# A. Project Management

## A1. Title and Approval Sheet

**U.S. Environmental Protection Agency**

**Office of Research and Development**

**Center for Environmental Measurement and Modeling**

***Click Here to Enter Division***

***Click Here to Enter Branch***

**Quality Assurance Project Plan**

**Title:** Click here to enter text.

**QA Category:**  A B

**ORD National Program Project/Task ID:** Click here to enter text.

**QAPP was Developed:**  Intramurally  Extramurally: Click here to enter text.

**QAPP Accessibility:** QAPPs will be made internally accessible via the [ORD QAPP intranet site](https://intranet.ord.epa.gov/quality-assurance/qapps?combine=&field_qapp_project_lead_value=&title=&field_lab_value=cemm&field_qapp_project_type_value=&field_division_value=) upon final approval *unless the following statement is selected*.

I do NOT want this QAPP internally shared and accessible on the ORD intranet site.

**Project Type(s) (check all that apply):**

Environmental Measurements  Environmental Technology  Decision Support Tool  Existing Data  Informatics Geospatial  Method Development  Model Application  Model Development

Software and Data Management Remote Sensing  Technical Assessment  Other

**­­­­­­­­­­­­­­­­­­­­­­­­­­**

**Approvals**

**Prepared by:**

Click here to enter name.

*Signature Date*

**Branch Chief:**

Click here to enter name.

*Signature Date*

**QA Manager:**

Click here to enter name.

*Signature Date*

***NOTE:*** *This Table of Contents (TOC) is Word generated. To update this TOC:*

*1. Right-click in the TOC*

*2. Click “Update Field”*

*3. Choose either “Update page numbers only” or “Update entire table”*

*A “List of Figures” & “List of Tables” may be added if desired. Contact your QA manager with any questions.*

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| --- | --- | --- | --- |
| **QAPP Revision History** | | | |
| **QAPP ID Number** | **Prepared By** | **Date of Revision** | **Description of Change** |
|  |  |  |  |
|  |  |  |  |

***NOTE:*** *For each section below, guidance for each section is provided in text boxes. Insert your text for each section below the text box. Delete the text box after each section is complete.*

## A3. Distribution List

Create a distribution list for the QAPP by including the names of key project personnel responsible for project implementation. Include the project personnel’s title/position, organization, email address, and telephone number. Tables may be used, if desired.

## A4. Project Organization

List all participants in the project including all investigators and project personnel contributing to the research project. It is recommended that the beneficiaries (persons who will be the end-users of the research data/products) also be included.

Include a brief description of their roles and responsibilities for each person. Include both EPA and non-EPA participants and list them by organization. A table is often helpful, especially if there is a long list of collaborators. Include contact info such as an email address and phone number since the QAPP should be used as a “go to” document during the project.

Organization charts are often included to show relationships and lines of communication among project personnel.

## A5. Problem Definition and Background

Give an intro on why this project is being implemented. Summarize any state of the science info you think is relevant to set up your objectives. Some researchers use this section for a future publication.

State your project objectives in a clear and concise manner. Bulleted lists will help to keep your objectives concise, and using clear objectives will help you write the rest of the QAPP.

## A6. Project/Task Description

Summarize the work (tasks) to be performed as well as product(s) anticipated. Include maps where appropriate. Details about your scientific approach and methods are described in later sections. If you have several distinct pieces to a project (e.g., you are looking for different types of microorganisms or distinct classes of analytes that use distinct methods), separate subsections can be used. Note that for projects with several distinct pieces that may have different objectives, you may find it helpful to restate your objective at the start of each subsection.

Give a timeline for the project tasks including publications and presentations with the knowledge that this is just a plan. One example of a timeline is presented below, but please use whatever style you prefer.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2014** | | | | | **2015** | | | | **2016** | |
| **Q1** | | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** |
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|  | |  |  |  |  |  |  |  |  |  |
|  | **Quality Assurance Project Plan preparation and approval** | | | | | | | | | |
|  | **Analyte identification and preparation of methods** | | | | | | | | | |
|  | **Sample collection** | | | | | | | | | |
|  | **Data analysis** | | | | | | | | | |
|  | **Present data at scientific venue** | | | | | | | | | |
|  | **Report/manuscript preparation and submission** | | | | | | | | | |

## A7. Quality Objectives and Criteria for Measurement Data

First, put in plain words those specific critical areas that need to be controlled if your project is to be successful. Second, decide what quality criteria need to be met for those critical areas to assure project achievement. List your data quality objectives (e.g., detection limits, precision, and accuracy; GPS resolution or location limitations) and the corresponding acceptance criteria. Use a table if desired.

**Note:** Do not confuse project quality objectives with QC limits for specific analytical techniques, which can be described in section B4 Analytical Methods or cited in SOPs or protocols. For example, if you have a method development project, you may be developing a method with certain detection limits based on health data or a screening method that has looser criteria and you would cite those criteria as project quality objectives. In contrast, if you are analyzing samples with SOPs that have specific QC limits, you may simply summarize the QC limits in the SOPS in section B4.

## A8. Special Training/Certifications

This section could include the need for analyses to be done by certified labs, the need for special training (e.g., GIS, analytical technique, human subjects, etc.), or special safety training (e.g., boat, field activity, or helicopter training). Specify how this information will be documented and where the records will be kept.

## A9. Documents and Records

Here you would simply list the types of documents and records (including electronic) that you may be generating including their expected format. Use this section to also plan for any records needs such as large amounts of data storage. Information on the final disposition of records and documents, including location and retention schedule should be included here.

This section is also used to describe the process and responsibilities for making sure that project personnel will receive the most recently approved QA Project Plan, Standard Operating Procedures (SOPs), and other documents used throughout the project operation. Describe how these documents will be updated and this information communicated. At a minimum, QAPPs should be reviewed and updated as needed on an annual basis, and appropriate revisions or amendments should be developed to cover the work being conducted for a project if it is not covered in the original QAPP. Your QAM can provide guidance on when revisions or amendments are needed.

# B. DATA GENERATION AND ACQUISITION

## B1. Experimental Design

An experimental design is nothing more than detailing the investigational approach you plan to follow to carry out the research needed to accomplish the task(s) at hand.

*“Keys to this element are the assumptions made and how the data will be obtained. This element explains the “how and why” of the project’s information collection design to ensure that the appropriate data are collected for this project” (EPA Guidance for QAPPs* [*EPA QA/G-5*](https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf)*).*

Include a sampling design if this is a field project. A complex sampling design would call for a separate sampling QAPP.

Include any limitations or special challenges that you can foresee for this project. This may help you plan for extra QC or other measures to help mitigate possible data issues (e.g., if a non-homogenous population were needed to be sampled or to deal with special challenges from matrix interferences, etc.).

## B2. Sampling Methods

Describe sample/data collection procedures. Include complete references (SOP title and ID number) to sampling SOPs or protocols to ensure consistent sampling if this project/task includes field sampling. Again, if this project includes a complicated field sampling effort, a separate sampling QAPP is recommended.

## B3. Sample Handling and Chain of Custody

*“Describe conditions that will be necessary for these samples to keep their original condition during sample collection, transportation, and storage. This may include the use of preservatives such as the addition of acid to the sample bottle before transportation and ice to the transport container, appropriate packing material, and a freezer for long-term storage.*

*Give maximum holding times for each type of sample. Holding times will vary with the analyte/matrix and are designed to ensure stability of the analyte/sample.” (EPA Guidance for QAPPs* [*EPA QA/G-5*](https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf)*)*

Include examples of sample labels, sample ID codes, field collection/chain of custody forms, and specify sample naming conventions.

Even if samples are generated in the lab instead of the field, you may want to include this section if the samples have special handling and storage needs. In that case, delete the reference to “chain of custody” in this section’s title.

## B4. Analytical Methods

Identify the analytical procedures needed to analyze the samples. You could use this section to expand on your experimental design, citing protocols, methods, or SOPs being used. Do not include the protocols in the body of the QAPP. Rather, add them as appendices. If citing standard EPA methods, provide the full reference. Describe and justify any modifications or deviations from the methods.

If analytical methods are yet to be developed or optimized, list the steps that will be taken to optimize and validate the analytical methods prior to using the analytical methods for sample analysis.

As used above, a “protocol” is a set of procedures used and managed by the researcher, a “method” refers to an EPA standard method (or other certifiable method such as ASTM or the APHA Standard Methods collection), and an “SOP” refers to a set of procedures that have been reviewed and approved by a QAM and Branch Chief and assigned an SOP ID number.

## B5. Quality Control

List quality control (QC) check samples that you will include in your sample collection or analyses. You could expand upon your experimental design or method development. Will you add surrogates? Field duplicates or field blanks for field collection projects? Lab replicates or calibration checks? Include the QC acceptance criteria and troubleshooting measures (corrective actions) should QC samples fail.

If all your QC is specified in SOPs or protocols that you have already referenced in section B4 Analytical Methods, you may reference those documents. However, it is still useful to pull a summary, especially in table form, of all the QC samples for the methods to be used in this QAPP. An **example** table is shown below.

|  |  |  |  |
| --- | --- | --- | --- |
| **QC Sample Type** | **Frequency** | **Acceptance Criteria** | **Corrective Action if QC Sample Fails** |
| Performance Surrogate | Every sample | 50- 150 % | Flag in comments |
| Laboratory Matrix Blank | One every batch analyzed | 0 μg/ L | Compound thrown out if < 10 times blank concentration |
| Laboratory Matrix Spike | One every batch analyzed | 50- 150 % | Flag in comments |
| Field Duplicate | Two at every other facility sampled (source and finished water) | RSD = ± 30 % | Flag in comments |
| Field Matrix Spike | Two at every other facility sampled (source and finished water) | 50- 150 % | Flag in comments |
| Continuing Calibration Verification | 1 every 6 injections | ± 20 % | Flag in comments |
| Instrument Blank | 1 every 6 injections | 0 μg/ L | Flag in comments, assess and fix instrument problems |

## B6/B7. Instrument/Equipment Calibration, Testing, Inspection, Maintenance

List any special instrumentation needed (lab and field) and the procedures/frequency for calibration and maintenance. For many projects, instrumentation is covered in the protocols, SOPs, or methods and those can be referenced. Otherwise, use this section to plan for major instrument calibration and maintenance needs (i.e., do not list every piece of labware or instrumentation used).

Please note that this section is also used to describe calibration of models.

## B8. Inspection/Acceptance of Supplies and Consumables

Identify any supplies that may be critical for your project. Identify, if needed, the supply source, procedures for tracking and retrieving supplies, who is responsible for maintaining the supplies. Describe any acceptance criteria for the items and how compliance with criteria will be ascertained (such as certificates of cleanliness).

## B9. Non-direct Measurements

Secondary data is defined as coming from existing sources (i.e., not generated from this project). Sources of secondary data according to [EPA QA/G-5](https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf) may include:

* *existing sampling and analytical data and files from a previous effort;*
* *photographs or topographical maps produced outside this project;*
* *information from the published literature;*
* *background information from facility or state files;*
* *measurements that are ancillary to addressing the project’s objectives (for example,*
* *meteorological data, primarily used to better predict or explain dispersion and*
* *concentration of airborne toxic compounds in a localized area).*

For section B9, list any sources and types of secondary (existing) data that will be used in this project. Describe how the secondary data will be used, how it will be (or has been) acquired, and how the data will be assessed for quality (making sure to include acceptance criteria for each data type).

## B10. Data Management

Describe how the data will be managed throughout the project lifecycle, from notetaking in the field through generation in the lab through data analysis, including storage of paper and electronic data and backup of the data. Describe any quality management procedures such as spot checking of data entered into databases or manual checking of calculations in spreadsheets. Indicate any hardware/software requirements for any computerized information systems used to manage or store data. Discuss who is responsible for each data management activity. Flowcharts or diagrams can be used to show the data management process if desired.

**Note**: The Scientific Data Management (SDM) plan guidelines also call for much of the same data management information, particularly data storage and retrievability. This information can be copied and pasted from the QAPP into the SDM plan or vice versa. It is acknowledged that some researchers prefer to capture this information in one place and wish to reference their SDM plan in their QAPP. If so, the SDM plan will need to be included as an appendix. Officially, SDM plans are not part of the QAPP and a separate SDM plan will need to be submitted via Science Hub along with the data set(s) associated with the project.

Table for records schedule, delete any lines that do not apply to your QAPP:

|  |  |  |  |
| --- | --- | --- | --- |
| **EPA Records No.** | **Series Title** | **Brief Description** | **Final Disposition** |
| 1035a | Significant Environmental Programs and Records |  | Permanent |
| 1035b | Basic, Exploratory Research Files | Records for proof-of-concept projects, method validation studies, or basic exploratory, conceptual research projects. | Disposable after 20 yrs |
| 1035d | Instrument Logbooks | Logbooks kept documenting routine maintenance, calibration, and repair of instruments. | 5 yrs |
| Complete description can be found: [EPA Records Schedule 1035](http://intranet.epa.gov/records/schedule/final/1035.html). | | | |

# C. ASSESSMENTS AND OVERSIGHT

## C1. Assessments and Response Actions

Describe any audits or assessments that will be done during the project. Will readiness reviews be done prior to sample collection or analysis? Will proficiency testing take place? Do field activities need to be audited after training? Describe corrective action procedures should audits reveal a deficiency (e.g., retraining of lab technicians).

If no additional audits are needed, simply defer to the CEMM QA audit program. The QA manager assigned to this project may determine that a project-specific audit is needed depending on the visibility of the project and may add this info to the QAPP when reviewing it.

## C2. Reports to Management

Describe the way management will be kept informed regarding the progress of the project including any assessment activities. Identify the type of progress reports that might be written, the frequency, and who reports will be delivered. Specify who is responsible for preparing and distributing the reports.

# D. DATA VALIDATION AND USABILITY

## D1/D2. Data Review, Verification, and Validation/Verification and Validation Methods

Describe how the data will be reviewed for completeness (including sample metadata), accuracy (as with transcription or transformation errors), and conformance to method specifications. Describe how you will reject or accept data. List any data qualifiers that will be reported with the data. Data validation should include an assessment of the data and its quality relative to the end use. Describe data verification and validation methods, including software to be used in verification or validation.

## D3. Analysis and Reconciliation with User Requirements

Describe what types of statistical analyses may be applied. State if a statistician was consulted. (Planning for the types of statistical analyses helps inform the experimental design.)

Direct from [EPA QA/G-5](https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf): *This element is to describe how you will evaluate the*

*validated data to see if it answers the original questions asked, i.e., the measurement quality objectives or data quality objectives.* *Describe how data will be presented, e.g., tables or charts, to illustrate trends, relationships, and anomalies. Discuss how limitations on the use of the data will be handled and reported to the decision makers.*

# E. References