EPA REGION 9 REQUIREMENTS
FOR
QUALITY ASSURANCE PROGRAM PLANS

R9QA/03.1

U.S. Environmental Protection Agency
Region 9
Quality Assurance Office
75 Hawthorne Street
San Francisco, CA 94105

DRAFT

August 2001

FOREWORD

The U.S. Environmental Protection Agency (EPA) Region 9 has developed this guidance to assist state and tribal governments develop Quality Assurance Program Plans (QAPrPs) (also referred to as program Quality Assurance Project Plans (program QAPPs)) in documenting the type and quality of data needed for environmental decisions and in describing the methods for collecting and assessing those data for environmental programs. For the purposes of this guidance, an environmental program is considered to be a series of activities which are based directly or indirectly on an act of Congress and defined in regulations promulgated by EPA, state, or tribal governments. The measurements under a program reflect on-going activities which do not have defined start and ending dates (not to be confused with grant cycles), although many of the specific activities conducted under them may have such dates. Program activities are usually of a recurring nature although specific activities may not recur. For example, each year Clean Water Act surface water monitoring may be conducted at a specific lake, but the parameters or location of the station might change.

EPA also funds environmental projects; those that are funded directly from EPA are required to have a QA Project Plan. If a project is funded through a program grant or cooperative agreement, the QAPrP should describe what type of activities or projects require a QAPP or other QA documentation and which are covered directly under the QAPrP. The QAPrP should also describe what information the QAPP should include or appropriate references, such as to EPA's R-5 QA Project Plan guidance. Projects are considered to be of a finite duration, with specific identifiable goals and objectives that are described in the QAPP. Objectives are often developed on a project specific basis using EPA's data quality objective (DQO) process or equivalent. Often projects are of a research or exploratory nature. Other possibilities might be technology evaluation, determination of the extent of contamination, and overall activities planned at a Superfund site. This list is by no means meant to be comprehensive.

A non-comprehensive list of examples of programs which might include environmental measurement activities funded under grants which would require a QA Program Plan might include:

The Safe Drinking Water Act (SDWA)
The Clean Water Act (CWA)
The Resource Conservation and Recovery Act (RCRA)
The Clean Air Act (CAA)
The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
The Comprehensive Environmental Restoration and Liability Act (CERCLA)
The Toxic Substances Control Act (TSCA)

In many cases, separate and distinct program activities may be funded under a given regulation and it may make more sense to create a series of QAPrPs than attempt to document all decisions

and activities under one large cumbersome and comprehensive document. For example, under the Clean Water Act it might be desirable to have separate QA Program Plans for:

The Total Maximum Daily Load (TMDL) Program
Biocriteria Assessment Program
Surface Water Monitoring Program
Non-Point Source Program
Wetlands Protection Program
National Pollution Discharge Elimination System (NPDES) Program
Enforcement and Compliance

Region 9 has no specific requirements for the way in which specific programs are combined in a given program plan, nor how many separate program plans are generated. Its only requirement is that all measurement activities funded by EPA are documented in a QAPrP or a QA Project Plan (QAPP or QAPjP)

It is expected that, when completed, each QAPrP will contain all the information required to assess the decisions to be made by a program and the data generation activities and quality systems that support those decisions. It is expected that the QAPrP will describe the activities, but that it will contain a number of appendices with supporting documentation. This supporting documentation would generally consist of the QA Plans of support organizations, such as a state environmental laboratory, the laboratory's Standard Operating Procedures (SOPs), and the SOPs used by the funded organization itself to collect data (e.g., sampling SOPS, chain of custody SOPs, etc.). Other possible appendix documents which might be included would be an example Field Sampling Plan, (FSP), an example Sampling and Analysis Plan (SAP), an example Inspector's Report Form, example field log sheets, an example audit form for field or laboratory audits, Data Quality Indicator (DQI) Tables, instrument manuals, etc. This is not a comprehensive list, and it is expected that documents will vary considerably from program to program.

The guidance describes the types of documentation expected under each section. It is up to the organization preparing the plan to determine how the material is presented.

Questions regarding this document should be addressed to:

U.S. EPA Region 9
Quality Assurance Office, PMD-3
75 Hawthorne Street
San Francisco, CA 94105-3901
Phone: (415) 744-1497
FAX: (415) 744-1476
e-mail: Taylor.David@epa.gov

EPA has prepared other documents as parts of its *EPA Quality System Series* which describe EPA policies and procedures for planning, implementing, and assessing the effectiveness of a quality system. Questions regarding other *EPA Quality System Series* documents should be directed to:

U.S. EPA
Quality Staff (2811R)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: (202) 564-6830
FAX: (202) 565-2441
e-mail: quality@epa.gov

Copies of *Quality System Series* documents may be obtained from the Quality Staff or by downloading them from the Quality Staff Home Page:

www.epa.gov/quality/qa_doc.html

ACKNOWLEDGMENTS

This document relies on other documents which reflect the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State, local, and Tribal governments, and private industry, and who reflect the diverse and broad range of needs and experiences common to environmental data collection programs, have provided the foundation on which this document is based. Their efforts are hereby acknowledged. In addition, this document reflects the efforts of members of the Region 9 Document Review Team who have assisted in its development. Their efforts are greatly appreciated.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Environmental programs conducted by or funded by the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends billions of dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. If decision makers (EPA and otherwise) are to have confidence in the quality of environmental data used to support their decisions, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA and EPA Region 9 are required to establish and implement a quality system. EPA Region 9 also requires that all environmental data used in decision making be supported by an approved Quality Assurance Project Plan (QAPjP). This requirement is defined in EPA Order 5360.1 CHG 1 (EPA 1998), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations. Non-EPA organizations funded by EPA are required to develop a QAPjP through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

Agency guidance (EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA 2001) and *EPA Guidance for Quality Assurance Project Plans (QA/G-5) (EPA 1998b))* is directed toward development of project QAPjPs, however, this guidance is not always clear on what requirements should be in a program QAPjP (hereafter called a QA Program Plan or QAPrP). The use of the term, "QA Program Plan," is specific to Region 9 and was adopted because of the confusion in differentiating between requirements for preparing a QA Project Plan intended to cover program activities and one to cover project activities. National QA guidance only covers project QA Project Plan preparation. A national guidance to assist states and tribes in preparing a program based QA Project Plan currently does not exist, with the exception of a guidance jointly prepared by the Office of Pesticide Programs (OPP) and the Office of Enforcement and Compliance Assistance (OECA).

The QAPrP described in this document integrates all technical and quality aspects of a program, including planning, implementation, and assessment. The purpose of the QAPrP is to document planning for environmental data generation and to provide a program-specific "blueprint" for obtaining the type and quality of environmental data needed for the range of decisions or uses reflected by program activities. The QAPrP should document how quality assurance (QA) and quality control (QC) are applied to assure that the results obtained are of the type and quality needed and expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QAPrP and its effective implementation. Stakeholders (i.e., the data users, data producers, decision makers, etc.) shall be involved in the planning process for a program or project to ensure that their needs are defined adequately and addressed. While time spent on such planning may seem unproductive and costly, the penalty for ineffective planning includes greater cost and lost time. Therefore, EPA Region 9 requires that a systematic process be used, wherever possible and appropriate, to plan all environmental data generation activities. In many cases, data quality requirements and associated decision making may be described by regulatory standards. In other cases they may be established by the program itself. In a third scenario, requirements may be established on a project specific basis. To facilitate the development of objectives, EPA has developed a process called the Data Quality Objectives (DQO) Process. The DQO Process is the Agency's preferred planning process and is described in the *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 1994). The QAPrP should document when regulatory standards are used and when a specific planning process such as the DQO Process should be used in planning. Similarly, it should describe when specific planning documents, such as QA Project Plans (QAPjPs), Field Sampling Plans (FSPs), Sampling and Analysis Plans (SAPs), Standard Operating Procedures (SOPs), or other document are required and what the review and approval process for these documents should be.

This guidance document presents specifications and instructions for the information that must be contained in a QAPrP for environmental data generation activities funded by EPA Region 9. The document also discusses the procedures for review, approval, implementation, and revision of QAPrPs. Users of this document should assume that all of the elements described herein are required in a QAPrP unless otherwise directed by EPA Region 9.

1.2 QAPrPs, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994

EPA Order 5360.1 CHG 1 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations funded by EPA. Components of the EPA Quality System are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. The QAPrP is a key component of the EPA Region 9 Quality System.

EPA Region 9 policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs.* The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. This standard recommends first documenting each organization-wide quality system in a Quality Management Plan (QMP) or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a QAPrP or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA Region 9 has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part B requirements of the standard.

A QMP, or equivalent Quality Manual, documents how an organization structures its quality system, defines and assigns QA and QC responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. The QMP may be viewed as the "umbrella" document under which individual projects are conducted. EPA Region 9 requirements for QMPs are defined in *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA 1999). The QMP is then supported by program specific QAPrPs and project-specific QAPPs depending on the nature of the activities which are being funded, the organization conducting the work, the scope of the program and other activities. In some cases, a QAPrP and a QMP may be combined into a single document that contains both organizational and program-specific elements. The Region 9 QA Manager has the authority to determine when a single document is applicable and will define the content requirements of such a document.

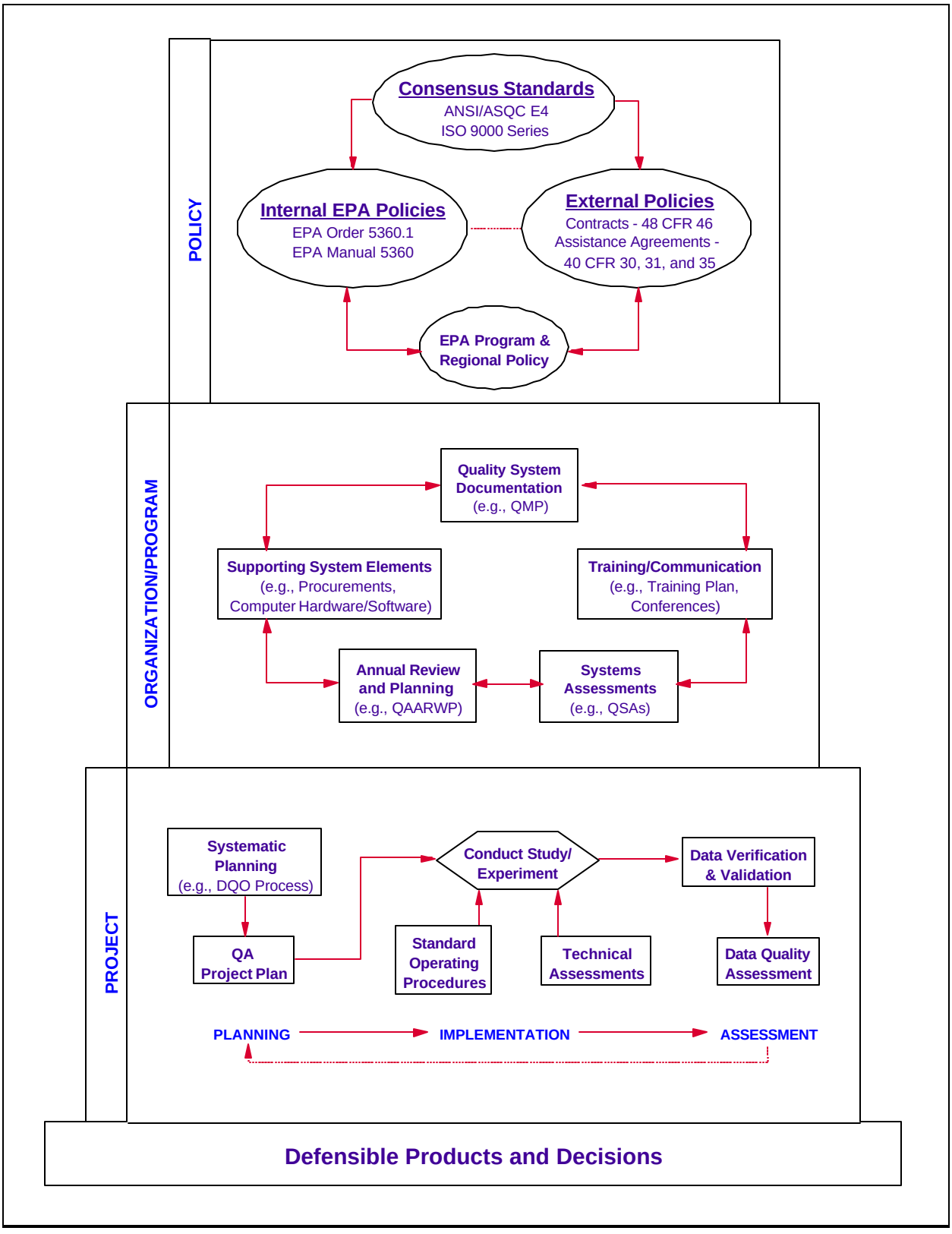

Figure 1. EPA Quality System Components and Tools

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Recognizing that a "one size fits all" approach to quality requirements will not work in all the organizations as diverse as those funded by EPA, implementation of the EPA Quality System is based on the principle of a graded approach. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives, size, structure, funding, and needs of the organization. For example, the quality expectations of a small tribal program are different from that of a regulatory compliance program for a large state because the size and regulatory structures differ and because the purpose or intended use of the data no doubt also are considerably different. The specific application of the graded approach principle to QAPrPs is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document is designed for organizations that conduct environmental data generation activities on behalf of EPA Region 9 through contracts, cooperative agreements, grants, other financial assistance agreements, and interagency agreements. This document contains the same basic requirements as EPA Order 5360.1 (EPA 2000), *The EPA Quality Manual for Environmental Programs*, which was developed for internal use by EPA organizations.

1.5 PERIOD OF APPLICABILITY

This document shall be valid for a period of up to five years from the official date of publication. After five years, it shall either be reissued without change, revised, or withdrawn from the Region 9 EPA Quality System.

1.6 ADDITIONAL RESOURCES

Guidance on preparing project QAPPs may be found in the documents, *EPA Requirements for Quality Assurance Project Plans, (QA/R-5)* (Final March 2001) and *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998b). These guidance documents discuss the application of project QAPP requirements and provides examples. Other documents that provide guidance on activities critical to successfully generate environmental data and complement the QAPrP and QAPP preparation effort include:

- *Guidance for the Data Quality Objectives Process (QA/G-4)*, (EPA 1994)
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*, (EPA 2001)
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, (EPA 1998a)

1.7 DISCLAIMER

This document is not related to QAMS-004/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans* (EPA 1980). The QAMS-004/80 document was replaced by QA/R-2 which provided guidance on the preparation of Quality Management Plans. When this change occurred, the term "QA Program Plan" was no longer used in national guidance.

CHAPTER 2

QAPrP REQUIREMENTS

2.1 POLICY

All work under a regulatory program that is funded by EPA Region 9 that involves the acquisition of environmental data generated from direct measurement activities, collected from or submitted by other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QAPrP (i.e., a program QAPjP). Data generated as part of a specific project which is funded separately by EPA should operate under a project QAPjP which also must be submitted to EPA for approval. Under its program, an organization may require project QAPjPs (or sampling plans or other planning documents). Although procedures for preparation and approval of project QAPjPs for specific projects funded under a program should be described as part of the organization's QAPrP, these documents generally do not have to be submitted to EPA for approval provided an EPA approved Quality Management Plan (QMP) describing a QA system is in place. Guidance for project QA Project Plans (QAPjPs) that must be submitted to EPA is provided elsewhere (EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA 2000) and EPA Guidance for Quality Assurance Project Plans (QA/G-5) (EPA 1998b)) and will not be repeated here. The QAPrP should describe what guidance, requirements, and approval procedures have been established for internally generated project QAPjPs.

The QAPrP should be developed, wherever possible and appropriate, using a systematic planning process based on a graded approach. No work covered by this requirement shall be implemented without a QAPrP being approved prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

2.2 PURPOSE

The QAPrP documents the planning, implementation, and assessment procedures of an environmental program and describes how specific QA and QC activities will be applied. If a QAPrP is developed under the requirements described herein, then it should be in conformance with Part B requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

This guidance applies to (but is not necessarily limited to) all environmental programs funded by EPA Region 9 that acquire, generate, or compile environmental data including work performed through cooperative agreements; interagency agreements; State-EPA Region 9 agreements; Performance Partnership Grants; and State, Local and Tribal Financial Assistance/Grants. Where specific Federal regulations require the application of QA and QC

activities, QAPrPs shall be prepared, reviewed, and approved in accordance with the regulation, but an attempt should be made to prepare documentation consistent with this document.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The QAPrP must be composed of standardized, recognizable elements covering the entire program from planning, through implementation, to assessment. Chapter 3 of this document describes specific elements to address. In some cases, it may be necessary to add special requirements to the QAPrP. The EPA Region 9 organization sponsoring the work (e.g., the Drinking Water Section, the Air Division) has the authority to define any special requirements beyond those listed in this document. If no additional requirements are specified, the QAPrP shall address all required elements. Each state or tribal organization should define its own organization-specific requirements for QAPrP and QAPjP documentation in its QMP. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

A QAPrP addresses the general, common activities of a program that are to be conducted over a long period of time. A QAPrP describes, in a single document, the information that is not site or time-specific, but applies throughout the program. Application-specific information is then added to the approved QAPrP as that information becomes known or completely defined or as the program changes. Each QAPrP should be reviewed periodically to ensure that its content continues to be valid and applicable to the program. A review each grant cycle by the organization's designated QA official is recommended.

2.4.2 Level of Detail

The level of detail of the QAPrP should be based on a graded approach. Thus, each QAPrP will vary according to the size and mandate of the organization performing the work, the nature of the work being performed and the intended use of the data. It is expected that most regulatory programs will be able to define the decisions they must make in terms of regulatory standards established by the Federal, state, or tribal government, but if this is not the case, the quantitative criteria on which decisions will be based should be described as appropriate for the program, or at least the process that will be followed to establish these objectives should be described in qualitative terms. The QAPrP should also define when other QA documentation must be prepared, the level of detail which may be required, and the review and approval process for such documents unless these requirements are defined for the program in the organization's QMP.

2.5 QAPrP PREPARATION AND APPROVAL

It is expected that most QAPrPs will be prepared by state agencies, tribal organizations, an assistance agreement holders, non-profit organizations which fund other organizations, or

Federal agencies operating under an interagency agreement. QAPrPs may be prepared by the organization's staff or by contractors or subcontractors, provided that the grantee or financial assistance agreement recipient funded by EPA assumes ultimate responsibility for its contents and for the implementation of the QA system it describes. If the program involves a regulatory program, this is considered by EPA to be an inherently government function. Except where specifically delegated by the EPA Region 9 Office, all QAPrPs prepared by non-EPA organizations must be approved by the EPA Region 9 QA Office before implementation.

Each QAPrP shall be reviewed and approved by authorized EPA Region 9 reviewers to ensure that the QAPrP contains the appropriate content and level of detail. The authorized reviewers are usually the EPA Region 9 project manager,[1] who reviews the document from a program perspective, and the EPA Region 9 QA Manager who reviews the document from a technical and QA perspective. The EPA Region 9 QA Manager must approve all QAPrPs.

2.6 QAPrP IMPLEMENTATION

None of the environmental work addressed by the QAPrP shall be started until the QAPrP has been approved and distributed to program personnel except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are generated or acquired before the QAPrP is approved and received by appropriate program personnel. However, EPA Region 9 may grant conditional approval of a QAPrP to permit some work to begin while non-critical deficiencies in the QAPrP are being resolved. Where a QAPrP has been approved in the past, but a revised plan is under-going review, comment, revision, and approval, work may proceed under the previously approved QAPrP until such time as the revised document is approved for implementation.

The organization performing the work shall ensure that the approved QAPrP is implemented as described and that all personnel involved in the work have direct access to a current version of the QAPrP and all other necessary planning, implementation, and assessment documents. These personnel should understand QAPrP requirements prior to the start of data generation activities.

2.7 QAPrP REVISION

Although the approved QAPrP must be implemented as prescribed, it is not intended to be inflexible. Because of the complex and diverse nature of environmental data generation, changes to original plans are often needed. When such changes occur, the organizations approving official(s) shall determine if the change significantly impacts the technical and quality objectives of the program. When a substantive change is warranted, the originator of the QAPrP

[1] This term refers to the EPA Region 9 official responsible for the program. This individual may also be called Project Officer, Delivery Order Project Officer, Work Assignment Manager, or Principal Investigator.

shall revise, amend, or add an addendum to the QAPrP to document the change(s.) A revision, an amendment, or an addendum should be submitted for approval to the same authorities that performed the original review, although a submission must be made to EPA only if there are major changes. A revision reflects a modification to the original document and could reflect either changes to existing policies and procedures or a change in the program itself which adds new or deletes old program elements. Alternatively, these changes can also be covered by amendments or addenda. For the purposes of this guidance, an "amendment" documents modifications or changes in the existing program, whereas a "addendum" documents program areas not originally covered. Only after the revision or amendment has been received and approved (at least verbally with written follow-up) by program personnel, shall the change be implemented. Note that it is expected that QAPrPs will include appendices or attachments (such as sampling SOPs, laboratory QA Plans, etc.), and it is acknowledged that these documents are also dynamic and subject to revision. EPA does not require these revised supporting documents be submitted for review unless the organization desires an independent assessment of the changes or they significantly affect the program. For example, a new laboratory is brought on board and its QC criteria differ substantially from its predecessor. The exception is if the overall QAPrP is being submitted (see below).

It is recommended that QAPrPs be reviewed at least annually by the organization's QA Manager and its Program Manager (or authorized representative). The QAPrP should be revised as necessary. Once approved a QAPrP does not have to be resubmitted to EPA Region 9 for review and approval for a period of five years unless significant changes occur in the program. However, EPA may elect to perform a Management Systems Review (MSR) of the implementation of the QAPrP at any time during this period as part of its oversight role. Any discrepancies between the program being implemented and the QAPrP that were noted during the MSR would then need to be corrected and documented in a revised QAPrP which EPA Region 9 would review.

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CHAPTER 3

QAPrP ELEMENTS

3.1 CONTENT REQUIREMENTS

The QAPrP is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of all program activities will satisfy stated performance criteria. The QAPrP must provide sufficient detail to demonstrate that:

- the program's regulatory, technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving program objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data generation activities require the coordinated efforts of many individuals, including managers, engineers, scientists, statisticians, and others. The QAPrP must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QAPrP, such as program managers, project managers, supervisors, and staff. Staff might include, but not be limited to: field sampling teams, analytical laboratory management and personnel, inspectors, permit writers, enforcement staff, modelers, and data reviewers.

In order to be effective, the QAPrP must specify the level or degree of QA and QC activities needed for the particular environmental data generation. Because this will vary according to the purpose and type of work being done, EPA Region 9 believes that a graded approach should be used in planning the work. This means that the QA and QC activities applied to a program will be commensurate with:

- the purpose of the environmental data operation (e.g., monitoring, enforcement, research and development, rulemaking, etc.),
- the type of work to be done (e.g., pollutant monitoring, site characterization, risk characterization, bench level proof of concept experiments, etc.), and

C the intended use of the results (e.g., compliance determination, selection of remedial technology, development of environmental regulation).

The QAPrP shall be composed of standardized, recognizable elements covering the entire program from planning, through implementation, to assessment. These elements are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

A Program Management - The elements in this group address the basic area of program management, including program objectives, roles and responsibilities of the managers, etc. These elements ensure that the program has defined goals, that use of the data in decision making is clear, and that the approaches to be used, and that the planning requirements and outputs are specified.

B Data Generation and Acquisition - The elements in this group address all aspects of program data generation and describes procedures to ensure that appropriate methods for data collection or sampling; measurement, analysis and data generation; data handling; and QC activities are employed and are properly documented.

C Assessment and Oversight - The elements in this group address the activities for assessing the effectiveness of the implementation of the program and associated QA and QC activities. The purpose of assessment is to ensure that the QAPrP is implemented as prescribed.

D Data Validation and Usability - The elements in this group address the QA activities that occur after the data collection or generation phase for the various program activities is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving program objectives.

All applicable elements must be addressed in the QAPrP. If an element is not applicable, this should be so stated in the QAPrP. Documentation, such as state environmental regulations, approved Work Plans, laboratory Quality Assurance Plans, Standard Operating Procedures, compendia of methods, etc., may be included as appendices and referenced in response to a particular required QAPrP element. This approach consolidates existing documentation into one comprehensive document and minimizes duplication or preparation of material already in place. Alternatively, rather than attaching documents to the QAPrP itself, they can be placed on file with the Region 9 QA Office and appropriate EPA Region 9 office. However, it is the organization's responsibility to ensure that reference documents are available to its staff as needed.

The QAPrP should be consistent with the organization's approved QMP. Material referenced that is contained in this document does not need to be included with the QAPrP. The

QAPrP should also address related QA planning documentation (e.g., Quality Assurance Project Plans, Sampling and Analysis Plans, etc.) required from suppliers of services (e.g., contractors, non-profits, local or municipal agencies, environmental laboratories, etc.) critical to the technical and quality objectives of specific program activities, projects or tasks.

3.2 GROUP A: PROGRAM MANAGEMENT

The elements in this group (Table 1) address program management, including program statutory authority, if applicable, objectives, roles and responsibilities of organization personnel, etc. These elements document that the program has defined goals, that program personnel and support organizations (contractors, laboratories, local agencies, etc.) understand the goals and the approach to be used, and that the planning outputs have been documented.

Table 1. Group A: Program Management Elements

A1	Title and Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Program Organization
A5	Problem Definition/Background
A6	Program Description
A7	Quality Objectives and Criteria for Measurement Data
A8	Special Training/Certification
A9	Documents and Records

3.2.1 A1 - Title and Approval Sheet

On the Title and Approval Sheet, include the title of the plan, the name of the organization(s) implementing the program, the effective date of the plan, and the names, titles, signatures, and approval dates of appropriate approving officials. Approving officials may include, but not be limited to:

- Organization's Program Manager (Division Director, Administrator, etc.)
- Organization's QA Manager
- Organization's Grant or Project Manager (i.e., the administrator for the EPA grant or financial agreement funding the program)

- EPA Region 9 Project Manager
- EPA Region 9 QA Manager (currently Vance S. Fong. P.E.)
- Others, as needed (e.g., division, branch or section supervisors, field operations manager, laboratory managers, tribal officials, other Federal agency officials, non-profit agency officials, local agency officials, etc.)

3.2.2 A2 - Table of Contents

Provide a table of contents for the document, including sections, figures, tables, references, and appendices. It is recommended (not required) that a document control format (Figure 2) be used on each page following the Title and Approval Sheet to track the date and revision number for each section. Some or all of the document control information can also be put in as a footer.

Section No. _____
Revision No. _____
Date _____
Page ___ of ___

Figure 2. Example Document Control Format

3.2.3 A3 - Distribution List

List the individuals and their organizations who need copies of the approved QAPrP and any subsequent revisions, including all persons responsible for implementation (e.g., division, branch or section supervisor, organization QA managers, staff, and representatives of all other organizations who are covered by or must implement the QAPrP). Paper copies need not be provided to individuals if equivalent electronic information systems can be used.

3.2.4 A4 - Program/Task Organization and Planning Documentation

3.2.4.1 Program/Task Organization

Identify the key individuals and/or organizations responsible for implementing the overall program and/or separate program areas and discuss their specific roles and responsibilities. Include the principal data users, decision makers, and the program QA manager. On a functional basis, describe the organizational structure and identify staff responsible for implementation. The organization should use its judgement in determining to what level the QAPrP will identify specific personnel versus functional positions, however, a QAPrP should identify, by name and title, a QA Manager and the specific managers who are responsible for data generation activities. The program QA Manager should be independent of direct data generation activities over which he/she has oversight. Arrangements where an individual from one unit acts as the QA Manager

for a different unit and vice versa will be considered on a case by case basis. If the size of the program or the organization precludes having an independent QA Manager, the QAPrP must describe an alternative approach to ensure that this function will be carried out effectively and objectively (This does not include being independent of senior officials, such as senior managers or agency administrators, who are responsible for, but not functionally involved in, data generation activities, data use, or decision making).

All alternative arrangements must be documented and justified in the QAPrP and will be considered by the Region 9 QA Manager on a case by case basis. The individual responsible for maintaining the official, approved QAPrP should be identified. Note that having a line supervisor also serve as the QA Manager does not constitute an organizationally independent QA function. If such an arrangement is proposed, it will be considered on a case by case basis. The QA Office recognizes that in smaller organizations, this may, in some situations, be necessary. For line supervisor/QA Manager joint positions, the QAPrP must describe how the potential "conflict of interest" between program priorities, budgets, and schedules will be mitigated so that these factors do not influence the supervisor's decisions concerning data quality.

The QAPrP should include one or more concise organization charts showing the relationships and lines of communication among all organization or program personnel. Thus, one chart might show the relationship of the organization to its regulated community, its contractors and subcontractors, local and municipal agencies, analytical laboratories, etc., and the other show the structure of the organization itself with its division directors, branch chiefs, section supervisors, etc. The inclusion of data users who might utilize data generated by the program is optional, provided they are in an informational rather than a direct decision making role. Thus, environmental groups, members of the public, legislative bodies, etc. do not have to be shown on the charts.

3.2.4.2 Planning Documentation

The QAPrP should define requirements for QA documentation. In many ways, the discussion in this section is critical in defining the overall structure of the program's QA system. Thus, if a QAPjP is to be required for a specific program activity, either one that is on-going or one that is on a one-time basis, this section should describe this requirement. This might include, but not be limited to, field sampling, laboratory analysis, compiling information from the literature for a database, use of a model or any other data generation activity used to support program decisions. If a sampling and analysis plan (SAP), a field sampling plan (FSP), one or multiple page planning form, an inspection report, or some other planning document must be prepared or a specific form filled out prior to samples being collected or data being generated, the requirements should be described in this section. For each specific document, the QAPrP should define what information the document must contain, the level of detail, the format, and the review and approval procedure to be followed before the document is implemented. The QAPrP should include examples of any blank forms and copies of SOPs used in the preparation of these documents. Cite references, as appropriate. If EPA guidance is to be cited, make sure it

is applicable to the program. For example, if a program never requires that a QAPjP be prepared, it makes no sense for the QAPrP to include references to EPA QAPjP guidance. Inclusion of an example QAPjP, example SAP, filled out form or report, or of the actual reference document (for example, an EPA guidance document) in an appendix is optional. Review and approval procedures should be documented. Approving officials should be identified. The QAPrP should discuss under what circumstances documents might be revised and how this would be carried out. The document should also describe under what circumstances deviations from the document would be acceptable and the mechanism by which such deviations or changes would be authorized or approved.

This section also should make clear how requirements for planning documentation "flow down." Basically, what individuals and which organizations (permittees, local agencies, responsible parties, volunteer or non-for-profit organizations, etc.) must prepare what type of documentation under what circumstances? For example, would state staff for an Underground Storage Tank program doing confirmation sampling have to prepare a SAP, whereas a certified tank puller doing confirmation sampling would not have to? Would SAP requirements be different for the two organizations? Would a brief sampling description need to be submitted or only a report on what took place? Would a contractor be required to use a state's SOPs if they are under state contract or would they have to submit their own for review? Could this be done on a generic basis or must it be done for each specific assignment? How would such decisions be made or defined and by whom? Who reviews and approves documents submitted to the organization? How does an inspector document collection of "samples of opportunity"? Must a certified laboratory submit its QA Plan for review? What kind of a QA system must a permittee have in place? Each organization should examine all the different sources from which it receives data and the ways in which it generates data and make sure that the QAPrP describes the system in place in each circumstance to ensure adequate planning and consideration of QA has taken place.

The QAPrP should identify any other records and documents applicable to the program that will be produced which are not described elsewhere. Note that this section should define what documentation should be prepared for planning, not necessarily what must be reported (this is covered below). Although it is recognized that there may be overlap, generally information need only be presented once in the QAPrP and possibly referenced in other sections.

3.2.5 A5 - Problem Definition/Background

The QAPrP should state the specific purpose of the program. This may reflect one or multiple areas of program responsibility. This section can paraphrase environmental regulations, define a specific problem to be solved, describe decisions to be made, or define an outcome to be achieved. The QAPrP should include sufficient background information to provide the reader a historical, scientific, and regulatory perspective. This section should be fairly general and qualitative in nature and is designed to provide an overall context. Specific decisions to be made

based on the data should be covered in the discussion of data quality objectives in Section 3.2.7 below.

3.2.6 A6 - Program/Task Description

Provide a summary of all work involving environmental measurements carried out under the program, whether routine on-going activities like monitoring, one-time events like a site investigation or a research project, review of data from permittees or other responsible parties, use of secondary data in modeling, etc. In each case, the nature and extent of the data to be generated should be described and a schedule provided for when these activities will take place. For recurring activities conducted by the organization itself, such as surface water monitoring, maps or tables should be included that show or identify the geographic locations of these recurring events (This information can be included in an appendix). This discussion need not be lengthy or overly detailed, but should give an overall picture of how the information relates to decisions that the program must make. In some cases this information may be contained in other documents For example a yearly work plan could be included as an appendix and referenced here. These types of documents should have been discussed previously in Section 3.2.5.

3.2.7 A7 - Quality Objectives and Criteria for Measurement Data

This section of the QAPrP defines the quantitative criteria on which program decisions will be made. It should discuss the quality objectives for the program and the performance criteria to achieve those objectives. Typically, these objectives are defined at two levels. At the first level the discussion should center on regulatory or action levels that are used by state or tribal governments to make decisions. For example, Drinking Water Maximum Contaminant Levels, Toxic Characteristic Leaching Procedure (TCLP) limits, or Clean Air Standards are all regulatory action levels on which decisions will be based by different programs. Where regulatory levels (Federal, state or tribal) are not defined, EPA Region 9 encourages the use of a systematic planning process to define these quality objectives, establish confidence criteria, set up null hypothesis testing, etc., as appropriate. Regardless of approach, the basis for these non-regulatory objectives should be documented, or at least the process which will be used described. The QAPrP should include regulatory or non-regulatory program action limit tables and describe their source. This information should be presented at all levels relevant to program decision making.

In some cases, criteria may need to be established on a project specific basis. In those circumstances, EPA recommends the use of the Data Quality Objectives process described in its G-4 guidance be followed. Regardless of whether the DQO process is used, the QAPrP should describe how DQOs and acceptance criteria are established for projects or non-routine events, and what type of project specific planning document will contain this information (the previous section can be referenced if this is already covered).

At the second level, objectives should be defined for those quality control (QC) measures relevant to the program's sampling and analysis activities. The acceptance criteria for specific measurements are described as "Measurement Quality Objectives" (MQOs) or, in Region 9, as "Data Quality Indicators (DQIs)." MQOs or DQIs are method and analyte specific limits for the "PARCC" parameters (precision, accuracy, representativeness, completeness, and comparability). Generally, the focus is on precision and accuracy, so this would be limits for relative percent difference of field and laboratory duplicates, spike recoveries for matrix spike or laboratory control samples, etc. The use of DQIs helps ensure that the data used in decision making are of acceptable quality so that rejected, or in some cases, qualified data, will not be used when regulatory or other decisions based on the limits defined above are made. MQO/DQI information would normally be called out or provided in Section 3.3.5 while DQO or regulatory information would be provided in this section.

The QAPrP should contain method and analyte specific limits, rather than generic limits. For example, "matrix spike recovers for lead are 80-120%," rather than "metals recoveries are 80-120%." In many cases, QC criteria related to sampling and analysis activities will be defined in other documents such as a field sampling plan, a laboratory quality assurance plan, or in SOPs. If this is the case, these documents should be referenced and included in appendices rather than repeating the information in the text. The QAPrP can also contain this information in tabular or narrative form. For example, if a state has several contract laboratories, it may have defined QC criteria in a statement of work which all the laboratories must adhere to. In that case, those criteria should be provided, rather than the individual laboratory's QA Plans or SOPs.

Emerging from this section should be a clear picture of what decisions the program makes, the criteria on which it bases those decisions, and the QA and QC requirements the program and supporting organizations (e.g., a laboratory or a contractor) must meet to ensure the data are of sufficient quality for their intended use.

3.2.8 A8 - Special Training/Certification

The QAPrP should identify and describe any specialized training or certifications needed by personnel in order to successfully implement all aspects of the program or specific tasks. The section should also discuss how such training will be provided and how the necessary skills will be assured or tested. The maintenance of training records should also be covered, unless this is carried out on a organization wide basis and the process is documented in its Quality Management Plan. If the program also requires specialized permits, such as for collecting endangered or threatened species or for using specialized methods such as electric shock methods for fish, the acquisition of these permits by staff should also be described.

3.2.9 A9 - Documents and Records

This section should describe the process and responsibilities for ensuring that appropriate program personnel have the most current approved version of this or related QAPrPs or

associated QA planning documents, including version control, updates, distribution, and disposition. It should also describe how records of QA planning documents (described above) are maintained, and by whom. If there is a requirement for document control (distribution of numbered copies that are signed for, etc.), this should be described.

Also to be covered in this section would be any program reporting requirements. This should especially relate to reporting QA and QC information. This might include, but not be limited to, for example, contents of QA sections in final reports, metadata to be reported by inspectors or field personnel, QA information or metadata to be reported by permittees or other organizations providing data to the program, and QC reporting requirements in laboratory reports.

This section should also discuss how long records are to be retained by the program or organization providing data to the program. For example, how long must laboratory data be maintained by a permittee or a laboratory under contract? The section should also specify or reference all applicable requirements for the final disposition of records and documents.

Finally, the QAPrP should define the information and records which must be included in reporting data, either generated as a result of in-house sampling and analysis or as reported by external parties. This would include examples or descriptions of any special reporting forms used by the program which would be used by inspectors, samplers, laboratories, permittees, responsible parties, municipalities, local agencies, or other organizations to report data to the organization. The QAPrP should specify the reporting format for hard copy and electronic data or reports. Reporting requirements might include (but are not limited to) all or part of the following: special hard copy or electronic reporting forms; specially formatted tables; summarized data from other sources such as data bases or literature; model input and output files; sampling information such as field logs, notebooks, chains of custody, etc.; and analytical information such as sample preparation and analysis logs, raw data or instrument printouts, results of calibration and QC checks, DQI information (precision data (e.g., relative percent difference), accuracy data (e.g., matrix spikes), method detection limits, blank contamination, etc.). This discussion should present a clear picture of how the organization documents the quality of its data and what information is available to external readers, such as EPA or the public, to enable an independent assessment of data quality.

This section does not need to describe reporting requirements related to Quality Assurance oversight activities, such as audits, etc. This is covered in a later section of the QAPrP.

3.3 GROUP B: DATA GENERATION AND ACQUISITION

The elements in this group (Table 2) address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following

QAPrP elements describe the requirements related to the actual methods or methodology to be used for the:

- collection, handling, and analysis of samples;
- data obtained from other sources (e.g., submitted by other organizations, such as permittees, responsible parties, local agencies, etc.), generated by a contractor, contained in a computer database from previous sampling activities, compiled from surveys, taken from the literature); and
- the management (i.e., compiling, handling) of the data.

The types of measurement activities to be conducted should have been summarized earlier in Section 3.2.6. The purpose here is to provide detailed information on the methods and procedures which will be followed by the organization or organizations generating or submitting data. If the designated methods are well documented and are readily available, these methods can be cited within the text, but detailed copies of the QC criteria and associated corrective action requirements must be included. Note that copies of the methods themselves are not required, but if the methods do not define acceptance criteria (and many EPA methods fail to define such criteria or fail to define corrective action procedures), the QAPrP should describe this information, or else a QA Plan or specific SOPs containing this information must accompany the QAPrP as attachments or appendices.

Table 2. Group B: Data Generation and Acquisition Elements	
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody
B4	Analytical Methods
B5	Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance
B7	Instrument/Equipment Calibration and Frequency
B8	Inspection/Acceptance of Supplies and Consumables
B9	Non-direct Measurements
B10	Data Management

3.3.1 B1- Sampling Design

Describe the sampling or data collection activities conducted under the program, including as appropriate:

- the types and numbers of samples required for on-going monitoring events or the process for establishing this information for one-time events,
- the design of any sampling networks for monitoring,
- sampling locations and frequencies for on-going sampling or how decision criteria for one-time events are established,
- the time period over which monitoring activities are to occur,
- sample matrices expected for program activities,
- measurement parameters of interest,
- the rationale for the design of monitoring networks, or how designs will be established and rationales for sampling locations for on-going events,
- requirements for specifying rationales for one-time events, and
- the rationale for the type of sample to be collected (e.g., composite or grab) and a description and rationale of the compositing procedure where applicable.

3.3.2 B2 - Sampling Methods

The QAPrP should describe the procedures used by, or that are acceptable to the program for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed for physical, chemical, or biological sampling. Where appropriate, sampling methods should be identified by number, source, date, and regulatory citation. If a method allows the user to select from various options, then the method citations should state which options are recommended or routinely used or how decisions should be made to choose among different options. For each sampling method, identify any support facilities needed (e.g., mobile laboratory, physical testing laboratory, air testing laboratory, etc.). The discussion should also address what to do when a failure in the sampling or measurement system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented. These requirements should be repeated for each type of sampling activity under the program. It is recommended that wherever possible, SOPs can be referenced and included in the appendix.

The QAPrP should describe the process for the preparation and decontamination of sampling equipment, including the disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, and preservation methods; and maximum holding times to sample extraction and/or analysis. This information is best provided in tables or SOPs.

The program's requirements for sampling methods should also make clear what its expectations are for those organizations generating or submitting data to it as versus when the program collects its own samples. This could include both contractors working directly for the organization as well as organizations submitting data to it, such as a responsible party, grantee, permittee, etc. If requirements are the same for all organizations, this should be explicitly stated. If requirements differ, the QAPrP should include provisions for review of the other organization's sampling equipment/methods as part of a planning document review (e.g., a review of a SAP or some SOPs). The QAPrP should describe how this process will be carried out to ensure program quality requirements are met by the secondary (contractor, grantee, locality, etc.) organization.

3.3.3 B3 - Sample Handling and Custody

This QAPrP section should describe the requirements for sample handling and custody in the field, transport from the field, and custody and storage at the laboratory, taking into account the nature of the samples, the maximum allowable sample holding times before processing (for example, extraction) or analysis, and available shipping options and schedules. Sample handling includes packaging, shipment from the site, and storage at the laboratory. Most organizations use SOPs to describe this information; these can be included in an appendix. Examples of sample labels, custody forms, and sample custody logs should be included with the SOPs.

Any requirements for external organizations or review of other organization's procedures in this area should be described.

3.3.4 B4 - Analytical Methods

This section, and the three that follow: 3.3.5 on Quality Control Requirements; 3.3.6 on Instrument/Equipment Testing, Inspection, and Maintenance Requirements; and 3.3.7 on Instrument Calibration and Frequency mainly relate to laboratory support activities. In many cases, this information will be found in laboratory SOPs, with possible summary tables in the laboratory's quality assurance plan, all of which can be referenced and included in the appendices. If this approach is taken, these sections may be brief. In some cases, an organization may rely wholly or in part on field based measurements. These may involve field screening techniques such as immunoassay techniques or the use of mobile instrumentation comparable to fixed laboratory methods. These methods, and the SOPs that support them should also be described, as well as the circumstances under which field based measurements might be used for decision making without fixed laboratory confirmation.

The QAPrP should identify the analytical methods and equipment appropriate to support all program activities, including sub-sampling or extraction methods, laboratory decontamination procedures and materials (such as would be needed to handle hazardous, infectious, or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method (since QC criteria are defined below, do not define or reference

them here). By performance requirements it is meant capabilities of the instrumentation or equipment itself (i.e., hardware specifications). Where appropriate, analytical methods should be identified by number, date, and regulatory citation. It is preferable if analytical methods are specified by the program, rather than defaulting to a laboratory's capabilities defined in a QA Plan in the appendix, since these methods should cover data generated for the program's in-house activities as well as data reported to it by other organizations, especially if these may differ. If work is contracted to a limited number of analytical laboratories, it may be more convenient to include a copy of the laboratory's QA Plan or SOPs, but if a prescriptive solicitation was used, it may make more sense to provide a copy of what the requirements for all the laboratories were. The mechanism by which work assignments are transmitted to the laboratory should also be described.

List any method performance standards (that is, method capabilities) that are essential. For example, minimum detection limits, suitability for field use, simplicity of use, etc. If a method allows the user to select from various options, then it should be stated exactly which options are being acceptable. Some regulatory programs are prescriptive in their method requirements (e.g., NPDES which requires that the Alternative Test Procedure protocol be followed), whereas others are more flexible (e.g., RCRA). If non-standard or performance based methods are allowed, such as might be necessary to characterize unusual sample matrices, to extend the use of a method to new analytes, or to analyze analytes for which no method exists, appropriate method performance study information may be needed to demonstrate the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed before they are used in the program. The QAPrP should define what information would typically be required to show that a method is appropriate for its intended use. For example, a spike recovery study, a method detection limit study, a calibration linearity study, a precision and accuracy study, a ruggedness study, etc., all or in part, are some typical studies EPA might require before it consideres a method acceptable. If such studies are required, the minimum number of repetitions needed to perform each study should be defined (EPA usually performs 5 to 7).

3.3.5 B5 - Quality Control

This section should describe any QC checks not defined in other QAPP elements and should reference other sections that contain this information where possible. This Data Quality Indicator (DQI) information should be used by a program to assess the acceptability and quality of the data it is using for decision making. Depending on the knowledge and experience of the potential audience who will be reviewing and implementing the QAPrP, it may be advantageous to separate field QC from laboratory QC requirements. Field QC may cover either QC associated with samples collected in the field, but analyzed in a fixed laboratory (e.g., a field duplicate or a field blank), or the QC measures associated with field measurements themselves (immunoassay kits, pH or conductivity measurements) or both, depending on the program. Analyses that are screening in nature which are made by a mobile laboratory should be treated as field measurements; those that are definitive in nature should be treated as if they would be carried out

in a fixed laboratory. The confirmation of field measurements that are screening in nature (e.g., x-ray fluorescence, immunoassay) should be discussed if the data will be used in decision making.

Because many environmental analytical methods (including EPA methods) are often vague or incomplete in specifying QC requirements, simply defaulting to the cited method to provide this information will not necessarily provide a clear picture of the quality of the data a program might use. Ideally, a QC summary table will be presented in the QAPrP or elsewhere in the appendices for most of the common methods used under the organization's program. This section should describe specific performance requirements for the methods. Since acceptance criteria for field measurements (e.g., immunoassay, conductivity) and field QC samples (i.e., agreement of field duplicates and co-located samples and acceptable levels of equipment or other types of blank contamination) will not be covered in a laboratory's QA Plan, this must be covered in the plan itself, or possibly a combination of the plan and field sampling/measurement SOPs. The frequency with which these field QC measurements are performed or which field QC samples will be collected, should be described.

Laboratory QC checks and criteria should also be defined, although this section can freely reference appendix material. A table or QC criteria and corrective action might also be found in the laboratory's QA plan, although many laboratories put this detailed information in method specific SOPs. Note that the program should establish MQO/DQI limits based on its regulatory or decision-making needs, not default to the capability of the methods or the laboratory performing the methods. Most of the QC acceptance limits provided in EPA methods are based on the results of extensive interlaboratory studies, however, this may not be the case for methods obtained from other sources. Because of improvements in measurement methodology and continual improvement efforts in individual laboratories, EPA method acceptance criteria may not be applicable to some situations. In some cases, acceptance limits are based on intralaboratory studies which often result in narrower acceptance limits than those based on interlaboratory limits). If a new, modified method, or a performance based measurement is used, MQOs/DQIs, the program should require that a method validation study be used to establish criteria (see previous discussion in the Analytical Methods Section).

Table 2 lists QC checks often included in analytical method SOPs. This list is for example purposes only. The approach taken by each laboratory for each method should be decided by each state or tribal program and/or its laboratory, based on program objectives and resources. Typically, at a minimum, each laboratory method would include a 3 point calibration step, a matrix spike, a duplicate analysis, and a laboratory or method blank. The frequency with which these or other QC checks will be run, and the associated acceptance criteria and corrective actions to take if criteria are exceeded on both an analysis and batch basis, should be described in this section or else in the laboratory's SOPs or QA Plan. These QA Plans or SOPs should be included as an appendix to the overall QAPrP, since they are integral in describing the program's QA system and requirements.

Table 2: Analytical QC Checks

QC Check	Information Provided
Blanks	
field blank	transport and field handling bias and laboratory analytical system
reagent blank	contaminated reagent
rinsate blank	contaminated equipment and laboratory analytical system
method or matrix blank	response of entire laboratory analytical system
Spikes	
matrix spike	analytical (preparation + analysis) bias and matrix effects
matrix spike replicate/duplicate	analytical bias and precision
instrument spike	instrumental bias
surrogate spike	analytical bias and matrix effects, extraction efficiency
blank spike (lab control sample)	analytical bias
post digestion spikes	matrix effects (inorganic)
Calibration Check Samples	
detection limit verification check	sensitivity below lowest calibration point
mid-range check (continuing calibration verification)	calibration drift and memory effects
standard verification	independent calibration verification using a NIST national standard or other external source of a certified standard
Replicates, splits, etc.	
co-located samples	matrix variability + sampling + measurement precision
field replicates	precision of all steps after acquisition
field splits	shipping + interlaboratory precision
laboratory splits	interlaboratory precision
lab/method duplicates/replicates	analytical precision
analysis duplicate/replicates	instrument precision

Other areas of discussion relevant to this section might include examples of applicable statistical (e.g., precision and bias, etc.) calculations and formulas. The accompanying narrative or explanation should specify clearly how the calculations will address potentially difficult situations such as missing data values, "less than" or "greater than" values, and other common data qualifiers. Also relevant would be any procedures used to document QC results, including control charts. If control charts are used, the laboratory quality assurance plan or SOPs should make clear exactly what data are to be plotted at what frequency on a method and analyte specific basis, and how control chart information will be used.

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Finally, this section, or possibly a later section on assessment, should cover how QC check data will be used to determine that measurement performance is acceptable from a program standpoint, i.e., how data that have been reviewed, qualified, rejected, etc., will be used when the data are compared to the regulatory standards or DQOs defined earlier.

3.3.6 B6 - Instrument/Equipment Testing, Inspection, and Maintenance

The QAPrP should describe how inspections and acceptance testing of instruments, equipment, and their components affecting quality will be performed and documented to assure their intended use will not be compromised. It is expected that this will mainly apply to sample

collection or equipment used for field measurements. The text should describe how deficiencies are to be resolved, when re-inspection will be performed, and how the effectiveness of any corrective actions shall be determined and documented. A table or SOP can be used to identify the equipment and/or systems requiring periodic maintenance. Also relevant to this section would be how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

3.3.7 B7 - Instrument/Equipment Calibration and Frequency

This section of the QAPrP should identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data generation or collection activities affecting quality that must be controlled and, at specified periods, calibrated, to maintain performance within specified limits. For example calibration might be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument. This information may be provided in referenced SOPs or other documents. It also might make sense to combine this section with Section 3.3.6.

Unless the program runs its own laboratory, it is expected that any discussion concerning calibration of laboratory analytical equipment would generally be found in the laboratory's QA Plan, the laboratory's method specific SOPs, or in a statement of work used by the organization to procure analytical support. If this is the case, a reference in this section is sufficient. If this is not the case, a table on a method specific basis giving initial and continuing calibration requirements would be appropriate.

3.3.8 B8 - Inspection/Acceptance of Supplies and Consumables

This section should describe the procurement of supplies, equipment, and consumables from a QA perspective. Thus, inclusion of state procurement and purchasing policies is neither required nor expected. The focus should be on how and by whom supplies and consumables (e.g., standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) shall be inspected and accepted for use in the program. This might include a discussion of who specifies the performance specifications for equipment. How is equipment checked to make sure it meets those specifications. Similarly, how is the purity of materials specified and checked? What procedures are followed if equipment or consumables do not meet specifications?

3.3.9 B9 - Non-direct Measurements

Environmental measurements are not always confined to data generated directly by the organization. In some cases, data from other sources may be used, either as a starting point or to

supplement data generated directly. This section should be discussing historical, or possibly contemporary data obtained from databases and reports generated by other state or Federal government agencies, non profits, trade associations, etc. The U.S. Geological Survey, the U.S. Weather Service, universities, the scientific literature, etc. are all examples of sources of secondary data. Requirements for QA planning documentation or QC information submitted to the program directly by grantees, permittees, local municipalities, etc., on an on-going basis should have been previously discussed and should not be repeated here. In limited cases, all data may be from other sources and the program will compile and interpret those data. To the extent that it is feasible, the QAPrP should identify any types of information and associated metadata the program needs for program implementation or decision making. If possible, the QAPrP should describe how secondary data is typically used by the program. The key point of the discussion is how will the information be evaluated to ensure it is of sufficient quality for its intended use? Will acceptance criteria be defined, and by whom? Will these acceptance criteria be specified? How are any limitations on the use of the data to be determined and documented? EPA has not defined requirements in this area, although discussions are on-going, thus, the discussion should focus on a common sense approach that does not result in use of secondary information in an inappropriate matter, given whatever limitations it may have.

In addition, this section should discuss the use of models by the program. This might include, but is not limited to selection of models, assumptions made relative to model use, boundaries or limitations to model use, descriptions of how boundaries were established, calibration or verification of models, data required for input to models, outputs from models, and descriptions of how model results will be qualitified and are related to decision making.

3.3.10 B10 - Data Management

This section should describe the program's data management process, tracing the path of the data from their generation to their final use or storage (e.g., the field, the laboratory, the office). For example, the QAPrP might describe or reference the organization's standard record-keeping procedures and its document control system. The approach used for data storage and retrieval on electronic media, any control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases would also be relevant. The QAPrP should also provide examples of any forms or checklists which it uses in verifying data input or data integrity.

The QAPrP should describe all data handling equipment and procedures used to process, compile, and analyze the data. This includes procedures for addressing data generated as part of the program as well as data from other sources. The discussion should also describe any required computer hardware and software as it might relate to specific performance requirements. For example, a super computer may be needed to run a groundwater or air transport model. This section should also describe any relevant procedures that will be followed to demonstrate acceptability of the hardware/software. Note that if most programs used are "off the shelf"

commercial software programs, the discussion can be very brief and just state that. The main focus here should be on either unusual programs or custom software.

If EPA data management requirements are applicable, such as the Chemical Abstract Service Registry Number Data Standard (EPA Order 2180.1), Data Standards for the Electronic Transmission of Laboratory Measurement Results (EPA Order 2180.2), or the Minimum Set of Data Elements for Ground-Water Quality (EPA Order 7500.1A), discuss how these requirements are addressed. It may be relevant to include SOPs describing data how are entered into EPA databases, such as STORET or AIRS.

3.4 GROUP C: ASSESSMENT AND OVERSIGHT

The elements in this group (Table 3) address the activities for assessing the effectiveness of program implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QAPrP is implemented as prescribed.

Table 3. Group C: Assessment and Oversight Elements

C1	Assessments and Response Actions
C2	Reports to Management

3.4.1 C1.1 Purpose/Background

During the planning process, many options for sampling, sample handling, sample cleanup, sample analysis, and data reduction are evaluated and chosen depending on the nature of enforcement or monitoring activity. In order to ensure that data collection is conducted as planned, a process of evaluation and validation should be performed. This element describes the internal and external checks that are necessary to ensure that all elements of this QAPrP are correctly implemented as prescribed; that the quality of data generated by the implementation of the QAPrP is adequate; and that corrective actions, when needed, are implemented in a timely manner and their effectiveness is confirmed.

Although any external assessments that are planned should be described in the QAPrP, the most important part of this element is documenting all planned internal assessments. Generally, internal assessments are initiated or performed by the Agency's QA Officer, the Program QA Officer or the Laboratory QA Officer so the activities described in this element should be related to the responsibilities of the QA Officers as discussed in Section A4.

3.4.2 C1.2 Assessment Activities and Program Planning

The following sections describe various types of assessment activities available to managers in evaluating the effectiveness of environmental program implementation.

3.4.2.1 C1.2.1 Assessment of Subsidiary Organizations

A. *Management Systems Review (MSR).* A form of management assessment, this process is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. The MSR is used to ensure that sufficient management controls are in place and carried out by the organization to adequately plan, implement, and assess the results of the program. See the *Guidance for the Management Systems Review Process* (EPA QA/G-3). A MSR is most likely to be carried out by EPA as part of its oversight responsibilities, although it can be carried out by the state or tribal organization.

If the state's Program conducts MSRs, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

B. *Readiness reviews.* A readiness review is a technical check to determine if all components of the program activity are in place so that work can commence on a specific phase.

If the state's Program conducts Readiness Reviews, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

3.4.2.2 C1.2.2 Assessment of Program Activities

A. *Surveillance.* Surveillance is the continual or frequent monitoring of the status of an activity (for example, misuse investigations including sampling and analysis) and the review of records to ensure that specified requirements are being fulfilled.

If the state's Program conducts surveillance, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

B. *Technical Systems Audit (TSA).* A TSA is a thorough and systematic onsite qualitative audit, where facilities, equipment, personnel, training, procedures, and record keeping are examined for conformance to the QAPrP or a QAPP for a specific project. The TSA is a powerful audit tool with broad coverage that may reveal weaknesses in management structure, policy, practices, or procedures. The TSA is ideally conducted after work has commenced, but before it has progressed very far, thus providing an opportunity for corrective action. A TSA could be carried out on field activities, laboratory activities, or the entire system. They can be informal internal audits (for example, the laboratory QA Officer audits activities in one particular section of the laboratory), or they can be more

formal comprehensive audits carried out by an independent third party. The level of detail can vary considerably depending on the purpose of the audit and what resources and time have been dedicated to the effort.

A TSA may be triggered as a result of unacceptable or questionable QC and/or sample data. As well, a TSA may result from a routine scheduled audit conducted on a quarterly or annual basis. For example, a field TSA may serve as a detailed review and/or evaluation of the various components of the measurement and sample collection procedures being used by field staff. It may be necessary to assess all or only some of those components within the scope of the field activities (such as decontamination, meter and sampler calibration, field measurements, matrix sampling, Quality Control measures, documentation, sample custody, etc.).

Similarly, a laboratory TSA may be conducted as the complement to implementation and use of internal SOPs and Quality Management Plans, in order to assure good Quality Assurance management practices. This type of audit may be a systems, project or performance audit and could be conducted to determine compliance with associated QMP, and/or QAPrPs. For example, a laboratory TSA may be triggered as a result of a control spike that has exceeded 3 standard deviations from the control mean. Accordingly, the QA Manager may conduct an inquiry into SOP compliance for method preparation, spiking procedures and/or instrument calibration. A report of the findings should be submitted for review to management and be summarized in an annual QA report (see Section C 3.2).

It is recommended that a TSA be conducted with routine frequency such as quarterly or annually by Quality Assurance personnel or persons knowledgeable in assessing Quality Assurance management practices (see Section C 1.3.2) that are independent of and lateral to the chain of authority responsible for laboratory management. It is conceivable that field or laboratory audits of selected systems be staggered throughout the year to accomplish a comprehensive program TSA. The use of standardized audit forms or checklists can help facilitate conducting a TSA.

If the state's Program conducts TSAs, then the nature and purpose of these audits should be described here. The process by which a TSA would be initiated should be described as should the individual or individuals who would conduct such audits. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

C. *Performance Evaluation (PE).* A PE is a type of audit in which the quantitative data generated by the measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory. "Blind" PE samples are those whose identity is unknown to those operating the measurement system. A "single blind" PE samples is one where the laboratory knows it is a PE

sample, but is not aware of the concentrations. Usually, the type of analysis is known and the sample comes prepared or in a ampule to be made up. A "double blind" PE often provides more representative results since they are sent as if they are a normal sample. This approach ensures that they are handled routinely and are not given the special treatment that undisguised PEs sometimes receive. The QAPrP should describe the PEs that are routinely used as part of program activities. If known, examples should be provided of:

- The constituents to be measured,
- the target concentration ranges,
- the sources from which PE samples are acquired,
- the timing/schedule for PE sample analysis, and
- the aspect of measurement quality to be assessed (e.g., bias, precision, and detection limit).

A number of EPA regulations and EPA-sanctioned methods require the successful accomplishment of PEs before the results of the test can be considered valid. PE materials are now available from commercial sources and a number of EPA Program Offices coordinate various interlaboratory studies and laboratory proficiency programs. Participation in these or in the National Voluntary Laboratory Accreditation Program (NVLAP, run by NIST) should be mentioned in the QAPrP. The QAPrP should also discuss how acceptance criteria are established and what corrective action will be taken in the event that the PE is failed. PE samples may be generated in a process internal to the laboratory, provided by the QA Officer or the organization submitting the environmental samples, or provided by an independent third party. They are an accepted part of contract laboratory oversight.

For example, an internal PE may be performed with the agreement between laboratory management and project management/field staff who are involved with the routine sampling of established monitoring programs. In this way, a field spike may be inserted into the sample set, without the knowledge of the laboratory staff, in order to evaluate the laboratory's performance with routine work. An evaluation of issues such as sample handling, custody, and overall method performance can be assessed once the results of the PE sample are completed and submitted for management review.

D. *Audit of Data Quality (ADQ).* An ADQ reveals how the data were handled, what judgments were made, and whether uncorrected mistakes were made. Performed prior to producing a program activity's final report, ADQs can often identify the means to correct systematic data reduction errors. These audits involve an extensive review of all the data used to generate the final result, including a review of instrument print-outs and other raw data. The process is comparable to a full data validation procedure except it is carried out at the laboratory site so that information not provided in the data package can be reviewed.

An ADQ may be conducted by the laboratory QA Manager or a Section Manager prior to submitting final results. A laboratory may include an ADQ as part of a normal quality review. In this way, the ADQ will provide an additional check for data completeness by reconstructing the sample history and/or custody, as well as a review of the analytical decisions and logic that were used to arrive at the final result. In doing so, an ADQ can provide confidence in the data generated for a specific sample or set of samples and insure the defensibility of data if litigation becomes necessary.

If the state's Program conducts ADQs, then the nature and purpose of these audits should be described here. Note that an ADQ usually does not result in the qualification or rejection of data; this is normally done through data validation or data review after the data have left the laboratory. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

E. *Peer review*. Peer review is not a TSA, nor strictly an internal QA function, as it may encompass non-QA aspects of a program activity and is primarily designed for scientific review. Whether a planning team chooses ADQs or peer reviews might depend upon the nature of the program activity, the intended use of the data, the policies established by the sponsor of the program activity, and the conformance of the program to the state's peer review policies and procedures. Reviewers are chosen who have technical expertise comparable to the program activity's performers, but who are independent of the program activity. ADQs and peer reviews ensure that program activities:

- were technically adequate,
- were competently performed,
- were properly documented,
- satisfied established technical requirements, and
- satisfied established QA requirements.

In addition, peer reviews assess the assumptions, calculations, extrapolations, alternative interpretations, methods, acceptance criteria, and conclusions documented in the program activity's report. Any plans for peer review should conform with the state's peer-review policy and guidance. The names, titles, and positions of the peer reviewers should be known to the QA Officer and can be provided in the QAPrP if they are known and are used on a regular basis (for example, in the form of a scientific advisory board). The QAPrP should outline what is expected of peer reviews, how the information will be reported, to whom it will be reported, and how the information will be used. The QAPrP should also discuss when peer review will be used, since many on-going program activities, as contrasted to special on-time projects, may not lend themselves to a peer review process. The QAPrP should discuss how responses will be documented, how responses will be handled, and reference where responses to peer-review comments may be located.

Peer review can also serve as a first level quality check of analytical data or as an ADQ. Used in this way, peer review is intended to provide a check of the analytical work performed in support of sample analyses. For example, a peer reviewer may be required to perform a check to ensure that instrument calibration is linear; methodology utilized is appropriate; QC data are within proper limits; and chromatographic integration is performed properly prior to submitting data for a more in-depth ADQ. Peer review may also utilize several of the tools available to reduce and validate analytical results and is intended for the more technical aspects of reviewing data quality such as measurement of bias, standard deviation, relative percent difference, etc.

F. *Data Quality Assessment (DQA).* DQA involves the application of statistical tools to determine whether the data meet the assumptions that the DQOs and data collection design were developed under and whether the total error in the data is tolerable. *Guidance for the Data Quality Assessment Process* (EPA QA/G-9) provides nonmandatory guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations. Aside from special projects, and possibly monitoring activities, it is not anticipated that many enforcement activities will generate sufficient information to permit statistical assessment to take place. This section should describe when such assessments may be appropriate.

3.4.3 C1.3 Documentation of Assessments

This section relates to the documentation of assessments. It should identify the organization and person(s) that shall perform the assessments, if this information is available, and describe how and to whom the results of the assessments will be reported. The following material describes what should be documented in a QAPrP after consideration of the above issues and types of assessments.

3.4.3.1 C1.3.1 Number, Frequency, and Types of Assessments

Depending upon the nature of the program activity, there may be more than one assessment. A schedule of the number, frequencies, and types of assessments required should be given.

Systems audits may be conducted by trained field or laboratory management and/or quality assurance staff to complement implementation and use of internal SOPs and other Quality Assurance Planning documents, in order to assure good Quality Assurance management practices. While annual audits of all field and laboratory operations is a minimum recommendation, it is conceivable that specific portions of these respective operations (field and lab) may be scheduled to occur with routine frequency in order to satisfy the recommendation for an overall annual program assessment. In this way, audits of selected systems may be staggered throughout the year to accomplish this goal and a final report containing the results of those specific systems audits can be submitted to management at the end of an annual cycle.

To this end, field and laboratory assessments may be performed through the use of a standardized protocol and/or list of minimum requirements which will constitute the style and scope of an audit and which will provide a list of criteria by which operational deficiencies can be detected (see Section C1.3.3). These protocols and criteria should reflect the intent of all internal SOPs and other QA Planning documents and should, at a minimum, conform to all EPA and program requirements for procedures and documentation. The use of standardized audit forms and checklists is recommended. If such checklists are used, it is recommended that they be included with the QAPrP as an appendices.

3.4.3.2 C1.3.2 Assessment Personnel

In an effort to define the scope of authority of the assessors, program management should define explicitly the unsatisfactory conditions under which the assessors are authorized to act and provide an appropriate schedule for the assessments to be performed. To this end, the QAPrP should specify the individuals, or at least the specific organizational units, who will perform the assessments. Internal audits are usually performed by personnel who work for the organization performing the program activity's work, but who are organizationally independent of the management of the program activity. External audits are performed by personnel of organizations not connected with the program activity, but who are technically qualified and who understand the QA requirements of the program activity.

It is up to program management to designate appropriate personnel as Quality Assurance staff and charge these officials with auditing responsibility and authority, preferably independent of and lateral to the chain of authority responsible for field and laboratory operations. If the overall organization has a QA Official (i.e., a QA Officer who supports multiple programs, not just one), this should be described. This has advantages in terms of providing independent assessment, but at the sacrifice of more limited program knowledge. It is also possible that key members within a chain of command may be charged with Quality Assurance responsibilities for different aspects of the process. By way of example, the Sample Custodian may be responsible for sample tracking, history and custody; peer reviewers and/or a Quality Assurance Officer may have the responsibility of assessing data accuracy and validity; and finally, management personnel would have the responsibility of performing a final ADQ.

However, depending on the size of a program's field and laboratory operations, it may not always be possible or feasible to dedicate staff to the QA process. In this case, individuals charged with the responsibility of Quality Assurance should be in a position of supervision and/or management and responsible for the outcome of program requirements. Lastly, it is recommended that all staff members be encouraged to adopt good Quality Assurance practices, at all levels of the organization and to perceive audits as an educational opportunity.

3.4.3.3 C1.3.3 Schedule of Assessment Activities

A schedule of audit activities, together with relevant criteria for assessment, should be given to the extent that it is known in advance of program activities. The lists provided below may serve as a guideline for field operations and laboratories developing criteria to serve in assisting audit activities. These lists are not comprehensive of all audit activities but are only an example of the type of areas that an audit would be concerned with.

Minimum Topics for Internal Laboratory Audit.

1. GENERAL PROCEDURES
   - A. Documentation of Procedures,
   - B. Sample Receipt and Storage,
   - C. Sample Preparation,
   - D. Sample Tracking.

2. ANALYTICAL METHODS
   - A. General Instrumentation Performance,
   - B. Calibration Procedures,
   - C. Extraction Procedures,
   - D. Internal Quality Control,
   - E. Data Handling Procedures.

The general topics represented above can be broken down further to include specific points or areas that will be covered when performing an audit in one of the above general areas. Using General Instrumentation Performance as an example of a laboratory audit, the following points may be included during an internal audit. Please note that this list may not be inclusive of specific points or areas that are necessary for a particular laboratory's internal audit. A QAPrP would include provision for all areas, not just the example area below. As in all parts of the QAPrP, an SOP or audit checklist could be come an appendix and not have to be repeated here.

1. ANALYTICAL METHODS
   - A. General Instrumentation Performance.
     1. Instrument performance records are maintained and include the following items:
        - a. Initial demonstration of capability,
        - b. Determination of linear dynamic range,
        - c. Method detection limits,
        - d. Initial and routine instrument calibration,
        - e. Performance of standard reference materials and/or QC check samples,
        - f. Instrument sensitivity and stability, and
        - g. Tuning checks.

Below is an example, similar to the laboratory internal audit list above, that may be utilized for a field audit. Again, this is not an inclusive list of assessment points and is provided here only to serve as an example.

Minimum Topics for Field Audit.

1. GENERAL FIELD PROCEDURES
   A. Field Standard Operating Procedures,
   B. Interviews,
   C. Investigations/Inspections, and
   D. Field Records.

Using procedures A and B as examples, the specific assessment points may include some of the following:

1. GENERAL FIELD PROCEDURES
   A. Field Standard Operating Procedures
      1. Site Assessment,
      2. Establishing Chain-of-Custody,
      3. Equipment Calibration,
      4. Decontamination Procedures,
      5. Well Development, and
      6. Sampling Records.
   B. Interviews
      1. Interview Records,
      2. Questionnaires, and
      3. Documentation of Site Characteristics.

3.4.3.4 C1.3.4 Reporting and Resolution of Issues

Audits, peer reviews, and other assessments often reveal findings of practice or procedure that do not conform to the written QAPrP. To the extent that such findings can be anticipated, the QAPrP should discuss how response actions to non-conforming conditions shall be addressed and by whom. Because these issues must be addressed in a timely manner, the protocol for resolving them should be given here together with the proposed actions to ensure that the corrective actions were performed effectively. The person to whom the concerns should be addressed, the decision making hierarchy, the schedule and format for oral and written reports, and the responsibility for corrective action should all be discussed in this element. The QAPrP should also identify who is responsible for implementing the response action and describe how response actions shall be verified and documented. To the extent possible, the QAPrP should explicitly define the unsatisfactory conditions upon which the assessors are authorized to act and list the program personnel who should receive assessment reports.

3.5.2 C2 REPORTS TO MANAGEMENT

3.5.21 C2.1 Purpose/Background

Effective communication between all personnel is an integral part of a quality system. Planned reports provide a structure for apprizing management of the program activity schedule, the deviations from approved QA and test plans, the impact of these deviations on data quality, and the potential uncertainties in decisions based on the data. Verbal communication on deviations from QA plans should be noted in summary form in element D1 of the QAPrP.

Quality assurance reports are designed to keep management and/or project members informed of the performance of QA/QC activities. The reports should include all subjects which address the validity and documentation of data gathering activities. They summarize project specific audits, list significant problems, and discuss the solutions and corrective actions implemented concerning QA/QC activities.

3.5.2.2 C2.2 Frequency, Content, and Distribution of Reports

The QAPrP should indicate the frequency, content, and distribution of reports so that management may anticipate events and move to ameliorate potentially adverse results. An important benefit of a status report is the opportunity to alert management of data quality problems, propose viable solutions, and procure additional resources. If program activity assessment (including the evaluation of the technical systems, the measurement of performance, and the assessment of data) is not conducted on a continual basis, the integrity of the data generated in the program activity may not meet quality requirements. Audit reports, submitted in a timely manner, will provide an opportunity to implement corrective actions when most appropriate.

For example, a QAPrP might contain the statement: "A quality assurance report is generated by field, technical and laboratory or quality assurance personnel and sent to [program, division] management at least once a year. More frequent reports may also be required depending on the laboratory program. The laboratory quality assurance report is prepared by the (Laboratory Manager) with the assistance of the senior staff. The report is submitted to the (Division Administrator) in written or oral form, depending on the problems observed." Each agency or program should determine the level of QA reporting it feels is necessary and appropriate given its organizational structure, resources, and priorities

Reports of this type might document the following:

- Changes in Quality Assurance Project Plan;
- Summary of quality assurance/quality control programs, training and accomplishments;
- Results of technical systems and performance evaluation audits;
- Significant quality assurance/quality control problems, recommended solutions and results of corrective actions;

- Summary of data quality assessment for precision, accuracy, representatives, completeness, comparability and method detection limit;
- Discussion of whether the quality assurance objectives were met and the resulting impact on technical and enforcement areas;
- Limitations on use of the measurement data and discussion of the effects of such limitations on the defensibility of the data.

As a suggestion (this guidance has no specific requirements in this area), QA reports to management or a program leader might be required as a result if any of the following issues:

- Sampling and support equipment other than that specified in the approved QAPrP were used;
- Preservation or holding time requirements for any sample were not met;
- Any quality control checks (field and laboratory) were unacceptable;
- Any analytical requirements for precision, accuracy, or MDL/PQL were not met;
- Sample collection protocols or analytical methods specified in the QAPrP were not met;
- Corrective action on any problem were initiated;
- An internal or external systems or performance audit was conducted; or
- Any other activity or event affected the quality of the data."

The following example contains a list of recommended topics that may be used to develop a comprehensive QA Report. QA Reports may contain some or all of the information listed below, and may be formatted as in this example or as the organization feels is appropriate or to be more consistent with existing field and laboratory QA program reporting formats. Other information specific to program requirements or needs may also be included.

1. Title Page - The following information must be listed:
   A. Time period of the report,
   B. QA Project Plan Title and/or Plan number,
   C. Laboratory name, address and phone number,
   D. Preparer's name and signature.
2. Table of Contents - Should be included if the report is more than ten pages long.
3. Audits - In table form, summarize all project specific audits that were performed during the specified time period:
   A. Performance audits must include the following:
      1. Date of the audit,
      2. System tested,
      3. Who administered the audit,
      4. Parameters analyzed,
      5. Reported results,
      6. True values of the samples (if applicable),
      7. If any deficiencies or failures occurred, summarize the problem area and the corrective action.

B. Systems audits must include the following:
   1. Date of the audit,
   2. System tested,
   3. Who administered the audit (agency or department),
   4. Parameters analyzed,
   5. Results of tests,
   6. Parameters for which results were unacceptable (include the reported and true values, if applicable),
   7. Explanation of the unacceptable results. Include probable reasons and the corrective action.

C. Copies of documentation such as memos, reports, etc. shall be enclosed.

4. Significant QA/QC Problems
   A. Identify the problem, and the date it was found,
   B. Identify the individual who reported the problem,
   C. Identify the source of the problem,
   D. Discuss the solution and corrective actions taken to eliminate the problem.
5. Corrective Actions Status
   A. Discuss the effectiveness of all corrective actions taken during the specified time frame as well any initiated during the previous report period,
   B. Discuss any additional measures that may be implemented as the result of any corrective action.

3.5.2.3 C2.3 Identify Responsible Organizations

It is important that the QAPrP identify the personnel responsible for preparing the reports, evaluating their impact, and implementing follow-up actions. It is necessary to understand how any changes made in one area or procedure may affect another part of the program. Furthermore, the documentation for all changes should be maintained and included in the reports to management. It is recommended that programs prepare reports documenting data quality assessment findings to management on a regular basis.

3.6 GROUP D: DATA VALIDATION AND USABILITY

The elements in this group address the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

3.6.1 D1 - DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

This part of the QAPrP should state the criteria used to review and validate–that is, accept, reject, or qualify–data, in an objective and consistent manner.

3.6.1.1 D1.1 - Purpose/Background

This section should discuss the criteria for deciding the degree to which data meet their quality specifications as described in Group B. Data generators and data users need to estimate the potential effect that each deviation from the Program QAPrP, the laboratory's quality assurance plan (which would typically be included as an appendix to the QAPrP), or established SOPs or other documents may have on the usability of the associated data, its contribution to the quality of the reduced and analyzed data, and its potential effect on decisions to be made.

The process of data verification requires confirmation by examination or provision of objective evidence that the requirements of specified QC acceptance criteria were met. Verification concerns the process of examining the result of a given activity to determine conformance to the stated requirements for that activity. For example, have the data been generated according to specified methods (such as sampling SOPs or EPA Guidance manuals for collection and established methods and SOPs for analysis) and have the data been faithfully and accurately recorded and transmitted? Did the data fulfill specified data format requirements and include appropriate associated supporting information (metadata)? For example, for sampling this might include information gathered prior to the field work on sampling conditions and chemicals of concern. After samples were collected it might include descriptions of how the sample was collected, notebook information, etc. For the laboratory, this might include extraction sheets, analysis logs, calibration curve information, etc. The process of data verification effectively ensures all the information required for decision making has been generated and is readily available to the decision maker whether this is a project officer, a technician, scientific staff, an inspector or management.

The process of data validation, as defined by EPA, requires confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. Validation concerns the process of examining a product or result to determine conformance to method requirements. The validation process effectively confirms the degree to which QC acceptance criteria or specific performance criteria have been met.

The EPA data validation process typically focuses on the analytical aspects of data generation and involves a third party review of all raw data associated with the generation of the final results. It examines whether all aspects of the method were followed correctly, QC data were met, holding times met, calibration standards made up properly, calibration curves were acceptable, etc. The result is a qualification of the data in terms of its perceived usability, from acceptable to qualitatively acceptable but quantitatively not reliable, to rejected. Various "flags" are used to qualify the data. Most state or tribal programs do not validate data per the EPA definition, and seldom is there a requirement or need to do so. However, if data are validated by a program, or if a different definition of validation is used by the state, its program QAPrP should describe what is done.

Each of the following areas of discussion should be included in the QAPrP as appropriate. The discussion applies to situations in which a sample is separated from its native environment and transported to a laboratory for analysis and data generation. In general, it is expected that for most situations involving routine activities, data validation procedures will not need to be described in the state's QAPP, however, assessment activities, as described below should be addressed. For specific projects, the QAPP for that project should describe what the process to be followed would normally be and the QAPrP should discuss when this might happen. If not relevant to the state's QAPrP, the sections can be omitted, or, preferably, a brief statement made indicating that the section does not apply to the activities covered by the QAPrP. In some cases, a detailed review of the areas below may only occur on a subset of the investigations conducted or samples collected. If so, the QAPrP should describe how these investigations are selected, the person conducting the review, and the review process itself.

3.6.1.2 D1.2 - Sampling Design

How closely a measurement represents the actual environment at a given time and location is a complex issue that is discussed in Section B1. Acceptable tolerances for each critical sample coordinate and the action to be taken if the tolerances are exceeded should be specified in Section B1 and vary considerably depending on the type of sample collection activity.

Each sample should be checked for conformity to any specifications which were defined, including type and location (spatial and temporal). By noting the deviations in sufficient detail, subsequent data users will be able to determine the data's usability under scenarios different from those for which the original data were generated. The strength of conclusions that can be drawn from data has a direct connection to the sampling intent and deviations from that intent. Where auxiliary variables are included in the overall data collection effort, they should be included in this evaluation. This section of the QAPrP should describe the process by which sample validity is checked.

3.6.1.3 D1.3 - Sample Collection Procedures

Details of how a sample is separated from its native time/space location are important for properly interpreting measurement results. Section B2, or related appendices, provides these details, which include sampling and ancillary equipment and procedures (including equipment decontamination). Acceptable departures (for example, alternate equipment) from the QAPrP/SOPs, and the action to be taken if the requirements cannot be satisfied, should be specified for each critical aspect, and the QAPrP should describe how it will be confirmed that these activities occurred correctly. Review procedures should be in place to identify potentially unacceptable departures from the QAPrP, departures for sampling protocols not contained as appendices in the QAPrP, or SOPs not included in the QAPrP. Comments from field surveillance on deviations from written sampling plans also should be noted.

3.6.1.4 D1.4 - Sample Handling

Details of how a sample is physically treated and handled during relocation from its original site to the actual measurement site are extremely important. Correct interpretation of the subsequent measurement results requires that deviations from Section B3 of the QAPrP, and the actions taken to minimize or control the changes, be detailed. Data collection activities should indicate events that occur during sample handling that may affect the integrity of the samples. This section of the QAPrP should describe how QA or other personnel confirm that activities took place according to required protocols.

At a minimum the QAPrP should describe how inspectors, management, or QA personnel evaluate that the sample containers and preservation methods used were appropriate to the nature of the sample and the type of data generated from the sample. The checks to be made on the identity of the sample (e.g., proper labeling and chain-of-custody records) as well as proper physical/chemical storage conditions (e.g., chain-of-custody and storage records) to ensure that the sample continues to be representative of its native environment as it moves through the sample handling process should be described.

3.6.1.5 D1.5 - Analytical Procedures

Each sample should be verified to ensure that the procedures used to generate the data (as identified in Section B4 of the QAPrP or in associated appendices) were implemented as specified. Acceptance criteria should be developed for important components of the procedures, along with suitable codes for characterizing each sample's deviation from the procedure. One way to accomplish this evaluation is through data validation, but, as previously indicated, it is not required that EPA defined data validation necessarily be a part of a state’s Program.

3.6.1.6 D1.6 - Quality Control

Section B5 of the QAPrP specifies the QC checks that are to be performed during sample collection, handling, and analysis. These might include analyses of check standards, field and

method blanks, method and laboratory (blank) spikes, and field and laboratory replicates, etc. These indicators provide the means to assess the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action (and changes) should have been specified earlier (such as in the laboratory's quality assurance plan or SOPs or in Section B5. This section should describe how it was assessed that the appropriate corrective actions were taken, that the affected samples were appropriately identified, if necessary, and that the potential effect of the actions on the validity of the data were documented.

3.6.1.7 D1.7 - Calibration

Section B7 addresses the calibration of instruments and equipment and the information that should be presented to ensure that the calibrations:

- were performed within an acceptable time prior to generation of measurement data;
- were performed in the proper sequence;
- included the proper number of calibration points;
- were performed using standards that "bracketed" the range of reported measurement results (otherwise, results falling outside the calibration range are flagged as such); and
- had acceptable linearity checks and other checks to ensure that the measurement system was stable when the calibration was performed.

This section should discuss the process to check that calibration problems were identified and that any data produced between the suspect calibration event and any subsequent recalibration were flagged to alert data users.

3.6.1.8 D1.8 - Data Reduction and Processing

Checks on data integrity evaluate the accuracy of "raw" data and include the comparison of important events and the duplicate rekeying of data to identify data entry errors.

Data reduction is an irreversible process that involves a loss of detail in the data and may involve averaging across time (for example, groundwater data collected at monthly intervals which are averaged) or space (for example, compositing results from samples thought to be physically equivalent such as multiple leaf samples collected in a FIFRA pesticide misuse investigation). Since this summarizing process by its nature relies on a few values to represent a group of many data points, how its validity will be assessed should be well-documented in the QAPrP.

The information generation step may also involve the synthesis of the results of previous operations and the construction of tables and charts suitable for use in reports or databases. How this information would be checked to ensure that it is of known quality appropriate for its intended use should also be addressed in this section. The steps taken to ensure that the information is synthesized and incorporated accurately (for example, data entry issues, compatibility of electronic files or software programs, sensitivity issues (i.e., different methods were used and detection limits are not the same), comparability of methods and units, etc., are some of the issues it would be relevant to address.

3.6.2 D2 - VALIDATION AND VERIFICATION METHODS

The requirement in R-5 states: *"Describe the process to be used for verifying and validating data, including the chain-of-custody for the data throughout the life of the project or task."*

3.6.2.1 D2.1 - Purpose/Background

The purpose of this section is to describe, in detail, the process for validating (determining if data satisfy program defined user requirements as defined earlier in the QAPrP) and verifying (ensuring that conclusions can be correctly drawn) program or special project data. The amount of data validated is directly related to the program data objectives developed for the data generating activity as well as each state's perception of the need for validation. The percentage of data to be validated for the program or specific project together with its rationale should be outlined or referenced. The QAPrP should have a clear definition of what is implied by "verification" and "validation" since each state's definition may vary.

3.6.2.2 D2.2 - Describe the Process for Validating and Verifying Data

If the state or tribe does validate data, the individuals responsible for data validation together with the lines of authority should be shown on an organizational chart and may be indicated in the chart in Section A7. The chart should indicate who is responsible for each activity of the overall validation and verification processes. In some states, this responsibility may be split up depending on the nature of the measurement activity and data generation responsibilities.

It is recommended that whatever data validation procedure is followed by the state or tribe be documented in SOPs for specific data validation. EPA's guidance for verification and validation issues will be described in *Guidance on Environmental Verification and Validation*, (EPA QA/G-8), which is currently under preparation. The EPA's Contract Laboratory Program (CLP) (used by EPA for analyses under Superfund) also has two documents; *"Functional Guidelines for the Validation of Organic Analyses,"* and *"Functional Guidelines for the Validation of Inorganic Analyses,"* which can also be consulted, but its applicability may be limited since they only cover data generated using CLP protocols. This means they are limited to volatile organics, semivolatile organics,

organochlorine pesticides, metals, and cyanide. These documents, however, does provide protocols which can be adapted to other analyses. This has been done both by EPA and various commercial validation firms.

3.6.3 D3 - RECONCILIATION WITH DATA QUALITY OBJECTIVES

3.6.3.1 D3.1 - Purpose/Background

The purpose of Section D3 is to outline and specify, if possible, the acceptable methods for evaluating the results obtained from the sampling and analysis effort. This section includes scientific and, if appropriate, statistical evaluations of data to determine if the data are of the right type, quantity, and quality to support their intended use.

3.6.3.2 D3.2 - Reconciling Results with Program Objectives or DQOs

Because, as discussed earlier in Section A, program objectives, or project DQOs will typically be defined by each individual state, although in many cases they will be based on Federal regulation. Thus, except for a specific project covered by a QAPP where the DQO process was used to establish objectives, reconciliation with DQOs may not be necessary for most QAPrPs. The DQA process is potentially more useful for cases where formal DQOs have been established, such as for special projects. Use of EPA's *Guidance for Data Quality Assessment* (EPA QA/G-9) document should be considered, although its statistical tests may not exactly fit many projects. It focuses on evaluating data for fitness in decision making and also provides many graphical and statistical tools. For other enforcement or routine monitoring situations, a formal reconciliation with DQOs is probably not justified, since violative evidence usually leads to regulatory or legal action and the data must be defensible.

Ideally, a reconciliation with DQOs is a key part of the assessment phase of the data life cycle from planning through data collection to final use of the data. This step occurs after an activity is over to determine whether objectives were realistic and whether the data were appropriate and usable. The assessment phase follows data validation and verification and determines how well the validated data supported their intended use. In a way, it is a "lessons learned" phase that examines whether the whole activity was planned and carried out properly and also whether the data were appropriate. Sometimes an activity can be brilliantly carried out only to discover that the information collected was not what was needed. If appropriate, the QAPrP should outline the proposed activities, describing how the data will be evaluated to ensure they are satisfactory for their intended use. For the purposes of a state's QAPrP, this section should describe when a DQA process might occur, and how it would be conducted. If most measurements are routine, this section should indicate this and state that since a formal DQO process is not used, this section does not apply.

3.7 QAPrP REVISIONS

During the course of a program's evolution, it is expected that changes may occur in program requirements, how the program is organized, the way environmental data are collected, how enforcement activities are defined, etc. Thus, it is recognized that this QAPrP is and should be a dynamic document, subject to revision as needed. EPA recommends that the document be examined and revised internally once a year by the state or tribe and that it be submitted to EPA at least once every five years for approval (this time period should be worked out by the state and the EPA Region 9 QA Manager and Project Manager). The state should keep its document current and keep its EPA Project Officer informed of significant changes so that he/she can decide whether a more formal evaluation of the changes involving EPA review is necessary. During the five year review, the QAPrP will be evaluated by the EPA QA Manager and EPA Project Officer to determine if the document still meets current EPA QA and Program requirements or needs to be updated. If so, the QAPrP should be revised and reapproved, and a revised copy should be sent to everyone on the distribution list.

REFERENCES

40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

40 CFR 35, Code of Federal Regulations, "State and Local Assistance."

48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.

EPA Directive 2100 (1998), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.1 (June 1987), *Chemical Abstract Service Registry Number Data Standard*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.2 (December 1988), *Data Standards for the Electronic Transmission of Laboratory Measurement Results*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360 (July 1998). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360.1 CHG 1 (July 1998), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 7500.1A (October 1992), *Minimum Set of Data Elements for Ground-Water Quality*, U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*, EPA/600/R-99/032, Office of Environmental Information.

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U.S. Environmental Protection Agency, 2000. *Functional Guidelines for the Validation of Organic Analyses*,

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U.S. Environmental Protection Agency, 1998a. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, EPA/600/R-96/084, Office of Research and Development.

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U.S. Environmental Protection Agency, 1995. *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (QA/G-6)*, EPA/600/R-96/027, Office of Research and Development.

U.S. Environmental Protection Agency, 1994. *Guidance for the Data Quality Objectives Process (QA/G-4)*, EPA/600/R-96/055, Office of Research and Development.

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans,* QAMS-005/80, Office of Research and Development.

APPENDIX A

TERMS AND DEFINITIONS

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

chain-of-custody - an unbroken trail of accountability that ensures the physical security of samples, data, and records.

contractor - any organization or individual that contracts to furnish services or items or perform work; a supplier in a contractual situation.

data quality assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

data quality indicators - the criteria used to define quality control limits used in sampling and analytical measurements. These might include, but not be limited to: blank acceptance criteria, matrix spike recoveries, duplicate of matrix spike duplicate recoveries, relative percent difference between duplicates or matrix spike duplicates, surrogate recoveries, laboratory control sample recoveries, and calibration acceptance criteria,
data usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

environmental conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

environmental data generation - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental processes - manufactured or natural processes that produce discharges to or that impact the ambient environment.

environmental programs - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples. An environmental program represents a series of activities which support regulations or on-going or recurring activities.

environmental project - work or activities involving the environment which are of a finite length or which are characterized by a an established beginning and ending point or which are design to accomplish a specific goal.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

field sampling plan - a site or activity specific document, supported by a quality assurance project plan which describes project objectives, sampling locations and rationales for their selection, sampling methods, analytical methods, preservation, chain-of-custody and shipping requirements. A FSP will contain quality control acceptance criteria for field samples but may or may not contain this information for laboratory analyses.

financial assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, performance partnership agreements, and government interagency agreements.

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

independent assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

information resources management - the planning, budgeting, organizing, directing, training and controls associated with information. The term encompasses both information itself and related resources such as personnel, equipment, funds and technology.

inspection - an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic.

management system - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

method - a body of procedures and techniques for performing an activity (e.g., sampling, modeling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

method detection limits - a statistically derived measure of the minimum amount of an analyte that an analytical method can reliably determine. EPA mainly uses the method outlined in 40 CFR 136 which requires that seven replicate measurements be conducted on non-consecutive days, the results averaged and the standard deviation of the results be multiplied by 3.14. Spiking levels are to be no higher than 5 times the estimated detection limit.

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

performance evaluation - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) - an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

quality assurance manager or officer - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

quality assurance program plan (QAPrP - a document describing in comprehensive detail the necessary decisions and decision criteria to be used by an overall regulatory program which need to be supported by a quality system. A QAPrP should define the QA, QC, and other technical activities that must be implemented to ensure that results of the work preformed will ensure that data generated for the program will be of sufficient quality for decision making

quality assurance project plan (QAPP) - a document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

quality management plan (QMP) - a document that describes a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted.

quality system - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

readiness review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond program milestones and prior to initiation of a major phase of work.

record - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

sampling and analysis plan - a document which describes a specific sampling activity but which incorporates elements of a quality assurance project plan such as data quality objectives, action levels, etc. A SAP also includes information on analytical methods and quality control criteria related to their use.

specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical systems audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.