



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
215 Fremont Street
San Francisco, Ca. 94105

14 JUL 1987

Commander
Western Division
Naval Facilities
Atten: Louise Lew, Code 1142E
P.O. Box 727
San Bruno, CA 94066

Dear Ms. Lew:

Enclosed is page 6 of EPA's comment package. Due to an oversight on my part, page 6 of EPA's comments were not included in the original comment package. Also enclosed is a complete copy of the Interim Guidelines and Specifications for Preparing Quality Assurance Project Plan (QAMs - 005/80, December 29, 1980) and the Draft Supplement to: Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAMs - 005/80, January 1986. I shall forward other quality assurance/quality control guidelines as they are made available.

EPA requests a response to the submitted comments approximately 30 days from the Navy's receipt of the comment package as discussed during our phone conversation on July 7, 1987. If you have any concerns regarding the time frame, please contact me at (415) 974-7537.

Sincerely,

Nancy Woo
Remedial Project Manager

cc: Randy Cate, NAS Alameda
Don Cox, DHS
Ken Theisen, RWQCB

January 1986

**DRAFT SUPPLEMENT TO: INTERIM GUIDELINES AND SPECIFICATIONS FOR
PREPARING QUALITY ASSURANCE PROJECT PLANS, QAMS-005/80**

1. Title and Signature Page

QUALITY ASSURANCE PROJECT PLAN FOR

Project Title

Document Control Number

Organization's Name

Address

Telephone Number

APPROVALS:

Name and Title of Organization's
Project Manager

Date

Name and Title of Organization's
Quality Assurance Official

Date

U.S. Environmental Protection Agency,
Region 9
Project Officer

Date

U.S. Environmental Protection Agency,
Region 9
Quality Assurance Officer

Date

2. Table of Contents

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15. Statistical Assessments of Data Quality	
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(Appendices if applicable)	

3. Project Description

Address the following:

Project objective (i.e. purpose or goal): _____

Pertinent background information: _____

Intended use of data (i.e. monitoring, enforcement): _____

Overview of project activities (i.e. scope of project, the approach taken to achieve goals): _____

Schedule of activities and anticipated completion. May include but is not limited to: initiation of sample collection, sample analysis, data review and reporting, data validation, and final report preparation. _____

4. Project Organization and Responsibility

Include a statement on each key individual, including the Quality Assurance Officers, who are responsible for ensuring collection of valid measurement data and the routine assessment of measurement systems for precision and accuracy. State their duties which may include the review of calculations and reports, providing training to personnel, and ensuring that established protocols and procedures are followed. Provide a flow diagram which includes the individuals discussed, their interaction with each other, and the line of authority. Also, provide information on the training provided to personnel to accomplish their tasks.

5. Quality Assurance Objectives for Measurement of Data in Terms of Precision, Accuracy, Completeness, Representativeness, and Comparability

For each major parameter provide the Quality Assurance objectives for precision, accuracy, and completeness for both field and laboratory analysis. Summarize these objectives in a table format (see Table 1 for example of format). Also, address representativeness and comparability for both field and laboratory analyses.

Field Analyses

Representativeness: _____

Comparability (units data reported in): _____

Laboratory Analyses

Representativeness: _____

Comparability (units data reported in): _____

Table 1
Example of Format to Summarize Precision, Accuracy and Completeness Objectives

Measurement Parameter (Method)	Reference	Precision	Accuracy	Completeness
---	------------------	------------------	-----------------	---------------------

Section # _____
Revision # _____
Date _____
Page _____ of _____

6. Sampling Procedures

Provide the following:

- Method of collection. Include enough detail to ensure reproducibility (i.e. an outside individual could read the instructions and collect sample in exactly the same manner). Standard Operating Procedures can be referenced but will need to be provided for review.
- How sample sites where selected.
- Special conditions for the preparation of sampling equipment and containers to avoid sample contamination. If CLP laboratory is used, contract requirements must be followed and can be referenced here.
- Description of decontamination procedures.
- Type and volume of sample containers. Refer to the Federal Register 10/26/84 for recommended sample containers. If CLP lab is used, contract requirements must be followed and can be referenced here.
- Holding times and preservation methods. Refer to the Federal Register 10/26/84 which contains recommended holding times and preservation methods. If a CLP laboratory is used, CLP contract holding times must be followed and can be referenced here.
- Time considerations for shipping samples promptly to the laboratory.
- Forms, notebooks and procedures to be used to record sampling history, sampling conditions and analyses.

7. Sample Chain of Custody Procedures

For field sampling involving a CLP laboratory, Chain of Custody procedures found in 'Preparation of a U.S. EPA Region 9 Sample Plan' must be followed.

CLP laboratories will follow the Chain of Custody procedures specified in the Statement of Work.

Non-CLP laboratories and field sampling efforts associated with these laboratories must address the following:

- Procedures and forms for recording the exact location and specific considerations associated with sample acquisition.
- Documentation of procedures for preparation of reagents or supplies which become an integral part of the sample (i.e. filters).
- Documentation of sample preservation method.
- Provide details on labeling techniques.
- A copy of the chain of custody form. Provide forms used in the field and laboratory.
- Identify the responsible laboratory personnel who acts as sample custodian.
- Laboratory procedures for sample handling, storage and dispersment for analysis.

8. Calibration Procedures and Frequency for Field and Laboratory Equipment

For CLP-HSL analyses, established calibration procedures for HSL analyses are provided in the Statement of Work and can be referenced.

For each major piece of equipment used in the field (including monitoring equipment) and in non-CLP laboratories and non-HSL CLP analyses, provide the information listed below. Quality Assurance manuals and methods may be referenced, but appropriate sections must be provided as appendices.

Field Equipment

Equipment: _____

Calibration Procedures: (Reference or description of procedures): _____

Frequency of Recalibration: _____

Calibration Standards Used: _____

Source of Standards: _____

Where Calibrations and Repairs Logged: _____

Laboratory Equipment

Equipment: _____

Calibration Procedures: (Reference or description of procedures): _____

Section # _____
Revision # _____
Date _____
Page _____ of _____

- Frequency of Recalibration: _____

Calibration Standards Used: _____

Source of Standards: _____

Where Calibrations and Repairs Logged: _____

Section # _____
Revision # _____
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9. Analytical Procedures

For CLP laboratories, analytical procedures for compounds identified on the HSL have been developed and are specified in the CLP Statement of Work and can be referenced.

For each analytical procedure performed in the field, by a non-CLP laboratory or for non-HSL analyses performed through the CLP, reference or cite the method name and number (copies may need to be provided) or provide a description of the analytical procedure. Include the analyte or parameter group, the name of the method, the method number (if applicable), and detection limit. See Appendix A for common sources of methods used for analyses.

10. Procedures used for data reduction, validation of methods, and procedure of reporting the data

For CLP laboratories, routine procedures for data reduction and reporting of HSL data are specified in the Statement of Work. Region 9 reviews and validates all data generated by a CLP laboratory. A summary of the results and any qualifiers are provided to the project officer.

Mathematical procedures used by non-CLP laboratories and non-HSL CLP generated data must be described below:

Equations used to calculate concentrations or value of measured parameter, and reporting units: _____

Principal criteria that will be used to validate data during collection and reporting of data. Also, address what per cent agreement must occur between field samples in order to be considered valid: _____

Methods used to identify and treat outliers: _____

Data flow or reporting scheme from collection of raw data through storage of validated analytical results:

Responsible individuals who will handle data: _____

Performance quality control samples: _____

Surrogate samples: _____

Calibration standards and devices: _____

Reagent checks: _____

Zero and span gases: _____

Control charts: _____

Other: _____

11. Internal Quality Control Checks and Frequency

Minimum field quality control suggested is as follows:

- 1 duplicate/matrix/day/concentration or 10% of samples
- 1 field blank/matrix/day/concentration/laboratory
- VOA travel blank 1/day/shipping container
- 1 background sample/day

For CLP-HSL analyses, the Statement of Work specifies the use and frequency of internal laboratory quality control requirements. For CLP-non HSL analyses, the methods and frequency must be addressed below.

Minimum laboratory quality control is dependent on the analyte and should be addressed in the laboratory's Quality Assurance Manual. The contractor should extract this information from the manual and provide it below.

The following are the most commonly used methods for quality control. Indicate the method(s) and frequency of internal quality control checks to be used for laboratory and field activities:

Replicates: _____

Spiked samples: _____

Split samples: _____

Blanks: _____

Background: _____

Internal standards: _____

12. Performance and System Audits

The Enviromental Monitoring and Support Laboratory-Las Vegas submits blinds on a quarterly basis to CLP laboratories. System audits are conducted on all CLP laboratories at a frequency determined by performance audit scores but at least annually.

The laboratory and field participate in the performance and system audits and quality control check sample programs listed below.

Internal Audits

General description of audits to be conducted: _____

Systems audits are conducted by _____

Person to receive audit reports: _____

External Audits

General description of audits to be conducted: _____

Systems audits are conducted by _____

Section # _____
Revision # _____
Date _____
Page _____ of _____

Frequency of audits: _____

Person to receive audit reports: _____

13. Preventive Maintenance

If a CLP laboratory is used, then the contract requirements must be followed.

A preventive maintenance program consisting of scheduled routine maintenance of laboratory and field equipment to minimize downtime and out-of-control situations is conducted. Equipment, their maintenance schedules, and critical spare parts maintained to reduce down time are as follows:

<u>Equipment</u>	<u>Maintenance</u>	<u>Interval</u>	<u>Critical Spare Parts</u>
------------------	--------------------	-----------------	-----------------------------

- 14. Specific Routine Procedures Used to Assess Data Precision, Accuracy and Completeness

The procedures used to assess data precision, accuracy, and completeness are: (address each measurement parameter and include the equations used to calculate precision, accuracy, and completeness. Examples of statistical procedures are: arithmetic mean, range, standard deviation, t-test, f-test, chi-square test, confidence limits).

Data precision _____

Data accuracy _____

Data completeness _____

15. Corrective Action

Corrective action procedures to be used must address the following:

Predetermined limits for data acceptability beyond which corrective action is required (i.e. spike recoveries less than 60% require corrective action):

Procedures for corrective action (i.e. re-evaluation of analyst's work, instrumentation checks): _____

Person(s) responsible for initiating the corrective action and for approving the corrective action:

16. Quality Assurance Reports to Management

Quality assurance reports to management should include the following information:

- Periodic assessment of measurement data accuracy, precision and completeness.
- Results of performance audits.
- Results of system audits.
- Significant Quality Assurance problems and recommended solutions.
- Other: _____

The final report includes a separate QA section which summarizes data quality information contained in the periodic reports.

The individual(s) responsible for preparing the reports is(are): _____

Frequency of reports: _____

Reports submitted to EPA: _____ Yes _____ No

DEFINITIONS

Accuracy: the degree of agreement of a measurement with an accepted reference or true value.

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

Completeness: the amount of valid data obtained from a measurement system compared to the amount that was expected and needed to be obtained to meet the project data goals.

Data Reduction: mathematical and/or statistical procedures used to convert raw measurement(s) to the final reported form.

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, and review.

Out-of-Control: generated data the fall outside established acceptance limits.

Performance Audit: procedure used to determine quantitatively the accuracy of measurement data through the use of performance evaluation samples.

Precision: a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Usually expressed in terms of the standard deviation.

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

Representativeness: refers to a sample or group of samples that reflects the characteristic of the media at the sampling point. It also includes how well the sampling point represents the actual parameter variations which are under study.

Systems Audit: a review of the total data generation process which includes on-site reviews of the field and laboratory operational systems, physical facilities for sampling, equipment calibrations, and measurement protocols.

APPENDIX A

SAMPLE COLLECTION AND ANALYTICAL REFERENCES

Environmental Protection Agency, Federal Register, 40 CFR Part 136, Friday, October 26, 1984, Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act

Table I List of Approved Test Procedures

Table II Required Containers, Preservation Techniques, and Holding Times

Sampling Methods

Water

1. Handbook for Sampling and Sample Preservation of Water and Wastewater, EPA 600/4-82-029, September 1982.
2. Addendum to Handbook for Sampling and Sample Preservation, EPA 600/4-83-039.
3. Manual of Groundwater Sampling Procedures, NWWA/EPA Series.
4. Sampling Protocols for Collecting Surface Water, Bed Sediment, Bivalves, and Fish for Priority Pollutant Analysis.

Hazardous Wastes

1. Characterization of Hazardous Waste Sites, A Methods Manual, Vol. II, Sampling Methods.
2. Samples and Sampling Procedures for Hazardous Waste Streams, EPA 600/2-80-018, January 1980.
3. Test Methods for Evaluating Solid Waste, SW-846.

Pesticides

1. NEIC Pesticide Sampling Guide, EPA-330/9-81-001, March 1981.

Analytical Methods

Water

1. Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020, revised March 1983.
2. Standard Methods for the Examination of Water and Wastewater, 15th Edition.

3. **Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, EPA 600/4-82-057, July 1982.**
4. **Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA 600/4-80-032, August 1980.**
5. **Microbiological Methods for Monitoring the Environment, EPA 600/8-78-017, December 1978.**

Hazardous Wastes

1. **Test Methods for Evaluating Solid Waste, SW-846, July 1982. Addendum of Proposed Sampling and Analytical Methods, 1984. RCRA**
2. **Methods for CERCLA Hazardous Substances, Vols. 1, 2, and 3, EPA 600/x-83-071, November 1983.**
3. **Characterization of Hazardous Waste Sites, A Methods Manual, Vol. III, Analytical Methods.**
4. **EPA Contract Laboratory Program (CLP) IFB Protocols. (Superfund only).**

Note: These publications are standard documents which are generally available upon special request or can be purchased. There are, however, additional "in house" and non-routine procedures maintained, developed and/or utilized by Regional personnel, and kept on file in the appropriate program divisions.

12 13 14 '81

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

This document has been prepared by the Quality Assurance Management Staff of the Office of Research and Development in cooperation with Systems, Science and Software of San Diego, California. We gratefully acknowledge the assistance of Mr. Darryl von Lehmden of the Environmental Monitoring and Systems Laboratory of Research Triangle Park, North Carolina. The assistance of the Agency's Quality Assurance Officers in reviewing the document and providing comments during its generation is also gratefully acknowledged.

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

SECTION 2.0 – DEFINITION, PURPOSE AND
SCOPE

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INTERIM GUIDELINES AND SPECIFICATIONS
FOR PREPARING QUALITY ASSURANCE
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DIANE C. SILVA
RECORDS MANAGEMENT SPECIALIST
NAVAL FACILITIES ENGINEERING COMMAND
SOUTHWEST
1220 PACIFIC HIGHWAY
SAN DIEGO, CA 92132

TELEPHONE: (619) 532-3676

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

SECTION 3.0 – PLAN PREPARATION AND
RESPONSIBILITIES

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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 responsibility 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.

SECTION 5.0 – PLAN CONTENT REQUIREMENTS

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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.

SECTION 5.0 – PLAN CONTENT REQUIREMENTS

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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%
.
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Section . . . 5
 Revision No. 4
 Date: December 29, 1980
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SECTION 5.0 – PLAN CONTENT REQUIREMENTS

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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.

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- Specification of laboratory sample custody procedures for sample handling, storage and dispersment 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).

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- 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

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Environmental Monitoring Systems Laboratory
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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.

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- 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.

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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, combustibility, 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

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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.

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APPENDIX A

GLOSSARY OF TERMS

AUDIT:

A systematic check to determine the quality of operation of some function 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:

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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.

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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.