for these activities.
- Describe how these activities will be performed and documented.
- Identify any critical parts and how spares will be supplied and stocked.
- If appropriate, simply reference existing SOPs which contain this information.
- Discuss the documentation and maintenance of the testing, maintenance and inspection records.

### 13.2 Instrument/Equipment Calibration and Frequency (B7)

- List the equipment that will require calibration.
- Describe the calibration or test methods, (may reference SOP), and any certified equipment or standards used in the calibration process.
- Describe required equipment maintenance, including frequency.
- Discuss the documentation and maintenance of the calibration records. (Note: This documentation must be traceable to the equipment being used and should include make, model and serial number of equipment, and lot number of any standards.)

### 13.3 Inspection/Acceptance of Supplies and Consumables (B8)

List any critical supplies or consumables, (i.e., pre-cleaned containers, pre-preserved containers, tubing). Identify the acceptance criteria for such items, (i.e., certificates of cleanliness or testing), as appropriate.

## **14.0 Data Management (B10)**

Describe the data management processes used throughout the life of the project. This includes: recording and transcribing field notes; logging and retrieval of instrument data; transmittal of automated field and laboratory results; data transformation and reduction procedures; and data storage, retrieval and security issues throughout the project. Describe the way data handling errors will be controlled, (i.e., spot checks for transcription or calculation errors).

## **15.0 Assessments/Oversight (C1)**

Assessments include various reviews and audits conducted by independent individuals and/or organizations or self assessments, designed to ensure that the QAPP will be followed throughout the project, to identify shortcomings or deviations, and to initiate corrective actions. If performing self assessments, a checklist may be a helpful tool for conducting the assessments. Assessments may also include participation in proficiency testing programs and performance evaluations of models used. Assessments are best when conducted early on in the project or throughout the entire project to identify problems early enough to allow time for corrective actions.

In this section list the reviews or audits of project management, field, laboratory, and data activities that will occur throughout the project. This might include readiness reviews, performance evaluations, technical system audits, management system audits, data quality audits, Peer Involvement, or Peer Review.

- Identify who will perform these assessments, their relationship to the project organization, and the frequency of the proposed assessments.
- Discuss how and to whom the results of assessment will be reported.
- Identify how response (or corrective) actions will be addressed and documented.

## **16.0 Data Review, Verification, Validation and Usability**

The goal of this section is to develop and document procedures for determining whether the results of the project may be used for the intended purpose. Data review, verification and validation are important steps in a project as they apply to both field and lab activities. To accomplish this, all aspects of the project (e.g. field monitoring activities and laboratory analyses) need to be examined to determine if any problems were encountered that might jeopardize the usability of the data. This examination can include both a qualitative review of field documentation as well as a quantitative review of QC results. This section of the QAPP will address various data assessment issues performed by samplers, laboratory and independent reviewers. It should list the criteria for accepting, rejecting or qualifying data.

### 16.1 Data Review, Verification, and Validation (D1 and D2)

Describe the process used to **review** the field and analytical data. Discuss what will be done, who will do it and how it will be done. Data review should include checks such as the following:

<b>Field</b>	<b>Lab</b>
Monitoring performed per SOPs or QAPP	Data entry and transcription errors
Samples properly preserved in the field	Calculation/reduction errors
Field QC samples collected	Holding time limits met
Chain of custody maintained	Lab QC samples analyzed
Deviations from QAPP/SOPs documented	Deviations from QAPP/SOPs documented
	Proper sample storage
	Missing samples documented

Describe the process and criteria used to **verify** the data. This involves evaluating the data according to pre-determined general specifications in a method, procedure or contract specification. Provide examples of any checklists to be used. Data verification is usually done internally by those generating the data, (sampler and laboratory). Data verification should include, for example:

- Comparing field and/or analytical QC results to SOPs or method criteria
- Checking dilution factors
- Checking for the use of appropriate reporting units, (i.e., wet wt. vs. dry wt.)

Finally, discuss the data **validation** process. Data validation is usually performed by someone external to the data generation. This may be the QA Officer of the laboratory. Here you will evaluate whether or not the data met the quality objectives for the project. You will use the results of the previous steps to help identify data groups for which the QAPP requirements might not have been satisfied.

- Discuss calculations that will be performed on the raw data to achieve the final results.
- Describe how errors, if detected, will be corrected.
- Describe how blanks, duplicates, spikes, etc., will be treated in all calculations.
- Discuss how any limitations on the data will be reported to the data users.

## 16.2 Reconciliation with User Requirements (D3)

Discuss how the results obtained from the project (the validated data) will be reconciled with the requirements defined by the user. This process of determining the utility of data sets is known as data quality assessment, and may involve statistical evaluation (tests for outliers, trends, etc.) or may be based on a scientific evaluation. A statistical analysis will result in quantitative statements about the quality of the data, while a scientific analysis will result in only qualitative statements. The question is whether any data quality problems are so serious that the data should not be used, or whether you can use the data even if some validations failed; the QAPP needs to describe the process that will answer it.

It is important to remember that this reconciliation process:

- includes consideration of both field and laboratory issues,
- focuses on the results of the review, verification, and validation
- looks at the data quality actually achieved, and
- takes into account any problems and/or issues encountered during the process.

There may also be issues affecting data usability when all of the data “pass” verification and validation. For example, if an important step in your project is to calculate an average concentration of a trace contaminant in a stream, but many of the samples contained concentrations below the detection limits, the average cannot be calculated accurately. The usability assessment would need to address what to do.

You may wish to consult the EPA document “Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8, EPA/240/R-02/004,” to assist in this section. Also, please note that if the DQO process was used to develop DQOs, the Data Quality Assessment (DQA) process should be used to evaluate how well the validated data can support their intended use. See EPA’s “Guidance for Data Quality Assessment: Practical Methods for Data Analysis, EPA G-9, QA00 Version, EPA/600/R-96/084, July 2000” for a complete description of the 5-step DQA process.

When all of the QC criteria were satisfied and no problems were encountered in the field or the lab, the data quality assessment can be straightforward. However, problems do arise, making the final assessment more complicated. The table below lists some typical data verification and validation issues in the left column, along with their potential implications for data usability on the right. You may find these examples helpful when thinking about data quality assessment issues for your project.

<b>Examples of Reconciling Data Quality Problems with Data Quality Goals</b>	
<b>Typical Data Verification and Validation Problems</b>	<b>Resulting Data Usability Assessment Issues</b>
Matrix spike/matrix spike duplicate recoveries are below the acceptance criteria; there were unexpected matrix interferences.	Even with the low recoveries, did the data reveal enough information to be useful for decision-making?
Precision and bias criteria were not achieved. Initial calibration criteria (response factors, correlation coefficient) may not have been appropriate for these analytes.	Were the acceptance criteria in the QAPP unnecessarily restrictive?
Some maximum allowable holding times have been exceeded. Thus, the results are either biased low or invalid.	Are the measured concentrations sufficiently above the action limits that the potential bias is not significant? The same question may even apply if the results are sufficiently low, as long as the detection limit is not an issue.
Because sample concentrations were higher than expected, the spike levels were not comparable with the unspiked concentrations, making the results essentially meaningless.	Are measured concentrations so far above the action limits that the low spike recoveries do not adversely affect the ability to confirm that the limits are exceeded?
Conditions in the field required that the sampling procedures be changed significantly.	Can we find evidence to support the contention that the samples are still sufficiently representative?

## 17.0 Reporting, Documents and Records (A9 and C2)

Describe the process used to manage project documents and records. This may include the use of a document control notation system such as that provided below.

Project # or Name	_____
Revision No.	_____
Date	_____
Page	_____ of _____

Identify where project data will be located, in what form (include paper, electronic, and database locations, as appropriate), how they can be retrieved at a later date, and the length of time they must be retained (e.g., kept in the project files for 1 year and then sent to the Federal Record Center for 7 years).

Specify the frequency of all reports, the names of the originators and to whom they will be issued. Itemize what information and records must be included in the report(s). This might include the following:

- Sample collection and handling records
- Analytical logbooks
- QC sample records
- Equipment calibration records
- Assessment reports
- Data reconciliation results and associated recommendations