NEW ENGLAND INTERSTATE WATER POLLUTION CONTROL COMMISSION
(NEIWPCC)

# GUIDE FOR DEVELOPMENT AND APPROVAL OF QUALITY ASSURANCE PROJECT PLANS (QA PROJECT PLANS)

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Approvals:

2/22/16

Michael Jennings Date
NEIWPCC - Quality Assurance Program Manager

2-22-16

Ronald Poltak Date
NEIWPCC - Executive Director

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## FOREWORD

The mission of the New England Interstate Water Pollution Control Commission (NEIWPCC) is to serve and assist its member states individually and collectively by providing coordination, public education, research, training, and leadership in water management and protection in the New England region and New York State. 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.

## 1.0 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, provides in one place a clear, concise, and complete plan for the environmental data operation and its quality objectives. The plan also identifies key project personnel.

The benefits of a QA Project Plan are 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.

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 what 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. In other words, 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.

### 1.1 Unique Circumstances of Model Development and Application Projects

In simplest terms, 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 Models 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 A 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 *QAPP Requirements for Secondary Data Research Projects*, which is available from the guidance section of the Office of Environmental Information's web page (www.epa.gov/quality/qapps.html). The guidance document used in EPA Region 1 for secondary data projects is contained in Appendix B of this guide.

## 2.0 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 internet (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 Deputy Director.

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.
- 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 and included in Appendix C.

### 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 program 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 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. In all circumstances, a QA Project Plan should be reviewed and approved by the NEIWPCC QAPM prior to being submitted to other agencies for their approval.

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.**

## 3.0 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.

## 4.0 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

[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 web site of EPA's Office of Environmental Information (www.epa.gov/quality). There is also a checklist contained in Appendix D of this guide detailing these elements and sub-elements.

- 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
- 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*.

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.

## 5.0 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 those preparing QA Project Plans contact the NEIWPCC Quality Assurance Program Manager (QAPM) to discuss the approval process for their project well in advance of planned data collection activities and before drafting a QA Project Plan**. The NEIWPCC QAPM can then contact any other organizations or individuals who might be involved in the approval process. This will allow for a coordinated and 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 SOP, titled *SOP for NEIWPCC QAPP Approval Process* (available at: www.neiwpcc.org/quality and attached Appendix C) that fully describes the current methodologies and routing of a draft QAPP.** What follows, is a simplified description of the review and approval process.

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 R-5 Checklist for QAPP Review (available at: www.neiwpcc.org/quality and Appendix D).

[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 web site of EPA's Office of Environmental Information (www.epa.gov/quality).

After the completeness check, the program manager would submit the draft QAPP to the review process, utilizing the QAPP Submission Form (available at: www.neiwpcc.org/quality and attached Appendix E), in accordance with the Approval SOP.

Once the NEIWPCC QAPM, or designee, has completed the initial review of the draft QA Project Plan, a memo will be prepared noting any deficiencies that need to be addressed or any supplemental information that needs to be incorporated into the draft plan. If necessary, the draft QA Project Plan can then be revised, before proceeding to the next step in the approval process.

Once the NEIWPCC QAPM, or designee, has provided comments and the draft QA Project Plan has been revised if necessary, the plan will be provided to other organizations involved in the review and approval process. If the project is funded by EPA, the draft plan will be submitted to the EPA Project Officer and an EPA Quality Assurance Officer. 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. This illustrates why pre-planning and coordination is essential to ensure a smooth and efficient review and approval process.

It is also possible that state environmental agency staff will be involved in the review and approval process at this stage, depending on the complexity of the project. State environmental agency staff would be involved if the funds supporting the project are of state origin. 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.

It is important to recognize that with proper early planning and coordination, some of the steps mentioned above can happen simultaneously or certain responsibilities could be delegated from the NEIWPCC QAPM, or designee, to NEIWPCC technical staff. This would increase the efficiency of the approval process and reduce the overall amount of time required to approve the QA Project Plan.

Once the draft QA Project Plan has been fully revised, the signature page must be completed by all individuals who sign off on the plan. When all 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.

A rough estimate of the amount of time that should be anticipated at each step in the approval process is contained in Appendix F of this guide.

### 5.1 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 or technical staff person 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.

### 5.2 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.

## 6.0 Resources

*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

*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

## 7.0 References

*EPA Requirements for Quality Assurance Project Plans (QA/R-5).* U.S. Environmental Protection Agency. March 2001. (EPA/240/B-01/003). Available at: http://www.epa.gov/quality/agency-wide-quality-system-documents

*Guidance for Quality Assurance Project Plans (QA/G-5).* U.S. Environmental Protection Agency. December 2002. (EPA/240/R-02/009). Available at: http://www.epa.gov/quality/agency-wide-quality-system-documents
*Guidance for Quality Assurance Project Plans for Modeling (QA/G-5M).* U.S. Environmental Protection Agency. December 2002. (EPA/240/R-02/007). Available at: http://www.epa.gov/quality/agency-wide-quality-system-documents

*EPA New England Compendium of Quality Assurance Project Plan Requirements and Guidance*. U.S. Environmental Protection Agency – Region 1. October 1999. Available at: http://www.epa.gov/quality/managing-quality-environmental-data-epa-region-1
*New England Interstate Water Pollution Control Commission Quality Management Plan*. New England Interstate Water Pollution Control Commission. Version5. January 24, 2013. Available at: http://www.neiwpcc.org/quality

## Appendix A

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 | ☐ | ☐ | ☐ | ☐ | |
| 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 | ☐ | ☐ | ☐ | ☐ | |



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**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 | ☐ | ☐ | ☐ | ☐ | |



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**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 | ☐ | ☐ | ☐ | ☐ | |
| 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 | ☐ | ☐ | ☐ | ☐ | |
| 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 | ☐ | ☐ | ☐ | ☐ | |



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

| Element | A | U | NI | NA | Comments |
|---|---|---|---|---|---|
| **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 | ☐ | ☐ | ☐ | ☐ | |
| Describes methods for assessment of model output and usability | ☐ | ☐ | ☐ | ☐ | |



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| Element | A | U | NI | NA | Comments |
|---|---|---|---|---|---|
| **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) | ☐ | ☐ | ☐ | ☐ | |



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## Appendix B

EPA Region 1 Secondary Data Project QAPP Guidance

# QAPP Guidance for Projects Using Secondary Data

A secondary data project involves the gathering, compiling and/or use of existing environmental data for purposes other than those for which they were originally collected. To ensure proper project decisions are made, it is essential that the limitations on the use of secondary data be identified.

Sources of secondary data include but are not limited to:

- 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.) Historical data may have been used in Section 5.2 to describe the site history and define the environmental problem.
- 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 generated from computer databases (such as manufacturers' process/product information, waste management or effluent information)
- Environmental indicator data obtained from federal/state/local records
- Computer models or algorithms
- Literature files/searches
- Publications
- Photographs
- Topographical Maps

For these projects, a QAPP should be prepared to include the minimum requirements described below. If secondary data will be used for environmental modeling then the project case team should follow the guidance provided in *Guidance for Quality Assurance Project Plans for Modeling (QA/G-5M)* available at **http://www.epa.gov/quality/qa_docs.html**
If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data.

## 1.0 PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1_ Title and approval page shall be included.

1.2_ QAPP Distribution list shall be included.

1.3_ The purpose of study and background information shall be clearly stated in the QAPP.

1.4_ Project objectives shall be clearly stated in the QAPP and include a discussion of how the secondary data will be used.

1.5_ The secondary data needed to satisfy the project objectives shall be identified in the QAPP. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.6_ The planned approach for evaluating project objectives (i.e., data analysis), including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included in the QAPP.

1.7_ Responsibilities of all project participants shall be identified in the QAPP, meaning that key personnel and their organizations shall be identified, along with the designations of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

1.8_ The project schedule, and interim reports and deliverables shall be described .

## 2.0 SOURCES OF SECONDARY DATA

2.1 The required sources(s) of the secondary data must be specified in the QAPP including the originating organization, report title and date. Information may be presented in tabular format as provided in Figure 25 of the *EPA NE QAPP Manual.*

2.2 The data generator must be identified in the QAPP including organization name, data types, and data generation/collection dates.

2.3 If a hierarchy of sources exists for the gathering of secondary data, that hierarchy must be specified in the QAPP.

2.4 The rationale for selecting the sources(s) identified shall be discussed in the QAPP.

2.5 The QAPP shall state that the sources of secondary data gathered will be identified in any

project deliverable.

## 3.0 QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified in the QAPP. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described in the QAPP. An example process of secondary data review and evaluation is provided in Diagram 5 of the *EPA NE QAPP Manual.*

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data cannot be determined, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data is unknown. The wording for the disclaimer shall be included in the QAPP.

## 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.)

References:

1) Example Guidance provided by EPA National Risk Management Research Laboratory, 7/1/99
2) EPA NE QAPP Manual, Section 14, Draft 9/98

## Figure 25. Example Non-Direct Measurements Criteria and Limitations Table

| **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*<br>*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*<br>*2. Limited number of wells exist to sample* |

## Appendix C

## SOP for NEIWPCC QAPP Approval Process

# SOP for NEIWPCC QAPP Approval Process

## I. Summary

This document was prepared to assist NEIWPCC staff in understanding the Commission's process for the review and approval of quality assurance project plans. It outlines roles, responsibilities, and procedures for two scenarios: the first scenario (section III) covers projects funded by EPA; the second scenario (section IV) covers projects funded by other organizations.

While this is intended to be a stand-alone document, it does not describe all aspects of the NEIWPCC Quality Management System, the process for determining when a QAPP is needed, or specific components and requirements of a quality assurance project plan. For additional guidance on these topics, go to NEIWPCC's Quality Management website (neiwpcc.org/quality).

Note that the procedures described below do not apply to a program that has QAPP-approval authority, in which case the program would have its own approval procedure.

## II. Definitions

**QAPP:** Quality assurance project plan (including all associated appendices, checklists, and forms)

**QAPP writer:** Person responsible for writing and revising a QAPP (may be NEIWPCC employee or contractor)

**NEIWPCC project manager:** NEIWPCC staff person responsible for oversight of project in need of an approved QAPP

**Checklist:** Any of several review templates used to assess completeness of a QAPP (The checklist used is based on type of project (primary data, secondary data, or modeling).)

**Receiver:** Designated administrative contact for QAPP tracking at the Lowell office (currently Shelly Jenkins)

**QAPP Tracker:** Database used to track information and status of QAPP review and approval

**QAPM:** Quality assurance program manager (NEIWPCC's QAPM, currently Michael Jennings, is the point-of-contact for all quality assurance activities.)

**QA designee:** An appropriately trained and certified staff person selected by the QAPM to review and approve a particular QAPP

**EPA QA coordinator:** NEIWPCC's primary point of contact at EPA for QA matters

**EPA project officer:** EPA staff person responsible for project oversight

**EPA QA reviewer:** EPA staff person responsible for reviewing and approving QAPP once it complies with EPA QAPP requirements

## III. Scenario 1: EPA Funded Project

***Step 1: Project Manager Review for Completeness***

***1.1:*** Whether the QAPP writer is a NEIWPCC employee or a contractor, the NEIWPCC project manager (PM) will review the draft QAPP by comparing it to the appropriate checklist, project scope of work, and advisory committee guidance to ensure that the QAPP adequately describes the project activities to be conducted and that all necessary QAPP elements are included. In addition, the PM will ensure that all applicable aspects of the project are detailed in the QAPP. If the QAPP is found to be inadequate, the PM will provide specific directions to the QAPP writer, who will make the necessary modifications. The PM must verify that all issues have been adequately addressed before proceeding to step 2.

***Step 2: Initial Submission of Draft QAPP***

***2.1:*** Once the PM has reviewed the draft QAPP and assessed it as complete, the PM will complete the electronic QAPP submission form (available at neiwpcc.org/quality).

***2.2:*** The PM will email both an electronic version of the draft QAPP and the completed electronic QAPP submission form to the receiver.

**NOTE**: From this point forward, the PM should be cc'd on all emails regarding review and approval of the QAPP.

***Step 3: Receipt of Draft QAPP***

***3.1:*** Upon receipt of the draft QAPP and corresponding QAPP submission form, the receiver will create a new record in QAPP Tracker. (Additional details pertaining to QAPP Tracker are provided in Section V of this document.)

***3.2:*** The receiver will create a new folder by project title in the designated location on the Common drive (for example*, I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects) and will save both the electronic draft QAPP and corresponding QAPP submission form within this folder.

***3.3:*** The receiver will email the draft QAPP to the quality assurance program manager (QAPM).

***Step 4: QAPP Review Assignment***

***4.1:*** Once the QAPM receives the draft QAPP, the QAPM will assign a QA designee to conduct the review, and the draft QAPP will be emailed to that individual. (The QA designee will typically be selected, in consultation with appropriate supervisory staff, based on availability and areas of technical expertise.) The QAPM will input the QA designee and assignment date into QAPP Tracker.

***4.2:*** Should the QAPP require approval from EPA Region 1, the QAPM will email it to the appropriate EPA Region 1 project officer and NEIWPCC's EPA QA coordinator for Region 1. The message to EPA will request that the agency's staff review the draft QAPP and email any necessary modifications to the PM. The message to EPA will also request that the agency's staff not approve (sign) the QAPP until the NEIWPCC review and approval process is complete. The process will then proceed as follows in steps 5

through 7. If, however, the QAPP requires approval through EPA Region 2, skip steps 5 through 7 below and follow the modified steps in the text box on page 5.

***Step 5: Reviewing Draft QAPP***

***5.1:*** The QA designee will review the draft QAPP, using (and completing) the appropriate review checklist.

***5.2:*** Upon completion of the checklist, the QA designee will generate a comment memo that details any needed modifications. The QA designee will save the completed checklist and comment memo in the appropriate electronic project file (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects). If the QA designee is not located in the Lowell office, the designee will email the comment memo and checklist to the receiver, who will save the files to the appropriate location.

***5.3:*** The QA designee will email the comment memo to the PM and EPA reviewers to initiate the revision process. Under most circumstances, the PM should receive the comment memo from the QA designee within 10 business days from the time the designee received the draft QAPP.

**5.4**: The QA designee will update the project record in QAPP Tracker to specify the date the comment memo was sent and will check the box indicating that the electronic checklist has been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

***Step 6: Draft QAPP Revision***

***6.1:*** The PM will email the QA designee's comment memo to the QAPP writer so that the writer can revise the draft QAPP to address issues identified in the memo.

***6.2:*** The QAPP writer will also incorporate any modifications identified during the concurrent EPA Region 1 review of the draft QAPP. (The PM is not required to save EPA's comments on the evaluation of the draft QAPP, but should this be desired, the PM may save EPA's comments to the QAPPS-PENDING folder (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects).) Files containing EPA's comments should indicate Do Not Delete in the file name. If the PM is not located in the Lowell office, the PM can email the necessary information to the receiver, who will save the file.

***Step 7: QAPP Revision Review***

***7.1:*** When revisions are complete, the PM will submit the revised QAPP to the QA designee, EPA Region 1 project officer (if applicable), and EPA Region 1 QA reviewer (if applicable) to determine if revisions are adequate.

**7.2:** The QA designee will update QAPP Tracker to specify the date the revised QAPP was received. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

***7.3:*** If the QA designee, EPA project officer, or EPA QA reviewer determine that the revisions are inadequate; the PM will be notified so the QAPP can be further revised. Steps 6.1, 6.2, and 7.1 will be repeated until the QA designee, EPA project officer, and/or EPA QA reviewer determine that the QAPP has been adequately revised.

***7.4:*** Once it is determined that the revisions are adequate, the signature process may be initiated. The QA designee will update QAPP Tracker to specify the date that the revisions were approved. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

**7.5:** The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved as a PDF by the QA designee and retained in the appropriate project folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will save the PDF in the appropriate project folder.

## If the QAPP requires approval from EPA Region 2:

***Step 5: Reviewing Draft QAPP***

***5.1:*** The QA designee will review the draft QAPP, using (and completing) the appropriate review checklist.

***5.2:*** Upon completion of the checklist, the QA designee will generate a comment memo that details any needed modifications. The QA designee will save the completed checklist and comment memo in the appropriate electronic project file (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects). If the QA designee is not located in the Lowell office, the designee will email the comment memo and checklist to the receiver, who will save the files to the appropriate location.

***5.3:*** The QA designee will email the comment memo to the PM to initiate the revision process. Under most circumstances, the PM should receive the comment memo from the QA designee within 10 business days from the time the designee received the draft QAPP.

**5.4**: The QA designee will update the project record in QAPP Tracker to specify the date the comment memo was sent and will check the box indicating that the electronic checklist has been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

***Step 6: Draft QAPP Revision***

***6.1:*** The PM will email the QA designee's comment memo to the QAPP writer so that the writer can revise the draft QAPP to address issues identified in the memo.

***Step 7: QAPP Revision Review***

***7.1:*** When revisions are complete, the PM will submit the revised QAPP to the QA designee to determine if revisions are adequate.

**7.2:** The QA designee will update QAPP Tracker to specify the date the revised QAPP was received. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

***7.3:*** If the QA designee determines that the revisions are inadequate, the PM will be notified so the QAPP can be further revised. Steps 6.1 and 7.1 will be repeated until the QA designee determines that the QAPP has been adequately revised.

***7.4:*** Once the designee determines that the revisions are adequate, the QA designee will notify the PM that the QAPP meets NEIWPCC QA requirements and can be sent to the appropriate EPA Region 2 project officer, who will coordinate the Region 2 review and approval process.

***7.5:*** The PM will email a Word version of the QAPP to EPA Region 2, so that modifications can be identified via the Track Changes feature.

***7.6:*** As the PM receives feedback on the draft QAPP from EPA Region 2, the PM will work to ensure that the QAPP is adequately revised to address identified issues.

***7.7:*** Once EPA Region 2 has indicated that the QAPP has been adequately revised, the signature process can be initiated.

***7.8:*** The QA designee will update QAPP Tracker to specify the date that the revisions were approved. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

***7.9:*** The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved by the QA designee as a PDF and retained in the appropriate project folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will save the PDF in the appropriate project folder.

***Step 8: Finalization of QAPP***

***8.1:*** The PM (or person assigned finalization responsibility within the QAPP) will circulate the complete, final QAPP to the appropriate individuals to obtain signatures. The QAPP should be circulated via email, with signatures added electronically, unless hard copies, with original signatures, are required.

***8.2:*** Once the PM (or assigned individual) receives all signatures, a PDF of the complete, approved QAPP will be emailed to the distribution list. The receiver will save a copy of the approved QAPP (with all signatures included) in the appropriate project folder. The receiver will also update the project record in QAPP Tracker to specify the date that the final QAPP was received.

***Step 9: Electronically Filing the QAPP***

***9.1:*** Once the completed QAPP has been saved, the receiver will delete previous drafts of the QAPP and ensure that the folder also contains the checklist, comment memo, submission form, and the email authorizing initiation of the signature process. The receiver will retain any files designated Do Not Delete.

***9.2:*** With the aforementioned documents included, the receiver will relocate the project folder to the "QAPPS – COMPLETE" folder on the Common drive (for example, *I:\COMMON\QUALITY\QAPPs\QAPPs – COMPLETE\Completed FY2015 QAPPs* for fiscal year FY2015 projects) and update QAPP Tracker accordingly.

## IV. Scenario 2: Project Funded By Other Organizations

***Step 1: Project Manager Review for Completeness***

***1.1:*** Whether the QAPP writer is a NEIWPCC employee or a contractor, the NEIWPCC project manager (PM) will review the draft QAPP by comparing it to the appropriate checklist, project scope of work, and advisory committee guidance to ensure that the QAPP adequately describes the project activities to be conducted and that all necessary QAPP elements are included. In addition, the PM will ensure that all applicable aspects of the project are detailed in the QAPP. If the QAPP is found to be inadequate, the PM will provide specific directions to the QAPP writer, who will make the necessary modifications. The PM must verify that all issues have been adequately addressed before proceeding to step 2.

***Step 2: Initial Submission of Draft QAPP***

***2.1:*** Once the PM has reviewed the draft QAPP and assessed it as complete, the PM will complete the electronic QAPP submission form (available at neiwpcc.org/quality).

***2.2:*** The PM will email both an electronic version of the draft QAPP and the completed electronic QAPP submission form to the receiver.

**NOTE**: From this point forward, the PM should be cc'd on all emails regarding review and approval of the QAPP.

***Step 3: Receipt of Draft QAPP***

***3.1:*** Upon receipt of the draft QAPP and corresponding QAPP submission form, the receiver will create a new record in QAPP Tracker. (Additional details pertaining to QAPP Tracker are provided in section V of this document.)

***3.2:*** The receiver will create a new folder by project title in the designated location on the Common drive (for example*, I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects) and will save both the electronic draft QAPP and corresponding QAPP submission form within this folder.

***3.3:*** Upon completion of ***3.1*** and ***3.2***, the receiver will email the draft QAPP to the quality assurance program manager (QAPM).

***Step 4: QAPP Review Assignment***

***4.1:*** Once the QAPM receives the draft QAPP, the QAPM will assign a QA designee to conduct the review, and the draft QAPP will be emailed to that individual. (The QA designee will typically be selected, in consultation with appropriate supervisory staff, based on availability and areas of technical expertise.) The QAPM will input the QA designee and assignment date into QAPP Tracker.

***4.2:*** Should the QAPP require approval from other organizations, the QAPM will email the draft QAPP to the appropriate reviewer. The message will request a review of the draft QAPP with any necessary modifications emailed to the PM. The message will also request that the other organization not approve (sign) the QAPP until the NEIWPCC review and approval process is complete.

***Step 5: Reviewing Draft QAPP***

***5.1:*** The QA designee will review the draft QAPP, using (and completing) the appropriate review checklist.

***5.2:*** Upon completion of the checklist, the QA designee will generate a comment memo that details any needed modifications. The QA designee will save the completed checklist and comment memo in the appropriate electronic project file (for example, the project-specific folder in *I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for fiscal year 2015 projects). If the QA designee is not located in the Lowell office, the designee will email the comment memo and checklist to the receiver, who will save the files to the appropriate location.

***5.3:*** The QA designee will email the comment memo to the PM to initiate the revision process. Under most circumstances, the PM should receive the comment memo from the QA designee within 10 business days from the time the designee received the draft QAPP.

**5.4**: The QA designee will update the project record in QAPP Tracker to specify the date the comment memo was sent and will check the box indicating that the electronic checklist has been saved in the appropriate folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

***Step 6: Draft QAPP Revision***

***6.1:*** The PM will email the QA designee's comment memo to the QAPP writer so that the writer can revise the draft QAPP to address issues identified in the memo.

***6.2:*** The QAPP writer will also incorporate any necessary modifications identified during the concurrent review of the draft QAPP by other approving organizations (if applicable). If the PM would like to save any comments (optional) on the evaluation of the draft QAPP, the PM can save them to the QAPPS-PENDING folder (for example, the project specific folder in *I:\COMMON\QUALITY\QAPPs\QAPPs - PENDING\FY2015* for FY2015 projects). Files containing comments should indicate Do Not Delete in the file name. If the PM is not located in the Lowell office, the PM can email the necessary information to the receiver, who will save the file.

***Step 7: QAPP Revision Review***

***7.1:*** When revisions are complete, the PM will submit the revised QAPP to the QA designee who will determine if revisions are adequate.

**7.2:** The QA designee will update QAPP Tracker to specify the date the revised QAPP was received. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will update QAPP Tracker.

***7.3:*** If the QA designee determines that the revisions are inadequate, the PM will be notified so the QAPP can be further revised. Steps 6.1, 6.2, and 7.1 will be repeated until the QA designee determines that the QAPP has been adequately revised.

***7.4:*** Once the QA designee determines that the revisions are adequate, the signature process may be initiated. The QA designee will update QAPP Tracker to specify the date that the revisions were approved. If the QA designee is not located in the Lowell office, the designee will email the receiver, who will update QAPP Tracker.

***7.5*:** The QA designee will send an email to the PM authorizing the signature process to begin. A copy of the email will be saved as a PDF by the QA designee and retained in the appropriate project folder. If the QA designee is not located in the Lowell office, the designee will email the necessary information to the receiver, who will save the PDF in the appropriate project folder.

***Step 8: Finalization of QAPP***

***8.1:*** The PM (or person assigned finalization responsibility within the QAPP) will circulate the complete, final QAPP to the appropriate individuals to obtain signatures. The QAPP should be circulated via email, with signatures added electronically, unless hard copies, with original signatures, are required.

***8.2:*** Once the PM (or assigned individual) receives all signatures, a PDF of the complete, approved QAPP will be emailed to the distribution list. The receiver will save a copy of the approved QAPP (with all signatures included) in the appropriate project folder. The receiver will also update the project record in QAPP Tracker to specify the date that the final QAPP was received.

***Step 9: Electronically Filing the QAPP***

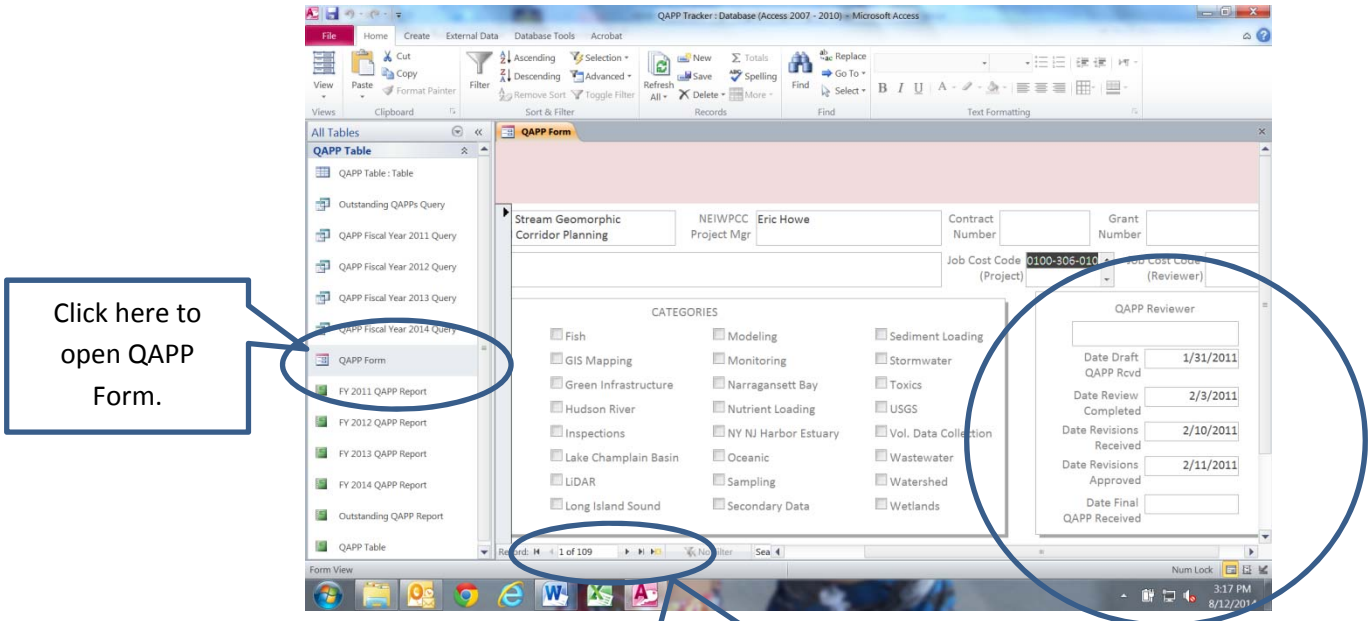
***9.1:*** Once the completed QAPP has been saved, the receiver will delete previous drafts of the QAPP and ensure that the folder also contains the checklist, comment memo, submission form, and the email authorizing initiation of the signature process. The receiver will retain any files designated Do Not Delete.

***9.2:*** With the aforementioned documents included, the receiver will relocate the project folder to the "QAPPS – COMPLETE" folder on the Common drive (for example, *I:\COMMON\QUALITY\QAPPs\QAPPs – COMPLETE\Completed FY2015 QAPPs* for fiscal year 2015 projects) and update QAPP Tracker accordingly.

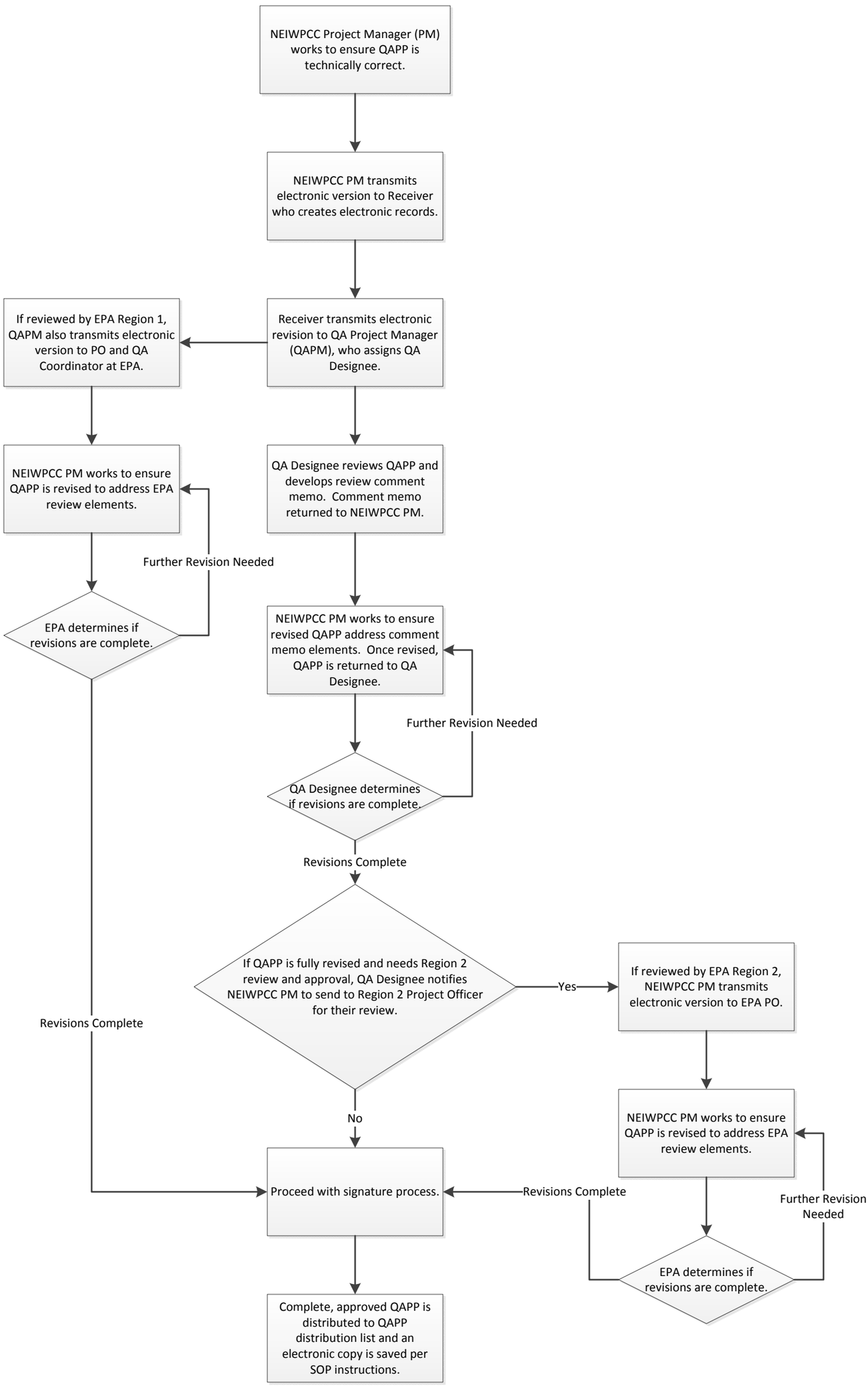
## V. QAPP Tracker

- QAPP Tracker is an Access database used to compile project-specific information pertaining to the QAPP review and approval process. It can be found at *I:\COMMON\QUALITY.*
- Once QAPP Tracker is opened, the navigation pane can be expanded and the QAPP Form opened. See Figure 1.
- When a new QAPP is submitted for review, the receiver will create a new record for the project and populate the fields within the record using information provided on the QAPP Submission Form.
- When the QA designee (or receiver) updates the project-specific record within QAPP Tracker, the appropriate record is first found using the scroll buttons. The fields for inserting relevant dates for that record are located at the far right of the form.

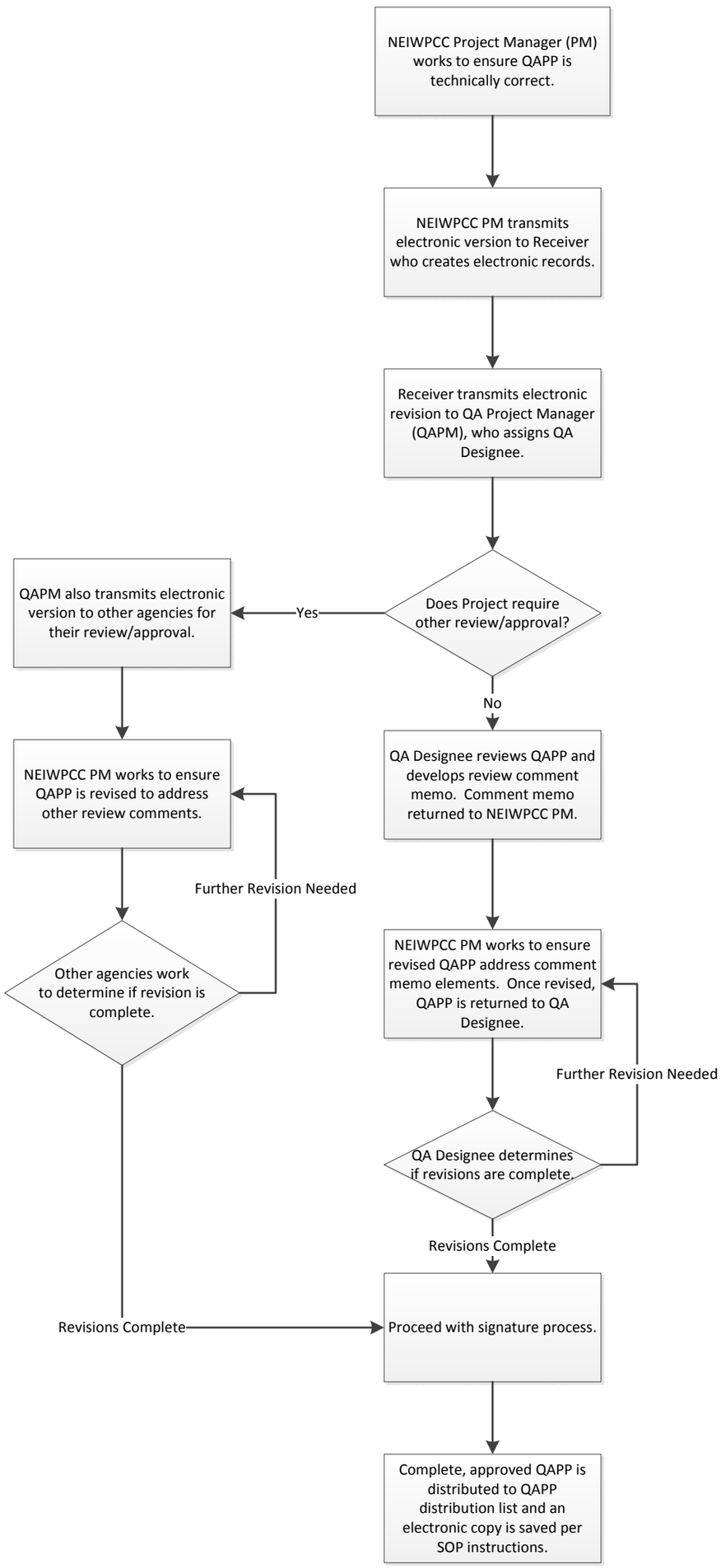
**Figure 1**



# EPA Funded Project



# Project Funded by Other Organizations



Appendix D

QA Project Plan 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 | ☐ | ☐ | ☐ | ☐ | |
| 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 | ☐ | ☐ | ☐ | ☐ | |
| **B2. Sampling Methods** | | | | | |
| Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken | ☐ | ☐ | ☐ | ☐ | |



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

| Element | A | U | NI | NA | Comments |
|---|---|---|---|---|---|
| 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 | ☐ | ☐ | ☐ | ☐ | |
| **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 | ☐ | ☐ | ☐ | ☐ | |



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

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



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

| 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 | ☐ | ☐ | ☐ | ☐ | |

**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 | ☐ | ☐ | ☐ | ☐ | |



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

| Element | A | U | NI | NA | Comments |
|---|---|---|---|---|---|
| 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 | ☐ | ☐ | ☐ | ☐ | |
| **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 | ☐ | ☐ | ☐ | ☐ | |
| 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 E

## NEIWPCC QAPP Submission Form

# QAPP SUBMISSION FORM

QAPP Title:

NEIWPCC Project Manager:

NEIWPCC Project Code/Contract Number:

Grant Number:

Job Cost Code (*Project*):

Job Cost Code (*For Reviewer's Use*):

Description (*A few sentences about project objectives and the type of data to be collected and analyzed.*):

Anticipated Start Date of Field Work:

Project End Date:

**Categories**

- ☐ Agriculture
- ☐ Algal Blooms
- ☐ Aquatic Invasive Species
- ☐ Aquatic Vegetation
- ☐ BMPs
- ☐ Climate Change
- ☐ Economic Valuation
- ☐ Ecosystem Indicators
- ☐ Fish
- ☐ GIS Mapping
- ☐ Green Infrastructure
- ☐ Hudson River
- ☐ Inspections
- ☐ Lake Champlain Basin
- ☐ LiDAR
- ☐ Long Island Sound
- ☐ Modeling
- ☐ Monitoring
- ☐ Narragansett Bay
- ☐ Nutrient Loading
- ☐ NY NJ Harbor Estuary
- ☐ Oceanic
- ☐ Sampling
- ☐ Secondary Data
- ☐ Sediment Loading
- ☐ Stormwater
- ☐ Toxics
- ☐ USGS
- ☐ Volunteer Data Collection
- ☐ Wastewater
- ☐ Watershed
- ☐ Wetlands

## Appendix F

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 could potentially 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 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 4 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 QA program manager, or designee, performs completeness check of draft QA Project Plan and provides comments to the NEIWPCC project manager. | 3 weeks |
| 3. Contractor and NEIWPCC project manager revise the draft QA Project Plan and re-submit to NEIWPCC QA program manager. | 4 weeks |
| 4. If revisions are adequate, NEIWPCC QA program manager or project manager submits the draft QA Project Plan to the EPA Project Officer and QA Officer. | 4 weeks |
| 5. EPA staff (project and QA) review the draft QA Project Plan and provide comments to the NEIWPCC project manager. | 7 weeks |
| 6. Contractor and NEIWPCC project manager revise the draft QA Project Plan and re-submit to EPA Project Officer and QA Officer. NEIWPCC QA Program Manger should be copied on all revisions. | 8 weeks |
| 7. If revisions adequately address the EPA comments, the QA Project Plan is finalized by circulating the signature page to all parties for authorization. | 8 weeks |
| 8. NEIWPCC project manager retains finalized plan and provides copies to all necessary parties. Work can commence on data collection activities. | 8 weeks |
| 9. Multi-year projects must be reviewed annually. | |