

235 Promenade Street, Suite 393 Providence, RI 02908 401-633-0550 info@nbep.org www.nbep.org

GUIDE FOR DEVELOPING AND APPROVING QUALITY ASSURANCE PROJECT PLANS (QAPPS)

Version 1. April 2022

Introduction

The Narragansett Bay Estuary Program (NBEP) is a leader in regional science for the Narragansett Bay, Little Narragansett Bay, Coastal Salt Ponds and their watersheds ("study area"). NBEP focuses on creative collaborative solutions to issues surrounding water quality, wildlife, and the way of life for people who live, work, and play in our study area. NBEP is funded through Section 320 of the Clean Water Act administered by the US Environmental Protection Agency (EPA). Roger Williams University (RWU) operates as NBEP's fiscal sponsor and host entity.

When NBEP 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 (QAPP).

EPA has provided <u>guidance</u> for QAPPs, and for this document we used <u>Guidance for QAPPs</u>. Additionally, we sought guidance from NEIWPCC's <u>Quality Management</u> team.

What is a QAPP and When is it needed?

A Quality Assurance Project Plan (QAPP) is a planning document that provides the plan for obtaining the type, quantity, and quality of data needed to support environmental decision making. If a project is using data to make a decision, then a QAPP is needed. The QAPP ensures that the data will meet project requirements.

Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature and evaluated for a project. Data is defined as both natural and social science information collected and analyzed for a project. This can be through direct measurements, or gathered from other sources, or compiled from existing databases. A QAPP is also needed when using or developing a computer model to aid in decision making.

The following is a table of the type of projects NBEP routinely funds organized by whether they require a QAPP. This table is not exhaustive. If unsure, the staff scientist will verify with the project partners and EPA if a particular project needs a QAPP.

Needs a QAPP	Does NOT need a QAPP
Research	Capacity-Building
≥ 60-70% design for permitting	≤ 60% design if no data collection, compilation, or modeling
Any design including data collection, compilation, or modeling	Shovel-Ready Implementation
Monitoring	Outreach
	Policy

The QAPP documents the results of a project's technical planning process and provides a clear, concise, and complete plan for the data operation and its quality objectives. The plan also identifies key personnel. This document will communicate how to implement the project to all individuals involved. While this does not guarantee successful collection of the highest quality data, implementing and following a QAPP improves the potential for success.

The QAPP must be written and approved prior to the start of any data collection or analysis. If the QAPP is not approved before work begins, a stop-work order will be issued.

A successful QAPP includes the following:

- The project's goals and objectives or questions to be investigated
- Specific roles of the individuals and organizations involved with the project
- Decision(s) to be made using the information obtained
- How, when, and where project information will be acquired or generated
- Possible projects that may rise and actions to mitigate their impact on the project
- The type, quality, and quantity of the data collected or retrieved
- A description of the tolerance for error within the data (how "good" the data must be to make a decision)
- How the data will be stored, analyzed, assessed, and reported (including signed agreement that RWU's Data Storage Policy will be followed).

The <u>Data Storage Policy</u> is also included as Appendix A

NBEP uses three types of QAPPs:

- 1. primary data collection QAPP (where the project team will go out and collect observations or samples)
- 2. secondary data QAPP (where previously published data are compiled and used to make a decision)
- 3. modeling QAPP (where the project team will develop or use a model to make a decision; this QAPP is very similar to a secondary data QAPP and will most likely only be used when the project relies solely on the model to make a decision)

Checklists defining exactly what will be reviewed for each QAPP are attached as Appendix B.

Template QAPPs are available through NBEP's website: https://www.nbep.org/projects-we-fund/forms-guidance and by email to NBEP's staff scientist.

Any questions about which QAPP is appropriate for the work should be directed to NBEP's staff scientist.

Who must prepare/read/sign a QAPP?

All recipients of a subaward through the Environmental Protection Agency (EPA) where data will be used to inform a decision must prepare a QAPP. NBEP maintains templates of the three types of QAPPs and checklists to ensure that preparers have included all the necessary information (available on website and by email).

QAPPs will be reviewed by NBEP, EPA, and senior members of the project team (see section below). Once the QAPP has gone through official review by EPA and NBEP, the QAPP must be signed by senior members of the project team, NBEP, and EPA. EPA holds final approval of the QAPP which allows work to proceed. Once approved, the QAPP should be distributed to all individuals listed in the QAPP and work can begin.

Management and Organization

This section describes the organizations and individuals involved in developing and approving QAPPs. Each project will have a specific list of individuals and organizations pertinent to the project, and therefore the following list is not exhaustive.

The Project Team: includes the organizations and individuals who are involved in managing the project or collecting/generating the data used for the project; writes QAPP

NBEP: is first point of contact for the project team for all proposal/subaward questions; review QAPPS; ensures QAPPs are being followed through review

RWU1: is responsible for financial management of the grant, and ensures fiscal responsibility

EPA: is responsible for reviewing QAPPS, and coordinates with NBEP and RWU on funding guidance

QAPP Review and Approval

All QAPPs will be reviewed by NBEP, EPA, and other groups as necessary. If NBEP is preparing a QAPP, they will secure an external review to ensure the QAPP meets the expectations.

QAPPS take time to develop and approve. Project teams should allow at least 3 months of lead time for QAPP development and approval. The preparation of the QAPP is dictated by the Project Team preparing the QAPP. On average, NBEP finds that the Project Team needs 2 weeks to draft the QAPP. The draft QAPP is then submitted to NBEP's Staff Scientist who will review it for completeness and provides a first round of feedback. Once that feedback is incorporated, NBEP will review the QAPP according to the checklists provided in Appendix A and will submit the QAPP to EPA's Quality Assurance Team and NBEP's EPA Coordinator, Caitlyn Whittle (R1QAPPS@epa.gov) and whittle.caitlyn@epa.gov) for simultaneous review. Memos containing comments will be shared with the Project Team, who will then revise the QAPP and submit it for a second review. Once all parties are satisfied, the QAPP will be signed and distributed. Below is an approximate timeline of milestones for QAPP review and approval.

¹ Roger Williams University will only read and approve QAPPs when their employees are on the Project Team. For all other QAPPs, review and approval rests with NBEP and EPA

Mil	estone	Time from Contract Award
1.	Project Team prepares QAPP	2 weeks
2.	NBEP reviews for completeness and provides first round of feedback	4 weeks
3.	Project Team revises QAPP	5 weeks
4.	Project Team submits QAPP to NBEP for review. NBEP submits QAPP to EPA for simultaneous review	6 weeks
5.	NBEP and EPA reviews QAPP and prepares memos with comments and necessary revisions	10 weeks
6.	Project Team revises QAPP and resubmits for review	12 weeks
7.	If revisions are adequate, QAPP is finalized by circulating the signature page to all parties for authorization	14 weeks
8.	NBEP retains finalized plan, and Project Team provides copies to all necessary parties	14 weeks

QAPP Modifications

If procedures and/or activities described in the original QAPP must be modified immediately (that is before or between annual reviews; see below) to achieve project objectives, the plan must be amended. The amendment must be reviewed and approved in the same manner as the original QAPP. Only after the amendment has been approved can the change be implemented.

Annual Review of Approved QAPPs

All approved QAPPs for multi-year projects will be reviewed annually by the project team to determine if any changes are necessary. Those changes will be documented in a letter shared with all organizations who approved the QAPP. The NBEP Staff Scientist is responsible initiating annual review. If significant changes are necessary, EPA and/or NBEP may require the QAPP undergo full update with review.

Appendix A

Roger Williams University Data Storage Policy

ROGER WILLIAMS UNIVERSITY Data Storage Policy

Purpose

Roger Williams University is committed to protecting its data. Data Storage environments including Cloud Storage are useful in many ways. However, there are inherent risks relative to security, copyright, privacy, and data retention. Unlike data stored on premise, when documents are saved in Cloud Storage environments, the University must identify the appropriate administrative and access controls for the stored data. This policy notes best practices and applies to all University employees and affiliates that store the University Data classifications outlined in this policy.

Scope

This policy applies to all persons accessing University data on premise and/or using 3rd party services capable of storing or transmitting protected or sensitive electronic data that are owned or leased by Roger Williams University, all consultants or agents of the University and any parties who are contractually bound to handle data produced by and in accordance with University contractual agreements and obligations.

Compliance with Legal and Regulatory Requirements

The University has many federal laws that it must follow, these include the Family Educational Rights and Privacy Act of 1974 (FERPA), and RI General Laws 11-49.3 (Identify Theft Protection Act) and 5-37.3 (Confidentiality of Health Care Communications and Information Act).

Definitions

Data Classifications:

Protected Data - Under state law, Personally Identifiable Information means an individual's first name or first initial <u>and last name in combination</u> with any one or more of the following data elements, when the name and the data elements are not encrypted or are in hard copy, paper format-

- Social security number
- Driver's license number, state identification card number, or tribal identification number
- Account number, credit, or debit card number, with or without any required security code, access
 code, password, or personal identification number, that would permit access to an individual's
 financial account
- Medical or health insurance information
- E-mail address with any required security code, access code, security Q&A, or password that would permit access to an individual's personal, medical, insurance, or financial account.

Sensitive Data – Data not meant for public distribution but not classified as Protected Data (i.e. internal policies, internal memos, Intranet information)

Public Data – Data meant for public distribution (i.e. external website, public relations materials, etc.)

Storage Classifications:

Cloud Storage – Cloud infrastructure provisioned for open use by the general public (i.e. Dropbox, Microsoft OneDrive - Personal, Google Docs - Personal, etc.)

University System on Premise– Private on premise Infrastructure provisioned for the exclusive use of Roger Williams University (i.e. Network Drives, Student Information System, Finance System, HR System etc.)

University System Cloud-based – Cloud Infrastructure provisioned for the exclusive use of Roger Williams University (i.e. RWU Microsoft O365, RWU Learning Management System, RWU Google etc.)

Local Storage – Personal or Roger Williams University devices not connected to a network controlled infrastructure (i.e. USB drives, laptops, desktop computers, etc.)

Policy Guidelines: The following guidelines note the permitted and prohibited storage systems for the data classifications outlined in this policy

Data Classification	Cloud Storage	University System on Premise	University System Cloud-based	Local Storage
Protected Data	Prohibited	Permitted	Permitted with Encryption	Prohibited
Sensitive	Prohibited	Permitted	Permitted with Encryption	Prohibited
Public	Permitted	Permitted	Permitted	Permitted

All Roger Williams University employees and affiliates looking to provision Cloud Storage services for work-related activities should consult with the Information Technology Department before doing so in order to ensure appropriate data security measures are taken.

Cross Policy References: Records Retention Policy [Retention Schedule], Written Information Security Program [Data Destruction Methods]





DATA STORAGE POLICY AGREEMENT

I, [name] of [organization] , have read Roger Williams University's <u>Data Storage Policy</u> and agree to all its stipulations for the NBEP-funded project entitled [project] .	
Signed,	
Signature	
Date	_

Appendix B

Primary Data QAPP Checklist (EPA R-5)

EPA R-5 (Primary Data) 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: Reviewer:	Date Submitted for Date of Re						
Note: A=Acceptable; U=Unacceptable; NI=N	lot Included; NA=Not	Appli	cable				
DOCUMENT CONTROL							
Element		Α	U	NI		NA	Comments
Document control information is indicate QAPP page	d in header of each]		
Project title is indicated							
QAPP version number and date are ind							
Page number is indicated in "Page X of	Y" format						
PROJECT MANAGEMENT Element		Α	U	NI		NA	Comments
A1.Title and Approval			1				
Contains project title				Т	1 [П	
Indicates revision number, if applicable							
Indicates EPA cooperative agreement n	umber				Ì		
Indicates RWU grant number							
Indicates organization(s)' name(s)							
Signature and date lines for organization	on(s)' project]		
Signature and date lines for organization manager(s) present	on(s)' QA]		
Other signatures, as needed							
A2. Table of Contents							•
Lists QA Project Plan information section page numbers	s and relevant]		
Document control information indicated				İE] [
A3. Distribution List							•
Includes all individuals who are to recei	ve a copy of the QA]		

Project Plan and identifies their organization												
Element	Α	U		NI	N/	4	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		$ \sqcup$			ΙШ	ĺ						
context) for initiating this project		_				,_						
Identifies regulatory information, applicable criteria, action		$ \sqcup$		Ш	ΙШ	j						
limits, etc., necessary to the project												
A6. Project/Task Description						1 1						
Summarizes work to be performed, for example,	Ш	$ \sqcup$		Ш	$ \sqcup$	j						
measurements to be made, data files to be obtained, etc.,												
that support the project's goals				_		1						
Provides work schedule indicating critical project points,	ΙШ	$ \sqcup$		Ш	ΙШ	1						
e.g., start and completion dates for activities such as												
sampling, analysis, data or file reviews, and assessments				$\overline{}$		1						
Indicates QAPP end date	Щ	╁╠		<u> </u>	H	\perp						
Details geographical locations to be studied, including		$ \sqcup$		Ш	ΙШ	i						
maps where possible				$\overline{\Box}$		1						
Discusses resource and time constraints, if applicable		Ш		Ш	Ш	Ш	<u>L</u>					
A7. Quality Objectives and Criteria		1		$\overline{}$								
Identifies performance/measurement criteria for all		$ \sqcup$		Ш	ΙШ	i						
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	\vdash	$\vdash \sqcap$	+	П	\vdash	\dashv						
Addresses bias	片片	ㅐ	+	旹	H	\vdash						
Discusses representativeness	H	$+$ \vdash \vdash		+	怡	\vdash						
Identifies the need for completeness	H	╁╫	+	+	H	\vdash						
Describes the need for comparability	╁╫╴	╁岩		\dashv	H	\vdash						
Describes the need for comparability				<u>ш</u>	\sqcup	1	<u> </u>					

Α	U		NI	NA	Comments
	<u> </u>				
	$ \sqcup$		Ш	Ш	
_			_		
			<u>Ц</u>	Ц	
			Ш		
Α	U		NI	NA	Comments
		-	_		
	ΙШ		Ш	Ш	
\vdash		-	$\overline{}$		
	ΙШ		Ш	Ш	
\vdash			$\overline{\Box}$		
			Ш	Ш	
\vdash		-	$\overline{}$		
+	H	-	H	H	
	$ \sqcup$		Ш	ш	
$\vdash \vdash$			\Box		
			Ш		
$\vdash \sqcap$		-			
			Ш		
		A U	A U	A U NI	A U NI NA

Element	Α	U	NI	NA	Comments					
B2. Sampling Methods										
Identifies all sampling SOPs by number, date, and		П	П							
regulatory citation, indicating sampling options or										
modifications to be taken										
Indicates how each sample/matrix type should be collected										
If in situ monitoring, indicates how instruments should be										
deployed and operated to avoid contamination and ensure										
maintenance of proper data										
If continuous monitoring, indicates averaging time and how										
instruments should store and maintain raw data, or data										
averages										
Indicates how samples are to be homogenized, composited,										
split, or filtered, if needed										
Indicates what sample containers and sample volumes										
should be used										
Identifies whether sampling equipment and samplers should	Ш	Ш								
be cleaned and/or decontaminated, identifying how this										
should be done and by-products disposed of										
Identifies any equipment and support facilities needed	Щ		Щ							
Addresses actions to be taken when problems occur,	Ш	Ш		Ш						
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	Ш	Ш	Ш	Ш						
collection to extraction and/or analysis for each sample										
type and, for <i>in situ</i> or continuous monitoring, the maximum										
time before retrieval of information										
Identifies how samples or information should be physically		ш		Ш						
handled, transported, and then received and held in the										
laboratory or office (including temperature upon receipt)										
Indicates how sample or information handling and custody		ш		Ш						
information should be documented, such as in field										
notebooks and forms, identifying individual responsible	\vdash		\vdash	_						
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	\vdash		\vdash							
track custody										

Element	Α	U	N	II	NA	Comments					
B4. Analytical Methods											
Identifies all analytical SOPs (field, laboratory and/or											
office) that should be followed by number, date and											
regulatory citation, indicating options or modifications to be											
taken, such as sub-sampling and extraction procedures											
Identifies equipment or instrumentation needed											
Specifies any specific method performance criteria											
Identifies procedures to follow when failures occur,											
identifying individual responsible for correct action and											
appropriate documentation											
Identifies sample disposal procedures											
Specifies laboratory turnaround times needed											
Provides method validation information and SOPs for											
nonstandard methods											
For projects in NY, if required by the funding source or a											
project partner (e.g. NYSDEC), specifies that laboratories to											
be used are NYSDOH ELAP certified for each parameter to											
be analyzed											
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	Ш	Ш		┚╽	Ш						
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		ΙШ	١L	╛╽	Ш						
maintenance, and the schedule for this			_								
Identifies testing criteria		Щ	1 <u>L</u>		Ц_						
Notes availability and location of spare parts	Щ	Ш									
Indicates procedures in place for inspecting equipment	Ш	Ш		╛╽	Ш						
before usage											
Identifies individual(s) responsible for testing, inspection and				╛╽							
maintenance			<u> </u>								
Indicates how deficiencies found should be resolved, re-			١L	┚╽							
inspections performed, and effectiveness of correct action											
determined and documented	l										

Element	Α	U	NI		NA	Comments						
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												
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	1	1	1						
Lists the number, frequency and type of assessment activities that should be conducted, with the approximate									
dates									
Identifies individual(s) responsible for conducting									
assessments, indicating their authority to issue stop work									
orders and any other possible participants in the									
assessment process			 	_					
Describes how and to whom assessment information should be reported									
Identifies how corrective actions should be addressed and									
by whom, and how they should be verified and									
documented Includes standard NBEP assessment language: "NBEP may			\vdash						
implement, at its discretion, various reviews of this project to									
assess conformance and compliance to the Quality									
Assurance Project Plan. NBEP may issue a stop work order									
and require corrective action(s) if nonconformance or									
noncompliance to the Quality Assurance Project Plan is									
found."									
C2. Reports to Management									
Identifies what project QA status reports are needed and how frequently									
Identifies who should write these reports and who should		П	П	П					
receive this information									
DATA VALIDATION AND USABILITY									
Element	Α	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	Ш		$ \sqcup $	╽Ш					
software should be used if any									

Element	Α	U	NI	NA	Comments
Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.					
Identifies issue resolution process, and method and individual responsible for conveying these results to data users					
Attaches checklists, forms and calculations					
D3. Reconciliation with User Requirements					
Describes procedures to evaluate the uncertainty of the validated data					
Describes how limitations on data use should be reported to the data users					



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

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

PROJECT TITLE:													
Preparer: Date Sc	bmitte	ed for	l for Review:										
Reviewer: Date of	Revie	:w: _		_									
Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=No DOCUMENT CONTROL	t Appl	icable											
Element	Α	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	ı					1							
Contains project title													
Indicates revision number, if applicable													
Indicates EPA cooperative agreement number													
Indicates RWU 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						
Element	Α	U	1	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			L			
outcomes expected from the information to be obtained	<u> </u>	<u> </u>				
Clearly explains the reason (site background or historical			L	IJ ┃		
context) for collecting secondary data and how that data						
will be used to meet project goals	<u> </u>	<u> </u>	١,			
Identifies regulatory information, applicable criteria, action	ΙШ	ΙШ	L	_	Ш	
limits, etc., necessary to the project						
A6. Project/Task Description					_	1
Summarizes work to be performed, for example, secondary	ΙШ	ΙШ	L	_]	Ш	
data files to be obtained, analyses to be performed etc.,						
that support the project's goals	_			_		
Provides work schedule indicating critical project points,			L	_	Ш	
e.g., start and completion dates for activities such as						
secondary data collection, analysis, data or file reviews,						
and assessments	\vdash		+-	_	$\overline{}$	
Indicates QAPP end date		H	<u> </u>	4	\perp	
Details geographical locations to be studied, including		ΙШ	L	_	Ш	
maps where possible	\vdash		+-			
Discusses resource and time constraints, if applicable	ļШ	Ш	<u> </u> L		Ш	
A7. Quality Objectives and Criteria			1 -		$\overline{}$	T
Identifies the secondary data needed to satisfy the project			L		Ш	
objectives	\vdash		+-	_	$\overline{}$	
Discusses types of secondary data	+#	ዙ	╁	╣	<u> </u>	
Addressed the age of data	H	H	<u> </u>	4	<u> </u>	
Discusses geographical representation of data	╀┼		ļĻ	4	<u> </u>	
Discusses temporal representation of data	ᄔ	H	<u> </u>	4	<u> </u>	
Discusses technological representation of data						

Element	Α	U	NI	NA	Comments
A8. Special Training/Certifications			ı	ı	
Identifies any project personnel specialized training or					
certifications					
Discusses how this training will be provided					
Indicates personnel responsible for assuring these are					
satisfied					
Identifies where this information is documented					
A9. Documentation and Records					
Identifies report format and summarizes all data report					
package information					
Lists all other project documents, records, and electronic					
files that will be produced					
Identifies where project information should be kept and for					
how long					
Discusses back up plans for records stored electronically					
States how individuals identified in A3 will receive the most					
current copy of the approved QA Project Plan, identifying					
the individuals responsible for this					
DATA ACQUISITION					
Element	Α	U	NI	NA	Comments
B1. Sources of Secondary Data			1	1	
Identifies sources of required secondary data, including the		П		П	
originating organization(s), and the report/publication title					
and date. May be displayed in tabular format					
Identifies the generators of required secondary data (if		П			
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					
				$\overline{}$	
Specifies that all sources of secondary data gathered will		$ \sqcup $		Ш	
be identified in project reports and deliverables					
			NI	NA NA	Comments

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							
Describes data management and storage scheme.							
Identifies data handling equipment/procedures that should]	
be used to process, compile, analyze and transmit data							
reliably and accurately							
Identifies individual(s) responsible for data management							
Describes the process for data archival and retrieval							
Describes procedures to demonstrate acceptability of							
hardware and software configurations							
Attaches checklists and forms that should be used							
ASSESSMENT and OVERSIGHT							
A CONTRACT OF THE PROPERTY OF							
Element	Α	U		NI	N	Α	Comments
C1. Assessments and Response Actions							<u></u>
Lists the number, frequency and type of assessment		ТГ	7 1			1	
activities that should be conducted, with the approximate		-	_	ш	-		
dates							
Identifies individual(s) responsible for conducting	ТП	ТГ	7		Т	1	
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	lП	Т			İΓ		
be reported			-			_	
Identifies how corrective actions should be addressed and							
by whom, and how they should be verified and							
documented							

Element	Α	U	NI	NA	Comments
Includes standard NBEP assessment language: "NBEP may	П		П	\Box	
implement, at its discretion, various reviews of this project to					
assess conformance and compliance to the Quality					
Assurance Project Plan. NBEP may issue a stop work order					
and require corrective action(s) if nonconformance or					
noncompliance to the Quality Assurance Project Plan is					
found."					
C2. Reports to Management		I	<u>l</u>		
Identifies what project QA status reports are needed and					
how frequently					
Identifies who should write these reports and who should					
receive this information					
DATA REDUCTION, REPORTING, AND VALIDATION					
Element	Α	U	NI	NA	Comments
Element D1. Data Reduction	A	U	NI	NA	Comments
	A	U	NI	NA	Comments
D1.Data Reduction	A	U	NI 🗆	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to	A	U	NI 🗆	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations	A	U	NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2.Verification and Validation Methods	A	U	NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation,	A		NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2.Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation	A		NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2.Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any	A		NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2.Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and	A		NI	NA	Comments
D1. Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and individual responsible for conveying these results to data users Attaches checklists, forms and calculations	A		NI	NA	Comments
D1. Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and individual responsible for conveying these results to data users Attaches checklists, forms and calculations D3. Reconciliation with User Requirements	A		NI	NA	Comments
D1. Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and individual responsible for conveying these results to data users Attaches checklists, forms and calculations D3. Reconciliation with User Requirements Describes procedures to evaluate the uncertainty of the	A		NI	NA	Comments
D1.Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and individual responsible for conveying these results to data users Attaches checklists, forms and calculations D3.Reconciliation with User Requirements Describes procedures to evaluate the uncertainty of the validated data	A		NI	NA	Comments
D1. Data Reduction Describes reduction and evaluation procedures specific to the project, including calculations and equations D2. Verification and Validation Methods Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any Identifies issue resolution process, and method and individual responsible for conveying these results to data users Attaches checklists, forms and calculations D3. Reconciliation with User Requirements Describes procedures to evaluate the uncertainty of the	A		NI	NA	Comments



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:												
•												
Reviewer: Date of	Date of Review:											
Note: A=Acceptable; U=Unacceptable; NI=Not Included; NA=Not Applicable												
DOCUMENT CONTROL												
Element	Α	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	Α	U	NI	NA	Comments							
A1.Title and Approval												
Contains project title												
Indicates revision number, if applicable												
Indicates EPA cooperative agreement number												
Indicates RWU 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						
Element	Α	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			$ \sqcup $]		
model is better to address the problem than other similar						
models						
A6. Project/Task Description						
Summarizes work to be performed, for example, secondary		ΙШ	Ш]	Ш	
data files to be obtained, analyses to be performed etc.,						
that support the project's goals				,	_	
Provides work schedule indicating critical project points,	Ш	ΙШ	∥Ш]	Ш	
e.g., start and completion dates for activities such as						
secondary data collection, analysis, data or file reviews,						
and assessments			<u> </u>	1	_	
Indicates QAPP end date	Щ	Щ	\perp		<u> </u>	
Details geographical locations to be studied, including	$ \sqcup $		$ \sqcup$	J	\Box	
maps where possible			\vdash			
Discusses resource and time constraints, if applicable					Ш	
A7. Quality Objectives and Criteria			1	1 1	_	
Description of specific task requiring modeling and the			$ \sqcup$]	Ш	
intended uses of modeling output to achieve the task						

Element	Α	U	NI		NA	Comments
Identifies performance/measurement criteria for all		П	$\vdash \Box$		П	
information to be collected for use in the model, including				'	Ш	
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					$\overline{\Box}$	
Discusses geographical representation of data		İΠ	Ī		$\overline{\Box}$	
Discusses temporal representation of data						
Discusses technological representation of data						
Lists required hardware/software configurations for those		同			$\overline{\sqcap}$	
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.		_	<u> </u>			
Identifies where project information should be kept and for	$ \sqcup $		ΙШ		Ш	
how long		<u> </u>	 		_	
Discusses back up plans for records stored electronically	닏	닏	\square		<u> </u>	
States how individuals identified in A3 will receive the most	$ \sqcup $		$ \sqcup $		Ш	
current copy of the approved QA Project Plan, identifying						
the individuals responsible for this						

DATA ACQUISITION AND MODEL USE OR DEVELOPMENT

Element	Α	U	NI	ı	NA	Comments
B1. Sources of Secondary Data			1			
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.			Щ	[
Identifies data handling equipment/procedures that should				[
be used to process, compile, analyze and transmit data						
reliably and accurately			<u> </u>	╽.		
Identifies individual(s) responsible for data management				ļ	<u> </u>	
Describes the process for data archival and retrieval				ļ		
Describes procedures to demonstrate acceptability of				[
hardware and software configurations			<u> </u>	1.		
Describes or attaches any data forms, checklists, or on-line			$ \sqcup $	[
interactive screens used in the modeling process						

Element	Α	U	NI	NA	Α	Comments
Includes any necessary graphics to document the data						
management process (e.g., process flow diagrams,						
modeling flow charts, etc.)				1_		
Describes how internal checks used during data entry should	Ш	Ш	Ш		J	
be documented				+_	_	
Describes how uncertainty and variability in the model	Ш	Ш	Ш]	
results will be determined or characterized (e.g., summary						
statistics, frequency distributions, goodness-of-fit tests)			_	+_	1	
Lists equipment, both hardware and software, that will be	Ш	Ш	ш		J	
used on the project			_	+_	1	
Describes system performance requirements, addressing	Ш	Ш	Ш		J	
security issues, software installation needs and associated						
documentation				1	1	
Describes plan for development of model coding standards	Щ	H	Щ	4		
Describes plan for model testing	Щ.	Щ.	Щ	4		
Describes plan for development of model user's manual	Ш	Ш	ш		J	
and/or maintenance manual				+-	1	
Describes how model source code will be stored and	Ш	Ш			J	
maintained	$\overline{}$			+	1	
Includes configuration management plan to control	Ш	Ш	ш		J	
software/hardware configuration during model						
development or application B4. Model Calibration						
					1	
Describes the objectives of model calibration activities, including acceptance criteria	Ш	Ш	ш		J	
Describes expected frequency of model calibration				\vdash	1	
activities	Ш	Ш	ш		J	
Details the model calibration procedure	П		\vdash	+	1	
Describes the method(s) of acquiring input data	+	H	H	╁┝	1	
Describes types of output generated by the model	+	H	H	╁┝	<u>. </u>	
calibration					J	
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		1		1		

ASSESSMENT and OVERSIGHT

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

Describes how linkages between model code and]			
uncertainty analysis will be checked Describes how model framework will be tested			\vdash	+	1			
Element	Α	U	NI	N/	A	Comments		
Describes planned integration tests (to check computational and transfer interfaces between model modules)								
Describes any planned regression tests	П	П	П	\top	1			
Describes stress testing of complex models (to ensure that	Ħ	ĦΠ	Ħ	╁┝	1			
maximum model load does not exceed system limitations)					_			
Describes process for beta testing of pre-release materials	П	П	П		1			
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			ш		J			
products								
C4. Reports to Management			_		_			
Identifies what project QA status reports are needed and how frequently				L]			
Identifies who should write these reports and who should receive this information]			
DATA VALIDATION AND USEABILITY								
Element	Α	U	NI	N/	A	Comments		
D1. Validation Criteria			_					
Describes data reduction and evaluation procedures		$ \sqcup $	Ш	L	_			
specific to the project, including calculations and equations				1_	_			
Describes criteria used to review and validate input data	Щ.	1	Н	╁╞	<u> </u>			
Describes criteria used to review and validate model			ш		J			
components such as theory, mathematical structure, code,								
and calibration	\vdash	 -	 -	+_	1			
Describes criteria used to test model performance	片	H	H	╀⊨	<u> </u>			
Describes criteria used to review and validate model					J			
outputs Do Verification and Verification Methods		1	<u> </u>					
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					
Element	Α	U	NI	NA	Comments
Describes methods for assessment of model output and					
usability					
D3. Reconciliation with User Requirements					
Describes procedures to evaluate the uncertainty of the					
validated data					
Describes how limitations on data use should be reported to					
the data users					
Describes any potential uncertainties related to decisions					
made based on limitations in model input data and/or					
limitations in the model and how this will be reported					
Describes how any departures from assumptions set in the					
planning phase of the model will be documented and					
reported to users					
Describes procedures for final acceptance testing (testing					
needed before a new model or model application is					
accepted by the end user)					