Guide for Development and Approval of Quality Assurance Project Plans (QAPPs)

New England Interstate Water Pollution Control Commission
(NEIWPCC)

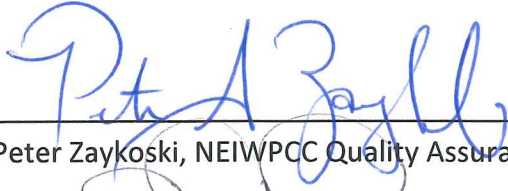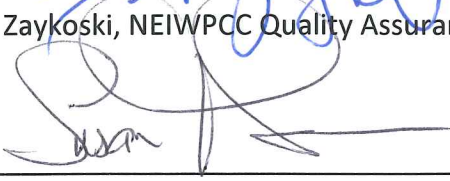September 2019

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FOREWORD

The New England Interstate Water Pollution Control Commission (NEIWPCC) serves as a community of problem solvers advancing clean water in the Northeast, in service to our states: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont. In carrying out its mission, NEIWPCC relies upon many different types of environmental information and data that enable it to better evaluate and measure existing environmental conditions, identify and understand areas of concern, and enhance credible communication on environmental issues to a wide variety of audiences. The NEIWPCC Quality Management System is the mechanism that ensures that information and data collected by or for NEIWPCC is appropriate, credible and defensible.

The NEIWPCC Quality Management Plan (QMP) – initially approved by EPA in November 2001 and periodically revised– describes the organization's Quality Management System and policies, as well as the roles and responsibilities of employees, contractors, and grantees as they relate to the Quality Management System.

When NEIWPCC receives or distributes funds for work involving the collection or evaluation of environmental data, such work must be carried out according to an appropriately reviewed and approved Quality Assurance Project Plan (QA Project Plan). A QA Project Plan is a formal document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the project performance criteria. The QA Project Plan must be fully approved before any data collection or evaluation activities begin.

This guide provides information describing the planning, development, and approval of QA Project Plans, under the NEIWPCC Quality Management System.

Projects requiring the preparation of a QA Project Plan have an additional level of planning and documentation that must be recognized and addressed with adequate resources. QA Project Plan preparation is intended to document the project planning and development process and to assure that data used and provided are of known and adequate quality. Before any efforts to develop a QA Project Plan have begun, it is highly recommended that those preparing the QA Project Plan contact the approving organizations to discuss the expectations for the project and the QA Project Plan.

Wherever possible throughout this guide, references to cited works are provided to allow the reader to obtain additional, detailed information. Users requiring further clarification or explanation of the NEIWPCC Quality Management System or the QA Project Plan planning, development, and approval process are encouraged to contact the NEIWPCC Quality Assurance Program Manager at the Lowell, Massachusetts, NEIWPCC office.

1. WHAT IS A QA PROJECT PLAN AND WHEN IS ONE NEEDED?

A QA Project Plan is a planning document that provides a "blueprint" for obtaining the type, quantity, and quality of data needed to support environmental decision making. More simply, a QA Project Plan is a written document describing the procedures that a project will use to ensure that the data or information collected and analyzed will meet project requirements. The QA Project Plan documents all quality assurance (QA), quality control (QC), and technical activities and procedures associated with planning, implementing, and assessing all environmental data operations.

The phrase "environmental data operation" refers to activities involving the collection, generation, compilation, management, analysis, evaluation, and/or use of environmental data. Environmental data can be generated from direct measurement activities (such as fish or bird surveys, water quality monitoring, or microbial source tracking), collected from other sources (such as previous studies, surveys, or evaluations), or compiled from computerized databases and information systems (such as state or federal databases or computer models).

The QA Project Plan also documents the results of a project's technical planning process and provides a clear, concise, and complete plan for the environmental data operation and its quality objectives. The plan also identifies key project personnel.

The QA Project Plan is used to communicate to all parties the specifications for implementation of the project design and to ensure that the quality objectives are achieved for the project. Alone, it does not guarantee success every time, but the potential for success is much greater if a QA Project Plan is developed and implemented.

All work involving the collection or use of environmental data, by or on behalf of NEIWPCC, must be done with an approved QA Project Plan. The QA Project Plan must be approved before any environmental data collection operation starts. Advance approval ensures that all of the planning steps, including connecting actions with needs, are completed. Clear documentation increases the likelihood that the project will achieve its intended result. It is important to note that if the QA Project Plan is not approved before work begins, a stop-work order may be issued and NEIWPCC will not pay for that work.

A properly planned, reviewed, and approved QA Project Plan will define and describe the following:
- The project's goals and objectives or questions and issues being investigated
- Specific roles of the various parties involved with the project
- Decision(s) to be made from the information obtained
- How, when, and where project information will be acquired or generated
- Possible problems that may arise and actions to be taken to mitigate their impact on the project
- The type, quantity, and quality of data specified
- How "good" those data have to be to support the decision to be made (tolerance for error)
- How the data will be analyzed, assessed, and reported

Since the content and level of detail in individual QA Project Plans will vary according to the work being performed and the intended use of the data, NEIWPCC supports a "graded approach" when preparing QA Project Plans. Using this approach, the degree of documentation and detail will vary based upon the complexity and cost of the project. Appropriate consideration will be given to the magnitude of the environmental problem to be investigated, the environmental decision to be made, and the impact on human health and the environment.

Specific elements that should be included in QA Project Plans are discussed further in Section 4 and a checklist that can be used to evaluate the contents of QA Project Plans is contained in Appendix A of this guide.

1.1. Unique Circumstances of Model Development and Application Projects

A model is a tool that creates predictions of future scenarios based on interpretations of dynamic processes and their impacts. While each modeling project is unique, most projects should involve a systematic planning process to determine modeling needs and project-specific requirements. From the planning process, decisions can be made as to whether a new model is to be developed (model development project) for situations where no existing models can be used to address the particular study objectives, or whether an existing or newly developed model can be applied (model application project).

A QA Project Plan is necessary for modeling projects even when no monitoring or other environmental data measurements are performed because modeling results frequently serve as a surrogate for these data, or are used for their interpretation. Additionally, planning for modeling projects is just as important as planning traditional environmental measurements for data collection projects. Because model outputs are frequently used in many applications, ranging from research to regulatory purposes, it is important to ensure that the model is scientifically sound, robust, and defensible.

The intended use of the model is a defining factor in the level of QA/QC needed, because it is an indication of the seriousness of the potential consequence or impacts that might occur due to quality-related problems. For example, models that provide initial "ballpark" estimates or non-regulatory priorities would not necessarily require the same level of quality assurance, quality control, and planning as models used to set regulatory requirements or support environmental management decisions.

For a more complete guide to QA Project Plan requirements for model development and application projects, EPA has a specific guidance document titled *Guidance for Quality Assurance Project Plans for Modeling EPA QA/G-5M* (EPA/240/R-02/007), which is available from the guidance section of the Office of Environmental Information's web page (www.epa.gov/quality). Additionally, a checklist used to evaluate the contents of QA Project Plans for modeling projects is contained in Appendix D of this guide.

1.2. Unique Circumstances of Secondary Data Projects

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. In other words, a secondary data project compiles already available environmental data and uses this information to answer new questions above and beyond the original purpose of the information. Secondary data may be obtained from many sources, including literature, previous studies or surveys, compilations from computerized databases and information systems (such as geospatial data or data from geographic information systems), and computerized or mathematical models of environmental processes. Secondary data projects also require systematic planning and QA Project Plans. If primary data (i.e., newly measured information) will also be generated as part of the project, then secondary data issues can be incorporated into the associated QA Project Plan.

For a more complete guide to QA Project Plan requirements for secondary data projects, EPA has a specific guidance document titled *Quality Assurance Project Plan Guidance For Environmental Projects Using Only Existing (Secondary) Data*, which is available from the guidance section of the Office of Environmental Information's web page (www.epa.gov/quality). This guidance document is contained in Appendix B of this guide.

2. ROLES AND RESPONSIBILITIES

The following section briefly describes the roles and responsibilities for QA Project Plan development and implementation, as they are outlined in the NEIWPCC Quality Management Plan. Additional information can be obtained by reviewing the NEIWPCC Quality Management Plan, which is available on the NEIWPCC QA website (www.neiwpcc.org/quality).

2.1. NEIWPCC's Role

EPA has designated those organizations performing work for or on behalf of EPA as Lead Organizations. This designation includes organizations performing work in response to voluntary, consensual, or unilateral enforcement agreements, decrees, and orders. Lead Organizations must develop, operate, and document their Quality Management System in a Quality Management Plan (QMP) to ensure the environmental data acquired are of known and documented quality and are suitable for their intended use.

NEIWPCC's QMP was initially approved in November 2001. It has been annually reviewed and periodically revised. At a minimum, the QMP is reauthorized every five years. Written within the QMP is the organization's commitment to provide procedures that ensure the highest level of quality assurance that is appropriate for the intended use of data collected by or for NEIWPCC. In addition, NEIWPCC views its commitment to quality assurance as extending beyond the context of EPA-funded projects. The NEIWPCC QMP applies the quality assurance-related policies, procedures, and obligations required for EPA-funded projects to all environmental data operations regardless of the source of project funds.

2.2. Role and Responsibility of the NEIWPCC Quality Assurance Program Manager

The NEIWPCC Quality Assurance Program Manager (QAPM) serves as the organization's designated QA/QC contact with EPA. The authority and responsibility for directing QA activities within NEIWPCC is delegated to the QAPM, who reports to the director of the Water Resource Protection division.

The following QAPM responsibilities are taken directly from the NEIWPCC QMP:

- The QAPM is responsible for and will oversee all aspects of QA activities and will keep upper level management and the appropriate EPA Quality Assurance Offices informed of QA needs, problems, and overall status.
- The QAPM will be the official point of contact for all QA matters and will coordinate for NEIWPCC with EPA and other state and federal agencies.
- The QAPM will be responsible for identifying and responding to QA needs, problems, and requests. The QAPM will provide technical QA assistance or obtain technical assistance from appropriate sources as necessary. This assistance will include help in preparing detailed QA plans, contracts or other extramural procurement packages needing QA, designing QA programs for new studies, etc.
- The QAPM will review and approve all Quality Assurance Project Plans (QAPPs) and QA related sections of all procurement packages.
- The QAPM will periodically assess a portion of ongoing environmental data operations projects to verify QAPP adherence. These assessments are implemented utilizing project-specific funds.
- The QAPM will work with the project manager and other NEIWPCC management to take appropriate corrective action when, where and however needed. This includes providing additional resources needed to correct a deficiency as determined by the QAPM.

The authority to review and approve QAPPs can be delegated to a QA designee. The QA designee would follow the NEIWPCC SOP for QAPP review and approval; available at www.neiwpcc.org/quality.

2.3. Role and Responsibilities of NEIWPCC Project Managers and Technical Staff

Each NEIWPCC employee is responsible for planning the work he or she conducts, documenting all work, and ensuring the quality of work completed meets or exceeds the quality objectives of the activity or project.

The following project manager and technical staff responsibilities are taken directly from the NEIWPCC QMP:

- Project managers will act as the Project QA Officer and coordinate with the QAPM on QA requirements to satisfy the data quality needs of the project. The project manager is responsible for ensuring that field personnel are adequately briefed on the QAPP and making periodic checks for compliance with the QA requirements.

- Project managers are responsible for ensuring that appropriate QA requirements and resources are included in all applicable projects.
- Project managers will be responsible for maintaining documentation for all QA plans and communications pertaining to QAPP approval.
- Project managers are responsible to assure all environmental data gathered or generated for their project is sufficiently reviewed and/or validated to assure its usefulness for the project, and that it meets the data quality objective stated in the QA project plan.
- Technical staff will coordinate and review QA requirements with the appropriate project managers to ensure that all environmental data utilized meets the needs of the project.

2.4. Role and Responsibilities of NEIWPCC Contractors or Grantees

NEIWPCC procures commodities and services for environmental data collection operations through a variety of mechanisms (e.g., purchase orders, contracts, Memorandums of Agreement/Understanding, etc.). These procurements can range from small watershed grants for volunteer monitoring groups to agreements or contracts with technical firms or commercial laboratories and may include state or federal government organizations (such as a state environmental laboratory or the U.S. Geological Survey). In all examples, the procurement of items and services must be controlled and documented to assure conformance with specified quality management requirements. These requirements will be included or referenced in procurement documents.

NEIWPCC has adopted standard contract language that documents the requirement to develop an appropriately approved QA Project Plan if environmental data or information are to be compiled or collected as part of any particular project. The QA Project Plan can be developed by the contractor or grantee in consultation with NEIWPCC technical and QA staff, or it can be developed by the NEIWPCC project manager in consultation with the grantee or contractor. However, it is critical for any project that environmental data operations do not begin until the QA Project Plan is fully approved and distributed to all parties involved with the project.

NEIWPCC project managers will coordinate to establish the data needs, data expectations, data quality objectives, and acceptance criteria and will discuss them with all contractors or grantees that collect environmental data for NEIWPCC.

2.5. Role and Responsibilities of Other Approving Agencies

NEIWPCC has not been delegated the authority to provide final approval for QA Project Plans prepared for work funded by EPA. As a result, QA Project Plans prepared for EPA-funded projects must be reviewed and approved by the EPA Project Officer and the Regional Quality Assurance Office. Often, the source of funding for projects involving environmental data operations will dictate other parties that must review and approve QA Project Plans. For example, projects funded with member-state funds may require the approval of member-state quality assurance offices. Specific approval processes will differ for individual projects based on the source of funds.

Each layer of approval requires a certain period of time for QA Project Plan review and modification. As the approval process becomes more complex, additional time will be required before data collection activities can commence**. For this reason, it is highly recommended that project managers who must prepare a QA Project Plan contact all of the approving organizations prior to initiating any effort to develop the plan, in order to discuss the expectations for the project and the QA Project Plan.**

3. QA PROJECT PLAN DEVELOPMENT

Systematic planning is the process in which the project manager or technical advisory committee for a particular project identifies the problem or issue to be investigated or the decision to be made. Through this planning process the project manager then defines the project's objectives, the type, quantity and quality of information needed, the technical and quality control activities, the project's tolerance for errors, and the level of oversight that will ensure project criteria are satisfied. Systematic project planning is a critical step in QA Project Plan development and the overall success of any environmental data operation project.

Done correctly, up-front planning can quickly eliminate approaches or methods that do not work well (or do not work at all). A well-developed QA Project Plan can reduce the cost of lost time and rework. Implementation of projects developed through a systematic planning process and documented in a QA Project Plan, with appropriate QC practices employed, should increase efficiency and provide for early detection of problems, either in the field or in the laboratory. This approach has the potential to save time and money by eliminating the possibility of having to redo substandard work and enabling decisions to be made more expeditiously.

Project planning necessitates the coordinated efforts of many individuals, such as those who will generate information and those who will use the information or make decisions based on it. These individuals can include decision makers, project managers, regulators, stakeholders, modelers, risk assessors, and technical staff (for example, hydrologists, chemists, data validators, samplers, and statisticians). In addition, peer reviewers and individuals with specific expertise ensure that technical areas are sufficiently addressed, thus helping to minimize problems during implementation.

A QA Project Plan is prepared either as part of or after the project planning process. **In all cases, the QA Project Plan must be completed and approved before data collection begins.**

The following is a brief summary of the process utilized to develop and implement a QA Project Plan:
1. Find out what needs to be done, based on what is known about the site or situation (i.e., the environmental decision to be made or study question to be answered).
2. Determine data collection needs, based on what is already known about the site, river, watershed, etc.
3. Assemble a project team with the necessary expertise.
4. Plan what can be done, or what will be done, to obtain data of known quality that will support the decisions to be made or the study questions to be answered.

5. Coordinate with the appropriate parties that will ultimately approve the QA Project Plan.
6. Draft the QA Project Plan.
7. Submit the QA Project Plan for peer review, input, and approval, revising it as needed. Once finalized, obtain all necessary approval signatures.
8. Distribute the approved QA Project Plan to all individuals involved with the project.
9. Begin work while implementing the plan, but remember to:
   - Document any changes in the QA Project Plan.
   - Get re-approval before initiating the change.
   - Distribute the updated version.
10. For multi-year projects, review the project and the QA Project Plan annually and revise as necessary.

4. REQUIRED QA PROJECT PLAN ELEMENTS

As previously stated, the QA Project Plan is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QA Project Plan must provide sufficient detail to demonstrate that:
   - The project technical and quality objectives are identified and agreed upon.
   - The intended measurements, data generation, or data acquisition methods are appropriate for achieving project objectives.
   - Assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained.
   - Any limitations on the use of the data can be identified and documented.

A QA Project Plan should have enough information to describe project objectives and details. The number of pages needed to address this information will vary with the complexity of the project and intended use of the information. A plan for some environmental data operations may include a qualitative discussion of the experimental process and its objectives, while a plan that describes a complex environmental project may need extensive documentation to adequately describe activities.

Referring to existing documents can reduce QA Project Plan preparation, length, and review time. Any relevant documents prepared before the QA Project Plan, such as standard operating procedures (SOPs), sampling and analysis plans (SAPs), work plans, environmental site assessments, literature files, and data sets from other projects, may be appended. Alternatively, they may be incorporated by reference, if those sources are readily available to both reviewers and project personnel who will implement the QA Project Plan.

In all situations, QA Project Plans will vary in their level of complexity, based both on the nature of the work being performed (such as the collection of new data or the use of previously collected information), available resources, and the intended use of the data.

The review process works best when the QA Project Plan is composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. These elements are generally subdivided into four categories as follows.[1]

A. Project Management - The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to use, and that the planning outputs are documented.

QA Project Plan items included in project management are:
- Title and Approval Sheet
- Table of Contents
- Distribution List
- Project/Task Organization
- Problem Definition/Background
- Project/Task Description
- Quality Objectives and Criteria
- Special Training/Certification
- Documents and Records

B. Data Generation and Acquisition - The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.

QA Project Plan items included in Data Generation and Acquisition are:
- Sampling Process Design (Experimental Design)
- Sampling Methods
- Sample Handling and Custody
- Analytical Methods
- Quality Control
- Instrument/Equipment Testing, Calibration, and Maintenance
- Instrument/Equipment Calibration and Frequency

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[1] Elaborate descriptions of all of the sub-elements for each of the four listed categories are available in the following documents: *EPA Requirements for Quality Assurance Project Plans EPA/QA R-5* (EPA/240/B-01/003), March 2001, and *Guidance for Quality Assurance Project Plans EPA/QA G-5* ((EPA/240/R-02/009), December 2002. Both documents are available for download from the website of EPA's Office of Environmental Information (www.epa.gov/quality). There is also a checklist contained in Appendix A of this guide detailing these elements and sub-elements.

- Inspection/Acceptance of Supplies and Consumables
- Non-Direct Measurement
- Data Management

C. Assessment and Oversight - The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.

QA Project Plan items included in Assessment and Oversight are:
- Assessment and Response Actions
- Reports to Management

All QA project plans developed for projects involving NEIWPCC must contain the following language in the Assessment and Oversight section of the plan: "NEIWPCC may implement, at its discretion, various audits or reviews of this project to assess conformance and compliance to the Quality Assurance Project Plan in accordance with the NEIWPCC Quality Management Plan. NEIWPCC may issue a stop work order and require corrective action(s) if nonconformance or noncompliance to the Quality Assurance Project Plan is found."

D. Data Validation and Usability - The elements in this group address the QA activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

QA Project Plan items included in Data Validation and Usability are:
- Data Review, Verification, and Validation[2]
- Verification and Validation Methods
- Reconciliation with User Requirements

Following the principle of the graded approach, if any of the elements listed above in section A. Project Management through D. Data Validation and Usability are not applicable, it is important to indicate why they are not relevant.

5. QA PROJECT PLAN REVIEW AND APPROVAL PROCESS

As has been stated earlier, for projects that involve data collection, it is essential that a QA Project Plan be approved before data collection activities begin. The particular route of the approval process will vary depending on the source of funds for the individual project. **It is strongly recommended that NEIWPCC**

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[2] An elaborate description of the data validation and verification process is available in: *EPA Guidance on Environmental Data Verification and Data Validation QA/G-8* (EPA/240/R-02/004), November 2002. This document is available for download from the website of EPA's Office of Environmental Information (www.epa.gov/quality).

project managers contact the NEIWPCC Quality Assurance Program Manager (QAPM) to discuss the QA Project plan approval process for their project well in advance of planned data collection activities and before drafting a QA Project Plan. Coordination with any other organizations or individuals who might be involved in the approval process and expectations on the specific process are critical for an efficient review and approval process.

Once a draft QA Project Plan has been planned and prepared following the guidance in Chapters 2 and 3 of this document, and after confirming it contains all of the pertinent elements listed in Chapter 4, it is ready to be submitted for review and approval.

The QA Project Plan review facilitates the following:
- Ensures that the information is accurate and complete
- Ensures that all appropriate elements are included
- Ensures that the plan identifies the project's technical and quality objectives, and that the intended measurement and data acquisition methods will satisfy these objectives
- Confirms that the planned assessment procedures will be adequate to evaluate the project
- Confirms that there is a process to identify any limitations on the use of the data

NEIWPCC has developed a stand-alone Standard Operating Procedure, titled Review and Approval Process for NEIWPCC Quality Assurance Project Plans (QAPPs) (available at: www.neiwpcc.org/quality)**. NEIWPCC project managers should review this SOP in advance of submitting any QAPP for review and should follow the SOP during the QAPP review and approval process.**

5.1. Review and Approval Process Overview
The process for review and approval of all NEIWPCC QAPPs consists of nine steps in three phases:

    Phase 1: Preparation and Initialization
- Step 1. Project Manager Review for Completeness
- Step 2. Initial Submission of Draft QAPP
- Step 3. Receipt of Draft QAPP

    Phase 2: Review and Revision
- Step 4. QAPP Review Assignment
- Step 5. Reviewing Draft QAPP
- Step 6. Draft QAPP Revision
- Step 7. QAPP Revision Review

    Phase 3: Finalization and Filing
- Step 8. Finalization of QAPP
- Step 9. Electronically Filing the QAPP

All QAPP review and approval processes share the same detailed process instructions for phases one and three; the specific process for phase two is dependent on the funding source of the project. Each

step in the process is detailed in the review and approval SOP, including specific guidance for projects needing EPA Region 1 and/or Region 2 approval and those funded by other organizations.

Critical aspects of the process for NEIWPCC project managers are summarized below. A rough estimate of the amount of time that should be anticipated at each step in the approval process is contained in Appendix E of this guide.

Phase 1: Preparation and Initialization
The first step in the review and approval process for any draft QA Project Plan – regardless of funding source – is a completeness check by the NEIWPCC project manager utilizing the appropriate review checklist (available at: www.neiwpcc.org/quality and provided in Appendices A, C, and D).

After the completeness check, the project manager submits the draft QAPP to the receiver (submissions should be made to qapps@neiwpcc.org) to initiate the review process, along with a completed QAPP Submission Form (fillable forms available at: www.neiwpcc.org/quality).

Phase 2: Review and Revision
The specific organizations and individuals involved in the review process and the sequence of review will vary by project. For example, the key difference between review processes involving EPA Region 1 and Region 2 is in the order of review: the Region 1 review process occurs concurrently with NEIWPCC review, while Region 2 review occurs subsequent to NEIWPCC review. If approval of both EPA Region 1 and Region 2 is required, the concurrent NEIWPCC and EPA Region 1 review should occur before Region 2 review is initiated. It should be noted that the particular individuals chosen to review the draft QA Project Plan will vary depending on which EPA region provided the funding or if the grant came from EPA's national headquarters.

It is also possible that state environmental agency staff will be involved in the review and approval process, depending on the complexity of the project and origin of funding. For instance if a project is funded solely with state money directed to NEIWPCC via contract, it is possible that EPA personnel would not be involved in reviewing and approving the QA Project Plan, and state QA and project staff would complete the final review and approval. This illustrates why pre-planning and coordination is essential to ensure a smooth and efficient review and approval process.

However the process is sequenced, at some point all reviewers will provide comments to the NEIWPCC project manager once they have completed their initial review. For example, the NEIWPCC QAPM, or designee, will prepare a memo will noting any deficiencies that need to be addressed or any supplemental information that needs to be incorporated into the draft plan. The project manager is responsible for coordinating with the individual(s) who prepared the QA Project Plan to ensure that appropriate revisions are made to the draft that address all reviewers' comments. The QA Project Plan is ready for signature once all reviewers have indicated that it has been adequately revised.

Phase 3: Finalization and Filing

When all applicable parties have signed the approval page, the fully-approved QA Project Plan should be circulated to the distribution list by the individual who is responsible for maintaining the plan. All personnel involved in the project should retain or have access to the complete, current version of the QA Project Plan. This may include the project manager, laboratory manager, field team leader, modeler, data reviewers, and any essential contractors and subcontractors involved with the project.

5.2. Annual Review of Approved QA Project Plans

For multi-year projects, approved QA Project Plans must be reviewed annually, and this annual review should be documented in a letter to all organizations that approved the initial plan. The NEIWPCC project manager is responsible for ensuring that projects are reviewed every year. Multi-year projects that are not annually reviewed are technically out of compliance with the NEIWPCC QMP. These reviews should be conducted in consultation with the appropriate approval authorities when determining if revisions are required.

If minor revisions need to be made to the approved QA Project Plan and they do not impact data quality, then these minor revisions can be documented in either a letter that outlines the revisions or in a revised QA Project Plan. If revisions are made that do impact data quality, re-approval is required and the revisions should be documented in a letter that accompanies the revised QA Project Plan. The revised QA Project Plan must be submitted for re-approval. If extensive minor revisions are necessary (i.e., greater than 10 pages affected and/or multiple impacts on data quality) re-approval is also required and a revised QA Project Plan must be submitted for review and re-approval.

5.3. Modification and Revision Procedures

If procedures and/or activities described in an original QA Project Plan must be modified immediately to achieve project objectives, then the plan must be amended. This amendment must be reviewed and approved in the same manner as the original QA Project Plan. The amendment should contain complete identifying information, as presented on the original Title and Approval Page, with updated signatures and dates. Only after the amendment has been approved can the change be implemented.

6. RESOURCES

6.1. NEIWPCC QA Program

As has been repeatedly emphasized, it is strongly recommended that those preparing QA Project Plans contact the NEIWPCC Quality Assurance Program Manager (QAPM) to discuss the approval process for their particular project well in advance of planned data collection activities and before drafting a QA Project Plan. The NEIWPCC QAPM may be able to provide examples of approved QA Project Plans for projects of similar design.

In addition, NEIWPCC has a web site devoted to quality management containing useful information. Information is available at: www.neiwpcc.org/quality

6.2. U.S. EPA – Office of Environmental Information

EPA's Office of Environmental Information is home to the agency's Quality Management System. All EPA quality assurance policies, guidance documents and requirements are available electronically from their website. There are also quality assurance training modules and conference proceedings available for download.

Information is available at: www.epa.gov/quality

7. REFERENCES

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Quality Assurance Project Plan Requirements for Secondary Data Research Projects. U.S. Environmental Protection Agency – Region 1. October 2009. Available at: https://www.epa.gov/quality/region-1-quality-systems-documents

APPENDIX A: QA PROJECT PLAN ELEMENTS / REVIEW CHECKLIST

(Extracted from EPA QA/G-5)

EPA R-5 Checklist for Review of Quality Assurance Project Plans

This checklist is an example of what could be used to either write or review a QA Project Plan, especially those involving field sampling and laboratory analyses. The items noted follow those elements found in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a).

PROJECT TITLE: _____

Preparer: _____   **Date Submitted for Review:** _____
Reviewer: _____   **Date of Review:** _____

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

DOCUMENT CONTROL

Element	A	U	NI	NA	Comments
Document control information is indicated in header of each QAPP page	☐	☐	☐	☐	
Project title is indicated	☐	☐	☐	☐	
QAPP version number and date are indicated	☐	☐	☐	☐	
Page number is indicated in "Page X of Y" format	☐	☐	☐	☐	

PROJECT MANAGEMENT

Element	A	U	NI	NA	Comments
A1. Title and Approval					
Contains project title	☐	☐	☐	☐	
Indicates revision number, if applicable	☐	☐	☐	☐	
Indicates EPA grant number	☐	☐	☐	☐	
Indicates organization(s)' name(s)	☐	☐	☐	☐	
Signature and date lines for organization(s)' project manager(s) present	☐	☐	☐	☐	
Signature and date lines for organization(s)' QA manager(s) present	☐	☐	☐	☐	
Other signatures, as needed	☐	☐	☐	☐	
A2. Table of Contents					
Lists QA Project Plan information sections and relevant page numbers	☐	☐	☐	☐	
Document control information indicated	☐	☐	☐	☐	
A3. Distribution List					
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
A4. Project/Task Organization					
Identifies key individuals involved in all major aspects of the project, including contractors	☐	☐	☐	☐	
Discusses their responsibilities	☐	☐	☐	☐	
Project QA Manager position indicates independence from unit generating data	☐	☐	☐	☐	
Identifies individual responsible for maintaining the official, approved QA Project Plan	☐	☐	☐	☐	
Organizational chart shows lines of authority and reporting responsibilities	☐	☐	☐	☐	
A5. Problem Definition/Background					
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained	☐	☐	☐	☐	
Clearly explains the reason (site background or historical context) for initiating this project	☐	☐	☐	☐	
Identifies regulatory information, applicable criteria, action limits, etc., necessary to the project	☐	☐	☐	☐	
A6. Project/Task Description					
Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals	☐	☐	☐	☐	
Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments	☐	☐	☐	☐	
Indicates QAPP end date	☐	☐	☐	☐	
Details geographical locations to be studied, including maps where possible	☐	☐	☐	☐	
Discusses resource and time constraints, if applicable	☐	☐	☐	☐	
A7. Quality Objectives and Criteria					
Identifies performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, including project action limits and laboratory detection limits and range of anticipated concentrations of each parameter of interest	☐	☐	☐	☐	
Discusses precision	☐	☐	☐	☐	
Addresses bias	☐	☐	☐	☐	
Discusses representativeness	☐	☐	☐	☐	
Identifies the need for completeness	☐	☐	☐	☐	
Describes the need for comparability	☐	☐	☐	☐	
Discusses desired method sensitivity	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
A8. Special Training/Certifications					
Identifies any project personnel specialized training or certifications	☐	☐	☐	☐	
Discusses how this training will be provided	☐	☐	☐	☐	
Indicates personnel responsible for assuring these are satisfied	☐	☐	☐	☐	
Identifies where this information is documented	☐	☐	☐	☐	
A9. Documentation and Records					
Identifies report format and summarizes all data report package information	☐	☐	☐	☐	
Lists all other project documents, records, and electronic files that will be produced	☐	☐	☐	☐	
Identifies where project information should be kept and for how long	☐	☐	☐	☐	
Discusses back up plans for records stored electronically	☐	☐	☐	☐	
States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individuals responsible for this	☐	☐	☐	☐	

DATA GENERATION and ACQUISITION

Element	A	U	NI	NA	Comments
B1. Sampling Process Designing (Experimental Design)					
Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample	☐	☐	☐	☐	
Details the type and total number of sample types/matrix or test runs/trials expected and needed	☐	☐	☐	☐	
Indicates where samples should be taken, how sites will be identified/located	☐	☐	☐	☐	
Discusses what to do if sampling sites become inaccessible	☐	☐	☐	☐	
Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.	☐	☐	☐	☐	
Specifies what information is critical and what is for informational purposes only	☐	☐	☐	☐	
Identifies sources of variability and how this variability should be reconciled with project information	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
B2. Sampling Methods					
Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken	☐	☐	☐	☐	
Indicates how each sample/matrix type should be collected	☐	☐	☐	☐	
If *in situ* monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data	☐	☐	☐	☐	
If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages	☐	☐	☐	☐	
Indicates how samples are to be homogenized, composited, split, or filtered, if needed	☐	☐	☐	☐	
Indicates what sample containers and sample volumes should be used	☐	☐	☐	☐	
Identifies whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of	☐	☐	☐	☐	
Identifies any equipment and support facilities needed	☐	☐	☐	☐	
Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented	☐	☐	☐	☐	
B3. Sample Handling and Custody					
States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for *in situ* or continuous monitoring, the maximum time before retrieval of information	☐	☐	☐	☐	
Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)	☐	☐	☐	☐	
Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible	☐	☐	☐	☐	
Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan	☐	☐	☐	☐	
Identifies chain-of-custody procedures and includes form to track custody	☐	☐	☐	☐	

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Element	A	U	NI	NA	Comments
B4. Analytical Methods					
Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures	☐	☐	☐	☐	
Identifies equipment or instrumentation needed	☐	☐	☐	☐	
Specifies any specific method performance criteria	☐	☐	☐	☐	
Identifies procedures to follow when failures occur, identifying individual responsible for correct action and appropriate documentation	☐	☐	☐	☐	
Identifies sample disposal procedures	☐	☐	☐	☐	
Specifies laboratory turnaround times needed	☐	☐	☐	☐	
Provides method validation information and SOPs for nonstandard methods	☐	☐	☐	☐	
B5. Quality Control					
For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency	☐	☐	☐	☐	
Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented	☐	☐	☐	☐	
Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data	☐	☐	☐	☐	
B6. Instrument/Equipment Testing, Inspection and Maintenance					
Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this	☐	☐	☐	☐	
Identifies testing criteria	☐	☐	☐	☐	
Notes availability and location of spare parts	☐	☐	☐	☐	
Indicates procedures in place for inspecting equipment before usage	☐	☐	☐	☐	
Identifies individual(s) responsible for testing, inspection and maintenance	☐	☐	☐	☐	
Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of correct action determined and documented	☐	☐	☐	☐	
B7. Instrument/Equipment Calibration and Frequency					
Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration	☐	☐	☐	☐	

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Element	A	U	NI	NA	Comments
Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment	☐	☐	☐	☐	
Identifies how deficiencies should be resolved and documented	☐	☐	☐	☐	

Element	A	U	NI	NA	Comments
B8. Inspection/Acceptance for Supplies and Consumables					
Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials	☐	☐	☐	☐	
Identifies the individual(s) responsible for this	☐	☐	☐	☐	
B9. Non-Direct Measurements					
Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used	☐	☐	☐	☐	
Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project	☐	☐	☐	☐	
Indicates the acceptance criteria for these data sources and/or models	☐	☐	☐	☐	
Identifies key resources/support facilities needed	☐	☐	☐	☐	
Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing	☐	☐	☐	☐	
B10. Data Management					
Describes data management scheme from field to final use and storage	☐	☐	☐	☐	
Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs	☐	☐	☐	☐	
Identifies data handling equipment/procedures that should be used to process, compile, analyze and transmit data reliably and accurately	☐	☐	☐	☐	
Identifies individual(s) responsible for this	☐	☐	☐	☐	
Describes the process for data archival and retrieval	☐	☐	☐	☐	
Describes procedures to demonstrate acceptability of hardware and software configurations	☐	☐	☐	☐	
Attaches checklists and forms that should be used	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

ASSESSMENT and OVERSIGHT

Element	A	U	NI	NA	Comments
C1. Assessments and Response Actions					
Lists the number, frequency and type of assessment activities that should be conducted, with the approximate dates	☐	☐	☐	☐	
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders and any other possible participants in the assessment process	☐	☐	☐	☐	
Describes how and to whom assessment information should be reported	☐	☐	☐	☐	
Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented	☐	☐	☐	☐	
Includes standard NEIWPCC assessment language: "NEIWPCC may implement, at its discretion, various audits or reviews of this project to assess conformance and compliance to the Quality Assurance Project Plan in accordance with the NEIWPCC Quality Management Plan. NEIWPCC may issue a stop work order and require corrective action(s) if nonconformance or noncompliance to the Quality Assurance Project Plan is found."	☐	☐	☐	☐	
C2. Reports to Management					
Identifies what project QA status reports are needed and how frequently	☐	☐	☐	☐	
Identifies who should write these reports and who should receive this information	☐	☐	☐	☐	

DATA VALIDATION AND USABILITY

Element	A	U	NI	NA	Comments
D1. Data Review, Verification and Validation					
Describes criteria that should be used for accepting, rejecting or qualifying project data	☐	☐	☐	☐	
D2. Verification and Validation Methods					
Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.	☐	☐	☐	☐	
Identifies issue resolution process, and method and individual responsible for conveying these results to data users	☐	☐	☐	☐	
Attaches checklists, forms and calculations	☐	☐	☐	☐	

D3. Reconciliation with User Requirements					
Describes procedures to evaluate the uncertainty of the validated data	☐	☐	☐	☐	
Describes how limitations on data use should be reported to the data users	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

APPENDIX B: EPA NEW ENGLAND SECONDARY DATA PROJECT QAPP GUIDANCE

EPA NEW ENGLAND

QUALITY ASSURANCE PROJECT PLAN GUIDANCE FOR

ENVIRONMENTAL PROJECTS USING ONLY

EXISTING (Secondary) DATA

U.S. EPA NEW ENGLAND

Quality Assurance Unit
Office of Environmental Measurement and Evaluation

Revision 2

Quality Assurance Project Plan Guidance
For Environmental Projects Using Only Existing (Secondary) Data

Purpose

EPA policy requires that <u>all</u> environmental data used by the Agency must be known and documented quality. This includes new data generated for a project <u>and</u> existing data that were previously collected for other projects. The purpose of this Guidance is to describe project information that should be included in a quality assurance plan for environmental projects based solely on existing data. Specifically, it describes a streamlined approach for planning and documenting projects that do not include sampling, testing or measurement determinations.

Using Existing (Secondary) Data in Environmental Projects

Environmental data projects typically involve planning, sampling, analysis, assessment and data review. In planning their investigations, project teams generally use existing data to develop sampling designs and to decide how much and what type of data to collect. The term existing data is used interchangeably with "secondary data" and "non-direct measurements." Existing data may come from a number of sources, including other studies, government databases, etc. The original purpose for collecting these secondary data may be very different from that of the current investigation. Also, these secondary data may have been collected using different sampling methods (composite vs. grab, random vs. hot spot sampling), and/or analytical methods than those selected for the current project.

Basing project decisions on existing data may result in errors if secondary data were not generated for the same purpose or using the same methods as the current investigation. Data could be biased and final conclusions could be impacted.

Therefore, before using secondary data, project team members should evaluate the data to identify any limitations on their use. Also, to ensure transparency in decision making, criteria and reasons for *including* and *excluding* certain data from use must be clearly documented. Failure to clearly document why data are included or excluded can result in the appearance of biased data selection and diminish the product's credibility.

Project personnel should describe the processes for selecting and for evaluating existing data in the quality assurance plan in accordance with ***EPA Requirements for Quality Assurance Project Plans*** QA/R-5 http://www.epa.gov/quality/qs-docs/r5-final.pdf .

For an in-depth discussion on when and how to use existing data in environmental projects, refer to EPA Guidance for Quality Assurance Project Plans QA/G-5 "Chapter 3: Projects Using Existing Data" http://www.epa.gov/quality/qs-docs/g5-final.pdf

Sources of secondary data include the following:
- Environmental indicator data obtained from federal/state/local databases and records
- Existing sampling and analytical data from a previous investigation of the area
- Computer model simulations and applications pertaining to other studies
- Historical data (e.g., from organization's/facility's corporate records and/or federal/state local records pertaining to previous monitoring events, site assessments, investigations, etc.)
- Background information/data from organization's/facility's corporate records and/or federal/state/local records pertaining to site-specific industrial processes, process by-products, past and current chemical uses, raw material and finished product testing, waste testing and disposal practices, and potential chemical breakdown products
- Data generated to verify innovative technologies and methods
- Data obtained from computer databases (such as manufacturers' process/product information, waste management or effluent information, and EPA or state data bases)
- Literature files/searches
- Publications
- Photographs
- Topographical maps
- Meteorological data

Projects Based Only on Existing Data

Although most environmental projects involve the generation of new data, projects based solely on the use of existing data are increasingly common. Re-purposing existing data saves time, resources and may resolve sampling access problems.

For projects using only existing data, EPA New England requires that ***Secondary Data Quality Assurance Project Plans*** **(QAPPs)** be developed and submitted to EPA for review and approval prior to the start of the project. For these projects, a QAPP should be prepared using a streamlined (graded) approach. For example, certain QAPP elements specific to sampling would not be applicable; therefore, certain standard QAPP sections could be omitted.

> **Note:** If secondary data will be used in the development, evaluation and/or application of

environmental models, then the project team should follow the template and checklist provided at the Region 1 web site http://epa.gov/ne/lab/qa/qamodeling.html

A graded approach to *Secondary Data QAPPs* would include the following QAPP elements:

1.0   PROJECT MANAGEMENT – ORGANIZATION AND RESPONSIBILITIES

1.1   **Title and Approval Page** (including signature dates). Include the following:
- EPA Project Officer and EPA QA Officer
- Project Officer and quality personnel from funded organization
- Other responsible project team members including contractors, consultants, voluntary organizations, etc.

1.2   **Table of Contents**

1.3   **QAPP Distribution List**. Include all personnel accountable for the outcome of the project; involved in gathering and evaluating secondary data; and project personnel who will ultimately use the project results. Include contact information.

1.4   **Project Organization.** Identify key project team members and their organizations. Include those responsible for selecting, compiling and evaluating existing data. Also identify those responsible for project planning, coordination, data analysis, report preparation, and quality assurance. Provide an organizational chart showing lines of communication.

Describe any specialized training or qualifications needed by team members to obtain and analyze existing data.

1.5   **Purpose of Study, Background Information, and Problem Definition.** Clearly state the reason for conducting the project. Discuss the desired outcome of the project in terms of decisions that can be made or actions that can be taken. Provide enough background information to put the project in programmatic context and to explain the environmental problem.

If this information is provided in another document (grant proposal, scope of work, etc.), reference the document and provide it as an attachment to the QAPP.

1.6   **Overview of Project Tasks.** Describe planned data activities including how existing data will be used to investigate the current environmental problem.
- Describe type and amount of data that will gathered (e.g., age of data, geographical representation, temporal representation)

- Explain how data sources will be selected or rejected for use
- Describe approach for analyzing data including formulas, calculations, units, definitions of terms, and statistical analysis, will be included and defined.

Similarly, if this information is provided in another document (grant proposal, scope of work, etc.), reference the document and provide it as an attachment to the QAPP.

1.7 **Quality Objectives and Criteria:** State the overarching quality objectives that must be met to ensure a successful outcome of the project. The quality objectives of the project are determined by the end users (e.g., risk assessors, regulators, local state government, citizen groups, etc.). For example, if the project quality objective is to compile and analyze scientifically sound, defensible and transparent data adequate for the development of a TMDL, then acceptance criteria used for evaluating the quality of existing data must be tight enough to minimize decision errors.

Specify acceptance criteria for each matrix and measurement (analytical) parameter and indicate QC sample or activity associated with the quality indicator. For example:

Matrix: Stream water
Measurement Parameter: Nitrate – Nitrogen

- ✓ Precision (e.g., Relative Percent Difference $\leq$20%, field duplicates)
- ✓ Precision (e.g., Relative Percent Difference $\leq$15%, laboratory duplicates)
- ✓ Accuracy (e.g., 85 – 115%, Spiked Control Samples)
- ✓ Sensitivity (0.05 mg/L, calibration standards)
- ✓ Comparability (all nitrate analyses generated in accordance with USEPA Method 300.1, Method citation)
- ✓ Representative sampling (Documented sampling SOPs must used by trained personnel, required training documentation)

Quality acceptance criteria are unique to each project; many environmental studies (e.g., non-TMDL projects) may require less stringent data quality acceptance criteria.

Once data acceptance criteria are established, the project team selects existing data that meet the criteria. In order to determine the quality "pedigree" and usefulness of the secondary data, supporting QC information must be reviewed. Information (a.k.a., metadata) about why, how, and when the existing data were collected provides the user with more confidence. Metadata are documented in project reports, validation reports and accompany database information.

2.0 **DATA SELECTION AND MANAGEMENT**

2.1   **Sources of Existing Data.** List the sources(s) of all secondary data that may be used, including:
- type of data and collection dates
- originating organization
- report title, author and date
- data base names

Note: Information may be presented in tabular format; an example is provided in Attachment 1.

Explain the reason(s) for selecting various sources(s) of existing data (data bases, reports, etc.).

To ensure transparency and defensibility in the decision making process, it is very important to document why certain *related* project reports and/or existing data were *not* used. For example, if reported dry weather data did not have associated information on number of antecedent dry days prior to collection, then the project team may decide not to use the data.

Describe the data format (e.g., electronic, hardcopy) and how data will be maintained for the project. If data are obtained from data bases, include as much accompanying quality control, temporal, locational data, etc. as needed to document and verify the quality of the data.

2.2   **Intended Use of Existing Data.** Describe how different types of data will be used. For example, certain data may be used to define the boundaries of a contaminated area, while other data may be used in identifying other suspected pollutants or breakdown products.

State how and when data that are found to have limitations (e.g., lab qualified data) will be used in the project.

2.3   **Limitations on the Use of Existing Data.** Specify criteria for selecting existing data for the project. Appropriate selection criteria will ensure that secondary data are "good enough" to support project conclusions, decisions or actions. Selection criteria support the general project quality objectives described in Section 1.7.

The following are some examples of selection criteria. **Note: These are examples; and may not apply to your project.**
- Data sets must include quality control (QC) metadata for precision and accuracy.

- Data must be generated under an approved QAPP or other sampling document
- Analytical methods must be sufficiently sensitive (i.e., low enough reporting limits) to support data reporting to state water quality criteria levels.
- All existing data sets used in the project must be generated using the same or comparable sampling and analytical methods or SOPs.
- Data must indicate if results are from composite or grab sampling.
- Sampling design must identify samples that were collected using statistical approach, i.e., "hot spot", random, or grid.
- Reported data must include laboratory qualifiers and qualifier definitions
- Dry weather data used in the project must be preceded by a minimum 72-hour dry period.
- Only data generated after 1/1/2000 will be used for the current investigation.

Identify personnel responsible for selecting project data and the process used.

If no known quality requirements were applied during the sampling and analysis of the existing data, then state this in the QAPP. A disclaimer should be added to any project deliverable to indicate that the quality of the secondary data is unknown. Include the wording for the disclaimer in the QAPP.

3.0   ASSESSMENTS AND OVERSIGHT

3.1   Explain how the project team will ensure that project tasks are completed as planned. Identify personnel responsible for conducting audits and/or overseeing the project.

3.2   Indicate how project oversight will be documented (e.g., assessment reports, memos, etc.)

3.3   Describe how problems will be resolved, including chain-of-command, and documentation process. Include examples of types of corrective actions that might be implemented (e.g., access other data sources, loosen or tighten acceptance criteria).

4.0   DATA REVIEW - VERIFICATION, VALIDATION AND EVALUATION

4.1   Describe how project members will review and verify or validate the adequacy of each data set data relative to the established acceptance criteria established in Section 1.7. Describe the following:
- how data qualifiers will be applied to data not meeting project acceptance criteria. Define laboratory and validation qualifiers (e.g., U, B, J, R, etc.)
- when data will be rejected (not used), and
- how limitations on the use of individual data sets will be documented.
    Note: Typically this is done in the Quality Control Section of the Final Report or

Project Deliverable.

4.2   Finally, describe how all the gathered data will be evaluated to ensure they can be used for project purposes. Describe any statistical applications used to identify outliers, etc. **Consider the following issues when reconciling data with the project objectives.**
- are the data unbiased and sufficiently representative to be used for the current project?
- are data sets complete?
- were data sets collected using the same or comparable methods or SOPs?
- were data collected and managed according to an approved QAPP?
- were data collected by trained personnel familiar with the appropriate SOPs?
- do data meet necessary detection limits and are they reported in the right units of measurement?

5.0   PROJECT SCHEDULE

Include a project time line/schedule including dates for meetings, product deliverables, and final report.

6.0   PROJECT REPORTING

Describe how project results will be reported (e.g., report, deliverable document, etc.). Provide the proposed document outline that includes a quality assurance section.

Also include a statement in this Section that the final project report will identify all sources of existing data that were used in the project, and that they will be either provided as attachments to the Final Report, available through embedded websites, or available upon request.

REFERENCES

1)   ***QAPP Requirements for Secondary Data Research Projects***
     Example Guidance provided by EPA National Risk Management Research Laboratory,
     July 1999 http://www.epa.gov/quality/qs-docs/found-data-qapp-rqts.pdf

2)   ***EPA Requirements for Quality Assurance Project Plans*** QA/R-5
     http://www.epa.gov/quality/qs-docs/r5-final.pdf

3)   ***EPA Guidance for Quality Assurance Project Plans*** QA/G-5 "Chapter 3: Projects
     Using Existing Data" http://www.epa.gov/quality/qs-docs/g5-final.pdf

4)   Workbook for ***Uniform Federal Policy for Quality Assurance Project Plans***, Version 1
     March 2005, http://www.epa.gov/fedfac/pdf/Wkbk_Mar05.doc

Attachment

Example UFP QAPP Worksheet #13 (*Uniform Federal Policy for Quality Assurance Plans***, Version 1 March 2005,**
http://www.epa.gov/fedfac/pdf/Wkbk_Mar05.doc

Identify information and/or data generated/collected outside of the current project activity that will
be used to make environmental decisions for the project. Specify how those acquired data/information
will be used and the limitations on their use. These limitations include data quality considerations/
problems as well as documentation completeness.

Non-Direct Measurement (Secondary Data)	Data Source (Originating Organization, Report Title and Date)	Data Generator(s) (Originating Org., Data Types, Data Generation/Collection Dates)	How Data Will Be Used	Limitations on Data Use
Soil Gas Data	*BioWatch Consulting, LTD: "Titanic Shipyard Investigation Report," 11/20/95*	*BioWatch Consulting, LTD: VOC Soil Gas Data, Sample Collection Dates: 10/19-23/95*	*To assess the potential sources of contaminated soil and resultant groundwater migration*	*1. Unvalidated data used to generate report 2. Insufficient data points to fully characterize on-site contamination and off-site migration*
Municipality Drinking Water Data	*XYZ Municipality: Quarterly Drinking Water Check Report, 6/95 - 6/96*	*Smith Laboratories, Inc.: VOC Drinking Water Data, Sample Collection Dates: 6/12/95, 9/15/95, 12/10/95, 3/6/96, 6/12/96*	*To assess existing groundwater contamination*	*1. Unvalidated data used to generate report 2. Limited number of wells exist to sample*

APPENDIX C: SECONDARY PROJECT QAPP ELEMENTS / CHECKLIST

(Extracted from EPA QA/G-5 and EPA NE Secondary Data Project QAPP Guidance)

Modified EPA R-5 Checklist for Review of Quality Assurance Project Plans Using Secondary Data

This checklist is an example of what could be used to either write or review a QA Project Plan, especially those that call solely for the collection and use of secondary data. The items noted follow those elements found in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a) as applicable, and *EPA New England QAPP Guidance for Projects Using Secondary Data, Revision* 2 (EPA, 2003).

PROJECT TITLE: _____
Preparer: _____   **Date Submitted for Review:** _____
Reviewer: _____   **Date of Review:** _____

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

DOCUMENT CONTROL

Element	A	U	NI	NA	Comments
Document control information is indicated in header of each QAPP page	☐	☐	☐	☐	
Project title is indicated	☐	☐	☐	☐	
QAPP version number and date are indicated	☐	☐	☐	☐	
Page number is indicated in "Page X of Y" format	☐	☐	☐	☐	

PROJECT MANAGEMENT

Element	A	U	NI	NA	Comments
A1.Title and Approval					
Contains project title	☐	☐	☐	☐	
Indicates revision number, if applicable	☐	☐	☐	☐	
Indicates EPA grant number	☐	☐	☐	☐	
Indicates organization(s)' name(s)	☐	☐	☐	☐	
Signature and date lines for organization(s)' project manager(s) present	☐	☐	☐	☐	
Signature and date lines for organization(s)' QA manager(s) present	☐	☐	☐	☐	
Other signatures, as needed	☐	☐	☐	☐	
A2. Table of Contents					
Lists QA Project Plan information sections and relevant page numbers	☐	☐	☐	☐	
Document control information indicated	☐	☐	☐	☐	
A3. Distribution List					
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
A4. Project/Task Organization					
Identifies key individuals involved in all major aspects of the project, including contractors	☐	☐	☐	☐	
Discusses their responsibilities	☐	☐	☐	☐	
Project QA Manager position indicates independence from unit generating data	☐	☐	☐	☐	
Identifies individual responsible for maintaining the official, approved QA Project Plan	☐	☐	☐	☐	
Organizational chart shows lines of authority and reporting responsibilities	☐	☐	☐	☐	
A5. Problem Definition/Background					
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained	☐	☐	☐	☐	
Clearly explains the reason (site background or historical context) for collecting secondary data and how that data will be used to meet project goals	☐	☐	☐	☐	
Identifies regulatory information, applicable criteria, action limits, etc., necessary to the project	☐	☐	☐	☐	
A6. Project/Task Description					
Summarizes work to be performed, for example, secondary data files to be obtained, analyses to be performed etc., that support the project's goals	☐	☐	☐	☐	
Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as secondary data collection, analysis, data or file reviews, and assessments	☐	☐	☐	☐	
Indicates QAPP end date	☐	☐	☐	☐	
Details geographical locations to be studied, including maps where possible	☐	☐	☐	☐	
Discusses resource and time constraints, if applicable	☐	☐	☐	☐	
A7. Quality Objectives and Criteria					
Identifies the secondary data needed to satisfy the project objectives	☐	☐	☐	☐	
Discusses types of secondary data	☐	☐	☐	☐	
Addressed the age of data	☐	☐	☐	☐	
Discusses geographical representation of data	☐	☐	☐	☐	
Discusses temporal representation of data	☐	☐	☐	☐	
Discusses technological representation of data	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
A8. Special Training/Certifications					
Identifies any project personnel specialized training or certifications	☐	☐	☐	☐	
Discusses how this training will be provided	☐	☐	☐	☐	
Indicates personnel responsible for assuring these are satisfied	☐	☐	☐	☐	
Identifies where this information is documented	☐	☐	☐	☐	
A9. Documentation and Records					
Identifies report format and summarizes all data report package information	☐	☐	☐	☐	
Lists all other project documents, records, and electronic files that will be produced	☐	☐	☐	☐	
Identifies where project information should be kept and for how long	☐	☐	☐	☐	
Discusses back up plans for records stored electronically	☐	☐	☐	☐	
States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individuals responsible for this	☐	☐	☐	☐	

DATA ACQUISITION

Element	A	U	NI	NA	Comments
B1. Sources of Secondary Data					
Identifies sources of required secondary data, including the originating organization(s), and the report/publication title and date. May be displayed in tabular format	☐	☐	☐	☐	
Identifies the generators of required secondary data (if different from source), including the originating organization(s) and data collection date(s)	☐	☐	☐	☐	
Specifies the hierarchy of sources for the gathering of secondary data, where applicable	☐	☐	☐	☐	
Discusses the rationale for selecting the data sources(s) identified	☐	☐	☐	☐	
Specifies that all sources of secondary data gathered will be identified in project reports and deliverables	☐	☐	☐	☐	
B2. Quality of Secondary Data					
Discusses quality requirements of secondary data and corresponding acceptance criteria	☐	☐	☐	☐	
Discusses accuracy requirements	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Discusses precision requirements	☐	☐	☐	☐	
Discusses representativeness requirements	☐	☐	☐	☐	
Discusses completeness requirements	☐	☐	☐	☐	
Discusses comparability requirements	☐	☐	☐	☐	
Describes the procedures that will be employed to determine the quality of secondary data	☐	☐	☐	☐	
Includes disclaimer to be used in all project work products and reports if no quality requirements are being employed or when the quality of secondary data cannot be determined	☐	☐	☐	☐	
B3. Data Management					
Describes data management and storage scheme.	☐	☐	☐	☐	
Identifies data handling equipment/procedures that should be used to process, compile, analyze and transmit data reliably and accurately	☐	☐	☐	☐	
Identifies individual(s) responsible for data management	☐	☐	☐	☐	
Describes the process for data archival and retrieval	☐	☐	☐	☐	
Describes procedures to demonstrate acceptability of hardware and software configurations	☐	☐	☐	☐	
Attaches checklists and forms that should be used	☐	☐	☐	☐	

ASSESSMENT and OVERSIGHT

Element	A	U	NI	NA	Comments
C1. Assessments and Response Actions					
Lists the number, frequency and type of assessment activities that should be conducted, with the approximate dates	☐	☐	☐	☐	
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders and any other possible participants in the assessment process	☐	☐	☐	☐	
Describes how and to whom assessment information should be reported	☐	☐	☐	☐	
Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Includes standard NEIWPCC assessment language: "NEIWPCC may implement, at its discretion, various audits or reviews of this project to assess conformance and compliance to the Quality Assurance Project Plan in accordance with the NEIWPCC Quality Management Plan. NEIWPCC may issue a stop work order and require corrective action(s) if nonconformance or noncompliance to the Quality Assurance Project Plan is found."	☐	☐	☐	☐	
C2. Reports to Management					
Identifies what project QA status reports are needed and how frequently	☐	☐	☐	☐	
Identifies who should write these reports and who should receive this information	☐	☐	☐	☐	

DATA REDUCTION, REPORTING, AND VALIDATION

Element	A	U	NI	NA	Comments
D1. Data Reduction					
Describes reduction and evaluation procedures specific to the project, including calculations and equations	☐	☐	☐	☐	
D2. Verification and Validation Methods					
Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any	☐	☐	☐	☐	
Identifies issue resolution process, and method and individual responsible for conveying these results to data users	☐	☐	☐	☐	
Attaches checklists, forms and calculations	☐	☐	☐	☐	
D3. Reconciliation with User Requirements					
Describes procedures to evaluate the uncertainty of the validated data	☐	☐	☐	☐	
Describes how limitations on data use should be reported to the data users	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

APPENDIX D: MODELING PROJECT QAPP ELEMENTS / CHECKLIST

(Extracted from EPA QA/G-5M)

Modified EPA R-5 Checklist for Review of Quality Assurance Project Plans for Modeling Projects Using Secondary Data

This checklist is an example of what could be used to either write or review a QA Project Plan, especially those that call solely for the collection and use of secondary data. The items noted follow those elements found in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a) as applicable, and *EPA New England QAPP Guidance for Projects Using Secondary Data, Revision* 2 (EPA, 2003).

PROJECT TITLE: _____
Preparer: _____   **Date Submitted for Review:** _____
Reviewer: _____   **Date of Review:** _____

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

DOCUMENT CONTROL

Element	A	U	NI	NA	Comments
Document control information is indicated in header of each QAPP page	☐	☐	☐	☐	
Project title is indicated	☐	☐	☐	☐	
QAPP version number and date are indicated	☐	☐	☐	☐	
Page number is indicated in "Page X of Y" format	☐	☐	☐	☐	

PROJECT MANAGEMENT

Element	A	U	NI	NA	Comments
A1. Title and Approval					
Contains project title	☐	☐	☐	☐	
Indicates revision number, if applicable	☐	☐	☐	☐	
Indicates EPA grant number	☐	☐	☐	☐	
Indicates organization(s)' name(s)	☐	☐	☐	☐	
Signature and date lines for organization(s)' project manager(s) present	☐	☐	☐	☐	
Signature and date lines for organization(s)' QA manager(s) present	☐	☐	☐	☐	
Other signatures, as needed	☐	☐	☐	☐	
A2. Table of Contents					
Lists QA Project Plan information sections and relevant page numbers	☐	☐	☐	☐	
Document control information indicated	☐	☐	☐	☐	
A3. Distribution List					
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
A4. Project/Task Organization					
Identifies key individuals involved in all major aspects of the project, including contractors	☐	☐	☐	☐	
Discusses their responsibilities	☐	☐	☐	☐	
Project QA Manager position indicates independence from unit generating data	☐	☐	☐	☐	
Identifies individual responsible for maintaining the official, approved QA Project Plan	☐	☐	☐	☐	
Organizational chart shows lines of authority and reporting responsibilities	☐	☐	☐	☐	
A5. Problem Definition/Background					
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained	☐	☐	☐	☐	
Clearly explains the reason (site background or historical context) for collecting secondary data and how that data will be used to meet project goals	☐	☐	☐	☐	
Identifies regulatory information, applicable criteria, action limits, etc., necessary to the project	☐	☐	☐	☐	
Explains why a modeling approach is appropriate to address the problem	☐	☐	☐	☐	
If a particular model has been selected, explains why that model is better to address the problem than other similar models	☐	☐	☐	☐	
A6. Project/Task Description					
Summarizes work to be performed, for example, secondary data files to be obtained, analyses to be performed etc., that support the project's goals	☐	☐	☐	☐	
Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as secondary data collection, analysis, data or file reviews, and assessments	☐	☐	☐	☐	
Indicates QAPP end date	☐	☐	☐	☐	
Details geographical locations to be studied, including maps where possible	☐	☐	☐	☐	
Discusses resource and time constraints, if applicable	☐	☐	☐	☐	
A7. Quality Objectives and Criteria					
Description of specific task requiring modeling and the intended uses of modeling output to achieve the task	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Identifies performance/measurement criteria for all information to be collected for use in the model, including acceptance criteria for information obtained from previous studies, project action limits and laboratory detection limits and range of anticipated concentrations of each parameter of interest	☐	☐	☐	☐	
Discusses types of secondary data	☐	☐	☐	☐	
Addressed the age of data	☐	☐	☐	☐	
Discusses geographical representation of data	☐	☐	☐	☐	
Discusses temporal representation of data	☐	☐	☐	☐	
Discusses technological representation of data	☐	☐	☐	☐	
Lists required hardware/software configurations for those studies involving software evaluation	☐	☐	☐	☐	
A8. Special Training/Certifications					
Identifies any project personnel specialized training or certifications	☐	☐	☐	☐	
Discusses how this training will be provided	☐	☐	☐	☐	
Indicates personnel responsible for assuring these are satisfied	☐	☐	☐	☐	
Identifies where this information is documented	☐	☐	☐	☐	
A9. Documentation and Records					
Identifies report format and summarizes all data report package information	☐	☐	☐	☐	
Lists all other project documents, records, and electronic files that will be produced, potentially including model science formulation reports, peer review/model evaluation group reports, model assessment reports, model calibration reports, a model users' manual, configuration and code maintenance manuals, and reports describing model code standards, code auditing and code testing, etc.	☐	☐	☐	☐	
Identifies where project information should be kept and for how long	☐	☐	☐	☐	
Discusses back up plans for records stored electronically	☐	☐	☐	☐	
States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individuals responsible for this	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

DATA ACQUISITION AND MODEL USE OR DEVELOPMENT

Element	A	U	NI	NA	Comments
B1. Sources of Secondary Data					
Identifies sources of required secondary data, including the originating organization(s), and the report/publication title and date. May be displayed in tabular format	☐	☐	☐	☐	
Identifies the generators of required secondary data (if different from source), including the originating organization(s) and data collection date(s)	☐	☐	☐	☐	
Specifies the hierarchy of sources for the gathering of secondary data, where applicable	☐	☐	☐	☐	
Discusses the rationale for selecting the data sources(s) identified	☐	☐	☐	☐	
Specifies that all sources of secondary data gathered will be identified in project reports and deliverables	☐	☐	☐	☐	
B2. Quality of Secondary Data					
Discusses quality requirements of secondary data and corresponding acceptance criteria	☐	☐	☐	☐	
Discusses accuracy requirements	☐	☐	☐	☐	
Discusses precision requirements	☐	☐	☐	☐	
Discusses representativeness requirements	☐	☐	☐	☐	
Discusses completeness requirements	☐	☐	☐	☐	
Discusses comparability requirements	☐	☐	☐	☐	
Describes the procedures that will be employed to determine the quality of secondary data	☐	☐	☐	☐	
Includes disclaimer to be used in all project work products and reports if no quality requirements are being employed or when the quality of secondary data cannot be determined	☐	☐	☐	☐	
B3. Data Management and Hardware/Software Configuration					
Describes data management and storage scheme.	☐	☐	☐	☐	
Identifies data handling equipment/procedures that should be used to process, compile, analyze and transmit data reliably and accurately	☐	☐	☐	☐	
Identifies individual(s) responsible for data management	☐	☐	☐	☐	
Describes the process for data archival and retrieval	☐	☐	☐	☐	
Describes procedures to demonstrate acceptability of hardware and software configurations	☐	☐	☐	☐	
Describes or attaches any data forms, checklists, or on-line interactive screens used in the modeling process	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Includes any necessary graphics to document the data management process (e.g., process flow diagrams, modeling flow charts, etc.)	☐	☐	☐	☐	
Describes how internal checks used during data entry should be documented	☐	☐	☐	☐	
Describes how uncertainty and variability in the model results will be determined or characterized (e.g., summary statistics, frequency distributions, goodness-of-fit tests)	☐	☐	☐	☐	
Lists equipment, both hardware and software, that will be used on the project	☐	☐	☐	☐	
Describes system performance requirements, addressing security issues, software installation needs and associated documentation	☐	☐	☐	☐	
Describes plan for development of model coding standards	☐	☐	☐	☐	
Describes plan for model testing	☐	☐	☐	☐	
Describes plan for development of model user's manual and/or maintenance manual	☐	☐	☐	☐	
Describes how model source code will be stored and maintained	☐	☐	☐	☐	
Includes configuration management plan to control software/hardware configuration during model development or application	☐	☐	☐	☐	
B4. Model Calibration					
Describes the objectives of model calibration activities, including acceptance criteria	☐	☐	☐	☐	
Describes expected frequency of model calibration activities	☐	☐	☐	☐	
Details the model calibration procedure	☐	☐	☐	☐	
Describes the method(s) of acquiring input data	☐	☐	☐	☐	
Describes types of output generated by the model calibration	☐	☐	☐	☐	
Describes the approach being used to characterize uncertainty (e.g., sensitivity analysis)	☐	☐	☐	☐	
Details corrective action to be taken if acceptance criteria are not met	☐	☐	☐	☐	
Details resources and responsibilities related to model calibration	☐	☐	☐	☐	
Discusses the analysis of model output relative to acceptance criteria	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

ASSESSMENT and OVERSIGHT

Element	A	U	NI	NA	Comments
C1. Assessments and Response Actions					
Lists the number, frequency and type of assessment activities that should be conducted, with the approximate dates	☐	☐	☐	☐	
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders and any other possible participants in the assessment process	☐	☐	☐	☐	
Describes procedures for both internal QA assessments (review of input data, code verification, calibration, benchmarking) and external assessments (peer review of model theory and/or structure)	☐	☐	☐	☐	
Describes how and to whom assessment information should be reported	☐	☐	☐	☐	
Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented	☐	☐	☐	☐	
Includes standard NEIWPCC assessment language: "NEIWPCC may implement, at its discretion, various audits or reviews of this project to assess conformance and compliance to the Quality Assurance Project Plan in accordance with the NEIWPCC Quality Management Plan. NEIWPCC may issue a stop work order and require corrective action(s) if nonconformance or noncompliance to the Quality Assurance Project Plan is found."	☐	☐	☐	☐	
Describes planned model code performance testing	☐	☐	☐	☐	
Describes planned model performance evaluations	☐	☐	☐	☐	
Describes planned sensitivity analysis for model outputs	☐	☐	☐	☐	
Describes planned uncertainty analysis for model outputs	☐	☐	☐	☐	
C2. Hardware/Software Assessments and Configuration Tests					
Describes how hardware and software configurations will be tested	☐	☐	☐	☐	
Describes model code development inspections and verification tests	☐	☐	☐	☐	
Describes how programming errors will be screened and corrected	☐	☐	☐	☐	
Describes how model equations will be checked for correct placement/relationships	☐	☐	☐	☐	
Describes how linkages between model code and uncertainty analysis will be checked	☐	☐	☐	☐	
Describes how model framework will be tested	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Describes planned integration tests (to check computational and transfer interfaces between model modules)	☐	☐	☐	☐	
Describes any planned regression tests	☐	☐	☐	☐	
Describes stress testing of complex models (to ensure that maximum model load does not exceed system limitations)	☐	☐	☐	☐	
Describes process for beta testing of pre-release materials	☐	☐	☐	☐	
C3. Model Peer Review					
Describes process for peer review of the theoretical basis for the model	☐	☐	☐	☐	
Describes process for peer review of the mathematical model structure	☐	☐	☐	☐	
Describes process for peer review of model outputs and predictions	☐	☐	☐	☐	
Describes process for peer review of model calibration procedures	☐	☐	☐	☐	
Describes process for peer review of final technical products	☐	☐	☐	☐	
C4. Reports to Management					
Identifies what project QA status reports are needed and how frequently	☐	☐	☐	☐	
Identifies who should write these reports and who should receive this information	☐	☐	☐	☐	

DATA VALIDATION AND USEABILITY

Element	A	U	NI	NA	Comments
D1. Validation Criteria					
Describes data reduction and evaluation procedures specific to the project, including calculations and equations	☐	☐	☐	☐	
Describes criteria used to review and validate input data	☐	☐	☐	☐	
Describes criteria used to review and validate model components such as theory, mathematical structure, code, and calibration	☐	☐	☐	☐	
Describes criteria used to test model performance	☐	☐	☐	☐	
Describes criteria used to review and validate model outputs	☐	☐	☐	☐	
D2. Verification and Validation Methods					
Describes methods for review of model components such as theory, mathematical structure, code, and calibration	☐	☐	☐	☐	
Describes methods used to test model performance	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

Element	A	U	NI	NA	Comments
Describes methods for assessment of model output and usability	☐	☐	☐	☐	
D3. Reconciliation with User Requirements					
Describes procedures to evaluate the uncertainty of the validated data	☐	☐	☐	☐	
Describes how limitations on data use should be reported to the data users	☐	☐	☐	☐	
Describes any potential uncertainties related to decisions made based on limitations in model input data and/or limitations in the model and how this will be reported	☐	☐	☐	☐	
Describes how any departures from assumptions set in the planning phase of the model will be documented and reported to users	☐	☐	☐	☐	
Describes procedures for final acceptance testing (testing needed before a new model or model application is accepted by the end user)	☐	☐	☐	☐	

Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable

APPENDIX E: TIME REQUIREMENTS FOR QA PROJECT PLAN APPROVAL

Time Requirements for QA Project Plan Approval

The following is provided for illustrative purposes only, to demonstrate the amount of time that <u>could potentially</u> be required for the planning, preparation, review and approval of a QA Project Plan developed by a contractor with funds provided by EPA Region 1. If EPA Region 2 or state review is required, this process may take longer. However, if the development process is well coordinated, most plans will not take this long to develop and approve. Every situation is unique and most plans should be approved in shorter time spans, although some could conceivably take longer. Project managers and technical staff – regardless of location or project funding source – should allow at least 2 months of lead time for QA Project Plan development and approval.

Under no circumstances should data collection activities commence prior to complete QA Project Plan approval.

QA Project Plan Milestones	Time From Contract Award
1. Contractor prepares a draft QA Project Plan with assistance from NEIWPCC.	2 weeks
2. NEIWPCC project manager performs completeness check of draft QA Project Plan and provides feedback to the contractor.	3 weeks
3. Contractor revises the draft QA Project Plan and NEIWPCC project manager submits draft QA Project Plan for NEIWPCC and EPA review.	4 weeks
4. NEIWPCC QA program manager (or designee) and EPA staff (project and QA) review the draft QA Project Plan and provide comments to the NEIWPCC project manager.	7 weeks
5. Contractor and NEIWPCC project manager revise the draft QA Project Plan and re-submit to NEIWPCC QA program manager (or designee) and EPA staff.	8 weeks
6. If revisions are adequate, the QA Project Plan is finalized by circulating the signature page to all parties for authorization.	8 weeks
7. NEIWPCC project manager retains finalized plan and the responsible project staff person provides copies to all necessary parties. Work can commence on data collection activities.	8 weeks
8. Multi-year projects must be reviewed annually.	