# Title and Approval Page (1.1)

## Quality Assurance Project Plan for Modeling [Project Name]

**Revision: 0
RAE/EPA Grant #: XXXX
Lead Organization:**

**Partner Organization(s):
January 27, 2021**

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| Thomas Ardito – Restore America’s Estuaries Grant Manager |  | Date |
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| Margherita Pryor – EPA Project Officer |  | Date |
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| Nora Conlon – EPA Quality Assurance |  | Date |
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# Distribution List (1.3)

*Includes all individuals who are to receive a copy of the QAPP and identifies their organization*

| **Organization** | **Contact / Address** | **Email Address** |
| --- | --- | --- |
| Organization Name | **Name** Job title**Name** Job titleAddress Line 1Address Line 2(111) 111-1111 | Email of Name 1 Email of Name 2 |
| Organization Name | **Name** Job title**Name** Job titleAddress Line 1Address Line 2(111) 111-1111 | Email of Name 1 Email of Name 2 |
| Organization Name | **Name** Job title**Name** Job titleAddress Line 1Address Line 2(111) 111-1111 | Email of Name 1 Email of Name 2 |
| Restore America’s Estuaries/Southeast New England Watershed Grants Program | **Thomas Ardito** Director2300 Calrendon Blvd., Suite 603Arlington, VA 22201(401) 575-6109 | tardito@estuaries.org |
| Environmental Protection Agency | **Nora Conlon** Quality Assurance11 Technology DriveNorth Chelmsford, MA 01863617-918-8335 | conlon.nora@epa.gov  |
| Environmental Protection Agency | **Margherita Pryor**, Project Officer5 Post Office Square, #100Boston, MA 02109617-918-1597 | pryor.margherita@epa.gov |

# Section 1: Project Management

The following section provides information regarding the background of the [Project Name], the tasks involved in completing the project, and the names and responsibilities of key project team members.

***NOTE: Text in italics is for guidance purposes only. It should be removed from the final product. Any sections that are not applicable to the Project should be removed from the QAPP with an explanation as to why they were not included.***

## 1.4: Project Task/Organization

*Identify the individuals and organizations participating in the project, and discuss their specific roles and responsibilities. Include program or project management, personnel responsible for conducting project activities, the project QA manager, and points of contact and associated organizations for all consultants and/or contractors. If associated names and contact information are not identified elsewhere, provide them here. Whenever possible (depending on the size of the organization), ensure that the project QA manager is independent of the staff generating the data and model outputs.*

*Provide a concise organization chart showing the relationships and lines of authority/ communication for all named people and organizations. Identify who is advisory only.*

See **Table 1** for a list of the specific members from each organization.

Table 1 Project Participants

|  |  |  |  |
| --- | --- | --- | --- |
| Name  | Title | Organization | Primary Responsibility |
| Name | Title | Organization Name | Role |
| Name | Title | Organization Name | Role |
| Name | Title | Organization Name | Role |
| Name | Title | Organization Name | Role |
| Name | Title | Organization Name | Role |
| Tom Ardito | Grant Manager | Restore America’s Estuaries  | Project oversight |
| Nora Conlon | EPA Quality Assurance | EPA | Final review and approval of QAPP |
| Margherita Pryor | EPA Project Officer | EPA | Project oversight and QAPP review |

### Organization 1

*Provide description of Organization’s role and project tasks for which they will be responsible.*

### Organization 2

*Provide description of Organization’s role and project tasks for which they will be responsible.*

### Organization 3

*Provide description of Organization’s role and project tasks for which they will be responsible.*

### Restore America’s Estuaries

Restore America’s Estuaries (RAE) has been selected by the Environmental Protection Agency (EPA) to manage the Southeast New England Watershed Grant Program (SNEP) for 2018 and 2019. RAE will oversee fiscal and technical aspects of the grant project.

### EPA

EPA is the grantor to RAE for the grant money that is being used for this project. The EPA will review and approve this Quality Assurance Project Plan (QAPP).

## 1.5: Problem Definition/Background

*State the specific environmental problem(s) to be investigated. Include sufficient background information to provide an historical and scientific perspective for future projects.*

*State decisions to be made, actions to be taken, or outcome expected from the information obtained from modeling activities.*

*Identify the regulatory information, applicable criteria, action limits, etc. that the model outcomes will reference.*

*Identify assumptions for the modeling process.*

*Provide for notification when new models will be created that will justify the inability to use existing models in certain situations.*

*Provide for notification of modifications to model code.*

*Describe how the suitability of models to resolve the application niche will be evaluated by:*

* *Mapping model attributes to problem statements*
* *Degree of certainty needed in model outputs*
* *Amount of reliable data, available resources and technical expertise*

## 1.6: Project Task Description and Schedule

*Provide a summary of the work to be undertaken in accordance with the remaining sections of this QAPP and the schedule or timing for implementation. Include a general overview of the various pertinent work activities (such as: work to be performed in model creation or application, measurements/analyses, data evaluation, etc.), products/reports to be generated, and a targeted schedule or estimated timing for each critical activity/report. Discuss resource and time constraints, if applicable.*

*Provide for identification of geographical locations to be studied, including maps where possible.*

Table 2 Project Tasks and Schedule

|  |  |  |  |
| --- | --- | --- | --- |
| Task | Deliverable | Timeline | Relevant Details/Comments |
| Task | Deliverable | Month-Month Year |  |
| Task | Deliverable | Month-Month Year |  |
| Task | Deliverable  | Month-Month Year |  |
| Task | Deliverable  | Month-Month Year |  |

### Task 1: QAPP Development

This QAPP describes the quality management system and procedures, as well as the roles and responsibilities of the Project Team. The QAPP provides an overview of the project and quality assurance related to data used for the project.

The Project Manager, [Name], will be responsible for maintenance and distribution of the approved QAPP. The QAPP will be provided electronically as needed.

### Task 2

*Model creation/application*

### Task 3

*Measurement/analyses*

### Task 4

*Data evaluation*

## 1.7: Quality Objectives and Criteria for Measurement Data and Models

*Describe the general objectives of the project(s) covered under the QAPP. Define how the model performance criteria and data quality acceptance criteria will be determined*

*(for all information to be collected including information obtained from previous studies). Explain how the data acceptance criteria relate to the desired quality of model outputs.*

### 1.7.1 Objectives and Project Decisions

*Include statement(s) of the general objectives and demonstrate knowledge of the overarching purpose for the project. Phrase decisions in terms of “…if…then…” type of statements.*

### 1.7.2 New Data Measurement Performance Criteria/Existing Data Acceptance Criteria

*Describe the data quality needed to support project decisions. Discuss the data quality indicators (DQIs) and the acceptance criteria/measurement performance criteria for each DQI, and identify the quality control (QC) or other mechanism to be used to assess if the criteria were met.*

* *Identify how acceptance/performance criteria will be established for:*
* *Existing data (including when data is deemed outdated or otherwise excluded)*
* *Model parameterization (calibration)*
* *Model corroboration (validation)*
* *Model sensitivity analysis*
* *Model uncertainty analysis*

## 1.8: Special Trainings/Certification

*Identify and describe any specialized training or certification requirements. Discuss how such training will be provided, as well as how and where the training records will be documented.*

*State that the QA Officer is responsible for overseeing training.*

*Indicate the personnel responsible for assuring that these tasks are satisfied.*

## 1.9: Documentation and Records

*Summarize the type of information necessary to be included in report packages, including electronic data deliverables.*

*Describe the format for reporting of model development/modification, evaluation and application and for model inputs and model outputs.*

*Identify any other project records to be maintained, how/where the records will be stored, and the length of time of storage. This should include information generated in assessment/oversight reports, interim progress/status reports and final reports, including:*

* *Technical reviews, model tests, data quality assessments of output data and results;*
* *Candidate model assessments for model selection, including references;*
* *Actual input used and data bases used;*
* *Pre- and post-software development information;*
* *Spreadsheet data files containing monitoring data; and*
* *Copy of modeling reports*

*Describe the type of information to be included in the final reports (for example: perhaps it will be summarized in a data base and/or Excel spreadsheet with all supporting information to be retained in a project file). Discuss back up plans for records stored electronically.*

### 1.9.1 QA Project Plan Distribution

*Describe the process and responsible individual for distributing the most current approved QAPP, as well as any revisions/updates, to appropriate project staff (see Section 1.4).*

# Section 2: Data Generation and Acquisition

This QAPP was developed with guidance from the EPA Guidance for Quality Assurance Project Plans for Modeling. *List any elements from Section 2 that are not applicable to your project.*

## 2.1: Data Acquisition Requirements (Non-Direct Measurements)

*Identify the range of data sources, for example, computer databases or literature files, and/or models that may be accessed and used. Describe the intended use of this information and the rationale for their selection, i.e., its relevance to the QAPP objectives.*

*Identify how acceptance criteria will be established for all previously collected information. Discuss precision, bias, representativeness, completeness and how it will be assessed in relation to model performance criteria.*

*Identify any types of data needed (for project implementation or decision making) that may be obtained from non-direct measurement sources such as existing data from another project, photographs and maps, literature files, and historical databases.*

*Discuss procedures to ensure that data used are not outdated and that there is consistency when excluding data and in documentation of excluded data.*

*Identify key resources/support facilities needed.*

## 2.2: Data Management

*Describe how the data will be managed, tracing the path of data generation in the field or laboratory to final use or storage.*

*Describe or reference the standard record-keeping procedures, and discuss the approach to be used for data storage and retrieval of electronic media.*

*Discuss the plan for detecting and correcting errors from conversion of data (e.g. metric/English, units-to-units, significant figures, etc.) as well as for preventing loss of data during reduction, reporting, and entry to forms, reports, and databases.*

*Identify and describe all data handling equipment and procedures to process, compile, analyze and interpret the model data, including any necessary computer hardware and software. Address any specific data management performance requirements and describe the procedures that will be followed to demonstrate acceptability of the necessary hardware/software configuration.*

*Identify who is responsible for each data management task.*

# Section 3: Assessment and Oversight

This section addresses the activities for assessing the effectiveness of the implementation of the quality assurance and quality control activities. The purpose of the assessment is to ensure that QAPP is implemented as described.

## 3.1: Assessments/Oversight and Response Actions

*Describe the assessments to be performed* “*during*” *the project(s) to ensure activities are being conducted as planned. State the frequency and purpose of each assessment, along with the success/acceptance criteria for each assessment proposed. List the approximate schedule or timing of activities, and identify potential organizations and participants.*

*Define the scope of authority of the assessors, including stop work orders. Discuss how response actions to non-conforming conditions shall be addressed and by whom. Define the conditions under which the assessors are authorized to act.*

*Describe how and to whom the results of the assessments shall be reported. Indicate that a summary of the assessments will be provided in the modeling report and kept in a modeling journal.*

*Provide examples of any forms or checklists to be used to document assessments and response/corrective action activities.*

# Section 4: Model Development or Modification

## 4.1: Applicability

*For mechanistic modeling of common environmental problems, one or more suitable model frameworks may exist. Many existing model frameworks in the public domain can be used in environmental assessments. When this is the case, the requirements in this section do not apply to QA plans.*

*Sometimes no model frameworks are appropriate to the task, and it is necessary to develop a new model framework or to modify an existing framework to include the additional capabilities needed to address the project needs. When this is the case, the requirements of this section apply to QA plans.*

*The objective is to develop the conceptual model that reflects the underlying science of the processes being modeled, and develop the mathematical representation of that science and encode these mathematical expressions in a computer program.*

*Model development can also be viewed as a process with three main steps: (a) specify the environmental problem (or set of issues) the model is intended to address and develop the conceptual model, (b) develop the model framework (develop the mathematical model), and (c) evaluate the model to develop the application tool (EPA 2009).*

## 4.2: Project Plan Requirements for Model Development of Modification

*Model development or modification should always be conducted using a graded approach that is adequate and appropriate to the decision at hand. Issues such as the infeasibility or non-applicability of any of these elements should be documented in the plan. The QA plan shall include, but not be limited to, consideration and development of the detailed specifications for model development identified below.*

* *Development and intended application of the software product;*
* *Specification of the scientific theories that form the basis for model(s);*
* *Software to be used in its development;*
* *Functional requirements of the software product;*
* *Most important functions that the software product must address;*
* *Computer hardware and operating system requirements for the software product;*
* *Any quantitative or qualitative quality objectives for the software product;*
* *Evaluation of each component model, as well as the full system of integrated models, where applicable;*
* *Documentation for the selected model clearly stating why and how the model can and will be used;*
* *Quality objectives for uncertainty analysis either qualitatively or quantitatively (See EPA 2009);*

### 4.2.1 Evaluation of the Model Framework

*The QA Plan shall indicate that the following will be evaluated and documented during model development or modification;*

* *Soundness of the science (including peer-reviewed theory and equations) underlying hypothesis;*
* *Appropriateness of model complexity for the problem at hand;*
* *Data quality and quantity objectives to support the choice of model;*
* *Consistency of model structure with all the relevant inputs described in the conceptual model;*
* *Identification of the model code and code verification, if completed;*
* *Implementation process for the software product and any applicable development standards;*
* *Internal quality checks applied during the development process (e.g., design and code verification, configuration control procedures, and change control procedures);*
* *Procedures for controlling, documenting, and archiving, all significant changes to the software and hardware;*
* *Testing strategies including individual module tests, integration tests, systems testing, acceptance testing, and beta testing, as applicable. The procedure for each test shall be provided and the process of confirming the test results included. That is, evaluation criteria are to be identified during the initial stages of model development;*
* *Requirements for project documentation (e.g., design document, source code, and user guide); and*
* *Expected maintenance and user support needed by the software product.*

*It is also recommended that the evaluation process apply the principles of scientific hypothesis testing (Platt 1964) using an iterative approach (Hilborn and Mangel 1997). When evaluating multiple model frameworks, it may be useful to statistically compare the performance of these competing models with observational, field, or laboratory data (EPA 2009). See Appendix A of the Template for Developing a Generic (or project-specific) QAPP for Model Development, Modification, Evaluation and Application (EPA, 2010).*

# Section 5: Lifecycle Model Evaluation

*Model evaluation in this template means to test that the model expressions have been encoded correctly into the computer program and test the model outputs by comparing them with empirical data. Model evaluation is an iterative process. Hence, it may be effectively applied throughout model development, testing, and application and should not be interpreted as the sequential step “model evaluation.”*

*Model evaluation is the process for generating information over the life cycle of the project that helps determine whether a model and its analytical results are of sufficient quality to serve as the basis for a decision. Model quality is an attribute that is meaningful only within the context of a specific model application. In simple terms, model evaluation in the QA plan shall provide information to help answer the following questions:*

* *How have the principles of sound science been addressed during model development?*
* *How is the choice of model supported by the quantity and quality of available data?*
* *How closely does the model approximate the real system of interest?*
* *How well does the model perform the specified task while meeting the objectives set by quality assurance project planning? (EPA 2009)*

## 5.1: Project Plan Requirements for Lifecycle Model Evaluation

*Model evaluation should always be conducted using a graded approach that is adequate and appropriate to the decision at hand. Issues such as the infeasibility or non-applicability of any of these elements should be documented in the plan. The plan shall include, but not be limited to, the questions above and consideration and development of the detailed specifications for model evaluation identified below:*

* *Identification of the mathematical algorithms and approaches to be used in executing the model computations;*
* *Appropriateness of input data (specify the availability and quality of monitoring and laboratory data to be used for both developing model input parameters and assessing model results);*
* *Appropriateness of boundary condition specifications;*
* *Assumptions and limitations and effect on model applicability, if any;*
* *Applicability and appropriateness of selected parameter values;*
* *Documentation and justification for adjusting model inputs to improve model performance (calibration, where applicable);*
* *Model application with respect to the range of its validity;*
* *Quality assurance and quality control (QA/QC) activities involving planning, implementation, documentation, assessment, reporting, and improvement to ensure that a model and its components are of the type needed for its task and that they will meet all required performance standards; and*
* *Requirements for documenting the model evaluation that allows individuals and groups outside modeling activities to comprehend either the processes followed in evaluation or the essential workings of the model and its outputs.*

*See Appendix B of the Template for Developing a Generic (or project-specific) QAPP for Model Development, Modification, Evaluation and Application (EPA, 2010).*

# Section 6: Model Application

## 6.1: Model Parameterization (Calibration)

*Describe the range of calibration performance measures that will be applied.*

*Identify the critical activities and qualitative and quantitative methods for model calibration. A few example calibration activities might be processing calibration data, decoupled calibration and sub-area calibration. A few examples of calibration methods are graphical, deviance, mean error, mean square error, automatic optimization, pure random search, multi-start and clustering methods, etc.*

*Describe how one or more criteria will be established to determine when to stop model parameterization (calibration).*

*Describe activities and methods for parameter estimation and criteria for defaulting to non site-specific data.*

*Describe how parameters used for calibration will be selected and how parameters to be kept constant shall be determined. Describe how parameters considered statistically important to the prediction process (and included as model inputs) will be determined.*

*Describe how the calibration uncertainty and soundness of calibration will be determined and how they will be related to calibration performance measures.*

*Discuss the activities and methods (e.g., Morris’s One-at-a-Time, differential analyses, Monte Carlo analyses and variance-based methods, etc.) that will be used for conducting sensitivity analyses.*

*Identify how records of model parameterization (calibration) and corroboration (validation) will be maintained.*

*Identify how deficiencies should be resolved and documented.*

## 6.2: Model Corroboration (Validation and Simulation)

*Describe the activities and (qualitative and quantitative (statistical) methods to be used for model corroboration (validation) as well as for documenting the process. A few examples of validation activities might include setting up test schemes and performance criteria to focus the simulations, processing validation data and performing validation tests. A few examples of validation methods might include graphical methods, deviance methods and statistical tests for bias and precision.*

*Describe how model corroboration (validation) performance measures will be established.*

*Describe how the soundness of validation (for example, professional judgment) and validation uncertainty will be evaluated (for example, error propagation, regression techniques and Monte Carlo simulation.)*

*Describe how the soundness of model simulations (for example, internal quality assurance, peer review and practical experience-based evaluations) and simulation uncertainty will be determined.*

*Describe the use of independent data sets for model parameterization and corroboration.*

*Discuss how issues shall be resolved and identify the authorities for resolving such issues.*

*Provide examples of any forms or checklists to be used in an appendix/attachment. All associated criteria identified in the documentation should be consistent with and/or supportive of the model quality objectives and performance criteria.*

## 6.3: Reconciliation with User Requirements

*Describe how the results (which have already been reviewed, verified, and validated/evaluated) obtained from the project will be reconciled with the project objectives and performance criteria/acceptance criteria.*

*Outline the proposed methods to analyze the modeling results and for determining possible anomalies or limitations on the use for the intended purpose and how departures from assumptions established in the planning phase of the modeling process will be assessed.*

*Describe how anomalies will be resolved, and discuss how limitations on the use of the data from anomalies and departure from assumptions will be reported to decision makers.*

# Section 7: Reports to Management

*Identify the frequency and distribution of reports issued to inform management of the status of the project, results of performance evaluations and systems assessments, results of data quality and modeling evaluations, and any significant quality assurance problems and recommended solutions.*

*Indicate that the reports will address the elements in Section 7.1 below.*

*Identify the preparer and the recipients of the reports, and any specific actions management is expected to take as a result of the reports.*

## 7.1: Reports

*Describe the content of the report(s) as including each of the following from sections 7.1.1 through 7.1.4 below.*

### 7.1.1 Model Development or Modification

* *Specification of environmental problem;*
* *Description of mathematical model;*
* *Software performance against any quantitative or qualitative objectives;*
* *Assessment of each model component and integrated models, where applicable;*
* *Assessment of why and how the model can be used; and*
* *Performance against objectives for uncertainty analysis.*

### 7.1.2 Evaluation of Newly Developed or Modified Existing Model

* *Describe the evaluation of the model framework including;*
* *Soundness of the science (including peer-reviewed theory and equations) underlying hypothesis;*
* *Appropriateness of model complexity for the problem at hand;*
* *Data quality and quantity objectives to support the choice of model;*
* *Consistency of model structure with all the relevant inputs described in the conceptual model;*
* *Identification of the model code and code verification, if completed;*
* *Implementation process for the software product and any applicable development standards;*
* *Internal quality checks applied during the development process (e.g., design and code verification, configuration control procedures, and change control procedures);*
* *Procedures for controlling, documenting, and archiving, all significant changes to the software and hardware;*
* *Testing strategies including individual module tests, integration tests, systems testing, acceptance testing, and beta testing, as applicable. The procedure for each test shall be provided and the process of confirming the test results included. That is, evaluation criteria are to be identified during the initial stages of model development;*
* *Design document, source code, and user guide); and*
* *Expected maintenance and user support needed by the software product.*

### 7.1.3 Model Application

*Introduction and Background*

*Purpose of Modeling/Modeling Objectives*

*Scope and Approach for Each Model Used (including):*

* *Physical Setting (and Hydrology, if applicable)*

*Observational Data Used to Support Modeling*

* *Quality of Acquired Data (and references to data quality reports)*
* *Achievement in Meeting Data Acceptance Criteria*
* *References to Monitoring Data*
* *Discussion on Excluded Data and Basis for Exclusion*

*Description of Model(s) (including):*

* *Documentation of Candidate Model Assessments*
* *Model Configuration (discusses how model was applied, including):*
	+ *Spatial and Temporal Resolution*
	+ *Nature of Grid, Network Design or Sub-watershed Delineation*
	+ *Application of Sub-models*
	+ *Model Inflows, Loads and Forcing Functions*
	+ *Key Assumptions (and associated limitations, if any)*
	+ *Changes and Verification of Changes Made in Code*

*Model Parameterization (Calibration) and Corroboration (Validation)*

* *Objectives, Activities and Methods*
* *Parameter Values and Sources*
* *Rational for Parameter Values Estimated in the Absence of Data*
* *Calibration Variables and Targets*
* *Measures of Calibration Performance*
* *Calibration Input, Output and Results Analysis*
* *Model Validation Results*

*Model Use Scenario Analysis and Results (should relate to purpose)*

* *Output of Model Runs and Interpretation*
* *Summary of Assessments and Response Actions, if any*
* *Soundness of the Calibration, Validation and Simulations*
* *Review of Initial Assumptions and Model Suitability Evaluation*

*Performance Against the Performance Criteria Including:*

* *Model Parameterization (Calibration) and Corroboration (Validation)*
* *Model Sensitivity and Uncertainty Analyses*

*Pre- and Post-Processing Software Development*

*Maps, Photographs and Drawings (if appropriate)*

*Deviations from the QAPP Including a List of Non-Applicable Reporting Elements with Explanations*

*Conclusions, Recommendations, References and Appendices*

### 7.14 Lifecycle Model Evaluation

*The QA plan should specify that in periodic reports to management and in final reports the following will be addressed:*

* *How have the principles of sound science been addressed during model development?*
* *How is the choice of model supported by the quantity and quality of available data?*
* *How closely does the model approximate the real system of interest?*
* *How well does the model perform the specified task while meeting the objectives set by quality assurance project planning?*

*The report shall also include the following:*

* *Identification of the mathematical algorithms and approaches used in executing the model computations;*
* *Appropriateness of input data (specify the availability and quality of monitoring and laboratory data used for both developing model input parameters and assessing model results);*
* *Appropriateness of boundary condition specifications;*
* *Assumptions and limitations and effect on model applicability, if any;*
* *Applicability and appropriateness of selected parameter values;*
* *Documentation and justification for adjusting model inputs to improve model performance (calibration, where applicable);*
* *Model application with respect to the range of its validity;*
* *Quality assurance and quality control (QA/QC) activities involving planning, implementation, documentation, assessment, reporting, and improvement to ensure that a model and its components are of the type needed for its task and that they will meet all required performance standards; and*
* *Documentation that allows individuals and groups outside modeling activities to comprehend either the processes followed in evaluation or the essential workings of the model and its outputs.*

# Section 8: References

Consult additional references listed in the *Template for Developing a Generic (or project-specific) QAPP for Model Development, Modification, Evaluation and Application (EPA, 2010).*

Hillborn, R., and M. Mangel. 1997. *The Ecological Detective: Confronting Models with Data*. Princeton, New Jersey: Princeton University Press. To order go to: http://press.princeton.edu/titles/5987.html

Platt, J.R. 1964. Strong inference. *Science* 146: 347-352.http://pages.cs.wisc.edu/~markhill/science64\_strong\_inference.pdf

U.S. EPA. 2010. Template for Developing a Generic (or Project-specific) QAPP for Model Development, Modification, Evaluation, and Application.

U.S. EPA. 2009. Guidance on the Development, Evaluation and Applicability of Regulatory Environmental Models http://www.epa.gov/crem/library/cred\_guidance\_0309.pdf

Attachment A – XXXXX

Attachment B – XXXXX