Elements of a Good Quality Assurance Project Plan (QAPP)

A. Project Management Elements

Al. Title and Approval Sheet/s - Includes the title of the plan, the name of the organization/s implementing the project, and the effective date of the plan. It should have signature and date lines for the organization/s Project Manager/s, the organization/s QA Officer, the DEC Project Officer and the DEC QA Officer.

A2. Table of Contents – Use the same numbering system as the EPA Quality Assurance Requirements document (EPA QA/R-5); i.e., A1, A2 etc. (See end of this document for EPA QA/R-5 website) Whenever a section is not relevant to a specific project QAPP, Not Applicable or NA, can be typed in. Each page following the Title and Approval pages should show the name of the project, date and revision number at the top or bottom of the page and number of pages. (See above right-hand corner for example).

A3. Distribution List – Includes a list the names and addresses of all who receive the approved QAPP and any subsequent revisions.

A4. Project/Task Organization – This narrative description identifies the individuals or organizations participating in the project and discusses their specific roles and responsibilities. It should include the principal data users, the decision makers, the project QA officer and all those responsible for project implementation. A concise organization chart should be included showing the relationships and lines of communication among project participants. This org.chart should include other data users outside of the organization generating data, but for whom the data is intended. It should also identify any subcontractor relevant to environmental data operations, including laboratories providing analytical services.

A5. Problem Definition/Background and Project Objective/s – Here state the specific problem to be solved, decision to be made or outcome to be achieved. There should be sufficient background information to provide a historical, scientific and possibly, regulatory perspective. State the reason (the project objective) for the work to be done.

A6. Project/Task Description – This section provides a ***summary*** of all work to be performed, ***products*** to be produced, and the ***schedule*** for implementation. Maps showing the geographic locations of field tasks should be included. This section should be short. Save the total picture for B1. Sample Process Design.

A7. Criteria for Measurement of Data –These are the performance criteria (criteria for measurement of data) to achieve the overall objective/s. List the parameters to be sampled for, the analytical methods to be used, the method detection limits or quantification/reporting limits, and the precision, accuracy, comparability, representativeness and completeness which are acceptable to meet the overall objective/s.

Some QAPP use tables to show this information. However, a good narrative is always necessary.

This version included in May 2008 NPDES Primacy application.

Note that representativeness is usually determined when the monitoring plan is developed, when decisions are made regarding what parameters to sample for, where to sample and how often to sample. Completeness is a measure of the percentage of samples that must be taken to make the monitoring effort valid.

Analyses completed in the field must have quality control checks and balances built into the monitoring plan. For example: will duplicate samples be taken and compared? Will different analyses methods be performed and compared?

It is not necessary to repeat the accuracy and precision requirements of contracted laboratories. It is sufficient to reference the laboratory's Quality Management Plan (QMP), if this document lists the precision and accuracy of the analyses. These QMPs are kept on file at ADEC.

A8 Special Training/Certifications – This section describes any specialized training or certifications needed by personnel in order to successfully complete the project or task. It should discuss how such training is to be provided and how the necessary skills are assured and documented. If the project is a research one, it is sufficient to include the resumes of consultants/staff in an appendix.

A9 Documents and Records – This section *itemizes* all the documents and records that will be produced, such as interim progress reports, final reports, audits, and Quality Assurance Project Plan revisions, etc. It also lists field logs, sample preparation and analysis logs, laboratory analysis, instrument printouts, model inputs and outputs, data from other sources such as databases or literature, the results of calibration and QC checks. Copies of example data sheets should be included in the appendix.

For electronic data entry, in order to assure consistency in data entry activities for grants and permits, ADEC is encouraging the following standard QAPP language, which requires specific information on how electronic data is to be submitted for use in the statewide database:

> *In addition to any written report, data collected for a project will be provided electronically to ADEC via a 3.5" diskette, CD-ROM, ZIP Disk or Email ZIP file. Both the original application file and a comma delimited text file will be provided. The text file will be an ASCII (text) file, with fields separated by commas (comma de-limited; often "CSV") text enclosed in quotes. Spaces are* ***not*** *permitted between fields. Blank lines are* ***not*** *permitted in the file. All dates* ***must*** *be formatted as "****MM-DD-YYYY****".*

Finally this section should specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

B. Data Generation and Acquisition

B1. Sampling Process Design (Experimental Design) - This section defines the key parameters, the types and numbers of samples, the design assumptions, the where, when and how samples are to be taken, and the rationale for the design. Unlike A6. Project/Task Description above, the level of

detail here should be sufficient that a person knowledgeable in this area could understand why and how the samples are to be taken.

B2. Sampling Methods – This section should describe the procedures for collecting the samples and identify the sampling methods, equipment calibration, maintenance, and specific performance requirements. Often this information can be provided by reference to existing equipment, methods, and laboratory Standard Operating Procedures (SOPs) and Quality Assurance/Quality Control (QA/QC) Manuals.

B3. Sample Handling and Custody – This section describes the requirements for sample handling and custody in the field and laboratory, taking into account the nature of the samples, holding times before extraction and analysis and shipping options and schedules. Examples of labels, custody forms, etc. can be included in the appendices.

B4. Analytical Methods – This section identifies the analytical methods and equipment required.

B5. Quality Control – This section describes quality control activities (both in the field and in the laboratory) such as use of blanks, duplicates, matrix spikes, laboratory control samples, etc. It should state or reference the control limits, and describe the corrective action to be taken when control limits are exceeded.

B6. Instrument/Equipment Testing, Inspection and Maintenance – This section discusses the procedures used to verify that all instruments and equipment are maintained in sound operating condition and are capable of operating at acceptable performance levels. Equipment testing, inspection and maintenance schedules should be listed as well as where to get replacement parts, standards, etc. Appending or referencing Standard Operating Procedures is an acceptable way to discuss equipment and sampling kits.

B7. Instrument/Equipment Calibration and Frequency – This section identifies all the tools, gauges, instruments, and other sampling, measuring and test equipment used for data collection activities affecting quality that must be controlled, and, at specified periods, calibrated to maintain performance within specified limits. It identifies the certified equipment and/or standards used for calibration. It indicates how records of calibration are to be maintained and traceable to the instrument.

B8. Inspection/Acceptance of Supplies and Consumables – This section describes how and by whom supplies and consumables (e.g. standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) are inspected and accepted for use in the project. The acceptance criteria should be stated.

B9. Non-direct Measurements – This section identifies the type of data needed for project implementation or decision making that are obtained from non-measurement sources such as maps, charts, GPS latitude/longitude measurements, computer data bases, programs, literature files and historical data bases. It describes the acceptance criteria for the use of such data and specifies any limitations to the use of the data.

B10. Data Management – This section describes the project data management process, tracing the path of the data from their generation to their final use or storage. It discusses the control mechanism for detecting and correcting errors.

C. Assessments and Oversight

C1. Assessments and Response Actions - This section describes the frequency, numbers and type of project assessments, such as surveillance, peer reviews and audits needed for this project. It discusses the assessment information expected and the success criteria. It describes how and to whom the results of the assessment are reported and it discusses how response actions to assessment findings, including corrective actions for deficiencies and non-conforming conditions, are to be addressed and by whom. It discusses the process for revising an approved QAPP, if necessary.

C2. Reports to Management – This section describes how information regarding project assessments is presented to management. It identifies the preparer and recipients of assessment reports and the actions to be taken.

D. Data Validation and Usability

D1. Data Review, Validation, & Verification Requirements – The purpose of this section is to state the criteria used to review and validate—that is, accept, reject or qualify—data in an objective and consistent manner. It is a way to decide the degree to which each data item has met its quality specifications as described in B above.
Validating data means determining if data satisfy QAPP-defined user requirements; that is, that the data refer back to the overall objectives.
Verifying data means ensuring that the conclusions can be correctly drawn.

D2. Validation and Verification Methods - This section describes the process for validating and verifying data. It discusses how issues are resolved and identifies the authorities for resolving such issues. It describes how the results are to be conveyed to the data users. This is the section in which to reference examples of QAPP forms and checklists (which could be provided in the appendices). Any project-specific calculations are identified in this section.

D3. Reconciliation with User Requirements – The purpose of this section is to outline and specify the acceptable methods for evaluating the results obtained from the project. It includes scientific and statistical evaluations to determine if the data are of the right type, quantity, and quality to support the intended use.

For additional assistance in developing a QAPP, refer to:
1) ADEC Water Program QAPP Review Checklist, Nov., 2001 or
http://www.dec.state.ak.us/water/wqsar/pdfs/QAPPChecklist.pdf),
2) EPA QA/R-5 at: http://www.epa.gov/r10earth/offices/oea/epaqar5.pdf , and
3) EPA QA/G-5 at: http://www.epa.gov/r10earth/offices/oea/epaqag5.pdf.