Elements of a Good Quality Assurance Project Plan (QAPP)

A. Project Management Elements

1. 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 Air QA Officer.

2. 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).

3. Distribution List – Includes a list of the names, title, organization, phone number and addresses (email and mail) of all who receive the approved QAPP and any subsequent revisions.

4. 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 will 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.

5. 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 regulatory perspective. State the reason (the project objective) for the work to be done.

6. 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 10. Sampling Process Design.

7. Quality Objectives and Criteria for Measurement of Data –These are the Measurement Quality Objectives (MQOs) for each parameter to be measured. Measurement Quality Objectives are designed to evaluate and control various phases (sampling, preparation, and analysis) of the measurement process to ensure that total measurement uncertainty is within the range prescribed by the data quality objectives. MQOs can be defined in terms of the following data quality indicators:

- Precision
- Accuracy
- Representativeness
- Detectability
- Completeness
- Comparability

MQOs for each of the ambient air criteria pollutants can be found in, EPA Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Part I Ambient Air Quality Monitoring Program Quality System Development, Appendix 3, EPA-454/R-98-004, August 1998.

For each parameter to be sampled, list the measurement analytical methods to be used and the MQOs to meet the overall data quality objectives.

Please summarize this section as much as possible in table format. In addition a good narrative is always necessary.

8. 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.

9 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.

In addition to any written report, data collected for Prevention of Significant Deterioration (PSD) or compliance related air monitoring projects will be provided electronically to ADEC via a 3.5" diskette or CD-ROM.

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

Please summarize this section as much as possible in table format.

B. Measurement and Data Acquisition

10. Sampling Process Design - This section includes four major activities:

- Developing and understanding the monitoring objective(s) and appropriate data quality objectives.
- Identifying the spatial scale most appropriate for the site(s)'s monitoring objective.

- Identifying the general site location(s) where monitoring site(s) should be placed.
- Identifying specific monitoring sites.

This section needs to define 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 section 6. 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.

11. Sampling Methods – This section should describe the procedures for collecting the samples and identify the sampling methods, equipment calibration and maintenance, and specific performance requirements. To establish the basic validity of such air monitoring data, it must be shown that:

- The proposed sampling method complies with the appropriate testing regulations.
- The equipment is accurately sited.
- The equipment was accurately calibrated using correct and established calibration methods.
- The organization implementing the data collection operation is qualified and competent.

Please summarize this section as much as possible in table format.

Some of this information can be provided by specific reference to existing equipment, methods, and laboratory Standard Operating Procedures (SOPs) and Quality Assurance/Quality Control (QA/QC) Manuals in the appendices.

12. Sample Handling and Custody – This section describes the requirements for sample handling and custody.
Sample handling - The various phases of sample handling are sample labeling, sample collection and sample transportation.
Chain of Custody – If the results of a sampling program are to be used as evidence, a written record must be available tracking location and possession of the sample/data at all times.

Sample in the field and laboratory, taking into account the nature of the samples, holding times before extraction and analysis and shipping options and schedules. Sample handling forms and SOPs, sample custody forms and SOPs, etc. can be included in the appendices.

13. Analytical Methods – This section identifies the analytical methods and equipment required for the analysis of ambient air samples. Generally these methods are manual sample collection methods for lead and particulates with subsequent laboratory analyses.

14. Quality Control (QC) – QC is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements defined by the customer. This section describes the quality control activities that will be used to control the monitoring process to validate sample data. This section must state the frequency, control limits, standards traceability and describe the corrective action to be taken when control limits are exceeded. Data QC/QA requirements will be summarized in table format (Data Validation Table) for each parameter to be measured.

Example Data Validation Tables for some parameters are available upon request. These validation tables define criteria for accepting/rejecting pollutant and meteorological data.

Please summarize this section as much as possible in table format.

15. 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. Elements to include in Instrument/Equipment Testing, Inspection and Maintenance documents should include:

- Equipment lists – by monitoring group or station
- Spare equipment/parts lists – by equipment, including suppliers
- Inspection/maintenance frequency – by equipment
- Equipment replacement schedules
- Sources of repair – by equipment
- Service agreements that are in place
- Monthly check sheets and entry forms for documenting testing, inspection, maintenance performed.

Please summarize this section as much as possible in table format.

Testing, inspection and maintenance procedures should be available at each monitoring station. Appending or referencing Standard Operating Procedures is an acceptable way to discuss equipment.

16. 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 identifies the standards (primary, secondary, etc.), their traceability to known master standards, their certification and expiration dates. For standards where certification extends over a measurement range (e.g., thermometers, flow meters, etc.) , this section also specifies the range these respective standards are traceable over. Please ensure that standards used are appropriate for the measurement range the equipment will be calibrated to and that the calibration range is representative of the ambient environment to be measured. This section also specifies how records of calibration are to be maintained. Documentation should be readily available for review and should include calibration data, calibration equations, analyzer identification, calibration date, analyzer location, shelter temperature, calibration standards used and their traceabilities and the person conducting the calibration.

Please summarize this section as much as possible in table format.

17.Inspection/Acceptance of Supplies and Consumables – This section describes how and by whom supplies and consumables (e.g. standard materials and solutions, filters, tubing, volumetric glassware, gas manifolds, sample bottles, water purity, calibration gases, reagents, electronic data storage media), etc. are inspected and accepted for use in the project. The acceptance criteria should be stated.

18. 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.

19. 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 as well as performance audits of the data management system.

Please summarize this section as much as possible in table format.

C. Assessments and Oversight

20. Assessments and Response Actions - This section describes the evaluation processes and criteria used measure the performance or effectiveness of a quality system, the monitoring network and sites and various measurement phases of the data operation. These assessments are:

- Management Systems Reviews
- Network Reviews
- Technical Systems Audits
- Performance Audits (Accuracy)

This section will specify the frequency, numbers, acceptance criteria and type of project assessments. 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.

Please summarize this section as much as possible in table format.

21. Reports to Management – This section describes the frequency, content and distribution of assessment reports to management and other recipients. Assessment Reports are:

- QA Annual Report
- Network Reviews
- Quarterly Reports (includes precision and accuracy)
- Technical Systems Audit Reports
- Response/Corrective Action Reports

D. Data Validation and Usability

22. 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.
Ambient Air and Meteorological data will be validated via Data Validation Tables that summarize all criteria to be considered in validating, qualifying or invalidating data. Some example data validation tables have been developed for specific criteria pollutants and meteorological parameters.

These validation templates should be maintained on-site, with the respective laboratory conducting air monitoring analysis, QA auditor as well as with project management. These tables are intended as a quick reference guide for all involved in air monitoring system. Please summarize data validation criteria tables

23. 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.

24. 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) EPA QA/R-5 at: www.epa.gov/r10earth/offices/oea/epaqar5.pdf ;
2) EPA QA/G-5 at: www.epa.gov/r10earth/offices/oea/epaqag5.pdf; and
3) EPA QA Quality Assurance Handbook for Air Pollution Measurement Systems Volume II: Part I, Ambient Air Quality Monitoring Program Quality System Development EPA-454/R-98-004, August 1998.