

**EPA REGION 9 GUIDANCE  
FOR  
QUALITY ASSURANCE PROGRAM PLANS**

**R9QA/03.2**

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

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## FOREWORD

The U.S. Environmental Protection Agency (EPA) Region 9 has developed this guidance to assist organizations in developing Quality Assurance Program Plans (QAPrP). QAPrPs are intended to establish policies that define and document the type and quality of data needed for program level environmental decisions and to describe the methods required for collecting, analyzing, and assessing data to support those decisions. For the purposes of this guidance, an environmental program is considered to be a series of activities that are based directly or indirectly on an act of Congress and defined in regulations promulgated by EPA, state, or tribal governments. The measurements taken under a program generally reflect on-going activities that do not have defined start and end dates. Program activities are usually of a recurring nature, although specific activities may not recur. For example, there may be on-going water monitoring, but sampling locations might change from year to year.

EPA and/or the EPA-funded organization may sponsor individual or one-time environmental projects. Projects are considered to be activities that have a definable beginning and a definable end. A project should have a QA Project Plan (QAPjP) or comparable QA planning document that is approved by EPA or by the funded organization.

A QAPrP should describe policies as to what type of grants, cooperative agreements, or activities require a QAPjP or other QA documentation, and which might be exempted from the requirement. For example, an on-going monitoring program would be covered by a QAPrP, while an investigation of an integrated pest management approach under FIFRA or an evaluation of a new wastewater treatment methodology would be considered projects that would not be covered under the broader environmental program and, therefore, would require a QAPjP. However, a QAPrP should describe what information the QAPjP should include or cite appropriate guidance, such as EPA's G-5 QA Project Plan guidance. Both QAPrPs and QAPjPs should include specific identifiable goals and objectives and discuss the uses of the data. Usually, but not always, program goals are more closely tied to environmental regulations, whereas project goals are developed for the specific investigation based on a systematic planning process.

The following is list of programs, not meant to be exclusive, that might include environmental measurement activities requiring a QAPrP:

- Safe Drinking Water Act (SDWA)
- Clean Water Act (CWA)
- Resource Conservation and Recovery Act (RCRA)
- Clean Air Act (CAA)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Comprehensive Environmental Restoration and Liability Act (CERCLA)
- Toxic Substances Control Act (TSCA)
- Brownfields Program
- Leaking Underground Storage Tank Program (LUST)

In many cases, a program may consist of several distinct activities. It may be more logical to describe each program activity separately and so create a series of QAPrPs, rather trying to fit all decisions and activities under one comprehensive document. For example, under Clean Water Act programs, it might be more useful to have separate QAPrPs for:

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

On the other hand, combining some programs, like surface water monitoring and non-point source programs, into a single QAPrP is an acceptable approach, provided that the programs share common objectives and/or methods. Region 9 has no specific requirements as to how individual programs are combined in a given program plan, nor how many separate program plans are prepared; this is up to the responsible agency.

It is expected that a QAPrP will contain all the information required to assess the data generation activities and quality systems that support decisions to be made by the program. The Plan also describe policies related to data review and database management, and should include important reference materials in a set of appendices.

The guidance should describe the type of information that should be included in each section of the QAPrP. The agency or organization should determine how best to present the material, by following the guidance as is, eliminating irrelevant sections, or adding more information as needed.

Questions regarding this document should be addressed to:

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EPA has prepared other documents as part of its *EPA Quality System Series* that 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  
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e-mail: [quality@epa.gov](mailto: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](http://www.epa.gov/quality/qa_doc.html)

Region 9 also has a web page with guidance documents. It can be found at:

[www.epa.gov/region09/qa](http://www.epa.gov/region09/qa)

## **ACKNOWLEDGMENTS**

This document relies on other documents that reflect the collaborative efforts of many quality management professionals committed to continual improvement in quality systems supporting environmental programs. These individuals represent the EPA, other Federal agencies, State, local, and Tribal governments, and private industry, and reflect the diverse and broad range of needs and experiences common to environmental data collection programs. They have provided the foundation on which this document is based and their efforts are hereby acknowledged. In addition, this document reflects the efforts of members of the Region 9 Quality Assurance Office 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 spends billions of dollars annually collecting environmental data in scientific research and regulatory decision making efforts. In addition, other environmental organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. In order for decision makers to have confidence in the quality of environmental data used to support their decisions, the organization must have structured and documented process for quality in place.

A quality system is a structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy organizational expectations or specifications. 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 CIO 2105 and 2106 (formerly 5360.1 CHG 1 (EPA 1998)), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations. Other organizations funded by EPA are required to develop a QAPP through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients;
- Mechanisms including consent agreements in enforcement actions; and
- Grant conditions.

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 2002)*) is directed toward development of project QAPjPs; however, this guidance is not always clear as to what requirements should be in a programmatic QA Program Plan (hereafter called a QAPrP). The use of the term, “Program Plan,” is specific to Region 9 and was adopted to distinguish more easily between requirements for preparing plans to describe program activities and those that cover project activities. National QA guidance relates directly only to project level QA Project Plan preparation, although a forthcoming revision to G-5 will expand its scope.

QAPrP requirements described in this document integrate all technical and quality aspects of a program, including planning, implementation, and assessment. The purpose of a 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. A 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 depends on the quality of the environmental data collected and used in decision-making, and this in turn depends on the requirements described in the QAPrP and their implementation. Stakeholders, such as data users, data producers, and decision makers, should be involved in the program planning process to ensure that their needs are defined adequately and addressed. A QAPrP should document when regulatory standards are used and when a specific process, such as the Data Quality Objectives (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 documents are required, and what their respective review and approval process 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 advised by EPA Region 9.

## **1.2 THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-2004**

EPA Order 5360.1 A2 is now [CIO 2105.0](#) (PDF 12pp, 94K) and EPA Manual 5360 A1 is [CIO 2105-P-01-0](#) (PDF 62pp, 169K). They and the applicable Federal regulations establish a mandatory Quality System that applies to all EPA and EPA-funded organizations. 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 those environmental technologies are designed, constructed, and operated according to defined expectations. A QAPrP is a key component of the EPA Region 9 Quality System.

EPA Region 9 policy is based on the national consensus standard, ANSI/ASQ E4-2004, *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*. The ANSI/ASQ E4-2004 standard describes the necessary management and technical elements for developing and implementing a tiered quality system. This standard recommends that each organization-wide quality system be documented in a Quality Management Plan (QMP) or Quality Manual to address requirements of *Part A: Management Systems* of the standard. The applicability of the quality system to technical activity-specific efforts is documented 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 internally for its mandatory Agency-wide Quality System. This guidance addresses Part B requirements of the standard and is directed at assisting organizations to be consistent with EPA requirements.

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 its quality system. A 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 2006). A QMP should be supported by program specific QAPrPs and project-specific QAPjPs, depending on the nature of the activities that are being funded, the organization conducting the work, the scope of the program and the regulations the program supports. In some cases, a QAPrP and a QMP may be combined into a single document that contains both organizational and program-specific elements. This QAPrP guidance does not discuss this type of document, but it may be used in conjunction with the Agency's R-2 guidance to develop a combined plan. The Region 9 QA Office will work with a grantee to determine whether a single document is appropriate and to offer suggestions on its content.

### **1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM**

EPA recognizes that a “one size fits all” approach to quality requirements does not work for the diversity of organizations with which the Agency works. Therefore, implementation of the EPA Quality System is based on the principle of a graded approach. This means that quality systems for different organizations and programs will vary according to the specific objectives, size, structure, funding, and needs of the organization. Thus the quality system expectations of a small tribal program monitoring program are different from those of a large organization, regulatory compliance program. Additionally, the purpose or intended use of data is so variable that a uniform approach would not be viable. The specific application of the graded approach principle to QAPrPs is described in Section 2.4.2.

### **1.4 INTENDED AUDIENCE**

This document is intended for use by 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. It contains the same basic requirements as EPA Order CIO 2106, which was developed for internal use by EPA organizations. It can be used by other EPA Regions or program offices with the permission of appropriate program or QA managers in those organizations.

### **1.5 PERIOD OF APPLICABILITY**

Documents generated under this guidance shall be valid for a period of up to five years from the official date of publication. After five years, it should be reissued without change, revised, or withdrawn. If revised or reissued, it should be submitted to the Region 9 QA Office for approval.

### **1.6 ADDITIONAL RESOURCES**

- Guidance on preparing project QAPPs may be found in the documents, *Requirements for Quality Assurance Project Plans, (QA/R-5)* (May 2006) and *Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 2002). These guidance documents discuss the application of project QAPjP

requirements, and provide examples. Other documents that provide guidance on activities needed to generate environmental data and complement a QAPrP and QAPjP preparation effort include:

- *Guidance for the Data Quality Objectives Process (QA/G-4)*, (EPA 2006)
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*, (EPA 2007)
- *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 “QAPrP” was no longer used in national guidance.

## **CHAPTER 2**

### **QAPrP REQUIREMENTS**

#### **2.1 POLICY**

All work under a regulatory program funded by EPA Region 9 that involves the acquisition of environmental data generated through direct measurements, 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. Data generated as part of a stand-alone project that is funded by EPA should be gathered using an approved QAPjP or Sampling and Analysis Plan (SAP). Under its own program, an organization may require other project planning documents. These documents generally do not have to be submitted to EPA for approval provided an EPA approved Quality Management Plan (QMP) is in place. A QAPrP should describe the guidance, requirements, and approval procedures that have been established for internally generated project QAPjPs.

A QAPrP should be developed, wherever possible and appropriate, 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**

A 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, it should be in conformance with Part B requirements of ANSI/ASQ E4-2004.

## **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, the existence of a Quality System must be documented. QAPrPs should be prepared, reviewed, and approved in accordance with any other regulatory requirements, but an attempt should be made to prepare documentation consistent with this guidance.

## **2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS**

### **2.4.1 General Content**

A QAPrP must be composed of standardized, recognizable elements covering the entire program from planning, through implementation, to assessment. Chapter 3 of this document describes the specific elements. In some cases, it may be necessary to add program-specific requirements. The EPA Region 9 organization sponsoring the work (e.g., the Drinking Water Office, the Air Division) has the authority to define any special requirements beyond those listed in this document. If no additional requirements are specified, a QAPrP shall address all required elements. Each funded organization should define its own organization-specific requirements for QAPrP and QAPjP documentation in its QMP, if it has one. Otherwise, a QAPrP shall define QA System requirements. A QAPrP must be consistent with all programmatic requirements.

A QAPrP defines policies that address the general, common activities of a program that are to be conducted over a long period of time. It describes in a single document the information that is not site- or time-specific, but applies throughout the program. Application-specific information is added to the approved QAPrP as it becomes known, better 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 during each grant cycle by the organization's designated QA official is recommended.

### **2.4.2 Level of Detail**

The level of detail of a QAPrP should be based on a graded approach. It is expected that QAPrPs 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. Most regulatory programs will be able to define decisions they make in terms of regulatory standards established by the

Federal, state, or tribal government. If this is not the case, the quantitative criteria on which decisions will be based should be described as appropriate for the program. If this is not appropriate, a QAPrP should describe the process that will be followed to establish these objectives in qualitative terms or indicate where this information will be defined. A QAPrP should also define when other QA documentation must be prepared, the information it should contain, the level of detail required, and the review and approval process in place, unless these requirements are defined for the program in the organization's QMP (See Section 3.2.4.2).

## **2.5 PREPARATION AND APPROVAL**

It is expected that QAPrPs will be prepared by state agencies, tribal organizations, assistance agreement holders, non-profit organizations, and/or organizations funded by these organization as well as other Federal agencies operating under an interagency agreement. QAPrPs may be prepared by the organization's staff or by contractors or subcontractors, but the grantee or financial assistance agreement recipient funded by EPA is ultimately responsibility for its contents and for the implementation of the QA system it describes. 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 it contains the appropriate content and level of detail. Authorized reviewers are the EPA Region 9 project manager,<sup>1</sup> 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 IMPLEMENTATION**

None of the environmental work addressed by a QAPrP shall be started until it 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. It is the responsibility of the organization performing the work to ensure that no environmental data are generated or acquired before a QAPrP is approved and distributed to appropriate program personnel. However, EPA Region 9 may grant conditional approval of a QAPrP to permit some work to begin while non-critical deficiencies are being addressed. Where a QAPrP or its equivalent has been approved in the past, and a revised plan is under-going review, comment, revision, and approval, work may proceed under the previously approved QA document until such time as the revised document is approved for implementation. QAPrPs can also be used to cover specific program activities while a more comprehensive QAPrP is under preparation or if an organization decides to not prepare a QAPrP.

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

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 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 REVISION**

Although the approved QAPrP must be implemented as written, it is not intended to be inflexible. Because of the complex and diverse nature of environmental work, changes to original plans are often needed. When such changes occur, the organization's 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 a QAPrP shall revise, amend, or add an addendum to a 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 that adds new or deletes old program elements. Alternatively, these changes may also be covered by amendments or addenda. For the purposes of this guidance, an "amendment" documents modifications or changes in the existing program, whereas an "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 subject to revision. EPA does not require that these revised supporting documents be submitted for review unless the organization wants an independent assessment of the changes or they significantly affect the program. For example, if a new laboratory is hired and its QC criteria differ substantially from its predecessor, then a new review might be appropriate. 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. It 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. EPA may elect to perform a Management Systems Review (MSR) of the implementation of a 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 and submitted to EPA Region 9 for review.

## CHAPTER 3

### QAPrP ELEMENTS

#### 3.1 CONTENT REQUIREMENTS

A 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 satisfy organizational performance criteria. A QAPrP must provide sufficient detail to demonstrate that:

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

Most environmental data generation activities require the coordinated efforts of many individuals, including managers, engineers, scientists, statisticians, and other support staff. A 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 implement the QA Program. 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, a QAPrP must specify the level or degree of QA and QC activities needed for the particular environmental program. Because this will vary according to the purpose and type of work being done, EPA Region 9 recommends 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 measurement activity (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
- the intended use of the results (e.g., compliance determination, selection of remedial technology, development of environmental regulation).



A 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. These are the same four elements found in the G-5 guidance on QA Project Plans, but the contents differ in that they have a broader, programmatic perspective. The four groups of elements and their intent are summarized as follows:

Program Management - The elements in this group address the basic area of program management, including program objectives, roles and responsibilities for QA by 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 planning requirements and outputs are specified.

Data Generation and Acquisition - The elements in this group address all aspects of program data generation and describe 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.

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 a QAPrP is implemented as prescribed.

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

All applicable elements must be addressed in a QAPrP. If an element is not applicable, this should be so stated. 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 as it relates to a specific required QAPrP element. This consolidates existing documentation into one comprehensive document and minimizes duplication or preparation of material already in place. Alternatively, rather than attaching documents to the Plan itself, they can be placed on file with the Region 9 QA Office and appropriate EPA Region 9 program section or division. Another alternative is to make all documents available for electronic review and download. It is the organization's responsibility to ensure that reference documents are available to its staff as needed.

A QAPrP should be consistent with the organization's approved QMP, if it has one. Material referenced in the QMP does not need to be included. A 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 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 these goals and that the approach to be used and planning outputs have been documented.

### **3.2.1 Title and Approval Sheet**

On the Title and Approval Sheet, include the formal 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**

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

#### **EPA Region 9**

- Project Manager
- QA Manager (currently Eugenia McNaughton, Ph.D.)
- 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 Table of Contents and Document Control Format**

Sections, figures, tables, references, and appendices should be included in the Table of Contents.

It is recommended, but 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 included in a footer.

	Section No. _____ Revision No. _____ Date _____ Page ____ of ____	
<b>Figure 1. Example Document Control Format</b>		

### 3.2.3 Distribution List

This section includes a list of the individuals and organizations that should have 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 covered by or implementing a QAPrP). Paper copies need not be provided to individuals if equivalent electronic copies are provided or if a copy can be downloaded.

### 3.2.4 Program/Task Organization and Planning Documentation

#### 3.2.4.1 Program/Task Organization

This section should 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. This would include the principal data users, decision makers, and the program QA manager. On a functional basis, the plan should describe the organization's structure and identify staff responsible for implementation. The organization should use its judgment in determining to what level its QAPrP will identify specific staff by name versus functional position, 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 s/he has oversight. Arrangements where an individual from one unit acts as the QA Manager for a different unit will be considered on a case by case basis. If the size of the program or the organization precludes having an independent QA Manager, a QAPrP must describe the approach by which this function will be carried out effectively and objectively. In some cases, it may be necessary for a senior manager to become the QA Manager/Officer. Note that a line supervisor serving as the QA Manager does not constitute an organizationally independent QA function. Although not optimal, such situations will be evaluated on a case by case basis and may be acceptable. All alternative arrangements must be documented and justified 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. In the case of line supervisor/QA Manager joint positions, the QAPrP should describe how potential conflict of interest between program priorities, budgets, and schedules can be set aside so that these factors do not influence decisions concerning data quality.

A QAPrP should include one or more organization charts showing the relationships and lines of communication among all organization or program personnel. For example, one chart might show the relationship of the organization to the regulated community, contractors and subcontractors, local and municipal agencies, analytical laboratories, etc., and the other 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. Non-governmental organizations, members of the public, legislative bodies, etc., do not have to be included on the charts.

#### 3.2.4.2 Planning Documentation

A QAPrP should define requirements for QA documentation. In many ways, the discussion in this section is critical for 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 ongoing or one that is only a one-time event, 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 or data use activity that supports program decisions. If a sampling and analysis plan (SAP), a field sampling plan (FSP), a one- or multiple-page planning form, an inspection report, or some other planning document must be prepared prior to samples being collected or data being generated, the requirements should be described in this section. For each specific document, the QAPrP should specify what information it must contain, the level of detail, the format, and the review and approval procedure to be followed before the document is implemented. Approving officials should be identified. A QAPrP should include examples of any blank forms and copies of SOPs used in the preparation of these documents, with references, as appropriate. If EPA guidance is to be cited, it should be applicable to the program and up-to-date. For example, if a program never requires that a QAPjP be prepared, a QAPrP should not include references to EPA QAPjP guidance. Inclusion of an example QAPP, example SAP, filled out form or report, or an actual reference document (for example, an EPA guidance document) in an appendix is optional. This section should include a discussion of the circumstances under which documents might be revised and how this would be done. The document should also describe when deviations from the document would be acceptable and the mechanism by which such deviations or changes would be authorized or approved.

This section should describe how requirements for planning documentation might flow down from the QAPrP authors to any organizations doing work for the organization. It should include the documentation these organizations (permittees, local agencies, responsible parties, volunteer or not-for-profit organizations, etc.) must prepare and under what circumstances. For example, state personnel doing confirmation sampling for an Underground Storage Tank program may have to prepare a SAP, while a certified tank puller doing confirmation sampling might document his work in a report that includes QC data. A contractor may be required to use a state's SOPs if s/he is under a state contract or s/he might be able to submit the firm's SOPs for review. For this type of repeated work, each specific assignment might need a new SAP or a generic plan might be used. Another type of data collection, the so-called "samples of

opportunity” taken during an inspection, should have a general planning document in place. Laboratory QA acceptability criteria should be reviewed and documented.

The personnel responsible for make these programmatic QA decisions should be identified in this section. The review and approval process of QA documents should be described. An organization should examine all the ways in which it generates data and the different sources from which it receives data. The QAPrP should include all the documentation needed for adequate planning and implementation throughout the data collection chain.

A QAPrP should identify any other records and documents applicable to the program that will be produced that are not described elsewhere. This section should define what documentation should be prepared for planning, not reporting, which is covered below. Please note that although this guidance may request similar information in more than one section, it need only be presented once and may be referenced in the following section(s).

### 3.2.5 Problem Definition/Background

A 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. It should include sufficient background information to provide 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 Program/Task Description

This section should provide a summary of all work involving environmental measurements carried out under the program, whether routine on-going activities (monitoring), one-time events (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 for data collection and analysis provided. For recurring activities conducted by the organization itself, such as surface water monitoring, maps or tables should be included that show the geographic locations of these recurring events. This information can be included in an appendix. The discussion need not be lengthy or overly detailed, but should give an adequate 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 in Section 3.2.5.

### 3.2.7 Quality Objectives and Criteria for Measurement Data

This section of a 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. On the first level, the discussion should focus 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 and Clean Air Standards are 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. Use of risk or health based criteria may also be appropriate in some situations for some programs. Whatever the approach, the basis for these non-regulatory objectives should be documented, or at least the process by which they will be developed should be used described. A 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 Data Quality Objectives process described in its G-4 guidance be followed. Regardless of whether the DQO process is used, a QAPrP should describe policies with respect to the establishment of DQOs and how acceptance criteria will be defined. The section should also describe what type of project specific planning document will contain this information. If this has already been discussed in the previous section, it can be included by reference.

If work relates to an evaluation of technology, a relative, but quantitative, objective might be set. For example, a treatment plan would be considered effective if it removes 95% or more of a pollutant of concern or a habitat would be considered restored if an 25% increase in diversity is achieved among a faunal population.

On the second level, objectives should be defined for those QC measures relevant to the program's sampling and analysis activities. The acceptance criteria for specific measurements are described as "Measurement Quality Objectives" (MQOs). MQOs are based on several qualitative and quantitative parameters termed "Data Quality Indicators" (DQIs). The "PARCCS" parameters (precision, accuracy, representativeness, completeness, comparability and sensitivity) constitute the DQIs. Precision, accuracy, completeness and sensitivity are quantitative and representativeness and comparability are qualitative measures.

The use of MQOs helps ensure that the data used in decision making are of acceptable quality. It is up to the decision maker to determine whether rejected or qualified data can be used for limited regulatory or other decisions based on how much and to what extent the quality control data failed to meet the MQOs. MQOs, which are often based on method specific quality control criteria, would normally be provided in Section 3.3.5 if defined on a program-wide basis. DQOs or regulatory information should be provided in this section, Section 3.2.7.

It is recommended that a QAPrP 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%.” Both DQOs and MQOs can be defined in subsidiary documents such as a field sampling plan, a laboratory quality assurance plan, or in SOPs, but it is helpful if program wide criteria are provided. A QAPrP can present this information in either tabular or narrative form. If an organization has several contract laboratories, it may have defined QC criteria in a statement of work to which all the laboratories must adhere. In that case, those criteria should be provided, rather than the individual laboratory’s QA Plans or SOPs. If only one laboratory is under contract, it may be possible to default to the laboratory’s QC criteria if they are consistent with program defined MQOs.

What should emerge from this section are clear statements as to what decisions the program makes, the criteria on which it bases those decisions, and the QA and QC requirements the program and supporting organizations must meet to ensure the data are of sufficient quality for their intended use.

### 3.2.8 Special Training/Certification

A QAPrP should identify and describe any specialized training or certification needed by personnel in order to perform different program activities. This usually relates to the areas of sampling, analysis, and data review, but competency in any of the areas of the program’s quality system might require training, such as document review and auditing. This section should also discuss how such training will be provided and how the trainee will demonstrate the necessary skills. The maintenance of training records should also be covered, unless this is carried out on an organization-wide basis and the process is documented in the Quality Management Plan. If the program requires specialized permits for some activities, these should be described. For example, the collecting of endangered or threatened species or use of specialized methods such as electric shock methods for fish might require such permits.

### 3.2.9 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, etc.), this should be described.

Any program policies with respect to reporting requirements relating to reporting QA and QC information should be described here. This might include, but not be limited to, contents of required 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 by organizations providing data to the program, such as laboratory data. The section should also specify or reference all applicable requirements for the final disposition of records and documents.

Finally, a 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 inspectors, samplers, laboratories, permittees, responsible parties, municipalities, local agencies, or other organizations. The reporting format for hard copy and electronic data or reports should be provided. 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 databases 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. This discussion should indicate 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.

Reporting requirements for Quality Assurance oversight activities, such as audits, are covered in a later section.

### **3.3 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:

- collecting, handling, and analyzing of samples;
- processing or using 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, or taken from the literature); and
- managing, compiling, handling and storing data.

The types of measurement activities to be conducted should have been summarized in Section 3.2.6. These sections are subdivided into three parts. In the first section, policies with respect to the subject are described. This covers all data generation activities conducted by or on behalf of the program. In the second, the organization can define when it is appropriate to defer the details on requirements for a given topic to a subsidiary document, such as a QAPjP. In the third, the QAPrP can provide requirements relevant to the subject. These requirements would



then apply every time the organization performs an activity. The advantage of this approach is that it is not necessary to provide this information in other documents and it is also clear to external parties exactly what the organization's policies are. This approach minimizes the information that must be provided to organizations that might generate information for the program. The program should define its requirements concerning when these options are appropriate and when they are not.

The purpose here is to provide detailed information on the methods and procedures which will be followed by the organization(s) generating or submitting data. If the designated methods are well documented and readily available, they can be cited within the text. Depending on the approach taken, detailed copies of the QC criteria and associated corrective action requirements should be included.

Note that it is not expected that a QAPrP include copies of the methods themselves, unless they reflect program-specific modifications to existing methods or newly developed methods that are not readily available. Inclusion of SOPs is encouraged and may facilitate the use of a QAPrP as a reference document.

### 3.3.1 Sampling Design

#### 3.3.1.1 Program Policy

This section should describe policies with respect to sampling or data collection activities conducted under the program, including as appropriate:

- How the program determines the types and numbers of samples required for on-going monitoring events or what process is used for establishing this information for one-time events. For example, are there requirements for a minimum number of samples for certain types of events or when a statistical design must be used?
- How standardized design requirements are established for future monitoring networks.
- How requirements for sampling locations and frequencies are determined for on-going sampling and how decision criteria for one-time events are established.
- How program requirements with respect to the time period over which on-going monitoring activities occur are determined.
- How the need for samples of different matrices relevant to program activities are established.
- How the measurement parameters relevant to program activities are identified for on-going or one-time event sampling.

- The type of rationales or justifications required for the design of monitoring networks, and how program expectations are established with respect to those designs and the information that must be provided as a rationale for sampling locations for on-going events.
- The level of detail required for rationales for one-time events.
- The rationales required for the types of samples to be collected (e.g., composite or grab) and the minimum information needed to describe acceptable compositing procedures, when applicable.

### 3.3.1.2 Deferral of Sampling Design Description

The program has the option to state that sampling designs will be described in site-specific QA Planning documents or in other short term documents, for example, a yearly plan that describes several events and sites. A QAPrP should state what information will be provided in these documents and when it is appropriate or expected that they will be used. The sampling design information methods specified in these documents would be subject to the requirements specified in the policy described in Section 3.3.1.1.

### 3.3.1.3 QAPrP Defined Requirements

To simplify creating sample designs in site specific documents, or to minimize their preparation altogether, a QAPrP can describe one or more on-going sampling or monitoring programs. These would include the information listed in 3.3.1.1, above. This might be presented in tables or appendices.

## 3.3.2 Sampling Methods

### 3.3.2.1 Program Policy

This section should describe program policies with respect to sampling. This would include methods that are required, those that might be acceptable, and the circumstances under which each could be used described. If the methods are widely available, the sources should be cited, for example, EPA Emergency Response Team Methods, Ambient Air monitoring methods, SW-846 methods, etc.

### 3.3.2.2 Deferral of Sampling Method Information

The program has the option of stating that sampling method requirements or related information will be described in site-specific QA Planning documents, or in other short term documents. For example, a program might prepare a plan that describes locations to be sampled that year and indicate the timing of the sampling (quarterly, monthly, etc.). A QAPrP should

state what information will be provided in these documents, and when they are to be used. The sampling methods specified in these documents would be subject to the requirements specified in the policy described in Section 3.3.2.1.

### 3.3.2.3 QA Program-Defined Requirements

If a certain collection of sampling method are routinely used, or are required, such as for certain air and drinking water programs, a QAPrP should describe these procedures or cite the relevant sources. The sampling methods and equipment, the procedures for using that equipment, sample preservation requirements, decontamination procedures, and materials needed for physical, chemical, or biological sampling should be described. Sampling methods should be identified by number, source, date, and regulatory citation. If a method allows the user to select from various options, the method citation should state program policies with respect to those 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 an appendix. A table can be used to summarize the information.

A 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 state what the expectations are for those organizations generating or submitting data. This could include both contractors working directly for the organization, as well as organizations, such as a responsible party, grantee, subcontractor, 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 that the program's quality requirements are met by the secondary organization.

## 3.3.3 Sample Handling and Custody

### 3.3.3.1 Sample Handling and Custody Policy

This section should describe any policies with respect to sample handling and custody, for example, whether custody is required for all samples or only those involving enforcement situations.

### 3.3.3.2 Deferral of Sample Handling and Custody Information

The program has the option of stating that sample handling and custody requirements or related information will be described in site-specific QA Planning documents, or in other short term documents. The sample handling and custody information specified in these documents would be subject to the requirements specified in the policy described in Section 3.3.3.1.

### 3.3.3.3 QA Program-Defined Requirements

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. This narrative should take into account the nature of the samples, the maximum allowable sample holding times before processing 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 or cite EPA sources 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 that external organization must meet in this area should be described.

## 3.3.3 Analytical Methods

### 3.3.3.1 Analytical Methods Policy

Program policies with respect to analytical methods may need to be prescriptive due to regulatory requirements. If there is flexibility in regard to the choice of methods, for example, if several methods would be acceptable or if methods can be performance based, this should be stated. This section should describe under what circumstances these options would be permitted. If use of new methods is permitted, the section should describe policies for documenting the validity of the method and to whom this information would need to be submitted.

### 3.3.4.2 Deferral of Information on Analytical Methods

As appropriate, this section should describe acceptable situations when the specification of analytical methods would be deferred to project-specific documents (e.g., QAPPs, SAPs, FSPs). The analytical methods specified in these documents would be subject to the requirements specified in the policy described in Section 3.3.4.1.

### 3.3.4.3 Program-Defined Analytical Method Requirements

A QAPrP should identify the analytical methods and equipment appropriate to support all program activities. This would include laboratory sub-sampling, extraction methods, or other sample preparation procedures and specific performance requirements. Since QC criteria are defined below, these would not need to be defined or referenced here. Analytical methods

should be identified by date and EPA method number or regulation number. If they are taken from a non-EPA source, the method number and source should be provided.

The advantages of specifying methods in a QAPrP are several. First, this makes program policies with respect to methods clear and easily accessible. Second, a QAPrP can then be referenced in subsidiary documents, such as sampling plans. Third, this will define the methods the program needs to generate data it can use, which will in turn provide clear instructions to contract or subcontractor laboratories as to the level of analysis required.

If work is contracted to a limited number of analytical laboratories, it may be convenient to include a copy of the laboratory's QA Plan or SOPs as an appendix. However, if a prescriptive solicitation was used that describes in detail exactly what protocols must be followed down to calibration and QC specifications, a copy of these requirements should be included in the Statement of Work. This would include a description of the mechanism by which work assignments are transmitted to the laboratory.

List any method performance standards (i.e., method capabilities), for example, minimum detection limits, suitability for field use, simplicity of use, etc. If the program permits the use of a method that allows the user to select from various options, then it should be stated which options are acceptable. Some regulatory programs are prescriptive in their method requirements (e.g., the NPDES program and the ambient air monitoring program), whereas others are more flexible.

If non-standard or performance based methods are allowed, appropriate method performance study information may be needed to demonstrate the appropriateness of the method for the particular matrix or atypical analytes. If previous performance studies are not available, the program should specify the necessary steps to obtain approval, for example, a spike recovery study, a method detection limit study, a calibration linearity study, a precision and accuracy study, a ruggedness test, etc. All are typical studies EPA might require before it considers a method acceptable. If such studies are required, the minimum number of repetitions needed to perform each study should be defined (EPA usually requires 5 to 7).

### 3.3.5 Quality Control

#### 3.3.5.1 Quality Control Program Policy

The generation of data of known quality requires that certain checks be in place so that possible errors or bias in the results can be identified and corrected. The program should describe policies with respect to minimum standards for quality control. The program may wish to define overall Measurement Quality Objectives (MQOs) for all the methods that are utilized under the program or it may only define what types of checks are expected and the frequency with which they should be run. Section 3.3.5.3 contains a table with the most frequently used QC checks. If the program chooses to be prescriptive, the requirements should be discussed as

well as whether they apply to the organization(s) providing data to the program. These requirements also might apply to the evaluation of data from secondary sources.

### 3.3.5.2 Deferral of Quality Control Requirements

The program can elect to have specifications for quality control samples described in project-specific documents. If this approach is used, requirements for the types of QC samples, the frequency at which they should be run and acceptance criteria should be provided in these other documents. This section should describe when this approach is acceptable. Documents prepared using this approach should be consistent with the policies defined in Section 3.3.5.1.

### 3.3.5.3 Program-Defined Quality Control Requirements

A QAPrP can be used as a vehicle to define QC requirements. QC checks are based on Data Quality Indicator (DQI) information and are 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 reviewing and implementing a 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. Screening analyses performed in a mobile laboratory should be treated as field measurements. The confirmation of screening field measurements (e.g., x-ray fluorescence, immunoassay) should be discussed if the data will be used in decision making. Definitive analyses should be treated as they would be if performed in a fixed laboratory.

Because many environmental analytical methods, including EPA methods, are often ambiguous or incomplete in specifying QC requirements, defaulting to the cited method for this information will not necessarily provide sufficient guidance on the quality of the data a program might require. Ideally, a summary table listing the most commonly used methods will be presented in the Plan or in the appendices. 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., field duplicates and co-located samples, and field blanks) will not be covered in a laboratory's QA Plan, this information should be addressed in the QAPrP. Possibly a combination of a QAPrP and a field sampling/measurement SOP could be used. The frequency with which these field QC measurements are performed or the frequency with which field QC samples will be collected should be described.

Laboratory QC checks and acceptance criteria should also be defined, although this section can freely reference appendix material. If the program only uses one laboratory, or if all the laboratories are consistent in their QC programs, the plan can reference table(s) of QC criteria and corrective action found in the laboratory's QA plan. Be advised that many laboratories put this detailed information in method specific SOPs, so that it may be necessary to make provisions for this information to be available to data reviewers or auditors.

Most QC acceptance limits provided in EPA methods are based on the results of extensive inter-laboratory 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 intra-laboratory studies which often result in narrower acceptance limits. If a new, modified method, or a performance based measurement is used, the program should require that a method validation study be cited to establish criteria (see previous discussion in the Analytical Methods Section). The program should ensure that it has the acceptance criteria from the studies.

Table 2 lists QC checks often included in analytical method SOPs. This list is intended only to provide *examples*. The policies of each organization or tribal program should dictate decisions regarding MQOs and acceptance criteria. Typically, at a minimum, each laboratory method would include a 3-point calibration, a matrix spike, a duplicate analysis, and a laboratory or method blank. Continuous monitors used in air or water monitoring may have different QC systems. Organic analyses would include surrogate recoveries, and the analysis of laboratory control samples from a second source standard is highly recommended. However, the frequency with which these or other QC checks will be run, and the associated acceptance criteria and corrective actions if criteria are exceeded, should be determined by what each program needs to ensure that it is acquiring and using data of known quality.

**Table 1: Analytical QC Checks**

<b>QC Check</b>	<b>Information Provided</b>
Blanks field blank reagent blank rinsate blank method or matrix blank	transport and field handling bias and laboratory analytical system system contaminated reagent contaminated equipment and laboratory analytical system response of entire laboratory analytical system
Spikes matrix spike matrix spike replicate/duplicate instrument spike surrogate spike blank spike (lab control sample) post digestion spikes	analytical (preparation + analysis) bias and matrix effects analytical bias and precision instrumental bias analytical bias and matrix effects, extraction efficiency analytical bias matrix effects (inorganic)
Calibration Check Samples detection limit verification check mid-range check (continuing calibration verification) standard verification	sensitivity below lowest calibration point calibration drift and memory effects independent calibration verification using a NIST national standard or other external source of a certified standard
Replicates, splits, etc. co-located samples field replicates field splits laboratory splits lab/method duplicates/replicates analysis duplicate/replicates	matrix variability + sampling + measurement precision precision of all steps after acquisition shipping + interlaboratory precision interlaboratory precision analytical precision 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 how the calculations will address potentially problematic situations such as missing data values, “less than” or “greater than” values, and detection of analytes below reporting limits. A discussion of data qualifiers should be deferred to the later section on data validation. 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 state 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.



### 3.3.6 Instrument/Equipment Testing, Inspection, and Maintenance

#### 3.3.6.1 Program Policies on Instrument/Equipment Testing, Inspection, and Maintenance

This section should describe any overarching program requirements regarding inspection and maintenance of instruments. In some cases, there may be a regulatory component to these policies.

#### 3.3.6.2 Deferral of Discussion of Instrument/Equipment Testing, Inspection and Maintenance

Information on instrument requirements can be deferred to QAPjPs or other QA Planning documents. If this is done, requirements should be consistent with the policies in Section 3.3.6.1.

#### 3.3.6.3 Program Defined Instrument/Equipment Testing, Inspection, and Maintenance

A 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 apply mainly 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 will 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 Instrument/Equipment Calibration and Frequency

#### 3.3.7.1 Program Policies for Instrument/Equipment Calibration and Frequency

If the program has any policies with respect to calibration of instruments, it should be discussed in this section. Generally, this topic will have been covered in the section discussing policies regarding methods, but if there are exceptions, they should be discussed here.

#### 3.3.7.2 Deferral of Discussion of Instrument/Equipment Calibration and Frequency

Discussion of instrument calibration can be deferred to QA Project Plans or other QA Planning documents. This section should describe the circumstances under which this will happen. Any deferral should be consistent with the policies described in Section 3.3.7.1.

### 3.3.7.3 Program-Defined Instrument/Equipment Calibration and Frequency

This section of a 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 will be maintained and be traceable to the instrument. This information may be provided in referenced SOPs or other documents. It also might be appropriate 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 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. In this case, a reference in this section is sufficient. If this is not the case, a table listing the specific method giving initial and continuing calibration requirements would be appropriate.

## 3.3. Inspection/Acceptance of Supplies and Consumables

### 3.3.8.1 Program Policies Concerning Inspection/Acceptance of Supplies and Consumables

This section should describe policies regarding the procurement of supplies, equipment, and consumables from a QA perspective. Thus, inclusion of organization procurement and purchasing policies is neither required nor expected, but this section should indicate that these requirements exist and provide citations, if appropriate. If there are any policies regarding acquisition of non-standard materials, they should be described.

### 3.3.8.2 Deferral of Information on Inspection/Acceptance of Supplies and Consumables

Discussion of this topic may be deferred to project-specific documents, if appropriate, but should be consistent with the policies provided in Section 3.3.8.1.

### 3.3.8.3 Program Defined Inspection/Acceptance of Supplies and Consumables

The focus of this section 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) will be inspected and accepted for use in the program. This might include a discussion of who defines the performance specifications for equipment; how the equipment checked to make sure it meets those specifications; how is the purity of materials specified and checked; and what procedures are followed if equipment or consumables do not meet specifications.

### 3.3.9 Non-direct Measurements

Data an organization uses to make decisions may come from other sources. This section should discuss the use of historical or contemporary data obtained from databases and reports generated by other organizations or government agencies, non-profits, trade associations, etc. The U.S. Geological Survey, the U.S. Weather Service, universities, the scientific literature, permittees, local organizations, and non-profits are all examples of possible sources of secondary data.

Requirements for QA planning documentation or QC information submitted to the program directly by grantees, permittees, local municipalities on an on-going basis should have been discussed previously; this section should focus on minimum standards expected for data quality from these organizations. Where all data comes from other sources and the program will compile and interpret those data, a QAPrP should identify any types of information and associated metadata requirements for program implementation or decision making. If possible, a QAPrP should describe how secondary data is typically used by the program.

The main point of the discussion is how the information will be evaluated to ensure that they are of sufficient quality for their intended use. The QAPrP should state who in the organization will have responsibility for defining acceptance criteria for secondary data and any limitations to their use. How the limitations will be determined and documented should also be included. EPA has not defined requirements for secondary data use. It is recommended that the organization take a common sense approach, the objective being not to use the information inappropriately.

Finally, this section should discuss the program's use of models. 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 qualified and are related to decision making.

### 3.3.10 Data Management

#### 3.3.10.1 Program Data Management Policies

This section should discuss policies with respect to data management, both hard copy and electronic. Minimum expectations with respect to documentation from the field and laboratory should be described. Policies with respect to data retention should be described. Electronic data keeping should also be covered. If there are particular formats or programs that should be used, they should be identified.

#### 3.3.10.2 Deferral of Data Management Requirements

Requirements for data management can be described in QA Plans or other more project-specific documents. In that case, the requirements in 3.3.10.1 should be followed.

#### 3.3.10.3 Program Defined Data Management Requirements

This section should describe the program's data management process, tracing the path of the data from their generation to final use or storage (e.g., the field, the laboratory, or the office). For example, a 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 be relevant. A QAPrP should provide examples of any forms or checklists that it uses to verify data input or data integrity.

A QAPrP should describe all data handling equipment and procedures used to process, compile, and analyze the data. This includes procedures data generated as part of the program and 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 brief, stating that fact. The main focus should be on either unusual programs or custom software.

If EPA data management requirements, 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) are applicable, discuss how these requirements are addressed. If relevant, the program should consider including SOPs that describe how data are entered into EPA databases, such as STORET/WQX or AIRS/AQS.

## 3.4 ASSESSMENT AND OVERSIGHT

This section addresses activities that assess the effectiveness of program implementation and associated QA and QC activities. Assessment helps ensure that a QAPrP is implemented as described.

### 3.4.1 Purpose/Background

This section describes the system of internal and external checks necessary to ensure that measurement activities or use of data by a program takes place according to the program's QAPrP. This system will depend on the nature of program activities. Some questions that should be answered include:

- Is enforcement stressed or is monitoring more the focus?
- What level of assessment can the organization perform given existing resources?
- What are the intended uses of the data and what level of confidence does the use require?

Once assessment policies are defined, there should be a system in place to evaluate their implementation. The other type of assessment in a quality system is the evaluation of data to determine whether they are of sufficient quality for their intended use.

Although any external assessments should be described in the appropriate planning document, the most important topic in this section is the documentation of all planned internal assessments. Generally, internal assessments are initiated or performed by the organization's QA Officer, the Program QA Officer, a project QA Officer, or a Laboratory QA Officer. The activities described below should be related to individuals with QA responsibilities, as discussed in Section 3.2.4.

### 3.4.2 Assessment Activities and Program Planning

The following sections describe various types of assessment activities to evaluate the effectiveness of the implementation of the environmental program quality system. Programs should choose those that are most appropriate and relevant for their operations.

#### 3.4.2.1 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 an 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 are being carried out by the organization to adequately plan, implement, and assess the results of program activities. See the *Guidance for the Management Systems Review Process* (EPA QA/G-3).

If the organization'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 consistent with the description in Section 3.4.3.

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

If the organization conducts Readiness Reviews, the nature and purpose of these reviews should be described here. The schedule and reports resulting from this type of audit should be consistent with the description in Section 3.4.3.

#### 3.4.2.2 Assessment of Program Activities

A. *Surveillance.* Surveillance is the continual or frequent monitoring of the status of an activity and the review of records related to that activity to ensure that specified requirements are being met.

If the organization's program conducts surveillance, the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be consistent with the description in Section 3.4.3.

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 a 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 on a regular basis, which provides the opportunity for corrective action and continuous improvement. A TSA can be carried out on field activities, laboratory activities, or the entire system. It can be an informal internal audit (for example, a laboratory QA Officer performing an audit in one particular section of the laboratory), or it be a formal, comprehensive audit 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 laboratory-only TSA may be conducted, for example, of a contract laboratory supporting a monitoring program or of a laboratory supporting an individual project. This type of audit examines system activities, project analyses, or laboratory performance. For example, a laboratory TSA may be triggered as a result of out of control QC results. In that case, the QA Manager could conduct an inquiry into SOP compliance for method preparation, spiking procedures and/or instrument calibration. A QAPrP should describe how the report of the findings would be submitted for review to management. It is recommended that the findings be summarized in an annual QA report (see Section 3.5.2).

It is recommended that TSAs be conducted on a routine basis, quarterly or annually by QA personnel or persons knowledgeable in assessing QA management practices (see Section 3.4.3.2) who are independent of and lateral to the chain of authority responsible for laboratory

management. Field or laboratory audits of selected systems could be staggered throughout the year. The use of standardized audit forms or checklists, which could be included with a QAPrP as appendices, can help facilitate a TSA program.

If the Program's policy is to conduct regular TSAs, the extent and purpose of these audits should be described here. The process by which a TSA would be initiated should be described and the individual or individuals who would conduct such audits identified. The schedule and reports resulting from this type of audit are described later in Section 3.5.2.

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. Samples are sent "blind." This means that the contents and concentrations are unknown to those operating the measurement system. A "single blind" PE sample is one where the laboratory knows it is a PE sample, but is not aware of the contents. Usually, the type of analysis is specified (e.g., metals, nutrients) and the sample comes prepared full strength or concentrated in an ampoule to be made up. A "double blind" PE often provides more representative results since it is sent as if it is an environmental sample. This approach ensures that it is handled routinely. A QAPrP the program activities or policies with respect to when the use of a PE sample might be mandatory or recommended.

Some EPA regulations and EPA-approved methods require the successful analysis of PE samples before the results of the test can be considered valid. PE materials are available from a variety of commercial sources and, under limited circumstances, from EPA. A QAPrP should discuss how acceptance criteria are established and what corrective action will be taken in the event that PE results are unacceptable. In many cases, this may be described in a project-specific QA Plan, but if an organization has contract laboratories, a QAPrP would be a more appropriate place to describe required corrective action. PE samples may be generated in a process internal to the laboratory, provided by the QA Officer, sent by the organization submitting the environmental samples, or provided by an independent third party.

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 how 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, but is usually carried out at the laboratory and does not result in the flagging of individual data points. This enables the reviewer to evaluate information not provided in the data package and to directly validate information that was provided.

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. This review adds a level of confidence that the data generated from a specific sample or set of samples are the result of the analyses performed and ensure the defensibility of data.

If the organization's Program conducts ADQs, the extent 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 the data verification and data validation that is performed after the data have been sent to the user. The schedule and reports of this type of audit should be described in Sections 3.4.3 and 3.4.3.4.

E. *Peer review.* Peer review is not strictly an internal QA function, as it may encompass non-QA aspects of a program activity and is primarily designed for research projects. There are two types of peer review: formal and informal.

An example of an informal peer review would be a bench chemist asking a colleague to review his or her data before a report is written. Informal peer review serves as a first level quality check of analytical data. For example, a peer reviewer may be asked 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 data review to a supervisor.

Whether to initiate a formal peer review 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 where the data will ultimately be published. The subject of the review is a finished product, perhaps a report of a special study. Reviewers should have technical expertise in the research area, but are independent of the data collection activity. This type of peer review ensures that program activities were technically adequate, competently performed, properly documented satisfied established technical requirements and met established QA requirements. In addition, formal 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 to the organization's peer-review policy and guidance. The names, titles, and positions of the peer reviewers should be known to the QA Officer and provided in a QAPrP if they are used on a regular basis (for example, in the form of a scientific advisory board). The types of projects that will undergo peer review should be described. 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 should be included. This section should discuss how responses to peer reviews will be documented and handled, and where responses to peer-review comments will be maintained.

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 non-mandatory 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 program activities will generate sufficient data to permit statistical assessment. This section should describe program expectations as to when such assessments may be appropriate.

### 3.4.3 Documentation of Assessments

This section relates to the documentation of assessments. It should identify the organization and person(s) that may 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 Number, Frequency, and Types of Assessments

Depending upon the nature of the program activity, there may be more than one assessment. If these are performed according to a schedule, then the number, frequencies, timing, and types of assessments required should be given.

Technical systems audits may be conducted by trained field or laboratory personnel and/or quality assurance staff to evaluate the implementation and use of internal SOPs and other Quality Assurance Planning documents, and to encourage good Quality Assurance practices. While annual audits of representative field and laboratory operations is a minimum recommendation, it is conceivable that specific portions of these respective operations (field and laboratory) 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. A final report containing the results of those specific systems audits can be submitted to management at the end of an annual cycle.

Field and laboratory assessments may be performed through the use of a standardized protocol and/or list of minimum requirements which will define the style and scope of an audit and which will provide a list of criteria by which operational deficiencies can be detected (see Section 3.4.3). 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 as appendices.

#### 3.4.3.2 Assessment Personnel

In an effort to define the scope of authority of the assessors, program management should enumerate the conditions under which the assessors are authorized to require corrective action and the scope of their authority. A QAPrP should specify the individuals, or at least the specific

organizational units, who will perform assessments. Internal audits are usually performed by personnel who are organizationally independent of and lateral to the chain of authority responsible for field and laboratory operations. External audits are performed by personnel from organizations not connected with the program, but who are technically qualified and who understand the QA requirements of the program or project.

It is the responsibility of program management to designate appropriate personnel and to charge these officials with auditing responsibility and authority. If the overall organization has a QA Officer who supports multiple programs, this person might be the most organizationally independent auditor. This has advantages in terms of providing independent assessment, but increases the probability that the individual will have limited program knowledge of the activity.

It is also acceptable that key members within a chain of command are charged with QA responsibilities for different aspects of the process. The Sample Custodian may be responsible for sample tracking, history and custody; peer reviewers and/or a QA Officer may have the responsibility of assessing data accuracy and validity; and finally, management personnel would have the responsibility of performing data assessments. Each staff person would be in a position to perform a limited audit of the other areas, but not to perform an overall assessment. Because all staff members should have some awareness of good QA practices, setting up a peer-to-peer review process may accomplish many of a program's goals without hiring additional staff. Use of managers for audits, especially those in parallel programs can be effective, but often other time demands make this less feasible than using other senior personnel.

#### 3.4.3.3 Schedule of Assessment Activities

A schedule of audit activities, together with relevant criteria for assessment, should be developed to the extent that it is known in advance of program activities. A suggested list of audit areas is provided in Appendix B. This can serve as a guideline for setting up audits of field and laboratory activities. These lists are not comprehensive but are only an example of the type of areas that an audit should address. Each program should define critical audit areas and incorporate them into its plan.

#### 3.4.3.4 Reporting and Resolution of Issues

Audits, peer reviews, and other assessments often reveal practices or procedures that do not conform to the written QAPrP. To the extent that such findings can be anticipated, a plan should discuss how response actions to non-conforming conditions will be addressed and by whom. Because these issues must be addressed in a timely manner, the protocol for resolving them should be given together with the proposed response 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 be discussed in this section. A QAPrP should also identify who is responsible for implementing response actions and describe how response actions will be verified and documented. Program personnel who should receive assessment reports should be listed.

## 3.5.2 Reports to Management

### 3.5.2.1 Purpose/Background

Effective communication between all personnel is an integral part of a quality system. Planned reports provide a structure for informing 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.

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 that 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 Frequency, Content, and Distribution of Reports

A 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 that it provides 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 during the program activities may not meet quality requirements. Audit reports, submitted in a timely manner, will provide an opportunity to implement corrective actions when most appropriate.

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 or designee with the assistance of senior staff. The report is submitted to the Division Manager in written or oral form, depending on the problems observed.” Each agency or program should determine the level of QA reporting is requires given its organizational structure, resources, and priorities.

Reports of this type might document the following:

- Changes in Quality Assurance Project Plans;
- Summary of QA/QC programs, training and accomplishments;
- Results of technical systems and performance evaluation audits;
- Significant QA/QC 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 QA objectives for different projects 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.

Although this guidance has no specific requirements, it is suggested that QA reports to management or a program leader might be required for any of the following issues:

- Sampling and support equipment other than that specified in the approved QA Program/Project Plan were used;
- Preservation or holding time requirements for any sample that were not met;
- Quality control checks (field and laboratory) were found to be unacceptable;
- 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 was initiated;
- An internal or external systems or performance audit was conducted; or
- An activity or event was noted that affected the quality of the program's 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 is appropriate for the organization. The reports should be consistent with existing field and laboratory QA program reporting formats. Other information specific to program requirements or needs may also be included.

Title Page - The following information must be listed:

- Time period of the report,
- QA Project Plan Title and/or Plan number,
- Laboratory name, address and phone number,
- Preparer's name and signature.

Table of Contents - Should be included if the report is more than ten pages long.

Audits - In table form, summarize all project specific audits that were performed during the specified time period:

Performance audits must include the following:

- Date of the audit
- System tested
- Who administered the audit
- Parameters analyzed
- Reported results
- True values of the samples (if applicable)
- If any deficiencies or failures occurred, summarize the problem area and the corrective action

Systems audits must include the following:

- Date of the audit
- System tested
- Who administered the audit (agency or department)
- Parameters analyzed,
- Results of tests,
- Parameters for which results were unacceptable (include the reported and true values, if applicable),
- Explanation of the unacceptable results. Include probable reasons and the corrective action.

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

#### Significant QA/QC Problems

- Identify the problem, and the date it was found
- Identify the individual who reported the problem
- Identify the source of the problem
- Discuss the solution and corrective actions taken to eliminate the problem

#### Corrective Actions Status

- Discuss the effectiveness of all corrective actions taken during the specified time frame as well any initiated during the previous report period,
- Discuss any additional measures that may be implemented as the result of any corrective action.

#### 3.5.2.3 Identify Responsible Individuals

It is important that a 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 DATA REVIEW**

The elements in this section address the QA activities that occur after the data collection phase is completed. Programs should have a system in place to ensure that the data it uses are complete and usable. This will require an evaluation to determine whether or not the data conform to program or project specified criteria as described in a QAPrP or in more project specific QA planning documents. Finally, there needs to be a mechanism in place to describe how data usability will be assessed

### 3.6.1 Data Verification, Validation and Assessment

This section of a QAPrP should define the different steps in the data review process, specifically data verification, validation, and assessment.

#### 3.6.1.1 Purpose/Background

The data review process should consist of three parts: verification, validation and assessment. Each program should define these terms to meet its needs. Users of this guidance should be aware that the suggested definitions and approaches to these three stages of data review are not completely consistent with national guidance provided by EPA. Definitions of these terms by different programs within the agency (Superfund, Air, Water, etc.) also may differ. The Region 9 QA Office has established its definitions as a guide or starting point. Consistency with other guidance is considered less critical than the importance of each state or tribal program establishing, defining, and documenting its own approach.

#### 3.6.1.2 Data Verification

Data verification is a process for evaluating the completeness, correctness, consistency, and compliance of data and/or QC data against a standard or contract. During data verification, results are evaluated for conformance to criteria established in the QAPrP, individual QA Project Plans, Sampling and Analysis Plans, SOPs, or analytical methods. The purpose is only to identify deficiencies, not to make recommendations. In this phase of data review, the reviewer examines the data submission for completeness and acceptability and whether all required information was submitted and whether the supporting QC data met the various criteria established in methods, SOPs, or QA planning documents. A QAPrP should discuss minimum programmatic expectations in terms of what information would typically be reviewed as part of the verification step. To the extent possible, the plan should identify the individual or individuals who would be responsible. In many cases, this decision might not be defined until a project-specific QA planning document is prepared, but, if this is the case, it should be stated. Verification applies to all aspects of data generation, both sampling and analytical.

#### 3.6.1.2 Data Validation

Data validation, as distinguished from verification, focuses on the analytical data themselves. In this part of data review process, an effort is made to evaluate the degree to which bias is present and to label data accordingly. Data identified as not conforming to criteria established for the program or project would be “flagged” or labeled in some way to alert the end user that problems were identified. It is desirable for the program to define the flags that it uses so that individuals or organizations generating data will know how acceptable or questionable data are to be labeled. This helps analytical laboratories, contractors, or other data generators providing data to the program, to flag data appropriately and consistently, minimizing “translation” steps required before the data can be used. Region 9 recognizes that validation requirements may differ depending on the source and eventual use of the data. The three

categories it uses are partial validation, focused validation, or full validation. These will be described more fully below. Other organizations should document their alternative systems in their plans. There is no requirement that these be consistent with Region 9, only that the system be described.

### 3.6.1.3 Data Assessment

Data assessment is the process of using the results of the verification and validation steps in conjunction with any other information known about the data collection event to determine overall data usability. If a program has guidelines defining data assessment, they should be described here. Data assessment is the last step before actual decisions are made, and brings together all the information known about the data. Generally, it will be a project or program manager who will perform this function, but the program plan should describe who is responsible.

### 3.6.2 Approaches to Verification, Validation, and Assessment

This section should describe what procedures are used in the verification, validation, and assessment steps described in the previous sections. Since a QAPrP is a policy document, this might consist of citing or including references, checklists, or SOPs developed for the purpose. A QAPrP should build on its definitions of “verification,” “validation,” and “assessment” provided in the sections above and make sure the approach is consistent with program definitions.

The organization should identify the individuals responsible for each step in the data verification, validation, and assessment processes, as well as the lines of authority, unless those responsibilities were described earlier in the roles and responsibilities section. In some organizations, this responsibility may be divided up, depending on the nature of the measurement activity and data generation responsibilities. These roles may also involve multiple organizations. For example, a contractor may have validated data on which the program will, in turn, perform a review.

The program should describe how data generators and data users should estimate the potential effect that each deviation from the Program’s QAPrP, project specific QAPjPs, contract laboratories’ QA plans, established SOPs, or other documents may have on the usability of the associated data. Requirements should apply to internally generated data, contractor generated data, and to data provided to the Program by external parties (i.e., secondary data).

EPA’s guidance on data verification is *Guidance on Environmental Verification and Validation*, (EPA QA/G-8). As previously mentioned, this Program Plan guidance should be aware that not all the definitions in this national guidance are consistent with those accepted by Region 9.

#### 3.6.2.1 Approaches to Data Verification

Programs should define their approach or approaches to data verification in this section. Region 9 encourages the use of checklists or preprinted forms with provisions for comments if a discrepancy is noted. It may be desirable to have field and laboratory checklists. Completeness of field measurements and supporting data, such as field instrument calibration, and the collection and proper shipping of the samples might be required field checklist elements. For the laboratory, the checklist might include: timely receipt of properly preserved and quality samples; percent of sample received that were actually analyzed; completeness of required data and metadata; completeness of QC checks; acceptability of QC checks. The intent is only to identify deficiencies or deviations from what was planned.

Verification can also be “contract compliance screening”, wherein deliverables from a laboratory are evaluated to ensure that all contractual requirements have been met. This may also be considered as a “forms review”. The latter terminology derives from a review of laboratory data reported on SW-846 forms or in equivalent tables. Depending on how the data are reported from the laboratory, the analytical part of verification may be conducted using software programs. If this is the case, the program should indicate what program is used and when its use is appropriate.

### 3.6.2.2 Approaches to Data Validation

Region 9 encourages the use of a graded approach to validation. Resource constraints often limit a program’s ability to perform full manual validation of all data unless there is a regulatory requirement, so providing a decision tree that defines when validation is required can be helpful. Region 9’s approach is to separate data validation into several types. The main division is between partial and full validation. In turn, full validation may consist of a focused or a total validation. These concepts will be discussed more fully below. Validation is a process based on the analytical methods, or data generated by instruments located in a laboratory. Field instrument data are seldom validated, although data generated in a mobile laboratory or collected via continuous monitors may be. The program should define the circumstances under which validation would be considered either appropriate or necessary.

A partial validation consists of a review of selected analytical data. This often would be based on discrepancies noted during the verification step. For example, perhaps some, but not all, surrogates in a method requiring an organic extraction are outside method defined acceptance criteria, but other QC data such as the precision of the measurements and blank data are acceptable. This might lead to a review that centered on surrogate recoveries. However, even this targeted review would probably not be done in the depth equivalent to a full validation. The intent would be to qualify data, if appropriate, so that the user is alerted that s/he should understand the limitations when making decisions based on the data.

A full validation requires a detailed examination of all information related to the generation of the analytical data. This may include review of extraction logs, looking at data on standards, checking calibration data, recalculating results, visually examining chromatograms or other raw data, and so forth. In some cases the laboratory staff might need to be interviewed. This process is usually time consuming and expensive, and typically results in data being



“accepted for any use,” “qualified as quantitatively or qualitatively uncertain,” or “rejected.” It is a good idea for a program plan to define acceptable “flags,” rules and provisions for using the flags, and to include a table showing what the various flags mean.

It is recommended that data validation procedures followed by the organization be documented in stand-alone SOPs specific to data verification or validation rather than being embedded in a sampling or analytical method SOP. These could be appended to a QAPrP to be used as the program’s “default” procedure. A QAPrP can also contain provisions that the description of validation procedures, or modification to the default procedures, be deferred to the QAPP or SAP level.

A focused validation is similar to a full validation, but its scope is limited. The data from certain locations may be of greater importance in decision making than others. Certain analytes or class of analytes (e.g., metals, pesticides, gaseous pollutants, etc.) may be of greater interest, so that full validation only is performed on a subset of the total data available.

EPA has several documents relevant to validation. For example, the EPA’s Contract Laboratory Program (CLP) (contract analytical services used by EPA under its Superfund Program) has two documents; “*Functional Guidelines for the Validation of Organic Analyses,*” and “*Functional Guidelines for the Validation of Inorganic Analyses,*” which can be consulted. The applicability of these data validation protocols may be limited because these references are based on data generated using EPA’s Contract Laboratory Program protocols, but they are often used as models for other analytical methods, such as those in SW-846. The Office of Air Quality Planning and Standards (QAQPS) web site should be consulted for validation protocols related to air analyses.

It is beyond the scope of this guidance to provide explicit protocols for validation, since these differ from one program to another. Each organization or program should be explicit in its definitions of validation and the means by which it will be accomplished.

### 3.6.2.3 Approaches to Data Assessment

The purpose of a data assessment is to integrate all aspects of data generation to determine the usability of the data. The final step in the process is to compare the data obtained to the data quality objectives established by the program in its QAPrP or else in project-specific planning documents. Decisions concerning data usability should be made based on a synthesis of all factors. The basic question to be asked is how well the QA Plan was executed in sampling, analysis control. Management is in the best position to evaluate whether all the aspects of the project contributed to the usability of the data. To the extent that the program can anticipate areas where there might be deficiencies that limit the usability of the data, it should provide such guidance.

Listed below are some possible aspects of a program which the data assessment process should evaluate and for which programmatic review policy criteria could be established:

- Sampling Design
- Sample Collection Procedures
- Field Measurements
- Field Quality Control Results
- Sample Handling, Temperature, Holding Times, etc.
- Calibration
- Laboratory Quality Control Results
- Appropriateness of Analytical Procedures
- Data Reduction and Processing

If the verification process finds that not all samples were collected as planned, does this affect the ability to make a decision? Similarly, if data validation identifies problems with a subset of the data so that some data are rejected, does this impair the organization's ability to make decisions? It is up to the person or program using the data to determine how missing, questionable, or rejected data affect the data's usability. In some cases, flagged or rejected data may still be usable. For example, if results greatly exceed action levels even though some QC criteria were not met, then it may still be possible to decide to move forward with a source mitigation effort. If the results are part of an on-going monitoring effort, then historical data can be compared with the recent effort to determine whether the results were reasonable. On the other hand, there may be regulatory requirements that dictate that a program cannot use qualified or rejected data for any purpose. It is useful if QAPrPs define policy with regard to when questionable or rejected data might be used, when an incomplete data set is still sufficient, or when data absolutely are not usable. The program also can choose to state that appropriate personnel will make these decisions on a case-by-case basis.

If appropriate, the program can specify when statistical evaluations of data should be part of the program's approach to data assessment.

### **3.7 RECONCILIATION WITH DATA QUALITY OBJECTIVES**

#### **3.7.1 Purpose/Background**

This section describes whether the overall program or project objectives can be met with the existing data. It describes the process by which it is determined whether there are sufficient data of known quality to make anticipated decisions or even as basic a question as to whether the project was planned properly in the first place.

#### **3.7.2 Reconciling Results with Program Objectives or DQOs**

Program or project DQOs will be defined by each organization's program and are usually based on Federal, state, or tribal regulations or based on the results of a project specific systematic planning process. Reconciliation with DQOs will focus on whether data of sufficient quality and quantity were obtained to meet program goals. Each program should have a process to evaluate data for appropriateness in decision making. This evaluation could be performed by

the data generator and/or the data user. The program defines the roles of each individual in this evaluation process. For enforcement actions, this step would determine whether the data are legally defensible. A QAPrP should discuss its policies with respect to this important feedback loop.

Reconciliation with program objectives is a key part of the assessment phase of the data life cycle from planning through data collection to final use of the data. The reconciliation process can be thought of as an evaluation to determine whether the project is finished, i.e., has met its objectives, or whether some aspect of the project must be repeated as originally planned or in a modified form. An evaluation must be made as to whether objectives were realistic and whether the data were appropriate, sufficient, and usable.

The project might have been successfully completed, but it may turn out the assumptions on which it was based were not correct. A review of a monitoring program may uncover data gaps that require that the network be redesigned before sampling is resumed. The rejection of data or unexpected problems in data collection may result in there being an insufficient number of samples to make a decision.

Even if every aspect of the project turned out as planned, there are improvements in planning, data collection, analysis, or data review that can be applied to future projects or to on-going monitoring efforts. A QAPrP should describe how the data and program/project will be evaluated to ensure that the most appropriate approaches will be taken in the future. The plan should also identify those individuals who will be responsible for this critical activity.

### **3.8 QAPrP REVISIONS**

During the course of a program's evolution, it is expected that changes will occur in program requirements, how the program is organized, how environmental data are collected, how enforcement activities are defined, etc. A QAPrP should be thought of as a dynamic document, subject to revision as needed. EPA recommends that the document be examined and revised internally once a year by the organization and that it be submitted to EPA at least once every five years for approval. This should be discussed and agreed upon by the organization and the Region 9 QA Manager and Project Officer.

The organization should keep its QAPrP current and inform the Project Officer of significant changes so that s/he can decide whether a more formal evaluation of the changes involving EPA review is necessary. During the five-year review, a 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. If not, a QAPrP should be revised and resubmitted. Once approved, a copy of the revised plan 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 5360.1 A2 (May 2000). *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.

EPA QA/G-1 (November, 2002) *Guidance for Developing Quality Systems for Environmental Programs*, EPA/240/R-02/008, 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.

U.S. Environmental Protection Agency, March 2001. *EPA Requirements for Quality Management Plans (QA/R-2)*, EPA/600/R-99/032, Office of Environmental Information.

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

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

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.

U.S. Environmental Protection Agency, 1998b. *Guidance for Quality Assurance Project Plans (QA/G-5)*, EPA/600/R-98/018, Office of Research and Development.

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 types of measures used to determine whether a field or analytical system is under control. Traditionally, these have consisted of precision, accuracy, representativeness, completeness, comparability, and sensitivity (the PARCCS parameters). The numerical or qualitative criteria themselves are defined as quality control (QC) criteria or measurement performance criteria (MPC) if they are of a generic nature such as might be found in a method or a Standard Operating Procedure (SOP). Alternatively these would be measurement quality objectives (MQOs) if they are associated with an actual data generation event such as would be described in a Sampling and Analysis Plan, a Quality Assurance Project Plan, or an on-going program

**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 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.

**Measurement Quality Objectives (MQOs)** – Quantitative or qualitative criteria used to define quality control limits used in sampling and analytical measurements related to a specific project or program. These measures are used to determine whether data are accepted, qualified, or rejected for their intended use. These might include, but not be limited to: blank acceptance criteria, matrix spike recoveries, duplicate or matrix spike duplicate recoveries, relative percent difference between duplicates or matrix spike duplicates, surrogate recoveries, laboratory control sample recoveries, calibration acceptance criteria, detection limits, reporting limits, percent completeness, etc.

**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 needs to be supported by a quality system. A QAPrP should define QA/QC policies and the QA/QC and technical activities that must be implemented to ensure that results of the work performed will ensure that data generated by or 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. Often, but not exclusively, used for one-time events.

**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.

## **APPENDIX B**

### **SUGGESTED AUDIT AREAS**

Minimum Topics for Internal Laboratory Audit.

#### **GENERAL PROCEDURES**

Documentation of Procedures,  
Sample Receipt and Storage,  
Sample Preparation,  
Sample Tracking.

#### **ANALYTICAL METHODS**

General Instrumentation Performance,  
Calibration Procedures,  
Extraction Procedures,  
Internal Quality Control,  
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. Alternatively, a SOP or audit checklist could be included as an appendix and then not have to be repeated here.

#### **ANALYTICAL METHODS**

General Instrumentation Performance.

Instrument performance records are maintained and include the following items:  
Initial demonstration of capability,  
Determination of linear dynamic range,  
Method detection limits,  
Initial and routine instrument calibration,  
Performance of standard reference materials and/or QC check samples,  
Instrument sensitivity and stability, and  
Tuning checks.

The following is a suggested field audit list. It is not meant to be inclusive but is provided here as an example.

Minimum Topics for Field Audit.

#### **GENERAL FIELD PROCEDURES**

Field Standard Operating Procedures,  
Interviews,

Investigations/Inspections, and  
Field Records.

Specific assessment points may include some of the following:

GENERAL FIELD PROCEDURES

Field Standard Operating Procedures  
Site Assessment,  
Establishing Chain-of-Custody,  
Equipment Calibration,  
Decontamination Procedures,  
Well Development, Sampling Records.

Interviews

Interview Records,  
Questionnaires, and  
Documentation of Site Characteristics.