

APPENDIX D

CONTENT OF PROJECT PLAN DOCUMENTS

D.1 Introduction

Project plan documents were discussed in Chapter 4, *Project Plan Documents*. This appendix will discuss appropriate content of plan documents. The content of project plan documents, regardless of the document title or format, will include similar information, including the project description and objectives, identification of those involved in the project activities and their responsibilities and authorities, enumeration of the quality control (QC) procedures to be followed, reference to specific standard operating procedures (SOPs) that will be followed for all aspects of the projects, and Health and Safety protocols.

The discussion of project plan document content in this appendix will rely on EPA's guidance on elements for a QA project plan (QAPP). MARLAP selected EPA's QAPP as a model for content of a project plan document since it is closely associated with the data quality objective (DQO) planning process and because other plan documents lack widely accepted guidance regarding content. MARLAP hopes that presentation of a project plan document in one of the most commonly used plan formats will facilitate plan writing by those less familiar with the task, provide a framework for reviewing plan documents, and aid in tracking projects.

The discussion of plan content in Sections D2 to D5 follows the outline developed by EPA requirements (EPA, 2001) and guidance (EPA, 2002) for QAPPs for environmental data operations. The QAPP elements are presented in four major sections (Table D.1) that are referred to as "groups":

- Project Management;
- Measurement/Data Acquisition;
- Assessment/Oversight; and
- Data Validation and Usability.

There are many formats that can be used to present the project plan elements. MARLAP does not recommend any particular plan format over another. The project planning team should focus on the appropriate content of plan documents needed to address the necessary quality assurance (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. Table D.2 provides a crosswalk between the table of

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contents of two example project plan documents—a QAPP and a work plan—and EPA’s (2002) project plan document elements.

TABLE D.1—QAPP groups and elements ^{a,b}

GROUP	ID	ELEMENT	APPENDIX SECTION	MARLAP CHAPTER
A Project Management	A1	Title and Approval Sheet	D2.1	NA
	A2	Table of Contents	D2.2	NA
	A3	Distribution List	D2.3	NA
	A4	Project/Task Organization	D2.4	2
	A5	Problem Definition/Background	D2.5	2
	A6	Project/Task Description	D2.6	2
	A7	Quality Objectives and Criteria for Measurement Data	D2.7	2, 3
	A8	Special Training Requirements/Certifications	D2.8	7
	A9	Documentation and Record	D2.9	7, 16
B Measurement/Data Acquisition	B1	Sampling Process Design	D3.1	NA
	B2	Sample Methods Requirements	D3.2	NA
	B3	Sample Handling and Custody Requirements	D3.3	11
	B4	Analytical Methods Requirements	D3.4	6
	B5	QC Requirements	D3.5	18
	B6	Instrument/Equipment Testing, Inspection and Maintenance Requirements	D3.6	15
	B7	Instrument Calibrations and Frequency	D3.7	18
	B8	Inspection/Acceptance Requirements for Supplies and Consumables	D3.8	NA
	B9	Data Acquisition Requirements (Non-direct Measurements)	D3.9	2
	B10	Data Management	D3.10	16
C Assessment/Oversight	C1	Assessments and Response Actions	D4.1	7
	C2	Reports to Management	D4.2	9
D Data Validation and Usability	D1	Verification and Validation Requirements	D5.1	8
	D2	Verification and Validation Methods	D5.2	8
	D3	Reconciliation with Data Quality Objectives	D5.3	9

(a) Based on EPA, 2002.

(b) MARLAP recommends a graded approach to project plan documents. All elements may not be applicable, especially for a small project. See Section 4.3, “A Graded Approach to Project Plan Documents” and Section 4.5.3, “Plan Content for Small Projects.”

This appendix also will discuss how the project plan document is linked to the outputs of the project planning process. Directed project planning is discussed in Chapter 2, *Project Planning Process*. The discussion of project plan documents in this appendix will use the DQO process

(EPA, 2000a) as a model for directed planning (see Appendix B, *The Data Quality Objectives Process*). References will be made in this appendix to the steps of the DQO process, where appropriate, to illustrate the linkage between the direct planning process and plan documents.

TABLE D.2—Comparison of project plan contents
I. Example QAPP^a using EPA guidance^b and EPA QAPP elements^b

QA PROJECT PLAN FOR RADIOLOGICAL MONITORING TABLE OF CONTENTS	EPA G-5 QA PROJECT PLAN ELEMENTS
Title Page Approval Sheet Distribution List	A1 Title and Approval Sheet A3 Distribution List
1.0 Table of Contents	A2 Table of Contents
2.0 Project Description 2.1 Site History 2.2 Project Objectives and Requirements 2.3 DQOs	A5 Problem Definition/Background A6 Project/Task Description
3.0 Project Organization and Responsibility	A4 Project/Task Organization
4.0 QA Objectives for Measurement Data (Precision, Accuracy, Representativeness, Comparability, Completeness)	A7 Quality Objectives and Criteria for Measurement Data
5.0 Sampling Procedures, including QC [Cited Field Sampling and Analysis Plan]	B1 Sampling Process Designs B2 Sampling Methods Requirements
6.0 Sample Custody 6.1 Sample 6.2 Sample Identification 6.3 COC Procedures	B3 Sample Handling and Custody Requirements
7.0 Calibration Procedures and Frequency (Field and Laboratory)	B7 Instrument Calibration and Frequency
8.0 Analytical Procedures 8.1 Background 8.2 Specific Analytical Procedures 8.3 Test Methods 8.4 Control of Testing 8.5 Limits of Detection	B4 Analytical Methods Requirements B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
9.0 Data Reduction, Validation and Reporting and Record	B10 Data Management D1 Data review, Validation, and Verification Requirements A9 Documentation and Records
10.0 Internal QC Checks	B5 Quality Control Requirements
11.0 Performance and Systems Audits 11.1 Systems Audits 11.2 Surveillance 11.3 Performance Audits 11.4 Resolution of Discrepancies 11.5 Review of Contractor Procedures	C1 Assessment and Response Actions
12.0 Preventive Maintenance	B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
13.0 Specific Routine Procedures to Assess Data Precision, Accuracy, Completeness	D3 Reconciliation with DQOs

Content of Project Plan Documents

QA PROJECT PLAN FOR RADIOLOGICAL MONITORING TABLE OF CONTENTS	EPA G-5 QA PROJECT PLAN ELEMENTS
14.0 Corrective Action	
15.0 QA Report to Management	C2 Response to Management
16.0 References	
	A8 Special Training Requirements/Certification
	B8 Inspection/Acceptance Requirements for Supplies and Consumables
	B9 Data Acquisition Requirement for Non-direct Measurements
	D2 Verification and Validation Methods

II. Example work plan^c and EPA QA/G-5 QAPP elements^b

Work Plan Table of Contents	EPA QAPP Elements
Cover Letter	A3 Distribution List
Title Page (including Document Number, Prepared by/Prepared for Identification)	A1 Title and Approval Sheet
Approvals	A1 Title and Approval Sheet
Table of Contents	A2 Table of Contents
1 Introduction/Background	
Site and Regulatory Background	A5 Problem Definition/Background
Project Scope and Purpose	A6 Project/Task Description
Project Organization and Management	A4 Project/Task Organization
Data Quality Objectives and Approach	A7 Quality Objectives and Criteria for Measurement Data
Environmental Setting	A5 Problem Definition/Background
Sampling Site Selection, Locations and Identification	B1 Sampling Process Design
2 Sampling and Analysis Plan	
Objective	B1 Sampling Process Design
QA Objectives for Field Measurements, Laboratory Measurements (including Calibration Procedures and Frequency)	A7 Quality Objectives and Criteria for Measurement Data B7 Instrument Calibrations and Frequency
Sample Collection Procedures	B2 Sample Methods Requirements
Sample Identification, Handling and Transport	B3 Sample Handling and Custody Requirements
Sample Analysis	B4 Analytical Methods Requirements
Sample Tracking and Records	B10 Data Management
Data Reduction, Validation and Reporting	D1 Data Review, Verification, and Validation Requirements D2 Verification and Validation Methods
Internal QC Checks	B5 QC Requirements
3 QA Project Plan	
QA Training and Awareness	

Work Plan Table of Contents	EPA QAPP Elements
Performance and Systems Audits	C1 Assessments and Response Actions
Preventive Maintenance	B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
Quality Improvement	B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
QA Reports to Management	C2 Reports to Management
Purchase Items and Service Control	B8 Inspection/Acceptance Requirements for Supplies and Consumables
4 Data and Records Management Plan Objectives Data Management Document Control Records Management System Administrative Records	A9 Documentation and Record B10 Data Management
5 Data Interpretation Plan Approach for Data Evaluation Data Interpretation and Comparisons	D3 Reconciliation with DQOs
6 Risk Analysis Plan	—
7 Health and Safety Plan	—
	B9 Data Acquisition Requirements (Non-direct Measurements)
	A8 Special Training Requirements/Certifications

- (a) Plan elements adapted from DOE, 1997.
- (b) EPA, 2002
- (c) Plan elements adapted from DOE, 1996.

It should be noted that although the project plan documents will address both sampling and analysis, MARLAP does not provide guidance on sampling design issues or sample collection. Discussion in D3.1, “Sample Process Design,” and D3.2, “Sample Methods Requirements,” are provided for completeness and consistency.

D.2 Group A: Project Management

This group consists of nine elements that address project management issues such as organization of the plan itself, management systems, and a description of project goals, participants and activities. These elements ensure that the project goals are clearly stated, the approach to be used is understood, and the project planning decisions are documented.

D.2.1 Project Management (A1): Title and Approval Sheet

The project title sheet should:

- Clearly identify the project in an unambiguous manner;

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- Include references to organizational identifiers such as project numbers (when appropriate);
- Clearly label and distinguish between draft and approved versions;
- Include the date of issuance of drafts or final approved version;
- Include revision or version numbers;
- Indicate if the document represents only a portion of the QAPP (e.g., Volume 1 of 4 Volumes);
- Include names of the organization(s) preparing the plan document and, if different, for whom the plan was prepared; and
- Identify clearly on the title page if the document is a controlled copy and subjected to no-copying requirements. If so, indicate the document control number.

QAPPs should be reviewed on an established schedule. QAPPs should be kept current and revised when necessary. Documented approval, as an amendment to the QAPP, should be obtained for modifications to the QAPP.

The approval sheet documents that the QAPP has been reviewed and approved prior to implementation. The approval sheet should consist of the name, title, organization, signature and signature date for:

- The project manager or other person with overall responsibility for the project;
- The QA manager or other person with overall responsibility for the quality of the project outputs;
- The project managers or QA managers for all organizations (e.g., sampling organization, laboratories, data validators) implementing project activities; and
- The representative of any oversight or regulatory organization.

The project manager or other person with overall responsibility for the project should require an approved QA program, management plan, or quality manual that supports all technical operations, including data collection and assessment activities.

D.2.2 Project Management (A2): Table of Contents

The table of contents should:

- List all sections and subsections of the document, references, glossaries, acronyms and abbreviations, appendices (including sections and subsections) and the associated page numbers;
- List all attachments and the associated page numbers;
- List all tables and associated page numbers;
- List all figures and diagrams and associated page numbers; and
- List titles of other volumes, if the QAPP consists of more than one volume.

A document control format is useful in maintaining reference to the latest version of the planned document, especially when only portions of a document have been copied and are being used to implement or discuss project activities.

D.2.3 Project Management (A3): Distribution List

The distribution list should identify all individuals, along with their titles and organizations, who will receive copies and revisions of the approved QAPP and subsequent revisions. Listed individuals should include, at a minimum, all managers and QA personnel responsible for the implementation and quality of the data collection activities. The project planning team or the core group (Section 2.4) should be included on the document distribution list.

D.2.4 Project Management (A4): Project/Task Organization

This QAPP element should:

- Identify the individuals and/or organizations participating in the project, as well as contact information (address, telephone number, fax number, e-mail). The stakeholders, data users, decision makers, and technical planning team members, and the person or organization that will be responsible for project implementation, are identified during the directed planning process (Appendix B, *The DQO Process*, Steps 1 and 7).
- Discuss the roles and responsibilities of the individuals and/or organizations that participate in the data collection, including the roles and responsibilities of the data users, decision makers, and QA manager.

- Include an organizational chart clearly showing the relationship, lines of authority and communication, and mechanisms for information exchange among all project participants.

Complex projects may require more than one organizational chart to properly describe the relationships among participants. At times, to clearly detail an organizations responsibilities and communications, a general inter-organizational chart with primary contacts, responsibilities, and communications may need to be accompanied by secondary charts that describe intra-organizational contacts, responsibilities, and lines of communication.

One of the keys to successful projects is communication. The QAPP should identify the point of contact for resolving field and laboratory problems. The QAPP may also summarize the points of contact for dissemination of data to managers, users and the public.

D.2.5 Project Management (A5): Problem Definition/Background

The “Problem Definition/Background” element (A5) and the subsequent elements “Project/Task Description” (A6) and “Quality Objectives and Criteria” (A7) constitute the project description. Separating the project description into three elements focuses and encourages the plan authors to address all key issues (identification of problem to be solved, description of site history, description of tasks and the quality objectives and data-acceptance criteria), some of which can be overlooked if a larger, less-focused section is written. Table D.3 provides bulleted components for these three elements. This section and sections D.2.6 and D.2.7 provide a more detailed discussion of these elements.

TABLE D.3—Content of the three elements that constitute the project description

Problem Definition/Background (A5)	Project/Task Description (A6)	Objectives and Criteria (A7)
<ul style="list-style-type: none"> • Serves as an Introduction • Identifies the “problem to be solved” or the “question to be answered” • Identifies the regulatory, legal or “informational needs” drivers • Presents the historical perspective 	<ul style="list-style-type: none"> • Describes measurements • Identifies regulatory standards and action levels • Identifies special personnel, procedural and equipment requirements • Summarizes assessment tools • Details schedule and milestones • Identifies record and report requirements 	<p>Quality Objectives</p> <ul style="list-style-type: none"> • Problem definition/Site history • Data inputs • Population boundaries • Tolerable decision error rates <p>Criteria for Measurement Data</p> <ul style="list-style-type: none"> • Measurement quality objectives (MQOs; such as the measurement uncertainty at some concentration; the detection capability; the quantification capability; the range; the specificity; and the ruggedness of the method)

The Problem Definition/Background element provides the implementation team with an understanding of the pertinent context of the project. This section does not discuss the details of project activities, which are described in a subsequent project management element. Much of the information needed for this element was collected and discussed during Step 1 of the DQO process (Appendix B3.1). The decision statement was developed during Step 2 of the DQO process.

The “Problem Definition/Background” element should:

- Introduce the project;
- Identify the “problem to be solved” or the “question to be answered” upon successful completion of the project—the decision rule (Appendix B3.6);
- Discuss the assumptions, limitations, and scope of the project;
- Identify the regulatory, legal, or “informational needs” drivers that are the underlying reasons for the project; and
- Describe the context of the project so that it can be put into a historical perspective. This section may include a description and maps of a facility or site, its location, its use, site topography, geology and hydrogeology, past data collection activities, historical data including analytes and concentrations, past and present regulatory status, past releases, seriousness and potential risk of any release, site maps, and utilities.

If the data collection activity is in support of a technology evaluation, it should also discuss the purpose of the demonstrations, how the technology works, its operating conditions, any required utilities, its effluents and waste by-products and residues, past and expected efficiencies, and multi-media mass-balances by analyte and matrix.

D.2.6 Project Management (A6): Project/Task Description

This element of the QAPP provides a discussion of the project and underlying tasks for the implementation teams. It should provide a description of the work to be performed to resolve the problem or answer the question, including the following information:

- A description of the measurements and the associated QA/QC procedures that are to be made during the course of the project. DQO Step 3 describes existing and needed data inputs, while Step 7 yields the optimized sampling and analytical designs as well as quality criteria.
 - Identification of the analytes of interest.

- A summary (preferably a table) of samples type (e.g., grab, spatial or temporal composite), number of samples, analyte or analyte class (e.g., ⁹⁹Tc, transuranic, gamma emitters) and analytical protocol specifications or method.
- A discussion of applicable regulatory standards or action levels to which measurements will be compared. Identify any applicable regulatory standard (e.g., gross alpha drinking water maximum contamination limit), or applicable or relevant and appropriate requirements (ARARs) that will be used as a metric or action level during decision-making. The DQO Step 6 details action levels and tolerable decision errors that will be the basis for decisions.
- Identify any special requirements required to implement project tasks.
 - Identify any special training (e.g., hazardous waste site health and safety training (29 CFR 1910.120), radiation safety training).
 - Identify any special protective clothing and sampling equipment.
 - Identify any boundary conditions (e.g., only sample after a rainfall of more than 1 inch).
 - Specify any special document format, chain-of-custody, or archival procedures.
 - Identify any special sample handling (e.g., freezing of tissue samples), instrumentation, or non-routine analytical protocols that are required to achieve specified performance criteria (e.g., very low detection limits) (see also Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*).
- Summarize the assessment tools that will be employed to determine whether measurement data complied with performance criteria and are suitable to support decision-making. Include a schedule of the assessment events. Assessment tools include performance evaluations, program technical reviews, surveillance, technical and systems audits, and verification and validation. Briefly outline:
 - A first tier of reviews (e.g., when field or lab personnel check each other's notes or calculations).
 - Reviews of the work, notes and calculations of subordinates by the supervisor (e.g., review and sign all notebook entries).
 - The percentage of data subject to review by internal QA staff.
 - Data verification and validation to be performed by an independent party and the guidelines or plan to be used.
 - Assessment of project activities to be conducted by personnel independent of project activities (e.g., performance evaluation samples, surveillance, audits).
 - Assessment of how results of the project will be reconciled with the project DQOs ("data quality assessment").
- Supply a schedule that includes start and completion dates for tasks and a list of completion dates for important milestones. Dates can be calendric, or as number of days following approval of the QAPP, or number of days following commencement of field operations. DQO Steps 1 and 4 identify deadlines and other constraints that can impact scheduling.

- Identify the records and reports that will be required. This should be a brief but complete listing of necessary reports and records (e.g., field and lab notebooks, sample logbooks, spectra, sample tracking records, laboratory information system print-outs, QA reports, corrective action reports).
- Identify whether the original documents are required or if photocopies are sufficient. More detailed information will be presented in “Documentation and Records” (A9) and “Data Management” (B10).

D.2.7 Project Management (A7): Quality Objectives and Criteria for Measurement Data

This element addresses two closely related but different issues, quality objectives for the project and criteria used to evaluate the quality of measurement data. The element summarizes outputs from all steps of the DQO process. A fundamental principle underlying plan documents is that requirements for the data quality must be specified by the project planning team and documented. By clearly stating the intended use of the data and specifying qualitative and quantitative criteria for system performance, a critical link between the needs of the project planning team and the performance requirements to be placed on the laboratory data is established. (See Chapter 3 for a discussion of MQOs.)

D.2.7.1 Project’s Quality Objectives

The project’s quality objectives or data quality objectives (DQOs) are qualitative and quantitative statements that:

- Clarify the intended use of the data (e.g., data will be used to determine if lagoon sediment contains ^{232}Th at concentrations greater than or equal to the action level);
- Define the type and quantity of data per matrix needed to support the decision (e.g., ^{232}Th concentrations in 300 composite sediments samples each composite consisting of 10 samples randomly collected from a 100 m² sampling grid adjacent to the point of discharge);
- Identify the conditions under which the data should be collected (e.g., sediment samples collected from the top 6 cm of sediment within a 100 m radius of the point of discharge into lagoon #1, following de-watering of the lagoon and prior to sediment removal); and
- Specify tolerable limits on the probability of making a decision error due to uncertainty in the data and any associated action levels (e.g., 95 percent confidence that the true concentration is actually below the action level).

Authors of project plan documents are often encouraged to condense the DQO outputs in a summary statement. This approach can have value as long as critical information is not lost in the summary process and the original information is cited and available for all project participants. The following is an example of a DQO summary statement:

“The purpose of this project is to determine, to within a lateral distance of 10 m, the extent of ²³²Th in soil along a pipeline at concentrations at or above 1,145 mBq/g, with a Type I error rate less than or equal to 5 percent; and to define within 1 m the vertical extent of measured ²³²Th concentrations greater than 7,400 mBq/g.”

D.2.7.2 Specifying Measurement Quality Objectives

Measurement quality objectives (MQOs) or measurements performance criteria are essential to the success of a project since they establish the necessary quality of the data. The quality of data can vary as a result of the occurrence and magnitude of three different types of errors (Taylor, 1990).

- BLUNDERS—mistakes that occur on occasion and produce erroneous results (e.g., mis-labeling or transcription errors);
- SYSTEMATIC ERRORS—mistakes that are always the same sign and magnitude and produce bias (i.e., they are constant no matter how many measurements are made); and
- RANDOM ERRORS—mistakes that vary in sign and magnitude and are unpredictable on an individual basis (i.e., random differences between repetitive readings) but will average out if enough measurements are taken.

The frequent occurrence of these types of errors is the reason why data quality is subject to question, why there is uncertainty when using data to make decisions and why measurement performance criteria are necessary.

During the DQO process, project DQOs are used to establish the MQOs. An MQO is a statement of a performance objective or requirement for a particular method performance characteristic. Examples of method performance characteristics include the measurement uncertainty at some concentration; the detection capability; the quantification capability; the range; the specificity; and the ruggedness of the method. MQOs for the project should be identified and described within this element of the QAPP. MARLAP provides guidance for developing MQOs for select method performance characteristics in Chapter 3 (*Key Analytical Planning Issues and Developing Analytical Protocol Specifications*) and Appendix C (*MQOs for Method Uncertainty and Detection and Quantification Capability*).

D.2.7.3 Relation between the Project DQOs, MQOs, and QC Requirements

The ultimate goal of all data collection operations is the collection of appropriately accurate data. Appropriately accurate data are data for which errors caused by imprecision and bias are controlled such that it is suitable for use in the context outlined by the DQOs (i.e., the overall error is less than that specified in the acceptable decision error). During the optimization of design in the planning process, DQO-specified decision error rates are translated into MQOs with the intention of monitoring, detecting, quantifying and controlling imprecision and analytical bias. During optimization, precautions are also incorporated into the design with the intention of preventing blunders and types of non-measurable bias not susceptible to measurement by QC samples.

The MQOs provide acceptance or rejection criteria for the quality control samples whose types and frequency are discussed in the Quality Control Requirements element (B5) (Appendix C). QC samples and the project's associated MQOs are key—but not the sole mechanisms—for monitoring the achievement of DQOs.

In summary, translating acceptable decision error rates into a design that will produce data of appropriate precision and bias is often a complex undertaking. The team must consider the synergistic and antagonistic interactions of the different options for managing errors and uncertainty. Accurate data require not only control of imprecision, but must also control the various forms of bias.

D.2.8 Project Management (A8): Special Training Requirements/Certification

All project personnel should be qualified and experienced in their assigned task(s). The purpose of this element is to add additional information regarding special training requirements and how they will be managed during implementation of the project. This element should:

- Identify and describe any mandated or specialized training or certifications that are required;
- Indicate if training records or certificates are included in the QAPP as attachments;
- Explain how training will be implemented and certifications obtained; and
- Identify how training documentation and certification records will be maintained.

D.2.9 Project Management (A9): Documentation and Record

This element of the QAPP will identify which records are critical to the project, from data generation in the field to final use. It should include what information needs to be contained in these records and reports, the formats of the records and reports, and a brief description of document control procedures. The following are suggested records and content:

- **SAMPLE COLLECTION RECORDS** should include sampling procedures, the names of the persons conducting the activity, sample number, sample collection points, maps and diagrams, equipment/protocol used, climatic conditions, and unusual observations. Bound field notebooks, pre-printed forms, or computerized notebooks can serve as the recording media. Bound field notebooks are generally used to record raw data and make references to prescribed procedures, changes in planned activities and implementation of corrective actions. Preferably, notebooks will contain pre-numbered pages with date and signature lines and entries will be made in ink. Field QC issues such as field, trip, and equipment rinse blanks, co-located samples, field-spiked samples, and sample preservation should be documented. Telephone logbooks and air bill records should be maintained.
- **SAMPLE TRACKING RECORDS** document the progression of samples as they travel from the original sampling location to the laboratory and finally to their disposal or archival. These records should contain sample identification, the project name, signatures of the sample collector, the laboratory custodian and other custodians, and the date and time of receipt. The records should document any sample anomalies. If chain-of-custody (COC) is required for the project, the procedures and requirements should be outlined (Chapter 11, *Sample Receipt, Inspection, and Tracking*).
- **ANALYTICAL QC** issues that should be documented include standard traceability, and frequency and results of QC samples, such as, method and instrument blanks, spiked samples, replicates, calibration check standards and detection limit studies.
- **ANALYTICAL RECORDS** should include standard operating procedures for sample receipt, preparation, analysis and report generation. Data report formats and the level of supporting information is determined by data use and data assessment needs.
- **PROJECT ASSESSMENT RECORDS** should include audit check lists and reports, performance evaluation (PE) sample results, data verification and validation reports, corrective action reports. The project may want to maintain copies of the laboratory proposal package, pre-award documentation, initial precision and bias test of the analytical protocol and any corrective action reports.

The QAPP should indicate who is responsible for creating, tracking, and maintaining these records and when records can be discarded, as well as any special requirements for computer, microfiche, and paper records.

D.3 Group B: Measurement/Data Acquisition

The Measurement/Data Acquisition group consists of 10 elements that address the actual data collection activities related to sampling, sample handling, sample analysis and the generation of

data reports. Although these issues may have been previously considered by project management elements, the project management section of the QAPP dealt with the overall perspective. The measurement/data section contains the details covering design and implementation to ensure that appropriate protocols are employed and documented. This section also addresses quality control activities that will be performed during each phase of data collection from sampling to data reporting.

D.3.1 Measurement/Data Acquisition (B1): Sampling Process Design

This element of the QAPP describes the finalized sampling design that will be used to collect samples in support of project objectives. The design should describe the matrices to be sampled, where the samples will be taken, the number of samples to be taken, and the sampling frequency. A map of the sampling locations should be included to provide unequivocal sample location determination and documentation.

If a separate sampling and analysis plan or a field sampling and analysis plan has been developed, it can be included by citation or as an appendix. This element will not address the details of standard operating procedures for sample collection, which will be covered in subsequent elements. This element will describe the sampling design and the underlying logic, so that implementation teams can understand the rationale behind and better implement the sampling effort. Understanding the rationale for the decisions will help if plans have to be modified due to conditions in the field. DQO Step 7 establishes the rationale for and the details of the sampling design.

This element should restate the outputs of the planning process and any other considerations and assumptions that impacted the design of the sampling plan, such as:

- The number of samples, including QC samples, sample locations and schedule, and rationale for the number and location of samples;
- A brief discussion of how the sampling design will facilitate the achievement of project objectives;
- A discussion of the population boundaries (temporal and spatial) and any accessibility limitations;
- A description of how the sampling design accommodates potential problems caused by the physical properties of the material being sampled (e.g., large particle size), the characteristic of concern (e.g., potential losses due to the volatility of tritium) or heterogeneity;
- A discussion of the overarching approach to sampling design (e.g., worse case or best case sampling versus average value) and assumptions made in selecting this approach (e.g., an

assumption that the darkened soil adjacent to the leaking tank would present a worse case estimate of soil contamination);

- A listing of guidance and references that were relied upon when designing the sampling plan;
- Identification of the characteristics of interest (e.g., ⁹⁹Tc activity), associated statistical parameters (e.g., mean, standard deviations, 99th percentile), and acceptable false error rates (e.g., false negative rate of less than 5%);
- Identification of relevant action level and how data will be compared to the action level (Appendix B3.2);
- A discussion of the anticipated range of the characteristic of interest and assumed temporal and spatial variations (heterogeneity), anticipated variance, anticipated sources and magnitude of error (e.g., heterogeneity of material being sampled, sampling imprecision, analytical imprecision), anticipated mean values and distribution of measurements and the basis (e.g., historical data, similar processes or sites) for any associated assumptions;
- If any level of bias is assumed, what is the assumed magnitude and the basis of the assumption (e.g., historical data, typical analytical bias for matrix type);
- It is usually assumed that the magnitude of measurements made at individual sampling locations are independent of each other (e.g., no correlation of concentration with location). Geostatistical approaches may be more appropriate if measurements are significantly correlated with locations (e.g., serial-correlation, auto-correlation) since serial-correlation can bias estimates of variance and invalidate traditional probabilistic techniques such as hypothesis testing; and
- A discussion of the rationale for choosing non-routine sampling protocols and why these non-routine protocols are expected to produce acceptable precision and bias.

D.3.2 Measurement/Data Acquisition (B2): Sampling Methods Requirements

This element of the QAPP describes the detailed sampling procedures that will be employed during the project. The preliminary details of sampling methods to be employed were established during Step 7 of the DQO process. The selected sampling procedures should be appropriate to (1) ensure that a representative sample is collected, (2) avoid the introduction of contamination during collection, and (3) properly preserve the sample to meet project objectives. Written SOPs should be included as attachments to the QAPP. This element and the appendices or other documents that it references should in total contain all the project specific details needed to successfully implement the sampling effort as planned. If documents to be cited in the QAPP are not readily available to all project participants, they must be incorporated as appendices. All

sampling personnel should sign that they have read the sampling procedures and the health and safety procedures.

Correct sampling procedures and equipment used in conjunction with a correct sampling design should result in a collection of samples that in total will represent the population of interest. A detailed discussion of sampling procedures, equipment and design are beyond the scope of MARLAP. In general, the selected procedures must be designed to ensure that the equipment is used properly and that the collected samples represent the individual sampling unit from which samples are collected. The sampling equipment should be chemically and physically compatible with the analyte of concern as well as the sample matrix. The sampling design should facilitate access to individual sampling units, result in an appropriate mass/volume of sample such that it meets or exceeds minimum analytical sample sizes, accommodates short-range heterogeneity (*i.e.*, does not preclude large particle sizes or lose small particles) and reduce or prevent loss of volatile components, if appropriate.

This element of the QAPP should:

- Identify the sampling methods to be used for each matrix, including the method number if a standardized method. If methods are to be implemented differently than specified by the standard method or if the standard method offers alternatives for implementation, the differences and alternatives should be specified;
- Identify the performance requirements of the sampling method. If the sampling method of choice is unlikely to be able to achieve the level of performance demanded by the project DQO, the project planning team should be notified;
- Identify the required field QC samples (e.g., trip blank, co-located duplicate);
- Identify any sample equipment preparation (e.g., sharpening of cutting edges, degreasing and cleaning) or site preparation (e.g., removal of overburden, establishing dust-free work space for filtering) for each method;
- Identify and preferably generate a list of equipment and supplies needed. For example, the sampling devices, decontamination equipment, sampling containers, consumables (e.g., paper towels), chain-of-custody seals and forms, shipping materials (e.g., bubble-pack, tape), safety equipment and paper work (e.g., pens, field books);
- Identify and detail logistical procedures for deployment, sample shipment and demobilization. If a mobile lab will be used, explain its role and the procedures for sample flow to the mobile lab and data flow to the data-user;

- Identify, preferably in a tabular form, sample container types, sizes, preservatives, and holding times;
- Identify procedures that address and correct problems encountered in the field (variances and nonconformance to the established sampling procedures);
- Identify for each sampling method, decontamination procedures and the procedures for disposing of contaminated equipment and used-decontamination chemicals and waters;
- Identify the disposal procedures for waste residuals generated during the sampling process (e.g., purged well waters, drilling dregs) for each method; and
- Identify oversight procedures (e.g., audits, supervisor review) that ensure that sampling procedures are implemented properly. The person responsible for implementing corrective actions should be identified.

D.3.3 Measurement/Data Acquisition (B3): Sample Handling and Custody Requirements

This element of the QAPP details how sample integrity will be maintained and how the sample history and its custody will be documented ensuring that (1) samples are collected, transferred, stored, and analyzed by authorized personnel, (2) the physical, chemical and legal integrity of samples is maintained, and (3) an accurate written record of the history of custody is maintained. DQO Step 1 describes the regulatory situation which can be used to identify the appropriate level of sample tracking. The QAPP should state whether COC is required. Sample handling, tracking and COC requirements are discussed in detail in Chapter 11, *Sample Receipt, Inspection, and Tracking*.

In the QAPP, the following elements should be documented:

- **INTEGRITY OF SAMPLE CONTAINERS:** Describe records to be maintained on the integrity of sample container and shipping container seals upon receipt. Describe records to be maintained if specially prepared or pre-cleaned containers are required.
- **SECURITY:** If wells are being sampled, whether the wellheads were locked or unlocked should be noted. Security of remote sampling sites or automatic samplers not maintained in locked cages should be discussed.
- **SAMPLE IDENTIFICATION:** The assignment of sample numbers and the labeling of sample containers is explained. If samples are to be assigned coded sample identifications (IDs) to preclude the possibility of bias during analysis, the sample code is one of the few items that will not be included in the QAPP, since the lab will receive a copy. The code and sample ID assignment process will have to be described in a separate document, which is made available

to the field team and the data validators. An example of a sample label should be included in the QAPP.

- **TRACKING OR CUSTODY IN THE FIELD:** Procedures for sample tracking or custody while in the field and during sample shipment should be described. When COC is required, a copy of the COC form and directions for completion should be included. A list of all materials needed for tracking or custody procedures should be provided (e.g., bound notebooks, shipping containers, shipping labels, tape, custody seals, COC forms).
- **SAMPLE PRESERVATION:** Sample preservation procedures, if desired, should be clearly described. Preservation of radiological samples is discussed in Chapter 10, *Field and Sampling Issues that Affect Laboratory Measurements*.
- **TRACKING OR CUSTODY IN THE LABORATORY:** A decision must be made as to whether the laboratory in general is considered a secure area such that further security is not required once the sample is officially received by the laboratory or whether internal tracking or custody procedures will be required as the samples are handled by different personnel within the lab. The laboratory's sample receipt SOP, laboratory security procedures, and—if needed—internal tracking or custody procedures should be described.
- **SPECIAL REQUIREMENT:** Any special requirements, such as shipping of flammable or toxic samples, or requirements for verification of sample preservation upon sample receipt by the laboratory should be clearly described.
- **ARCHIVAL:** Document the rationale for the request to archive samples, extracts, and digestates. Describe how samples, extracts, and digestates will be archived. Identify how long samples, extracts, digestates, reports, and supporting documentation must be maintained.

D.3.4 Measurement/Data Acquisition (B4): Analytical Methods Requirements

This element of the QAPP should identify the analytical protocol specifications (APSs) including the MQOs that were employed by the laboratory to select the analytical protocols. (See Chapter 3 for guidance on developing APSs.) This element integrates decisions from three DQO steps: Step 3 which identified the analyte of interest and needed inputs to the decision, Step 6 that identifies the allowable uncertainty, and Step 7 that identifies the optimized analytical design. Input from all three steps drive the choice of analytical protocols. The discussion of the selected analytical protocols should address: subsampling, sample preparation, sample clean-up, radiochemical separations, the measurement system, confirmatory analyses and pertinent data calculation and reporting issues. A tabular summary of the analytical protocol by matrix type can facilitate reference for both the plan document development team and the laboratory analytical team.

This element of the QAPP should clearly describe the expected sample matrices (e.g., groundwater with no sediments, soils with no rocks larger than 2 cm in diameter) and what should be done or who should be contacted if sample matrices are different than expected. Subsampling is a key link in the analytical process which is often overlooked during planning leaving important decisions to laboratory staff, this element should specify appropriate subsampling procedures.

This QAPP element should:

- Identify the laboratories supplying analytical support. If more than one laboratory will be used, detail the analyses supplied by each laboratory;
- Identify analyses to be performed in the field using portable equipment or by a mobile lab;
- Identify the sample preparation techniques. Non-routine preparatory protocols, such as novel radiochemical separations, should be described in detail and documented in an SOP including pertinent literature citations and the results of validation studies and other performance data, when they exist;
- Identify the analytical protocols to be used. The protocol documentation should describe all necessary steps including the necessary reagents, apparatus and equipment, standards preparation, calibration, sample introduction, data calculation, quality control, interferences, and waste disposal;
- If the selected analytical protocols have not been demonstrated for the intended application, the QAPP should include information about the intended procedure, how it will be validated, and what criteria must be met before it is accepted for the project's application (Chapter 6, *Selection and Application of an Analytical Method*);
- If potential analytical protocols were not identified during the project planning process and existing analytical protocols can not meet the MQOs, an analytical protocol will have to be developed and validated (Section 6.6, "Method Validation"). If this issue was not identified by the project planning team, the project planning team must be contacted because the original project objectives and the associated MQOs may have to be revisited and changed (Appendix B);
- If both high concentration and low concentration samples are expected, discuss how the two sample types will be identified and handled in a manner that will prevent cross-contamination or other analytical problems;
- Discuss reporting requirements (e.g., suitable data acquisition and print-outs or electronic data archival that will capture all necessary information), the proper units (dry weight versus

wet weight), the method to be employed to report the final result and its uncertainty, and reporting package format requirements; and

- Identify oversight procedures (e.g., QC samples, audits, supervisor review) for ensuring that analytical procedures are implemented properly and procedures for correcting problems encountered in the laboratory. The person responsible for implementing corrective actions in the lab should be identified.

The project plan document should be a dynamic document, used and updated over the life of the project as information becomes available or changes. For example, under a performance based approach, the analytical protocols requirements in the project plan documents should initially reflect the Analytical Protocol Specifications established by the project planning team and issued in the statement of work (or task order). When the analytical laboratory has been selected (Appendix E, *Contracting Laboratory Services*) the project plan document should be updated to reflect the identification of the selected laboratory and the analytical protocols, that is, the actual analytical protocols to be used should be included by citation or inclusion of the SOPs as appendices.

D.3.5 Measurement/Data Acquisition (B5): Quality Control Requirements

This element of the QAPP should include enough detail that the use and evaluation of QC sample results and corrective actions will be performed as planned and support project activities. The QC acceptance limits and the required corrective actions for nonconformances should be described. DQO Step 7 identified the optimized analytical design and the desired MQOs which will help determine the QC acceptance criteria. Refer to Chapter 18, *Laboratory Quality Control*, for a detailed discussion of radioassay QC and quality indicators. A discussion of QC requirements in the QAPP should include the following information:

- A list of all QC sample types by matrix;
- The frequency of QC sample collection or analysis, preferably a tabular listing;
- A list of QC sample acceptance criteria or warning limits and control limits;
- Procedures for documenting QC sample results;
- Equations and calculations used to evaluate QC sample results and to determine measurement performance acceptability;
- Actions to be taken if QC samples fail to meet the acceptance criteria; and
- Identification of the appropriate responsible person to whom QC reports should be sent.

Acceptance criteria for QC samples should be based on the project MQOs, in particular the MQO for measurement uncertainty at some concentration. Appendix C provides guidance on developing acceptance criteria for QC samples based on the project's MQO for the method's measurement uncertainty at some concentration, typically the action level.

D.3.6 Measurement/Data Acquisition (B6): Instrument/Equipment Testing, Inspection, and Maintenance Requirements

The QAPP should include a discussion of testing, inspection and maintenance requirements that will be followed to ensure that equipment and instrumentation will be in working order during implementation of project activities. An instrument or testing equipment will be deemed to be in working order if it is maintained according to protocol and it has been inspected and tested and meets acceptance criteria.

This element of the QAPP should:

- Discuss the maintenance policy for all essential instrumentation and equipment, what it involves, its frequency, whether it is performed by internal staff or if it is a contracted service, and whether an inventory of spare parts is maintained;
- Describe the inspection protocols for instrumentation and equipment. This ranges from the routine inspections (i.e, gases, nebulizers, syringes and tubing) prior to instrument or equipment use and more detailed inspections employed while troubleshooting an instrument or equipment problem. Mandatory inspection hold points, beyond which work may not proceed, should be identified; and
- Address the frequency and details of equipment and instrument testing. This may involve the weighing of volumes to test automatic diluters or pipets, the use of a standard weight prior to weighing sample aliquots to the use of standards to test sophisticated instrumentation. If standards (e.g., National Institute of Standards and Technology [NIST] standard reference material [SRM]) are used during testing, the type, source and uncertainty of standard should be identified.

There is not always a clear distinction between the testing component of this element and the previous element addressing the use of QC samples to determine whether an instrument is within control. In any case, it is important to describe in either of these elements of the QAPP, all procedures that are deemed important to determining whether an instrument/equipment is in working order and within control.

D.3.7 Measurement/Data Acquisition (B7): Instrument Calibration and Frequency

This element of the QAPP details the calibration procedures including standards, frequencies, evaluation, corrective action measures and documentation. Summary tables may be used to complement the more detailed discussions in the text. The following issues should be addressed in this element:

- Identify all tools, gauges, sampling devices, instruments, and test equipment that require calibration to maintain acceptable performance;
- Describe the calibration procedures in enough detail in this element or by citation to readily available references so that the calibration can be performed as intended;
- Identify reference equipment (e.g., NIST thermometers) and standards, their sources, and how they are traceable to national standards. Where national standards are not available, describe the procedures used to document the acceptability of the calibration standard used;
- Identify the frequency of calibration and any conditions (e.g., failed continuing calibration standard, power failure) that may be cause for unscheduled calibration;
- Identify the procedure and the acceptance criteria (i.e., in control) to be used to evaluate the calibration data;
- Identify the corrective actions to be taken if the calibration is not in control. When calibration is out of control, describe the evaluations to be made to determine the validity and acceptability of measurements performed since the last calibration; and
- Identify how calibration data will be documented, archived and traceable to the correct instrument/equipment.

See Chapter 15, *Quantification of Radionuclides*, for a discussion of radiochemical instrument calibration.

D.3.8 Measurement/Data Acquisition (B8): Inspection/Acceptance Requirements for Supplies and Consumables

This element of the QAPP deals with inspecting and accepting all supplies and consumables that may directly or indirectly affect the quality of the data. For some projects, this information may be provided by citation to a chemical safety and hygiene plan. The contents of this element should contain enough supportive information that the project and the data will be sufficient to undergo solicited and unsolicited reviews. The following detail should be included in this element, so the inspection process can be accurately implemented:

- Identify and document all supplies and consumables (e.g., acids, solvents, preservatives, containers, reagents, standards) that have the potential of directly or indirectly impacting the quality of the data collection activity;
- Identify the significant criteria that should be used when choosing supplies and consumables (e.g., grade, purity, activity, concentration, certification);
- Describe the inspection and acceptance procedures that will be used for supplies or consumables, including who is responsible for inspection, the timing of inspections and the acceptance and rejection criteria. This description should be complete enough to allow replication of the inspection process. Standards for receiving radiological packages are provided in 10 CFR 20 Section 20.1906 “Procedures for Receiving and Opening Packages” or an Agreement State equivalent;
- Describe the procedures for checking the accuracy of newly purchased standards, other than SRMs, by comparison to other standards purchased from other sources;
- Identify any special handling and storage (e.g., refrigerated, in the dark, separate from high concentration standards, lead shielding) conditions that must be maintained;
- Describe the method of labeling, dating and tracking supplies and consumables and the disposal method for when their useful life has expired; and
- Describe the procedures and indicate by job function who is responsible for documenting the inspection process and the status of inventories.

D.3.9 Measurement/Data Acquisition (B9): Data Acquisition Requirements for Non-Direct Measurement Data

This element of the QAPP addresses the use of existing data. Non-direct measurement data is defined as existing data that is independent of the data generated by the current project’s sampling and analytical activities. Non-direct data may be of the same type (e.g., mBq/g of ²³²Th in soil) that will complement the data being collected during the project. Other non-direct data may be of a different type such as weather information from the National Weather Service, or geological and hydrogeological data from the U.S. Geological Survey.

To achieve project objectives it is important that the data obtained from non-direct sources be subjected to scrutiny prior to acceptance and use. Use of existing data is discussed during Step 1 and 3 of the DQO process. If existing data of the same type is to be used to achieve project objectives, it has to be evaluated in terms of its ability to comply with MQOs established in DQO Step 7. The limitations on the use of non-direct measurements should be established by the project planning team.

This element should:

- Identify the type and source of all non-direct data that will be needed to achieve the project objectives;
- State whether the same quality criteria and QC sample criteria will be applied to the non-direct measurement data. If the same criteria cannot be applied, then identify criteria that will be acceptable for the non-direct data but at the same time won't bias or significantly add to the uncertainty of decisions for the project;
- Identify whether the data will support qualitative decisions (e.g., rain occurred on the third day of sampling) or if the data will be used quantitatively (e.g., used to calculate a mean concentration that will be compared to an action level);
- Identify whether enough information exists to evaluate the quality of the non-direct data (e.g., spike and collocated sample data, minimum detectable concentrations, reported measurement uncertainties); and
- If the non-direct data are to be combined with project-collected data, identify the criteria that will be used to determine if the non-direct data are comparable (e.g., sampled the same population, same protocol).

D.3.10 Measurement/Data Acquisition (B10): Data Management

This element of the QAPP should present an overview of the data management process from the receipt of raw data to data storage. The overview should address all interim steps, such as, data transformations, transmittals, calculations, verifications, validations and data quality assessments. The procedures should address how internal checks for errors are made. Laboratories should follow accepted data management practices (EPA, 1995). Applicable SOPs should be included as attachments to the QAPP. (See Chapter 16, *Data Acquisition, Reduction, and Reporting for Nuclear Counting Instrumentation*, for a discussion of radiochemical data generation and reduction.)

The discussion of data management should address the following issues:

- **DATA RECORDING:** The process of the initial data recording steps (e.g., field notebooks, instrument printouts, electronic data storage of alpha and gamma spectra) should be described. Examples of unique forms or procedures should be described. Describe the procedures to be used to record final results (e.g., negative counts) and the uncertainty.
- **CONVERSIONS AND TRANSFORMATIONS:** All data conversions (e.g., dry weight to wet weight), transformations (conversion to logs to facilitate data analysis) and calculation of statistical

parameters (e.g., uncertainties) should be described, including equations and the rationale for the conversions, transformations and calculations. Computer manipulation of data should be specified (e.g., software package, macros).

- **DATA TRANSMITTALS:** Data transmittals occur when data are sent to another location or person or when it is converted to another format (incorporated into a spreadsheet) or media (printed reports keyed into a computer database). All transmittals and associated QA/QC steps taken to minimize transcription errors should be described in enough detail to ensure their proper implementation.
- **DATA REDUCTIONS:** Identify and explain the reasons for data reductions. Data reduction is the process of changing the number of data items by arithmetic or statistical calculations, standard curves, or concentration factors. A laboratory information management system may use a dilution factor or concentration factor to change raw data. These changes often are irreversible and in the process the original data are lost.
- **DATA VERIFICATION, VALIDATION AND ASSESSMENTS:** Since these assessment issues are discussed in a subsequent element of the QAPP (D2), only an overview should be provided identify the timing and frequency of these assessments.
- **DATA TRACKING, STORAGE AND RETRIEVAL:** Describe the system for tracking and compiling data as samples are being analyzed, how data are stored, and the mechanism for retrieving data (e.g., from archived back-up tapes or disks).
- **SECURITY:** Describe procedures for data and computer security.

D.4 Group C: Assessment/Oversight

The elements of this group are intended to assess progress during the project, facilitate corrective actions in a timely manner (Section D.4.1), and provide reports to management (Section D.4.2). It should be stressed that early detection of problems and weaknesses—before project commencement or soon thereafter—and initiation of corrective actions are important for a project's success. The focus of the elements in this group is the implementation of the project as defined in the QAPP. This group is different from the subsequent group, data validation and usability, which will assesses project data after the data collection activity is complete.

D.4.1 Assessment/Oversight (C1): Assessment and Response Actions

The QAPP authors have a range of assessment choices that can be employed to evaluate on-going project activities, which include surveillance, peer review, systems reviews, technical systems audits (of field and laboratory operations), and performance evaluations. A detailed discussion of

laboratory evaluation is presented in Chapter 7, *Evaluating Methods and Laboratories*. It is important to schedule assessments in a timely manner. An assessment has less value if its findings become available after completion of the activity. The goal is to uncover problems and weaknesses before project commencement or soon thereafter and initiate corrective actions so the project is a success.

This element of the QAPP should:

- Identify all assessments by type, frequency and schedule;
- Identify the personnel who will implement the assessments;
- Identify the criteria, documents, and plans upon which assessments will base their review;
- Describe the format of assessment reports;
- Identify the time frame for providing the corrective action plan; and
- Identify who is responsible for approving corrective actions and ensuring that they are implemented.

D.4.2 Assessment/Oversight (C2): Reports to Management

Reports to management are a mechanism for focusing management's attention on project quality and on project issues that may require the management's level of authority. To be effective reports to management and management's review and response must be timely. The benefit of these status reports is the opportunity to alert management of data quality problems, propose viable solutions and procure additional resources.

At the end of the project, a final project report which includes the documentation of the DQA findings should be prepared (Chapter 9, *Data Quality Assessment*). It may also be beneficial for future planning efforts for the project planning team to provide a summary of the "lesson learned" during the project, such as key issues not addressed during planning and discovered in implementation or assessment, specialist expertise needed on the planning team, experience with implementing performance-based analytical protocol selection.

This element of the QAPP should address the following issues:

- Identify the various project reports that will be sent to management;
- Identify non-project reports that may discuss issues pertinent to the project (e.g., backlog reports);
- Identify QA reports that provide documentary evidence of quality (e.g., results of independent performance testing, routine QC monitoring of system performance);

- Identify the content of “reports to management” (e.g., project status, deviations from the QAPP and approved amendments, results of assessments, problems, suggested corrective actions, status on past corrective actions);
- Identify the frequency and schedule for reports to management;
- Identify the organization or personnel who are responsible for authoring reports; and
- Identify the management personnel who will receive and act upon the assessment reports.

D.5 Group D: Data Validation and Usability

This group of elements ensures that individual data elements conform to the project specific criteria. This section of the QAPP discusses data verification, data validation and data quality assessment (DQA), three processes employed to accept, reject or qualify data in an objective and consistent manner. Although there is good agreement as to the range of issues that the three elements, in total, should address, within the environmental community there are significant differences as to how verification, validation and DQA are defined. The discussion of this group of elements will use the definitions which are defined Chapter 8, *Radiochemical Data Verification and Validation*.

D.5.1 Data Validation and Usability (D1): Verification and Validation Requirements

This element of the QAPP addresses requirements for both data verification and data validation. The purpose of this element is to clearly state the criteria for deciding the degree to which each data item and the data set as a whole has met the quality specifications described in the “Measurement/Data Acquisition” section of the QAPP. The strength of the conclusions that can be drawn from the data is directly related to compliance with and deviations from the sampling and analytical design. The requirements can be presented in tabular or narrative form.

Verification procedures and criteria should be established prior to the data evaluation.

Requirements for data verification include the following criteria:

- Criteria for determining if specified protocols were employed (e.g., compliance with essential procedural steps);
- Criteria for determining if methods were in control (e.g., QC acceptance criteria);
- Criteria for determining if a data report is complete (e.g., list of critical components that constitute the report);

- Criteria for determining if the analysis was performed according to the QAPP and the SOW;
- Criteria and codes used to qualify data; and
- Criteria for summarizing and reporting the results of verification.

A discussion of verification can be found in Chapter 8.

Data validation should be performed by an organization independent of the group that generated the data to provide an unbiased evaluation. Validation procedures and criteria should be established prior to the data evaluation. Requirements for data validation include the following:

- An approved list of well-defined MQOs and the action level(s) relevant to the project DQOs;
- Criteria for assigning qualifiers based on the approved list of MQOs;
- Criteria for identifying situations when the data validator's best professional judgement can be employed and when a strict protocol must be followed; and
- Criteria for summarizing and reporting the results of validation.

A discussion of validation can be found in Chapter 8.

D.5.2 Data Validation and Usability (D2): Verification and Validation Methods

D.5.2.1 Data Verification

Data verification or compliance with the SOW is concerned with: complete, consistent, compliant and comparable data. Since the data verification report documents whether laboratory conditions and operations were compliant with the SOW, the report is often used to determine payment for laboratory services. Chapter 5, *Obtaining Laboratory Services*, discusses the need to prepare a SOW for all radioanalytical laboratory work regardless of whether the work is contracted out or performed in-house.

This element of the QAPP should address the following issues to ensure that data verification will focus on the correct issues:

- Identify the documents (e.g., other QAPP sections, SOW, contracts, standard methods) that describe the deliverables and criteria that will be used to evaluate compliance;

- Identify the performance indicators that will be evaluated (e.g., yield, matrix spikes, replicates). See Chapter 18, *Laboratory Quality Control*, for a discussion of radiochemistry performance indicators;
- Identify the criteria that will be used to determine “in-control” and “not-in-control” conditions;
- Identify who will perform data verification;
- Describe the contents of the verification report (e.g., a summary of the verification process as applied; required project activities not performed or not on schedule or not according to required frequency; procedures that were performed but did not meet acceptance criteria; affected samples; exceptions); and
- Identify who will receive verification reports and the mechanism for its archival.

D.5.2.2 Data Validation

Chapter 8, *Radiochemical Data Verification and Validation*, discusses radiochemical data validation in detail. MARLAP recommends that a data validation plan document be included as an appendix to the QAPP. The data validation report will serve as the major input to the process that evaluates the reliability of measurement data.

This element of the QAPP should address the following issues:

- Describe the deliverables, measurement performance criteria and acceptance criteria that will be used to evaluate data validity;
- Identify who will perform data validation;
- Describe the contents of the validation report (e.g., a summary of the validation process as applied; summary of exceptional circumstances; list of validated samples, summary of validated results); and
- Identify who will receive validation reports and the mechanism for its archival.

D.5.3 Data Validation and Usability (D3): Reconciliation with Data Quality Objectives

This element of the QAPP describes how project data will be evaluated to determine its usability in decision-making. This evaluation is referred to as the “data quality assessment.” DQA is the process that scientifically and statistically evaluates project-wide knowledge in terms of the project objectives to assess the usability of data. DQA should be ongoing and integrated into the

project data collection activities. On project diagrams and data life cycles, it is often shown as the last phase of the data collection activity. However, like any assessment process, DQA should be considered throughout the data collection activity to ensure usable data. EPA guidance (EPA, 2000b) provides a detailed discussion of that part of the DQA process that addresses statistical manipulation of the data. In addition to statistical considerations, the DQA process integrates and considers information from the validation report, assessment reports, the field, the conceptual model and historical data to arrive at its conclusions regarding data usability. DQA is discussed in Chapter 9, *Data Quality Assessment*.

The DQA considers the impact of a myriad of data collection activities in addition to measurement activities. This element of the QAPP should direct those performing the DQA to:

- Review the QAPP and DQOs;
- Review the validation report;
- Review reports to management;
- Review identified field, sampling, sample handling, analytical and data management problems associated with project activities;
- Review all corrective actions; and
- Review all assessment reports and findings (e.g., surveillances, audits, performance evaluations, peer reviews, management and technical system reviews).

In addition to the above, this element of the QAPP should address the following issues:

- Identify who will perform the DQA;
- Identify what issues will be addressed by the DQA;
- Identify any statistical tests that will be used to evaluate the data (e.g., tests for normality);
- Describe how MQOs will be used to determine the usability of measurement data (i.e., did the measurement uncertainty in the data significantly affect confidence in the decision?);
- Describe how the representativeness of the data will be evaluated (e.g., review the sampling strategy, the suitability of sampling devices, subsampling procedures, assessment findings);
- Describe how the potential impact of non-measurable factors will be considered;
- Identify what will be included in the DQA report; and
- Identify who will receive the report and the mechanism for its archival.

D.6 References

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