

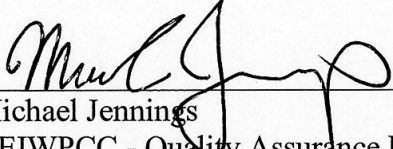
NEW ENGLAND INTERSTATE WATER POLLUTION CONTROL COMMISSION  
(NEIWPC)

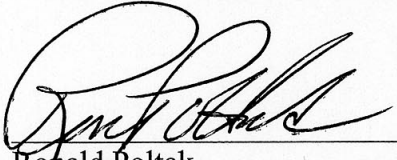
GUIDE FOR DEVELOPMENT AND APPROVAL OF QUALITY ASSURANCE PROJECT  
PLANS (QA PROJECT PLANS)

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VERSION 1.0

Approvals:

 3-31-06  
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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) – approved by EPA in November 2001 – 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 or information 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 facilitate 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 NEIWPC, 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, NEIWPC 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](http://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](http://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 NEIWPCCC Quality Management Plan. Additional information can be obtained by reviewing the NEIWPCCC Quality Management Plan, which is available on the internet ([www.neiwpc.org/quality](http://www.neiwpc.org/quality)).

### **2.1 NEIWPCCC'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.

NEIWPCCC's QMP was approved in November 2001. 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 NEIWPCCC. In addition, NEIWPCCC views its commitment to quality assurance as extending beyond the context of EPA-funded projects. The NEIWPCCC 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 NEIWPCCC Quality Assurance Program Manager**

The NEIWPCCC 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 NEIWPCCC is delegated to the QAPM, who reports to the Deputy Director.

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

- The QAPM is responsible for and will oversee all aspects of QA activities and will keep upper level management and the EPA Regional Quality Assurance Office 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 NEIWPCCC with the EPA.

- 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 Region 1's Quality Assurance Office 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 QA Project Plans and QA-related sections of all procurement packages.
- The QAPM will be responsible for maintaining documentation for all QA Project Plans and communications with EPA.
- The QAPM will work with the project manager and other NEIWPCC management to take appropriate corrective action when necessary.

### **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:

- QA Project Plans shall be prepared by the originating program manager or project coordinator (in cooperation with grantees and contractors as necessary).
- 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 QA Project Plan and making periodic checks for compliance with the QA requirements.
- Project managers are responsible for including appropriate QA requirements in all projects.
- Project managers are responsible for assuring that all data compiled or generated for a project are sufficiently reviewed and/or validated to assure their usefulness for the project, and that the data meet 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 obtained meet the needs of the project or study.

### **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<sup>1</sup>.

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

QA Project Plan items included in project management are:

- Title and Approval Sheet
- Table of Contents
- Distribution List
- Project/Task Organization
- Problem Definition/Background
- Project/Task Description
- Quality Objectives and Criteria

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<sup>1</sup> 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](http://www.epa.gov/quality)). There is also a checklist contained in Appendix C of this guide detailing these elements and sub-elements.

- 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 NEIWPC must contain the following language in the Assessment and Oversight section of the plan: *NEIWPC 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 NEIWPC 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<sup>2</sup>
- 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 NEIWPC 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 NEIWPC 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

The first step in the review and approval process for any draft QA Project Plan – regardless of funding source – is submittal to the NEIWPC QAPM for initial review. The NEIWPC QAPM will conduct a completeness check using the checklist contained in Appendix C. The NEIWPC QAPM will also verify that the draft QA Project Plan complies with the NEIWPC QMP<sup>3</sup>.

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<sup>2</sup> 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](http://www.epa.gov/quality)).

<sup>3</sup> The minimum amount of time that should be allocated to each step in the approval process is described in Appendix D of this guide.

Once the NEIWPCQ QAPM 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 NEIWPCQ QAPM 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 NEIWPCQ, 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 planning and coordination early in the review and approval process, some of the steps mentioned above can happen simultaneously or certain responsibilities could be delegated from the NEIWPCQ QAPM to NEIWPCQ 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 should be completed by all individuals who must sign off on the plan. When all parties have signed the approval page, the original QA Project Plan should be returned to the NEIWPCQ project manager who is responsible for maintaining the plan. All personnel involved in the project (especially those listed in the Distribution section of the plan) should retain or have access to the complete, current version of the QA Project Plan. This may include the project manager, laboratory manager, field team leader, modeler, data reviewers, and any essential contractors and subcontractors involved with the project.

### **5.1 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 NEIWPCQ 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 NEIWPCQ 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](http://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](http://www.epa.gov/quality)

### *U.S. EPA – Region 1 Office of Environmental Measurement and Evaluation (OEME)*

EPA Region 1's OEME is home to the Region 1 Quality Assurance Unit. Their staff is responsible for QA technical assistance and QA Project Plan review and approval. A number of guidance documents and examples of QA Project Plans are available for download from their website.

Information is available at: [www.epa.gov/region1/lab/qa/index.html](http://www.epa.gov/region1/lab/qa/index.html)

*U.S. EPA – Region 2 Quality Assurance Program*

The website for EPA Region 2's Quality Assurance Program provides useful information on the QA Project Plan review and approval process in Region 2.

Information is available at: [www.epa.gov/region2/qa/](http://www.epa.gov/region2/qa/)

*New Hampshire Department of Environmental Services*

The website for NH DES's Quality Assurance Program contains examples of QA Project Plans, as well as technical assistance and contact information.

Information is available at: [www.des.state.nh.us/QA/index.html](http://www.des.state.nh.us/QA/index.html)

*Maine Department of Environmental Protection*

The website for ME DEP's Quality Management System contains examples of QA Project Plans, as well as technical assistance and contact information.

Information is available at: [www.maine.gov/dep/qms.htm](http://www.maine.gov/dep/qms.htm)

*Volunteer Monitoring*

A wealth of information is available on the subject of QA for volunteer monitoring projects.

EPA's Office of Wetlands, Oceans, and Watersheds has a volunteer monitoring web page, available at: [www.epa.gov/owow/monitoring/vol.html](http://www.epa.gov/owow/monitoring/vol.html)

The Massachusetts Volunteer Monitor's Guidebook to Quality Assurance Project Plans is available at: [www.mass.gov/dep/brp/wm/files/qapp.pdf](http://www.mass.gov/dep/brp/wm/files/qapp.pdf)

## **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/qs-docs/r5-final.pdf>

*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/qs-docs/g5-final.pdf>

*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/qs-docs/g5m-final.pdf>

*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/region1/measure/qappcompendium.pdf>

*New England Interstate Water Pollution Control Commission Quality Management Plan*. New England Interstate Water Pollution Control Commission. November 2001. Available at: <http://www.neiwpcc.org/quality>

## **Appendix A**

Modeling Project QAPP Elements / Checklist

(extracted from EPA QA/G-5M)

## APPENDIX C

### CHECKLIST FOR QA PROJECT PLAN ELEMENTS FOR MODELING

Name of Project this QA Project Plan is for: \_\_\_\_\_

#### GROUP A: PROJECT MANAGEMENT

##### A1. Title and Approval Sheet

Contents this element may contain:

- ' Title of QA Project Plan
- ' Revision number of QA Project Plan
- ' Effective date of QA Project Plan revision
- ' Names of all organizations involved in modeling project
- ' Names of all key project officials responsible for the work, with space for dated signatures

##### A2. Table of Contents and Document Control Format

Contents this element may contain:

- ' Title of all sections, including subsections, tables, figures, references, appendices
- ' Page numbers for each section
- ' Section for each QA Project Plan element
- ' Document control box

##### A3. Distribution List

Contents this element may contain:

- ' List of all individuals (and their role on the project) who will be provided copies of the approved QA Project Plan, including all persons responsible for implementation, including project managers, QA Managers, and representatives of all groups involved.

##### A4. Project/Task Organization

Contents this element may contain:

- ' Concise organizational chart showing the relationships and lines of communication among all project participants, other data users, and any subcontractors relevant to environmental data operations
- ' Project name and organizations involved, and a description of their respective responsibilities

## **A5. Problem Definition/Background**

Contents this element may contain:

- ' Goals and objectives of this project that will address this problem
- ' Definition of the population the problem targets and what measures within this population the problem addresses
- ' Reason the project includes a modeling approach to address the problem (is it a new predictive tool?)
- ' Types of decisions that may be made as a result of this project
- ' Names of those responsible for making these decisions
- ' Any other types of problems that the project may address
- ' Background information on the problem
- ' Reasons the project is important, how it supports other existing research, programs, or regulations
- ' Conflicts or uncertainties that will be resolved by this project
- ' Reasons one model is determined to be better than another for this application

## **A6. Project/Task Description and Schedule**

Contents this element may contain:

- ' Summary of all work to be performed, products to be produced, and the schedule for implementation
- ' List of products, deliverables, and milestones to be completed in the various stages of the project
- ' Schedule of anticipated start and completion dates for the milestones and deliverables, and persons responsible for each

## **A7. Quality Objectives and Criteria for Model Inputs/Outputs**

Contents this element may contain:

- ' Project data quality objectives (DQOs), performance criteria, and acceptance criteria
- ' Description of task that needs to be addressed and the intended uses of the output of the modeling project to achieve the task
- ' List of requirements associated with the hardware/software configuration for those studies involving software evaluation

## **A8. Special Training Requirements/Certification**

Contents this element may contain:

- ' Types of required training and certification needed by the project team
- ' Plan for obtaining training and/or certification
- ' Documentation of training and/or certification

## **A9. Documentation and Records**

Contents this element may contain:

- ' Description of information to be included in reports
- ' Proper document control and distribution procedures
- ' Details on document storage
- ' Backup plan for records stored electronically
- ' Description of the change control process (who approves changes, etc.)
- ' Length of retention periods for each record
- ' Data assessment reports, interim project progress reports
- ' Model science formulation report, peer review reports
- ' Model assessment reports, interim project progress reports
- ' Code standards, code auditing and testing reports, interim project progress reports
- ' Model calibration report
- ' Model evaluation records (How well does the model report variability and uncertainty in its output?)
- ' User's manual
- ' Configuration management (after production version) and code maintenance (e.g., or software internal documentation of logic and structure) manuals

## **GROUP B: MEASUREMENT AND DATA ACQUISITION**

### **B7. Calibration**

Contents this element may contain:

- ' Objectives of model calibration activities, including acceptance criteria
- ' Frequency of model calibration activities
- ' Details on the model calibration procedure
- ' Method(s) of acquiring input data
- ' Types of output generated by the model calibration
- ' Approach to characterize uncertainty (e.g., sensitivity analysis)
- ' Corrective action to be taken if criteria are not met
- ' Resources and responsibilities for calibrating the model
- ' Analysis of model output relative to acceptance criteria

## **B9. Non-direct Measurements (Data Acquisition Requirements)**

Contents this element may contain:

- ' Types of data needed for implementing a project that are obtained from non-measurement sources such as databases, literature files
- ' Need for non-direct measurements, intended use of data
- ' Method(s) of identifying and acquiring data
- ' Method of determining the underlying quality of the data
- ' SOPs and field or lab-specific deviations associated with these procedures
- ' Acceptance criteria for non-direct measurements: such as completeness, representativeness, bias, precision, qualifying data

## **B10. Data Management and Hardware/Software Configuration**

Contents this element may contain:

- ' Information on the project data management process (field, office, and lab)
- ' Record-keeping procedures, document control system, audit trails
- ' Control mechanism for detecting and correcting errors, preventing loss of data
- ' Procedures for assuring applicable Agency resource management requirements are satisfied
- ' Required computer hardware/software and any specific performance requirements

### **Data Management**

- ' Any data forms, checklists, on-line interactive screens used in the modeling process
- ' Any graphics developed to document the data management process (process flow diagrams, modeling flow charts, etc.)
- ' Documentation of internal checks used during data entry
- ' Data calculations and analyses that should to be highlighted in the QA Project Plan
- ' Plans for characterization of uncertainty and variability in the model results (e.g., summary statistics, frequency distributions, goodness-of-fit tests)

### **Hardware/Software Configuration**

- ' List of equipment, hardware, and software that will be used on the project
- ' Description of performance requirements
- ' Decisions regarding security issues
- ' Decision regarding communication issues
- ' Decisions regarding software installation issues
- ' Decisions regarding response time issues
- ' Plans for requirements documentation

- ' Coding standards
- ' Testing plans
- ' Plans for data dictionary (may not need to be a separate document)
- ' Plans for a user's manual
- ' Plans for a maintenance manual (explaining software logic and organization)
- ' Plans for source code for the ultimate user of the model or model framework
- ' Configuration management plan (procedures to control software/hardware configuration during development of the original model version)

## **GROUP C: ASSESSMENTS AND OVERSIGHT**

### **C1. Assessment and Response Actions**

Contents this element may contain:

- ' Assessment/oversight strategies and schedule of assessment activities, order of events
- ' Organizations and individuals expected to participate in assessments, including peer reviews
- ' Information expected, success criteria
- ' Scope of authority of assessors to recommend or direct changes to the model (corrective actions)
- ' Qualitative and quantitative assessments
- ' Internal assessments (internal QA officer's review of input data, code verification, calibration, benchmarking) and external assessments (peer review of model theory or mathematical structure)
- ' Surveillance activities (continued monitoring of status and progress of the project, tracking project milestones and budgets)
- ' Plans for model performance evaluations
- ' Plans for sensitivity analysis
- ' Plans for uncertainty analysis
- ' Plans for data quality assessment
- ' Plans for code testing

### **Hardware/Software Assessments**

- ' Plans for hardware and software configuration testing, if appropriate
- ' Plans for code verification tests
- ' Plans for internal and external peer reviews
- ' Plans for checking for programming errors
- ' Plans for checking for correct insertion of model equations
- ' Plans for checking for code's linkage to analysis of uncertainty

## **Hardware/Software Configuration Tests**

- ' Plans for software code development inspections
- ' Plans for software code performance testing
- ' Plans for a test of the model framework
- ' Plans for integration tests (check computational and transfer interfaces between modules)
- ' Plans for regression tests
- ' Plans for stress testing of complex models (to ensure that maximum load during peak usage does not exceed limits of the system)
- ' Plans for acceptance testing (contractually-required testing needed before a new model or model application is accepted by the customer and final payment is made)
- ' Plans for beta testing of pre-release hardware/software, recording of anomalies
- ' Plans for checking for programming errors

## **Plans for science and product peer review**

- ' Theoretical basis for the model
- ' Mathematical model structure
- ' Model algorithms
- ' Model predictions
- ' Model calibration
- ' Plans for data quality assessment
- ' Plans for peer review of final technical product

## **C2. Reports to Management**

Contents this element may contain: plans for documentation of:

- ' Project reporting schedule
- ' Frequency, content, and distribution of reports
- ' Deviations from approved QA Project Plan
- ' Need for response actions to correct deviations
- ' Potential uncertainties in decisions based on input data and model limitations
- ' Data Quality Assessment findings

## **GROUP D: DATA VALIDATION AND USABILITY**

### **D1. Departures from Validation Criteria**

Contents this element may contain:

- ' Criteria used to review and validate (accept, reject, or qualify) model components such as theory, mathematical procedures, code, and calibration (convergence criteria, etc.)
- ' Criteria used to review and validate input data
- ' Criteria used to test model performance
- ' Criteria used to review or validate model outputs

### **D2. Validation Methods**

Contents this element may contain:

- ' Methods for review of model components such as theory, mathematical procedures, code, and calibration (peer review, etc.)
- ' Methods for review of input data
- ' Methods for review of model performance tests
- ' Methods for assessment of model output and usability

### **D3. Reconciliation with User Requirements**

Contents this element may contain:

- ' Discussion of project or task results
- ' List of departures from assumptions set in the planning phase of the model
- ' Report on limitations on use of output data for decision makers or users

## **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](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

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

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

## **Appendix C**

### QA Project Plan Review Checklist

(extracted from EPA QA/G-5)

## EXAMPLE OF A QA PROJECT PLAN REVIEW CHECKLIST

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

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>PROJECT MANAGEMENT</b>						
<b>A1. Title and Approval Sheet</b>						
Contains project title						
Indicates revision number, if applicable						
Indicates organization's name						
Dated signature of organization's project manger present						
Dated signature of organization's QA manager present						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Other signatures, as needed						
<b>A2. Table of Contents</b>						
Lists QA Project Plan information sections						
Document control information indicated						
<b>A3. Distribution List</b>						
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization						
<b>A4. Project/Task Organization</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>A5. Problem Definition/Background</b>						
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						
<b>A6. Project/Task Description</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>A7. Quality Objectives and Criteria</b>						
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						
<b>A8. Special Training/Certifications</b>						
Identifies any project personnel specialized training or certifications						
Discusses how this training will be provided						
Indicates personnel responsible for assuring these are satisfied						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Identifies where this information is documented						
<b>A.9 Documentation and Records</b>						
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 individual responsible for this						
<b>DATA GENERATION and ACQUISITION</b>						
<b>B1. Sampling Process Design (Experimental Design)</b>						
Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
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						
<b>B2. Sampling Methods</b>						
Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken						
Indicates how each sample/matrix type should be collected						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
If <i>in situ</i> 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 samples should be preserved and indicates methods that should be followed						
Indicates 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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented						
<b>B3. Sample Handling and Custody</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>B4. Analytical Methods</b>						
Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures						
Identifies equipment or instrumentation needed						
Specifies any specific method performance criteria						
Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation						
Identifies sample disposal procedures						
Specifies laboratory turnaround times needed						
Provides method validation information and SOPs for nonstandard methods						
<b>B5. Quality Control</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
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						
<b>B6. Instrument/Equipment Testing, Inspection, and Maintenance</b>						
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 corrective action determined and documented						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>B7. Instrument/Equipment Calibration and Frequency</b>						
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						
<b>B8. Inspection/Acceptance for Supplies and Consumables</b>						
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						
<b>B9. Non-direct Measurements</b>						
Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
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						
<b>B10. Data Management</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Describes procedures to demonstrate acceptability of hardware and software configurations						
Attaches checklists and forms that should be used						
<b>ASSESSMENT and OVERSIGHT</b>						
<b>C1. Assessments and Response Actions</b>						
Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates						
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process						
Describes how and to whom assessment information should be reported						
Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented						
<b>C2. Reports to Management</b>						
Identifies what project QA status reports are needed and how frequently						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Identifies who should write these reports and who should receive this information						
<b>DATA VALIDATION and USABILITY</b>						
<b>D1. Data Review, Verification, and Validation</b>						
Describes criteria that should be used for accepting, rejecting, or qualifying project data						
<b>D2. Verification and Validation Methods</b>						
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						

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
<b>D3. Reconciliation with User Requirements</b>						
Describes procedures to evaluate the uncertainty of the validated data						
Describes how limitations on data use should be reported to the data users						

## **Appendix D**

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 NEIWPCCC.  | 2 months |
| 2. NEIWPCCC QA Program Manager performs completeness check of draft QA Project Plan and provides comments to the NEIWPCCC Project Manager.   | 3 months |
| 3. Contractor and NEIWPCCC Project Manager revise the draft QA Project Plan and re-submit to NEIWPCCC QA Program Manager.  | 4 months |
| 4. If revisions are adequate, NEIWPCCC QA Program Manager or Project Manager submits the draft QA Project Plan to the EPA Project Officer and QA Officer.                                      | 4 months |
| 5. EPA staff (project and QA) review the draft QA Project Plan and provide comments to the NEIWPCCC Project Manager.   | 5 months |
| 6. Contractor and NEIWPCCC Project Manager revise the draft QA Project Plan and re-submit to EPA Project Officer and QA Officer. NEIWPCCC QA Program Manger should be copied on all revisions. | 6 months |
| 7. If revisions adequately address the EPA comments, the QA Project Plan is finalized by circulating the signature page to all parties for authorization.                                      | 6 months |
| 8. NEIWPCCC Project Officer retains finalized plan and provides copies to all necessary parties. Work can commence on data collection activities.  | 6 months |
| 9. Multi-year projects must be reviewed annually.  |          |