MODEL QUALITY ASSURANCE PROGRAM PLAN FOR ENVIRONMENTAL MONITORING AGENCIES

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1.0 QUALITY ASSURANCE PROGRAM PLAN IDENTIFICATION FORM

Document Title: _____

Document Control Number: _____

Organization Title: _____

Address: _____
_____
_____

DIRECTOR: _____ PHONE NUMBER: _____

TITLE: _____

QA OFFICE: _____

ADDRESS: _____
_____
_____

PLAN COVERAGE: _____
_____
_____
_____
_____
_____
_____

CONCURRENCES:

(1) NAME: _____

TITLE: _____
(Quality Assurance Officer)

SIGNATURE: _____ DATE: _____

(2) NAME: _____

TITLE: _____

SIGNATURE: _____ DATE: _____

APPROVAL:

NAME: _____

TITLE: _____
(Agency Director)

SIGNATURE: _____ DATE: _____

NAME: _____

TITLE: _____
(Regional Administrator or designee)

SIGNATURE: _____ DATE: _____

RA COMMENTS: _____

2.0 INTRODUCTION

The _____ is strongly committed to good science and aggressive quality assurance (QA) practices. This commitment complements the U.S. Environmental Protection Agency's (EPA) own emphasis given to a comprehensive and coordinated QA program.

The _____ has already developed and integrated QA practices into monitoring and measurement activities within its purview. These QA practices are specifically designed to generate and process data of known and appropriate quality in a cost-effective manner.

The purpose of this document is to establish _____-wide consistency in the application of these individual QA practices. Further, it ensures that all monitoring and measurement activities funded by EPA will be conducted in accordance with EPA's monitoring and QA requirements.

This document describes the _____ QA program plan. Its objectives are to clearly delinate the _____ QA policy and management structure which will be used to implement the QA strategy and the QA monitoring requirements necessary to document the reliability and validity of environmental data.

3.0 QUALITY ASSURANCE POLICY

It is the policy of the _____ that there shall be sufficient QA activities conducted within the _____ to ensure that all environmental data generated and processed will be scientifically valid, of known precision and accuracy, of acceptable completeness, respresentativeness, and comparability and where appropriate, legally defensible. This goal can be achieved by ensuring that adequate QA steps and procedures are used throughout the entire monitoring process (from initial study planning through data usage).

A. Specifically it is the policy of _____ that:

1. All environmental data generated will be of known and acceptable quality. The data quality information developed with all environmental data will be documented and available.

2. The intended use(s) of the data will be defined before the data collection effort begins, so that appropriate QA measures may be applied to ensure a level of data quality commensurate with the monitoring objectives. The determination of this level of data quality shall also consider the prospective data needs of secondary users. The assigned level of data quality, specific QA activities, and data acceptance criteria will be explicitly described in each monitoring activity's QA project plan.

3. Quality assurance activities will be designed in the most cost-effective fashion possible without compromising data quality objectives.

4. All _____ monitoring activities will ensure that acceptable QA requirements are included and implemented in all applicable external procurements funded by EPA.

5. Each program which generates environmenal data will develop QA project plan addressing the major elements contained in Appendices A and B and will ensure that adequate resources (both monetary and staff) are provided to support the QA effort, and will be responsible for implementing the plan. The QA project plan will specify the mechanism by which timely corrective action can be taken when data quality under goes degradation. The project plan will specify the detailed procedures required to assure quality data.

6. The technical and administrative authority for all QA matters within the _____ will be assigned to the Quality Assurance Officer (QAO). The QAO will review, comment, and concur on all _____ QA project plans. The QAO will be the focal point for interaction between EPA's Regional QA program, _____ programs, and other environmental monitoring agencies in QA related matters.

7. All applicable programs will adhere to the requirements and specifications stated in the QA program and in all QA project plans, (when they are developed.)

4.0 QUALITY ASSURANCE MANAGEMENT

In order to properly manage the QA activities of environmental monitoring programs within the _____, all QA management responsibilities shall be assigned to the QAO. The QAO will be under the administrative management direction and support of the _____. Each applicable monitoring program will designate a person to serve as program Quality Control Coordinator (QCC). The organizational structure is shown in Figure 1.

4.1 Assignment of Responsibilities

A. Responsibilities of the QA Officer

1. The QAO will be the official contact for all QA matters of the _____.

2. The QAO will be responsible for identifying and responding to QA needs, problems, and requests from within the _____. The QAO will provide technical QA assistance or obtain technical assistance from EPA's Regional Quality Assurance Management office (RQAMO) as necessary. This will include assistance in preparing detailed QA plans, contract or other external procurement packages requiring QA measures, designing QA programs for new studies, etc.

3. The QAO will review and approve all _____ QA project plans and all the QA-related sections of procurement packages which includes or requires QA measures.

4. The QAO will work with the individual program managers and other _____ management to take appropriate corrective action when where and however needed.

5. The QAO will serve as liaison between EPA's Regional QA program, _____ programs, and other environmental monitoring agencies in QA related matters.

6. The QAO will prepare and submit QA reports to _____ management and when appropriate, EPA RQAMO.

Figure 1

B. Program Quality Control Coordinator

1. The QCC is responsible for ongoing identification and coordination of activities within their programs(s), which result in the generation and/or processing of environmental data.

2. The QCC will facilitate development and implementation of QA project plans for those activities with the assistance of the QAO.

3. The QCC will inform QAO of new legislation or regulations which affect the QA program.

4.2 Communication/Reporting

A system for the dissemination of both written and oral communication relative to QA program status/needs will be developed and implemented to ensure that QA programs are effectively coordinated within the _____ purview. The QAO and QCC will have direct access to the program managers or laboratory directors on specific QA matters as problems arise. The QAO will keep responsible management informed at all times of the performance of the data-production systems and of any program problems and needs. Responsible management will in turn adequately respond to identified program problems and needs (including resource aspects) and ensure their resolution.

By October 1 of each year, the QAO will submit a QA status report to _____ management and to EPA RQAMO. These reports will contain at least the following types of information:

A. Status of QA plans.

B. Data quality assessments, to include:

1. Accuracy
2. Precision
3. Completeness
4. Representativeness
5. Comparability

C. Significant QA problems, corrective actions, progress, plans and recommendations.

D. Results of performance audits.

E. Results of system audits.

F. Summary of QA-related training.

G. Other information specifically requested by _____ management and EPA.

4.3 QA Program Review and Audit

The QA program will include periodic reviews and audits to ensure achievement of expressed QA objectives. The nature and frequency of these reviews/audits will be determined on a project-specific basis. Generally, they shall include the following:

A. Review of Program and Project Plans

As part of the QAO's responsibility for QA program overview, all existing programs, future program plans, study/project plans, experimental designs, and external procurements will be reviewed by the QAO for adequacy, and be modified as necessary. These reviews will ensure that acceptable QA/QC activities and requirements are included, that proper QA was considered at the project's inception, and that the project will be able to produce data of the required quality in a reliable and cost-effective manner.

B. External Reviews/Audits of Performance

System and performance audits and inter-laboratory/inter-field comparision studies shall be conducted on each external (e.g., contractor laboratories) monitoring program within the _____ as required by the QAO. These audits will assess the adequacy of, and adherence to, the respective QA plans.

C. Internal Review/Audit of Performance

The QAO will develop and implement a quarterly blind field spike and duplicate program when appropriate. Corrective actions will be taken and the reports submitted to appropriate _____ management.

5.0 GENERAL QUALITY ASSURANCE REQUIREMENTS FOR MONITORING

Adequate QA will be applied throughout the entire monitoring process to ensure that all environmental data generated and processed will be scientifically valid, defensible, of known qaulity, complete, representative and comparable. The QA elements which will be incorporated into monitoring activities (both internal and externally procured) by all program offices are defined in Appendices A and B. Deviations from these QA monitoring requirements will be justified and documented. The specific requirements and level(s) of effort applicable to these QA elements will be described in individual QA project plans which will be prepared for each monitoring activity.

The QAO will review all QA project plans provide input, recommend changes, and approve final QA plans . The QAO will maintain a current file of all approved QA plans for every environmental monitoring program.

6.0 PERSONNEL QUALIFICATIONS

All QA personnel will have adequate education, training, and experience both in the area of their technical expertise and in quality assurance to meet their designated responsibilities.

All other monitoring personnel will possess adequate experience and knowledge to perform satisfactorily all technical tasks assigned.

7.0 FACILITIES, EQUIPMENT, AND SERVICES

The QA program requires that all applicable _____ facilities, equipment and services will be capable of producing acceptable quality data in a efficient manner with minimum risk to personnel. Specifically, the _____ ensures provision of the following :

(a) acceptable facilities (e.g., lighting, ventilation, temperature, noise levels, etc.) in their laboratory.

(b) acceptable utility services (e.g., electricity and voltage control; purity, pressure, and supply of water and air; etc.) in their laboratory.

(c) acceptable general laboratory equipment (e.g., analytical instrumentation support, air conditioners, furnaces, generators, refridgerators, incubators, laboratory hoods, sinks, counters etc.) in their laboratory.

(d) acceptable monitoring equipment used in the field.

(e) routine inspection and preventive maintenance will be performed for all facilities and equipment.

The above applies to any contractor receiving State/EPA funds for monitoring.

8.0 IMPLEMENTATION REQUIREMENTS AND SCHEDULE

Implementation of the _____ QA program requires that each major milestone be identified and scheduled for accomplishment. Milestones include:

	Milestones	Dates
1.	Designation of QA officer	_____
2.	QA program plan approved by _____	_____
3.	QA program plan approved by EPA Region _____	_____
4.	Preparation of QA project plan	On-going
5.	Prepare and submit QA program status report	On-going
6.	Review and update of QA plan	On-going
7.	Participation in annual performance or system audits.	On-going

APPENDIX A

Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans QAMS -005/80, December 29, 1980.

INTERIM GUIDELINES AND SPECIFICATIONS FOR

PREPARING QUALITY ASSURANCE PROJECT PLANS

QAMS-005/80

Office of Monitoring Systems and Quality Assurance
Office of Research and Development
United States Environmental Protection Agency
Washington, D.C. 20460

December 29, 1980

ACKNOWLEDGEMENTS

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DISCLAIMER

Mention of trade names or commercial products does not constitute EPA endorsement or recommendation for use.

ABSTRACT

The Agency-wide quality assurance policy stipulates that every monitoring and measurement project must have a written and approved Quality Assurance (QA) Project Plan. A QA Project Plan is a written document, which presents, in specific terms, the policies, organization (where applicable), objectives, functional activities, and specific QA and quality control (QC) activities designed to achieve the data quality goals of a specific project(s) or continuing operation(s). The QA Project Plan is required for each specific project or continuing operation (or group of similar projects or continuing operations). The QA Project Plan will be prepared by the responsible Program Office, Regional Office, Laboratory, contractor, grantee, or other organization.

This document describes the sixteen elements which must be considered for inclusion in all Quality Assurance Project Plans, and establishes criteria for plan preparation, review and approval. All QA Project Plans must describe procedures which will be used to document and report precision, accuracy and completeness of environmental measurements.

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1.0 INTRODUCTION

Environmental Protection Agency (EPA) policy requires participation by all EPA regional offices, program offices, EPA laboratories and States in a centrally-managed quality assurance (QA) program as stated in the Administrator's Memorandum of May 30, 1979. This requirement applies to all environmental monitoring and measurement efforts mandated or supported by EPA through regulations, grants, contracts, or other formalized means not currently covered by regulation. The responsibility for developing, coordinating and directing the implementation of this program has been delegated to the Office of Research and Development (ORD), which has established the Quality Assurance Management Staff (QAMS) for this purpose.

Each office or laboratory generating data has the responsibility to implement minimum procedures which assure that precision, accuracy, completeness, and representativeness of its data are known and documented. In addition, an organization should specify the quality levels which data must meet in order to be acceptable. To ensure that this responsibility is met uniformly across the Agency, each EPA Office or Laboratory must have a written QA Project Plan covering each monitoring or measurement activity within its purview.

2.0 DEFINITION, PURPOSE AND SCOPE

2.1 Definition

QA Project Plans are written documents, one for each specific project or continuing operation (or group of similar projects or continuing operations), to be prepared by the responsible Program Office, Regional Office, Laboratory, Contractor, Grantee, or other organization. The QA Project Plan presents, in specific terms, the policies, organization, objectives, functional activities, and specific QA and quality control (QC) activities designed to achieve the data quality goals of the specific project(s) or continuing operation(s). Other terms useful in understanding this document are defined in Appendix A.

2.2 Purpose

This document (1) presents guidelines and specifications that describe the 16 essential elements of a QA Project Plan, (2) recommends the format to be followed, and (3) specifies how plans will be reviewed and approved.

2.3 Scope

The mandatory QA program covers all environmentally-related measurements. Environmentally-related measurements are defined as all field and laboratory investigations that generate data. These include (1) the measurement of chemical, physical, or biological parameters in

the environment, (2) the determination of the presence or absence of pollutants in waste streams, (3) assessment of health and ecological effect studies, (4) conduct of clinical and epidemiological investigations, (5) performance of engineering and process evaluations, (6) study of laboratory simulation of environmental events, and (7) study or measurement on pollutant transport and fate, including diffusion models. Each project within these activities must have a written and approved QA Project Plan.

3.0 PLAN PREPARATION AND RESPONSIBILITIES

3.1 Document Control

All Quality Assurance Project Plans must be prepared using a document control format consisting of information placed in the upper right-hand corner of each document page:

- Section Number
- Revision Number
- Date (of revision)
- Page

3.2 Elements of QA Project Plan

Each of the sixteen items listed below must be considered for inclusion in each QA Project Plan:

(1) Title page with provision for approval signatures

(2) Table of contents

(3) Project description

(4) Project organization and responsibility

(5) QA objectives for measurement data in terms of precision, accuracy, completeness, representativeness and comparability

(6) Sampling procedures

(7) Sample custody

(8) Calibration procedures and frequency

(9) Analytical procedures

(10) Data reduction, validation and reporting

(11) Internal quality control checks and frequency

(12) Performance and system audits and frequency

(13) Preventive maintenance procedures and schedules

(14) Specific routine procedures to be used to assess data precision, accuracy and completeness of specific measurement parameters involved

(15) Corrective action

(16) Quality assurance reports to management

It is Agency policy that precision and accuracy of data shall be assessed on all monitoring and measurement projects. Therefore, Item 14 must be described in all Quality Assurance Project Plans.

3.3 Responsibilities

Intramural Projects - Each Project Officer working in close coordination with the QA Officer is responsible for the preparation of a written QA Project Plan for each intramural project that involves environmental measurements. This written plan must be separate from any general plan normally prepared for the project (see caveat presented in Section 6). The Project Officer and the QA Officer must ensure that each intramural project plan contains procedures to document and report precision, accuracy and completeness of all data generated.

Extramural Projects - Each Project Officer working in close coordination with the QA Officer has the responsibility to see that a written QA Project Plan is prepared by the extramural organization for each project involving environmental measurements. The elements of the QA Project Plan must be separately identified from any general plan normally prepared for the project (see caveat presented in Section 6). The Project Officer and the QA Officer must ensure that each extramural project plan contains procedures to document and report precision, accuracy and completeness of all data generated.

4.0 PLAN REVIEW, APPROVAL AND DISTRIBUTION

Intramural Projects - Each QA Project Plan must be approved by the Project officer's immediate supervisor and the QA Officer. Completion of reviews and approvals is shown by signatures on the title page of the plan. Environmental measurements may not be initiated until the QA Project Plan has received the necessary approvals, unless emergency response is necessary. A copy of the approved QA Project Plan will be distributed by the Project Officer to each person who has a major responsibility for the quality of measurement data.

Extramural Projects - Each QA Project Plan must be approved by the funding organization's Project Officer and the QA Officer. In addition, the extramural organization's Project Manager and responsible QA official must review and approve the QA Project Plan. Completion of reviews and approvals is shown by signatures on the title page of the plan. Environmental measurements may not be initiated until the QA Project Plan has received the necessary approvals. A copy of the approved QA Project Plan will be distributed by the extramural organization's Project Director to each person who has a major responsiblity for the quality of the measurement data.

5.0 PLAN CONTENT REQUIREMENTS

The sixteen (16) essential elements described in this section must be considered and addressed in each QA Project Plan. If a particular element is not relevant to the project under consideration, a brief explanation of why the element is not relevant must be included. EPA-approved reference, equivalent or alternative methods must be used and their corresponding Agency-approved guidelines must be applied wherever they are available and applicable.

It is Agency policy that precision and accuracy of data shall be assessed routinely and reported on all environmental monitoring and measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis during the project must be described in each QA Project Plan. Procedures to assess data quality are being developed by QAMS and the Environmental Monitoring Systems Support Laboratories. Additional guidance can be obtained from QA handbooks for air, water biological, and radiation measurements (References 1, 2, 3, 12, 17, and 18).

The following subsections provide specific guidance pertinent to each of the 16 components which must be considered for inclusion in every QA Project Plan.

5.1 Title page

At the bottom of the title page, provisions must be made for the signatures of approving personnel. As a minimum, the QA Project Plan must be approved by the following:

A. For intramural projects
   1. Project Officer's immediate supervisor
   2. QA Officer

B. For extramural projects
   1. Organization's Project Manager
   2. Organization's responsible QA Official
   3. Funding organization's Project Officer
   4. Funding organization's QA Officer

5.2 Table of Contents

The QA Project Plan Table of Contents will address each of the following items:

- Introduction.
- A serial listing of each of the 16 quality assurance project plan components.
- A listing of any appendices which are required to augment the Quality Assurance Project Plan as presented (i.e., standard operating procedures, etc.).

At the end of the Table of Contents, list the QAO and all other individuals receiving official copies of the QA Project Plan and any subsequent revisions.

5.3 Project Description

Provide a general description of the project, including the experimental design. This description may be brief but must have sufficient detail to allow those individuals responsible for review and approval of the QA Project Plan to perform their task. Where appropriate, include the following:

- Flow diagrams, tables and charts.
- Dates anticipated for start and completion.
- Intended end use of acquired data.

5.4 Project Organization and Responsibility

Include a table or chart showing the project organization and line authority. List the key individuals, including the QAO, who are responsible for ensuring the collection of valid measurement data and the routine assessment of measurement systems for precision and accuracy.

5.5 QA Objectives for Measurement Data in Terms of Precision, Accuracy, Completeness, Representativeness, and Comparability

For each major measurement parameter, including all pollutant measurement systems, list the QA objectives for precision, accuracy and completeness. These QA objectives will be summarized in a table. (See Table 1 for example of format.)

All measurements must be made so that results are representative of the media (air, water, biota, etc.) and conditions being measured. Unless otherwise specified, all data must be calculated and reported in units consistent with other organizations reporting similar data to allow comparability of data bases among organizations. Definitions for precision, accuracy and completeness are provided in Appendix A.

Data quality objectives for accuracy and precision established for each measurement parameter will be based on prior knowledge of the measurement system employed and method validation studies using replicates, spikes, standards, calibrations, recovery studies, etc, and the requirements of the specific project.

5.6 Sampling Procedures

For each major measurement parameter(s), including all pollutant measurement systems, provide a description of the sampling procedures to be used. Where applicable, include the following:

Table 1

EXAMPLE OF FORMAT TO SUMMARIZE PRECISION, ACCURACY AND COMPLETENESS OBJECTIVES

Measurement Parameter (Method)	Reference	Experimental Conditions	Precision, Std. Dev.	Accuracy	Completeness
NO_2 (Chemiluminescent)	EPA 650/4-75-011 February 1975	Atmospheric samples spiked with NO_2 as needed	<±10%	±5%	90%
SO_2 (24 hr) (Pararosaniline)	EPA 650/4-74-027 December 1973	Synthetic atmosphere	<±20%	±15%	90%
.	.	.	.	.	.
.	.	.	.	.	.
.	.	.	.	.	.

- Description of techniques or guidelines used to select sampling sites.
- Inclusion of specific sampling procedures to be used (by reference in the case of standard procedures and by actual description of the entire procedure in the case of nonstandard procedures).
- Charts, flow diagrams or tables delineating sampling program operations.
- A description of containers, procedures, reagents, etc., used for sample collection, preservation, transport, and storage.
- Special conditions for the preparation of sampling equipment and containers to avoid sample contamination (e.g., containers for organics should be solvent-rinsed; containers for trace metals should be acid-rinsed).
- Sample preservation methods and holding times.
- Time considerations for shipping samples promptly to the laboratory.
- Sample custody or chain-of-custody procedures (to be described later in this document).
- Forms, notebooks and procedures to be used to record sample history, sampling conditions and analyses to be performed.

5.7 Sample Custody

Sample custody is a part of any good laboratory or field operation. Where samples may be needed for legal purposes, "chain-of-custody" procedures, as defined by the Office of Enforcement, will be used. However, as a minimum, the following sample custody procedures will be addressed in the QA Project Plans:

A. Field Sampling Operations:

- Documentation of procedures for preparation of reagents or supplies which become an integral part of the sample (e.g., filters, and absorbing reagents).

- Procedures and forms for recording the exact location and specific considerations associated with sample acquisition.

- Documentation of specific sample preservation method.

- Pre-prepared sample labels containing all information necessary for effective sample tracking. Figure 1 illustrates a typical sample label applicable to this purpose.

- Standardized field tracking reporting forms to establish sample custody in the field prior to shipment. Figure 2 presents a typical sample of a field tracking report form.

B. Laboratory Operations:

- Identification of responsible party to act as sample custodian at the laboratory facility authorized to sign for incoming field samples, obtain documents of shipment (e.g., bill of lading number or mail receipt), and verify the data entered onto the sample custody records.

- Provision for a laboratory sample custody log consisting of serially numbered standard lab-tracking report sheets. A typical sample of a standardized lab-tracking report form is shown in Figure 3.

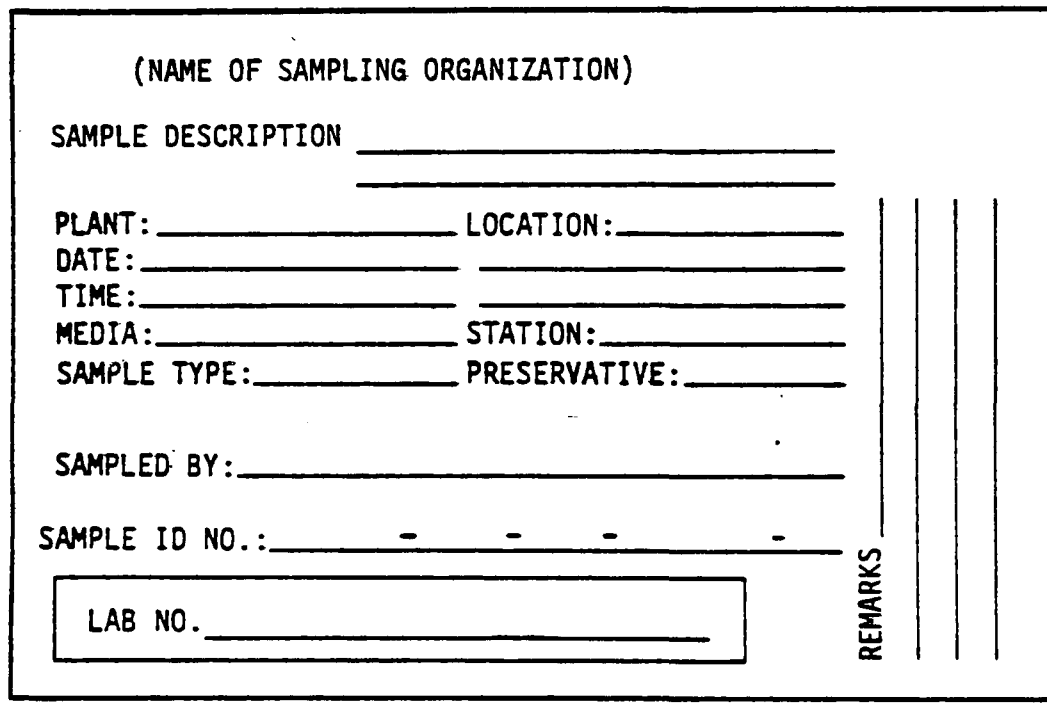

Figure 1. Example of General Sample Label

W/O No. _____ Page____

FIELD TRACKING REPORT: ____-____
(LOC-SN)

FIELD SAMPLE CODE (FSC)	BRIEF DESCRIPTION	DATE	TIME(s)	SAMPLER

Figure 2. Sample of Field Tracking Report Form

W/O No. _____ Page____

LAB TRACKING REPORT: ____-____-____
(LOC-SN-FSC)

FRACTION CODE	X	PREP/ANAL REQUIRED	RESPONSIBLE INDIVIDUAL	DATE DELIVERED	DATE COMPLETED

Figure 3. Sample of Lab-Tracking Report Form

- Specification of laboratory sample custody procedures for sample handling, storage and dispersement for analysis.

Additional guidelines useful in establishing a sample custody procedure are given in Section 2.0.6 of Reference 2, and Section 3.0.3 of Reference 3, and References 13 and 14.

5.8 Calibration Procedures and Frequency

Include calibration procedures and information:

- For each major measurement parameter, including all pollutant measurement systems, reference the applicable standard operating procedure (SOP) or provide a written description of the calibration procedure(s) to be used.
- List the frequency planned for recalibration.
- List the calibration standards to be used and their sources(s), including traceability procedures.

5.9 Analytical Procedures

For each measurement parameter, including all pollutant measurement systems, reference the applicable standard operating procedure (SOP) or provide a written description of the analytical procedure(s) to be used. Officially approved EPA procedures will be used when available. For convenience in preparing the QA Project Plan, Elements 6, 8 and 9 may be combined (e.g., Sections 5.6, 5.8 and 5.9).

5.10 Data Reduction, Validation and Reporting - For each major measurement parameter, including all pollutant measurement systems, briefly describe the following:

- The data reduction scheme planned on collected data, including all equations used to calculate the concentration or value of the measured parameter and reporting units.
- The principal criteria that will be used to validate data integrity during collection and reporting of data.
- The methods used to identify and treat outliers.
- The data flow or reporting scheme from collection of raw data through storage of validated concentrations. A flowchart will usually be needed.
- Key individuals who will handle the data in this reporting scheme (if this has already been described under project organization and responsibilities, it need not be repeated here).

5.11 Internal Quality Control Checks

Describe and/or reference all specific internal quality control ("internal" refers to both laboratory and field activities) methods to be followed. Examples of items to be considered include:

- Replicates
- Spiked samples
- Split samples
- Control charts

- Blanks
- Internal standards
- Zero and span gases
- Quality control samples
- Surrogate samples
- Calibration standards and devices
- Reagent checks

Additional information and specific guidance can be found in References 17 and 18.

5.12 Performance and System Audits

Each project plan must describe the internal and external performance and systems audits which will be required to monitor the capability and performance of the total measurement system(s).

The systems audit consists of evaluation of all components of the measurement systems to determine their proper selection and use. This audit includes a careful evaluation of both field and laboratory quality control procedures. Systems audits are normally performed prior to or shortly after systems are operational; however, such audits should be performed on a regularly scheduled basis during the lifetime of the project or continuing operation. The on-site systems

audit may be a requirement for formal laboratory certification programs such as laboratories analyzing public drinking water systems. Specific references pertinent to systems audits for formal laboratory certification programs can be found in References 19 and 20.

After systems are operational and generating data, performance audits are conducted periodically to determine the accuracy of the total measurement system(s) or component parts thereof. The plan should include a schedule for conducting performance audits for each measurement parameter, including a performance audit for all measurement systems. As part of the performance audit process, laboratories may be required to participate in analysis of performance evaluation samples related to specific projects. Project plans should also indicate, where applicable, scheduled participation in all other inter-laboratory performance evaluation studies.

In support of performance audits, the Environmental Monitoring Systems/Support Laboratories provide necessary audit materials and devices and technical assistance. Also, these laboratories conduct regularly scheduled inter-laboratory performance tests and provide guidance and assistance in the conduct of systems audits. To make arrangements for assistance in the above areas, these laboratories should be contacted directly:

Environmental Monitoring Systems Laboratory
Research Triangle Park, NC 27711
Attention: Dr. Thomas R. Hauser, Director

Environmental Monitoring and Support Laboratory
26 W. St. Clair Street
Cincinnati, OH 45268
Attention: Mr. Robert L. Booth, Director

Environmental Monitoring Systems Laboratory
P.O. Box 15027
Las Vegas, NV 89114
Attention: Mr. Glen Schwitzer, Director

5.13 Preventive Maintenance

The following types of preventive maintenance items should be considered and addressed in the QA Project Plan:

- A schedule of important preventive maintenance tasks that must be carried out to minimize downtime of the measurement systems.
- A list of any critical spare parts that should be on hand to minimize downtime.

5.14 Specific Routine Procedures Used to Assess Data Precision, Accuracy and Completeness

It is Agency policy that precision and accuracy of data must be routinely assessed for all environmental monitoring and measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis on the project must be described in each QA Project Plan.

For each major measurement parameter, including all pollutant measurement systems, the QA Project Plan must describe the routine procedures used to assess the precision, accuracy and completeness of the measurement data. These procedures should include the equations to calculate precision, accuracy and completeness, and the methods used to gather data for the precision and accuracy calculations.

Statistical procedures applicable to environmental projects are found in References 1, 2, 3, 12, 17, and 18. Examples of these procedures include:

- Central tendency and dispersion
  - Arithmetic mean
  - Range
  - Standard deviation
  - Relative standard deviation
  - Pooled standard deviation
  - Geometric mean
- Measures of variability
  - Accuracy
  - Bias
  - Precision; within laboratory and between laboratories
- Significance test
  - u-test
  - t-test
  - F-test
  - Chi-square test

- Confidence limits
- Testing for outliers

Recommended guidelines and procedures to assess data precision, accuracy and completeness are being developed.

5.15 Corrective Action

Corrective action procedures must be described for each project which include the following elements:

- The predetermined limits for data acceptability beyond which corrective action is required.
- Procedures for corrective action.
- For each measurement system, identify the responsible individual for initiating the corrective action and also the individual responsible for approving the corrective action, if necessary.

Corrective actions may also be initiated as a result of other QA activities, including:

(1) Performance audits

(2) Systems audits

(3) Laboratory/interfield comparison studies

(4) QA Program audits conducted by QAMS

A formal corrective action program is more difficult to define for these QA activities in advance and may be defined as the need arises.

5.16 Quality Assurance Reports to Management

QA Project Plans should provide a mechanism for periodic reporting to management on the performance of measurement systems and data quality. As a minimum, these reports should include:

- Periodic assessment of measurement data accuracy, precision and completeness.
- Results of performance audits.
- Results of system audits.
- Significant QA problems and recommended solutions.

The individual(s) responsible for preparing the periodic reports should be identified. The final report for each project must include a separate QA section which summarizes data quality information contained in the periodic reports.

6.0 QUALITY ASSURANCE PROJECT PLANS VERSUS PROJECT WORK PLANS

This document provides guidance for the preparation of QA Project Plans and describes 16 components which must be included. Historically, most project managers have routinely included the majority of these 16 elements in their project work plans. In practice, it is frequently difficult to separate important quality assurance and quality control functions and to isolate these functions from technical performance activities. For those projects where this is the case, it is not deemed necessary to replicate the narrative in the Quality Assurance Project Plan section.

In instances where specific QA/QC protocols are addressed as an integral part of the technical work plan, it is only necessary to cite the page number and location in the work plan in the specific subsection designated for this purpose.

It must be stressed, however, that whenever this approach is used a "QA Project Plan locator page" must be inserted into the project work plan immediately following the table of contents. This locator page must list each of the items required for the QA Project Plan and state the section and pages in the project plan where the item is described. If a QA Project Plan item is not applicable to the work plan in question, the words "not applicable" should be inserted next to the appropriate component on the locator page and the reason why this component is not applicable should be briefly stated in the appropriate subsection in the QA Project Plan proper.

7.0 STANDARD OPERATING PROCEDURES

A large number of laboratory and field operations can be standardized and written as Standard Operating Procedures (SOP). When such procedures are applicable and available, they may be incorporated into the QA Project Plan by reference.

QA Project Plans should provide for the review of all activities which could directly or indirectly influence data quality and the determination of those operations which must be covered by SOP's. Examples are:

- General network design
- Specific sampling site selection
- Sampling and analytical methodology
- Probes, collection devices, storage containers, and sample additives or preservatives
- Special precautions, such as heat, light, reactivity, combustability, and holding times
- Federal reference, equivalent or alternative test procedures
- Instrumentation selection and use
- Calibration and standardization
- Preventive and remedial maintenance
- Replicate sampling
- Blind and spiked samples

- Colocated samplers
- QC procedures such as intralaboratory and intrafield activities, and interlaboratory and interfield activities
- Documentation
- Sample custody
- Transportation
- Safety
- Data handling procedures
- Service contracts
- Measurement of precision, accuracy, completeness, representativeness, and comparability
- Document control

8.0 SUMMARY

Each intramural and extramural project that involves environmental measurements must have a written and approved QA Project Plan. All 16 items described previously must be considered and addressed. Where an item is not relevant, a brief explanation of why it is not relevant must be included. It is Agency policy that precision and accuracy of data must be routinely assessed and reported on all environmental monitoring and measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis during the project must be described in each QA Project Plan.

REFERENCES

1. Quality Assurance Handbook for Air Pollution Measurement Systems. Volume I - Principles. EPA-600/9-76-005, March 1976.

2. Quality Assurance Handbook for Air Pollution Measurement Systems. Volume II - Ambient Air Specific Methods. EPA-600/4-77-027a, May 1977.

3. Quality Assurance Handbook for Air Pollution Measurement Systems. Volume III - Stationary Source Specific Methods. EPA-600/4-77-027b, August 1977.

4. Systems Audit Criteria and Procedures for Ambient Air Monitoring Programs. Currently under development and available from address shown in Reference 1 after July 1, 1980.

5. Techniques to Evaluate Laboratory Capability to Conduct Stack Testing.

6. Performance Audit Procedures for Ambient Air Monitoring Programs. Currently under development.

7. Appendix A - Quality Assurance Requirements for State and Local Air Monitoring Stations (SLAMS). Federal Register, Vol. 44, No. 92, pp. 27574-81, May 10, 1979.

8. Appendix B - Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring, Federal Register. Vol. 44, No. 92, pp. 27582-84, May 10, 1979.

9. Appendix E - Quality Assurance Requirements for Continuous Emission Monitoring Systems (CEMS). To be submitted as a proposed regulation to amend 40 CFR 60.

10. Test Methods for Evaluating Solid Waste - Physical/Chemical Methods. EPA SW-846, 1980.

11. Quality Assurance Guidelines for IERL-CI Project Officers. EPA-600/9-79-046. December 1979.

12. Handbook for Analytical Quality Control in Water and Wastewater Laboratories. EPA-600/4-79-019, March 1979.

13. NEIC Policies and Procedures Manual. Office of Enforcement, EPA-330-9-78-001, May 1978.

14. NPDES Compliance, Sampling and Inspection Manual. Office of Water Enforcement, Compliance Branch, June 1977.

15. Juran, J. M. (ed), Quality Control Handbook. Second Edition, McGraw Hill, New York, 1962.

16. Juran, J. M. and F. M. Gryna, Quality Planning and Analysis. McGraw Hill, New York, 1970.

17. Handbook for Analytical Quality Control and Radioactivity Analytical Laboratories. EPA-600/7-77-088, August 1977.

18. Manual of Analytical Quality Control for Pesticides and Related Compounds in Human and Environmental Samples. EPA-600/1-79-008, January 1979.

19. Procedure for the Evaluation of Environmental Monitoring Laboratories. EPA 600/4-78-017, March 1978.

20. Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies - Criteria and Procedures. EPA 600/8-78-008, August 1978.

APPENDIX A

GLOSSARY OF TERMS

AUDIT:

A systematic check to determine the quality of operation of some functon or activity. Audits may be of two basic types: (1) performance audits in which quantitative data are independently obtained for comparison with routinely obtained data in a measurement system, or (2) system audits of a qualitative nature that consist of an on-site review of a laboratory's quality assurance system and physical facilities for sampling, calibration, and measurement.

DATA QUALITY:

The totality of features and characteristics of data that bears on its ability to satisfy a given purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, and comparability. These characteristics are defined as follows:

- Accuracy - the degree of agreement of a measurement (or an average of measurements of the same thing), X, with an accepted reference or true value, T, usually expressed as the difference between the two values, X-T, or the difference as a percentage of the reference or true value, 100 (X-T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system.

- Precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is best expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions."

- Completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.

- Representativeness - expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

- Comparability - expresses the confidence with which one data set can be compared to another.

DATA VALIDATION

A systematic process for reviewing a body of data against a set of criteria to provide assurance that the data are adequate for their intended use. Data validation consists of data editing, screening, checking, auditing, verification, certification, and review.

ENVIRONMENTALLY RELATED MEASUREMENTS:

A term used to describe essentially all field and laboratory investigations that generate data involving (1) the measurement of chemical, physical, or biological parameters in the environment, (2) the determination of the presence or absence of criteria or priority pollutants in waste streams, (3) assessment of health and ecological effect studies, (4) conduct of clinical and epidemiological investigations, (5) performance of engineering and process evaluations, (6) study of laboratory simulation of environmental events, and (7) study or measurement on pollutant transport and fate, including diffusion models.

PERFORMANCE AUDITS:

Procedures used to determine quantitatively the accuracy of the total measurement system or component parts thereof.

QUALITY ASSURANCE:

The total integrated program for assuring the reliability of monitoring and measurement data. A system for integrating the quality planning, quality assessment, and quality improvement efforts to meet user requirements.

QUALITY ASSURANCE PROGRAM PLAN:

An orderly assemblage of management policies, objectives, principles, and general procedures by which an agency or laboratory outlines how it intends to produce data of known and accepted quality.

QUALITY ASSURANCE PROJECT PLAN:

An orderly assembly of detailed and specific procedures which delineates how data of known and accepted quality data is produced for a specific project. (A given agency or laboratory would have only one quality assurance program plan, but would have a quality assurance project plan for each of its projects.)

QUALITY CONTROL:

The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process.

STANDARD OPERATING PROCEDURE (SOP):

A written document which details an operation, analysis or action whose mechanisms are thoroughly prescribed and which is commonly accepted as the method for performing certain routine or repetitive tasks.

APPENDIX B

Regional Quality Assurance Monitoring Protocals

Environmental Sampling and Quality Assurance Protocol

It is the policy of Region 10 that every study or activity involving environmental data collection results in data of adequate statistical quantity and known precision and accuracy. To ensure that this is achieved, a sampling protocol should be followed and a study plan prepared. The plan should describe the specific study details and discuss the procedures to be used to assure that the data is of known and sufficient quality to satisfy the study objectives. The following sampling protocol and study plan development outline are intended to be a guide for EPA staff and/or EPA contractors conducting environmental monitoring or measurement activities within Region 10.

I. Scope and purpose of the monitoring or measurement activity.

   A. Technical objectives.

   B. Intended use of data and associated levels of data quality required.

   C. Time frames and schedules.

   D. Organization and responsibilities.

   E. Reporting format (reports, samples only, etc.)

II. Preliminary activities.

   On any detailed survey other than those requiring just one or two grab samples to be collected, the following activities should be considered:

   A. If necessary, conduct a pre-survey site visit to obtain pertinent information for conducting the sampling survey; such as logistics problems, equipment needs, access to sample location, etc.

   B. Develop a preliminary plan of study which includes recommendations for any changes in the original objectives, survey timing, anticipated problems, etc.

   C. If necessary, appropriate representatives of EPA and the sampling entity will meet to discuss the preliminary plan of study; especially any changes in objectives or survey timing. At that time, any changes required will be agreed upon by all parties.

III. Detailed plan of study.

   The sampling entity must develop this plan to satisfy EPA analytical sampling and quality assurance requirements and inform appropriate staff how the study is to be conducted. The plan of study should:

A. Discuss the final agreed upon objectives including an objective which addresses possible limitations of data use and level of data quality.

B. Contain a brief explanation of past sample analysis results if known.

C. Identify responsibilities for:

1. Conducting the survey.

2. Quality assurance activities.

3. Providing equipment.

4. Sample analysis.

5. Interpretation and analysis of results.

6. Scheduled report outputs.

D. Include a description of activities associated with sample collection, including:

1. Discussion of parameters to be collected, sampling procedures, and methods employed.

2. Listing of equipment to be used.

3. Discussion of potential sample collection problems that may be encountered.

4. Listing of sample containers used, volumes of samples to be collected, and preservatives to be used.

5. Discussion of field and laboratory analysis to be performed and rationale.

6. Listing of methodology or reference to a standard methodology for all field and laboratory analysis including reporting units.

7. Discussion of documentation to be used including field data forms, analysis request forms, and sample routing forms if appropriate.

8. Discussion of quality assurance activities associated with field and laboratory monitoring or measurement analysis, including:

a) Analytical procedures.

For each major qualitative and/or quantitative analysis, list or provide a description of the analytical procedures to be used. Where applicable, analytical procedures recognized by EPA as standard methods should be used.

b) Calibration procedures and frequency.

For each qualitative and/or quantitative analysis, list or provide a description of the calibration procedures to be used. List the frequency planned for scheduled recalibration. Where applicable, list those calibration standards whose concentrations or values will be established or compared to standards of higher quality. This process is called traceability. List the standards of higher quality that will be used for this traceability.

c) Quality control checks.

For each qualitative and/or quantitative analysis, describe the frequency and type(s) of operational check(s) planned during routine sampling and routine analysis, the established control limits, and corrective action to be initiated before measurements are continued.

d) Preventative maintenance procedures.

Include a schedule of important preventative maintenance tasks that must be carried out to minimize downtime of the measurement systems. Where appropriate, list critical spare parts that should be on hand to minimize downtime due to parts failure.

e) Precision and accuracy assessments.

It is EPA's policy that precision and accuracy of data shall be routinely assessed on all applicable environmental monitoring and measurement data. Describe a procedure to be used to routinely assess the precision and accuracy of environmental data. Include in this procedure the equations to calculate precision and accuracy and the activity planned to gather data for the precision and accuracy calculation.

Accuracy--The mechanism which will demonstrate that the reported data are favorably comparable to the true value(s).

Precision--The mechanism which will demonstrate the reproducibility of the measurement process.

9. Identify how samples are to be transported.

10. Identify the chain-of-custody procedures to be used (if any).

VI. Analytical Methods.

All field and laboratory environmental measurements shall adhere to established EPA regulations, guidelines, and Regional standard operating laboratory procedures (SOP). SOP's shall be detailed documents describing who does what, when, where, how, and why in a stepwise manner. They shall be sufficiently complete and detailed to ensure that data of known precision and accuracy are generated. SOP's shall be prepared or referenced for all routine tasks but are not required to be contained in the plan.

Recommended EPA Laboratory procedures are described in the Federal Register, NPDES Amendments, Dec. 1, 1976, Vol. 41 No. 232, pp. 52780-86, "Guidelines Establishing Test Procedures for the Analysis of Pollutants", or the most recent update which is expected around January 1, 1980. Also refer to the following references:

Methods for Chemical Analysis of Water and Wastes, March 1979, EPA-600/4-79-020.

Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA-600/4-79-019.

Microbiological Methods for Monitoring the Environment, Water, and Wastes, EPA-600/8-78-017.

Copies of the above-referenced documents can be obtained through the Region 10 Quality Assurance Management Office. Address and telephone number are as follows:

Mr. Barry Towns
Regional Quality Assurance Management Office
U.S. EPA M/S 345
1200 6th Avenue
Seattle, WA 98101

Telephone (206) 442-1106

V. Data Management and Reporting Requirements.

This section addresses the management and reporting requirements of environmental data from sample collection through laboratory

analysis to the final deposition of data including storage into the STORET national water quality data base. Data management questions will be resolved through the EPA Data Coordinator, Ray Peterson. His address and telephone number are as follows:

Ray Peterson M/S 345
EPA Region 10
1200 Sixth Avenue
Seattle, WA 98101

Telephone (206) 442-1193

A. Project area identification and characteristics:

1. Provide a map of the study area identifying all basins or similar drainage areas considered in the project. In addition, all project area characteristics gathered such as land use, soil maps, drainage conveyance systems, rainfall maps, etc., shall be reported to the Data Coordinator, on the sampling entities reporting form.

B. Monitoring site identification.

1. Provide the following information on all monitoring sites:

a) Identification number, if any (12 character maximum).

b) Name (48 character maximum).

c) Latitude/longitude to nearest second.

d) State.

e) County.

f) Purpose/description of monitoring site.

g) Copy (xerox okay) of USGS quad map with site located.

2. The EPA Data Coordinator in turn will perform the following within three weeks of receipt of information from sampling entity.

a) Detemine which stations (sites) are to be entered in STORET.

b) Assign permanent STORET identification primary and secondary numbers as necessary and supply this information to the sampling entity for future handling of data.

c) Code and store sites in EPA computer system(s)

d) Send printout back to sampling entity for verification.

C. Collected physical/chemical data.

1. All data collected will be submitted to the EPA Data Coordinator on sampling entities reporting form within one month of availability.

2. For all data identified by the EPA Data Coordinator as appropriate, the sampling entity has the responsibility to get that data coded on forms, punched on cards, or transferred to tape in a format suitable for storage in the EPA STORET computer system within three months of availability. Coding, punching, or tape formating details shall be approved by the Data Coordinator prior to submission. The Data Coordinator will store the data on STORET at no cost to the sampling entity. Within one month of receipt of the data, the Data Coordinator will provide a STORET printout for verification of all stored data. Verification of stored data is manditory and will be the sampling entity's responsibility.

3. EPA will (as approved by the Data Coordinator) provide standard STORET data retrievals to the sampling entity of raw data, summaries, statistical analysis, and/or graphics at no cost within two weeks of request.

VI. Report of findings.

The responsibilities for degree and type of reporting should be spelled out in the objectives. They should include the following:

A. Interpretation of lab results and other factors useful in interpreting data.

B. Have objectives been met?

C. Recommendations on additional work.

Quality Assurance Sample Plan
Outline

Project Name_____ Project Code_____

Project Officer_____ Date Initiated_____

QA Officer_____ Date Approved_____

Date Due_____ Peer Review Yes_____ No_____

Date Completed_____

1. Purpose: (This includes agency requesting justification for conducting sampling; Technical objectives, intended use of data, data quality required.)

2. Sampling Site: (Description of problem area.)

3. Parameters: (What analyses requested of Lab; Limit of detection sought.)

4. Laboratory notification: (Lab number, instructions on containers and documentation.)

5. Coordination; (Names of contacts at requesting agency and at laboratory; scheduling data.)

6. Sample Documentation: (Check list of required records; Chain-of-custody procedures.)

7. Sample Collection: (Narrative description of proposed sampling.)

8. Quality Assurance: (Listing of blanks taken and controls cited for sampl

9. Sampling handling: (Any special methods or devices used; How samples are to be transported.)

10. Safety precautions:

11. Final Report/Data Usage. (This may range from a Reporting Format for samples only to a full report including interpretation of results, objective critique, recommendations on additional sampling, peer review and administrative approval.)