

4 PROJECT PLAN DOCUMENTS

4.1 Introduction

The project plan documents are a blueprint for how a particular project will achieve data of the type and quality needed and expected by the project planning team. In the planning documents, the data user’s expectations and requirements, which are developed during the planning process—including the analytical protocol specifications (APSs) and measurement quality objectives (MQOs)—are documented along with the standard operating procedures (SOPs), health and safety protocols, and quality assurance/quality control (QA/QC) procedures for the field and laboratory analytical teams. The objectives of this chapter are to discuss:

- The importance of project plan documents;
- The elements of project plan documents; and
- The link between project planning and project plan documents, in particular the incorporation of the analytical protocols.

The importance of project plan documents is discussed in Section 4.2. Section 4.3 discusses a graded approach to project plan documents. The different types of planning documents and the elements of the project plan documents are discussed in Sections 4.4 and 4.5, respectively. The link between project planning and project plan documents is discussed in Section 4.6.

The project plan documents should be dynamic documents, used and updated over the life of the project. Under a performance-based approach, the analytical protocols requirements in the project plan documents initially may reflect the APSs established by the project planning team and issued in the statement of work (SOW). When the analytical laboratory has been selected, the project plan documents should be updated to reflect the actual protocols to be used. The protocols should be cited, or the SOPs for the protocols should be included as appendices. (APSs and the relation to project measurement quality objectives (MQOs) are discussed in Chapter 3 and represented in Figure 3.2 and 3.3).

While this chapter will address the documentation of QA/QC used in project activities, MARLAP recognizes and fully endorses the need for a quality system as documented in a management plan or quality manual. The development of the project plan documents should be addressed in the quality system requirements documentation. The project plan documents should reflect, and be consistent with, the organization’s QA policies and procedures. Guidance on elements of a quality

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system for environmental data collection activities is available from several sources including ANSI/ASQC E-4 and ISO 9001. QA requirements have been developed by several federal agencies, and they include the following:

- 10 CFR 830.120
- 10 CFR 50, Appendix B
- ANSI N42.23
- ASME NQA-1
- DOE Order 414.1A on QA
- EPA Order 5360.1.A2 on quality systems (2000)
- DOD QA requirement MIL-Q-9858A (1963)

4.2 The Importance of Project Plan Documents

Project plan documents are important in environmental data collection activities to ensure that the type and quantity of data are sufficient for the decision to be made. These documents provide a record of the decisions made during the planning process and integrate the technical operations with the management and quality system practices. Project plans also:

- Support data defensibility for environmental compliance;
- Can be used to defend project objectives and budget; and
- Are a tool for communication with stakeholders.

The development of project plan documents and the implementation of the project plan provide the following benefits:

- Full documentation for legal, regulatory, and historical use of the information;
- Specification of data collection and quality control;
- Documentation of analytical requirements through the incorporation of an APS;
- Implementation of planned data collection activities (through internal and external assessment and oversight activities); and
- Meeting project-specific criteria (i.e., MQOs, DQOs) through data validation and usability assessment.

4.3 A Graded Approach to Project Plan Documents

A graded approach bases the level of management controls applied to an item or work on the intended use of the results and the degree of confidence needed in the quality of the results (ANSI/ASQC E-4). MARLAP recommends a graded approach to project plan development because of the diversity of environmental data collection activities. This diversity in the type of project and the data to be collected impacts the content and extent of the detail to be presented in the plan document. The plan document development team should be flexible in its application of guidance according to the nature of the work being performed and the intended use of the data.

Under a graded approach, a mix of project-specific and site-based quality system documentation may be relied upon to ensure quality. For example, the project specific plan may:

- Address design, work processes, and inspection; and
- Incorporate by citation site-wide plans that address records management, quality improvement, procurement, and assessment.

A comprehensive and detailed project plan is required for some data collection activities because of the need for legal and scientific defensibility of the data. A comprehensive and detailed plan also may be necessary to obtain approval from the Office of Management and Budget for a public survey under the Paperwork Reduction Act to carry out the project (e.g., NRC/EPA survey of Publicly Owned Treatment Works).

Other environmental data collection activities, such as basic studies or small projects, may only require a discussion of the experimental process and its objectives, which is often called a “project narrative statement,” “QA narrative statement,” or “proposal QA plan” (EPA, 2002). Basic studies and small projects generally are of short duration or limited scope and could include proof of concept studies, exploratory projects, small data collection tasks, feasibility studies, qualitative screens, or initial work to explore assumptions or correlations. Although basic studies and small projects may be used to acquire a better understanding of a phenomenon, they will not by themselves be used to make significant decisions or establish policy. Further discussion on the content of plan documents for basic studies and small projects is provided in Section 4.5.3.

4.4 Structure of Project Plan Documents

The ANSI/ASQC E-4 definition for a QAPP, which is also applicable to other integrated project plan documents, 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 the work performed will satisfy the stated performance criteria.” The project plan documents should

contain this information in a clear and integrated manner so that all implementation teams can understand their role and the project objectives.

Project plan documents vary in size and format and are referred to by a variety of names. The size of the project plan documents tends to reflect the issuing agency's requirements, complexity, and scope of the project activities. Some projects with multiple phases may have more than one plan document. For example, separate plan documents may be developed for scoping surveys, characterization, and the final status survey for the same site because of the different objectives and data requirements. Available guidance on project plans follows in Section 4.4.1, and a general discussion of various approaches is in Section 4.4.2.

4.4.1 Guidance on Project Plan Documents

National standards guidance on project plan documents is available in:

- ASTM D5283, *Standard Practice for Generation of Environmental Data Related to Waste Management Activities: Quality Assurance and Quality Control Planning and Implementation*;
- ASTM D5612, *Standard Guide for Quality Planning and Field Implementation of a Water Quality Measurements Program*; and
- ASTM PS85, *Standard Provisional Guidance for Expedited Site Characterization of Hazardous Waste Contaminated Sites*.

Guidance on project plans for federal environmental data collection activities is also available (EPA, 2002; 40 CFR 300.430; NRC, 1989; and USACE, 1997 and 2001). Other federal agencies may follow or adapt EPA guidance for quality assurance project plans (QAPPs) (EPA, 2002).

The Intergovernmental Data Quality Task Force (IDQTF) has developed a *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP) and a *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS). Agencies participating in IDQTF are the Environmental Protection Agency, Department of Defense, and Department of Energy. The *UFP-QAPP Manual* is a consensus document prepared by the IDQTF work group, and it provides instructions for preparing QAPPs for any environmental data collection operation. Information on IDQTF, including these policies, may be found at www.epa.gov/swerffrr/documents/data_quality/ufp_sep00_intro.htm#quality.

4.4.2 Approaches to Project Plan Documents

The approach and naming of project plan documents is usually a function of the authoring organization's experience, any controlling federal or state regulations, or the controlling Agency. Project plan, work plan, QAPP, field sampling plan, sampling and analysis plan, and dynamic work plan are some of the names commonly used for project plan documents. The names can however often represent different documents to different agencies, states, companies and even to different people within the same organization.

A work plan is often the primary and integrating plan document when the data collection activity is a smaller supportive component of a more comprehensive project (for example, data collection activity in support of an aspect of an environmental impact statement for a large multi-year project). The QAPP is often the primary document when the data collection activity is a major portion of the project (for example, data collection activity in support of an initial site investigation). A National Contingency Plan (NCP) format (40 CFR 300.430) is appropriate when data collection activities are in support of National Priorities List (NPL) Superfund site projects. The NCP format has a sampling and analysis plan as the primary plan document. The project documentation consists of two integrated documents: a field sampling plan and a QAPP. Stand-alone health and safety plans are also developed.

Traditional site investigations are generally based on a phased engineering approach, which collects samples based on a pre-specified grid pattern and does not provide the framework for making changes in the plan in the field. The work plan (the project plan document) for the site investigation typically will specify the number of samples to be collected, the location of each sample and the analyses to be performed. A newer concept is to develop a dynamic work plan (the project plan document), which, rather than specifying the number of samples to be collected and the location of each sample, would specify the decisionmaking logic that will be used in the field to determine where the samples will be collected, when the sampling will stop, and what analyses will be performed. Guidance on dynamic work plans is available in ASTM PS85 and EPA (2003).

MARLAP does not recommend a particular project plan document approach, title or arrangement. Federal and state agencies have different requirements for the various environmental data collection activities. In certain cases there are regulatory requirements. If an organization has successful experience addressing the essential content of plan documents (Section 4.5) in a well-integrated, documented format, it is usually unnecessary and wasteful of time and monies to change a proven approach. The project plan document should reflect, and be consistent with, the organization's QA policies and procedures.

MARLAP recommends a primary project plan document that includes other documents by citation or as appendices. The primary project plan document serves to integrate the multi-

disciplinary sections, other management plans, and stand alone documents into a coherent plan. Appropriate management plans may include the Health and Safety Plan, Waste Management Plan, Risk Analysis Plan, Community Relations Plan, or Records Management Plan. If a detailed discussion of the project already exists in another document, which is available to project participants, then a brief description of site history and incorporation of the document into the project plan document by reference may be appropriate. Incorporation by citation may also be appropriate when the complexity of the project requires an extensive discussion of background issues. Other documents that should be integrated, if available, are the report on the planning process, the data validation plan (Chapter 8), and the DQA plan (Chapter 9). If stand alone documents are not immediately available to project participants, they should be appended to the (primary) project plan document.

4.5 Elements of Project Plan Documents

A project plan document must address a range of issues. The extent of the detail is dependent on the type of project and the intended use of the results as previously discussed in applying a graded approach to plan documents (Section 4.3). For all projects, the project plan document must provide the project information and decisions developed during the project planning process. Project plan documents should address:

- The project's DQOs and MQOs;
- The sampling and analytical protocols that will be used to achieve the project objectives; and
- The assessment procedures and documentation that are sufficient to confirm that the data are of the type and quality needed.

Content of plan documents is discussed in Section 4.5.1. The integration of project plan documents is discussed in Section 4.5.2. Special consideration of project documentation for small projects is discussed in Section 4.5.3.

4.5.1 Content of Project Plan Documents

The plan document development team should remain flexible with regard to format and should focus instead on the appropriate content of plan documents needed to address the elements listed above. The content of plan documents, regardless of the title or format, will include similar information, including:

- The project description and objectives;

- Identification of those involved in the data collection and their responsibilities and authorities;
- Enumeration of the QC procedures to be followed;
- Reference to specific SOPs that will be followed for all aspects of the projects; and
- Health and safety protocols.

The project plan document(s) should present the document elements as integrated chapters, appendices, and stand alone documents, and plans should be included by citation. Table 4.1 provides summary information on project plan elements for three different plan documents: project plans, dynamic work plans, and QAPPs as provided in ASTM and EPA guidance. The table also illustrates the similarity of project plan content.

TABLE 4.1 — Elements of project plan documents

Project Plan (ASTM D5283 and D5612)	Dynamic Work Plan (ASTM PS85)	QAPP (EPA, 2002)
Project Management Identify individuals with designated responsibility and authority to: (1) develop project documents; (2) select organizations to perform the work; (3) coordinate communications; and (4) review and assess final data.		A. Project Management A1 Approval Sheet A2 Table of Contents A3 Distribution List A4 Project Organization
Background Information Reasons for data collection. Identify regulatory programs governing data collection.	1. Regulatory Framework 2. Site Descriptions and History of Analyte Use and Discovery 3. Analysis of Prior Data and Preliminary Conceptual Site Model	A5 Problem Definition and Background
Project Objectives <ul style="list-style-type: none"> • Clearly define objectives of field and laboratory work. • Define specific objectives for the sampling location. • Describe intended use of data. 	Dynamic Technical Program <ul style="list-style-type: none"> • Essential questions to be answered or specific objectives. • Identify the investigation methods and the areas in which they may be applied. • Provide clear criteria for determining when the project objectives have been met. 	A6 Project Description. A7 Quality Objectives and Criteria for Measurement Data. A8 Special Training Requirements/Certifications. A9 Documentation and Records.

Project Plan Documents

Project Plan (ASTM D5283 and D5612)	Dynamic Work Plan (ASTM PS85)	QAPP (EPA, 2002)
Sampling Requirements Sample requirements are specified, including: <ul style="list-style-type: none"> • Sampling locations. • Equipment and Procedures (SOPs). • Sample preservation and handling. 	Field Protocols and Standard Operating Procedures (this section may be attached as a separate document) [* see footnote]	B. Measurement/Data Acquisition B1 Sampling Process Designs. B2 Sampling Method Requirements. B3 Sample Handling and Custody Requirements.
Analytical Requirements The analytical requirements are specified, including: <ul style="list-style-type: none"> • Analytical procedures (SOPs). • Analyte list. • Required method uncertainty. • Required detection limits. • Regulatory requirements and DQO specifications are considered. 		B4 Analytical Methods Requirements.
Quality Assurance and Quality Control Requirements <ul style="list-style-type: none"> • QA/QC requirements are addressed for both field and laboratory activities. • Type and frequency of QC samples will be specified. • Control parameters for field activities will be described. • Performance criteria for laboratory analysis will be specified. • Data validation criteria (for laboratory analysis) will be specified. 	Quality Assurance and Quality Control Plan	B5 Quality Control Requirements. B6 Instrument/Equipment Testing Inspection and Maintenance Requirements. B7 Instrument Calibration and frequency. B8 Inspection/Acceptance Requirements for Supplies and Consumables. B9 Data Acquisition Requirements for Non-direct Measurements. B10 Data Management.
Project Documentation All documents required for planning, implementing, and evaluating the data collection efforts are specified, may include: <ul style="list-style-type: none"> • SOW, Work Plan, SAP, QAPP, H&S Plan, Community Relations Plan. • Technical reports assessing data. • Requirements for field and analytical records. 	<ol style="list-style-type: none"> 1. Data Management Plan 2. Health and Safety Plan 3. Community Relations Plan 	C. Assessment/Oversight C1 Assessments and response Actions. C2 Reports to Management. D. Data Validation and Usability D1 Data Review, Verifications and Validation Requirements. D2 Verification and Validation Methods. D3 Reconciliation with DQO.

* The combined Dynamic Technical Program section and Field Protocols and SOPs section is the functional equivalent of a Field Sampling and Analysis Plan.

Appendix D (*Content of Project Plan Documents*) provides more detailed guidance on the content of project plan documents following the outline developed by EPA requirements (EPA, 2001) and guidance (EPA, 2002) for QAPPs for environmental data operations. The EPA element identifiers (A1, A2, etc.) and element titles are used in the tables and text of this chapter

for ease of cross reference to the appropriate section in Appendix D. The EPA elements for a QAPP are used to facilitate the presentation and do not represent a recommendation by MARLAP on the use of a QAPP as the project plan document format.

4.5.2 Plan Documents Integration

MARLAP strongly discourages the use of a number of stand-alone plan components of equivalent status without integrating information and without a document being identified as a primary document. For large project plan compilations, it is appropriate to issue stand-alone portions of the plan that focus on certain activities such as sampling, analysis or data validation, since it can be cumbersome for sampling and laboratory personnel to keep the entire volume(s) of the project plan document readily available. However, each stand-alone component should contain consistent project information, in addition to the component specific plan information, such as the following:

- A brief description of the project including pertinent history;
- A brief discussion of the problem to be solved or the question to be answered (DQO);
- An organizational chart or list of key contact persons and means of contact;
- The analyte(s) of interest; and
- The appropriate health and safety protocols and documentation requirements.

In addition, a cross-referenced table is helpful in the primary document, which identifies where project plan elements are located in the integrated plan document.

4.5.3 Plan Content for Small Projects

The project plan documents for small projects and basic studies (Section 4.3) generally consist of three elements: the title and approval sheet, the distribution list, and a project narrative. The project narrative should discuss in a concise manner the majority of issues that are normally addressed in a project plan document, such as a QAPP. A typical project narrative may be a concise and brief description of the following list (keyed to the QAPP column in Table 4.1, [EPA, 2001]):

- Problem and site history (A5)
- Project/task organization (A4)
- Project tasks, including a schedule and key deliverables (A6)
- Anticipated use of the data (A5, A6)
- MQOs (A7)
- Sampling process design requirements and description (B1)
- Sample type and sampling location requirements (B2)
- Sample handling and custody requirements (B3)
- Analytical protocols (B4)

- QC and calibration requirements for sampling and analysis (B5, B7)
- Inspection and maintenance of analytical instrumentation (B6)
- Plans for peer or readiness reviews prior to data collection (C1)
- Assessments to be conducted during actual operation (C1)
- Procedure for data review (D2)
- Identification of any special reports on QA/QC activities, as appropriate (C2)
- Reconciliation with DQOs or other objectives (D3)

4.6 Linking the Project Plan Documents and the Project Planning Process

Directed planning processes (Chapter 2 and Appendix B) yield many outputs, such as the APSs (Chapter 3), which must be captured in project plan documents to ensure that data collection activities are implemented properly. MARLAP recommends that the project plan documents integrate all technical and quality aspects for the life cycle of the project, including planning, implementation, and assessment.

The project plan should be a dynamic document, used and updated over the life of the project. For example, the analytical methods requirements in the project plan documents (B4) will initially reflect the APSs established by the project planning team (Chapter 3) and issued in the SOW or BOA task order (Chapter 5). When the analytical laboratory has been selected (Chapter 7), the project plan document should be updated to reflect the specific analytical protocols: the actual protocols to be used, which should be included by citation or inclusion of the SOPs as appendices. MARLAP also recommends using a formal process to control and document changes if updates of the original project plan document are needed.

Table 4.2 presents a crosswalk of the elements of the EPA QAPP guidance with outputs of a directed planning process to illustrate how to capture and integrate the outputs of the planning process into the plan document(s).

TABLE 4.2 — Crosswalk between project plan document elements and directed planning process

ID	Project Plan Document Elements (QAPP—EPA, 2001)*	Content	Directed Planning Process Input
PROJECT MANAGEMENT			
A1	Title and Approval Sheet	Title and approval sheet.	
A2	Table of Contents	Document control format.	
A3	Distribution List	Distribution list for the plan document revisions and final guidance.	Include the members of the project planning team and stakeholders.
A4	Project/Task Organization	1) Identify individuals or organizations participating in the project and discuss their roles and responsibilities.	The directed planning process: <ul style="list-style-type: none"> • Identifies the stakeholders, data users, decisionmakers.

ID	Project Plan Document Elements (QAPP—EPA, 2001)*	Content	Directed Planning Process Input
		2) Provide an organizational chart showing relationships and communication lines.	<ul style="list-style-type: none"> • Identifies the core planning team and the technical planning team members responsible for technical oversight. • Identifies the specific people/organizations responsible for project implementation (sampling and analysis).
A5	Problem Definition/ Background	1) State the specific problem to be solved and decision to be made. 2) Include enough background to provide a historical perspective.	Project planning team: <ul style="list-style-type: none"> • Documents the problem, site history, existing data, regulatory concerns, background levels and thresholds. • Develops a decision statement.
A6	Project/Task Description	Identify measurements, special requirements, sampling and analytical methods, action levels, regulatory standards, required data and reports, quality assessment techniques, and schedules.	Project planning team identifies: <ul style="list-style-type: none"> • Deadlines and other constraints that can impact scheduling. • Existing and needed data inputs. Project planning team establishes: <ul style="list-style-type: none"> • Action levels and tolerable decision error rates that will be the basis for the decision rule. • The optimized sampling and analytical design as well as quality criteria.
A7	Quality Objectives and Criteria for Measurement Data	1) Identify DQOs, data use, type of data needed, domain, matrices, constraints, action levels, statistical parameters, and acceptable decision errors. 2) Establish MQOs that link analysis to the user's quality objectives.	Project planning team: <ul style="list-style-type: none"> • Identifies the regulatory standards and the action level(s). • Establishes the decision rule. • Describes the existing and needed data inputs. • Describes practical constraints and the domain. • Establishes the statistical parameter that is compared to the action level. • Establishes tolerable decision error rates used to choose quality criteria. • Establishes quality criteria linked to the optimized design. • Establishes data verification, validation and assessment criteria and procedures. • Establishes APSs and MQOs.
A8	Special Training Requirements/ Certification	Identify and discuss special training/certificates required to perform work.	Project planning team: <ul style="list-style-type: none"> • Identifies training, certification, accreditation requirements for field and laboratory.

ID	Project Plan Document Elements (QAPP—EPA, 2001)*	Content	Directed Planning Process Input
			<ul style="list-style-type: none"> • Identifies federal and state requirements for certification for laboratories. • Identifies federal and state requirements for activities, such as disposal of field-generated residuals.
A9	Documentation and Record	Itemize the information and records, which must be included in a data report package including report format and requirements for storage etc.	Project planning team: <ul style="list-style-type: none"> • Indicates whether documents will be controlled and the distribution list incomplete. • Identifies documents that must be archived. • Specifies period of time that documents must be archived. • Specifies procedures for error corrections (for hard copy and electronic files).
MEASUREMENT/DATA ACQUISITION			
B1	Sampling Process Designs (Experimental Designs)	(1) Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest. (2) Identify non-standard methods and validation process.	Project planning team establishes the rationale for and details of the sampling design.
B2	Sampling Methods Requirements	Describe sampling procedures, needed materials and facilities, decontamination procedures, waste handling and disposal procedures, and include a tabular description of sample containers, sample volumes, preservation and holding time requirements.	Project planning team specifies the preliminary details of the optimized sampling method.
B3	Sample Handling and Custody Requirements	Describe the provisions for sample labeling, shipment, sample tracking forms, procedures for transferring and maintaining custody of samples.	Project planning team describes the regulatory situation and site history, which can be used to identify the appropriate sample tracking level.
B4	Analytical Methods Requirements	Identify analytical methods and procedures including needed materials, waste disposal and corrective action procedures.	Project planning team: <ul style="list-style-type: none"> • Identifies inputs to the decision (nuclide of interest, matrix, etc.). • Establishes the allowable measurement uncertainty that will drive choice of the analytical protocols. • Specifies the optimized sampling and analytical design.

ID	Project Plan Document Elements (QAPP—EPA, 2001)*	Content	Directed Planning Process Input
B5	Quality Control Requirements	(1) Describe QC procedures and associated acceptance criteria and corrective actions for each sampling and analytical technique. (2) Define the types and frequency of QC samples should be defined along with the equations for calculating QC statistics.	Project planning team: <ul style="list-style-type: none"> Establishes the allowable measurement uncertainty, which will drive QC acceptance criteria. Establishes the optimized analytical protocols and desired MQOs.
B6	Instrument/Equipment Testing Inspection and Maintenance Requirements	1) Discuss determination of acceptable instrumentation performance. 2) Discuss the procedures for periodic, preventive and corrective maintenance.	
B7	Instrument Calibration and Frequency	(1) Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. (2) Describe how the calibration should be done.	Project planning team establishes the desired MQOs, which drive acceptance criteria for instrumentation performance.
B8	Inspection/Acceptance Requirements for Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.	
B9	Data Acquisition Requirements (Non-direct Measurements)	Define criteria for the use of non-direct measurement data such as data that come from databases or literature.	Project planning team: <ul style="list-style-type: none"> Identifies the types of existing data that are needed or would be useful. Establishes the desired MQOs that would also be applicable to archived data.
B10	Data Management	(1) Outline of data management scheme including path of data, use of storage and record keeping system.(2) Identify all data handling equipment and procedures that will be used to process, compile, analyze the data, and correct errors.	
ASSESSMENT/OVERSIGHT			
C1	Assessments and Response Actions	(1) Describe the number, frequency and type of assessments needed for the project. (2) For each assessment: list participants and their authority, the schedule, expected information, criteria for success and unsatisfactory conditions and those who	Project planning team establishes the MQOs and develops statements of the APSs, which are used in the selection of the analytical protocols and in the ongoing evaluation of the protocols.

ID	Project Plan Document Elements (QAPP—EPA, 2001)*	Content	Directed Planning Process Input
		will receive reports and procedures for corrective actions.	
C2	Reports to Management	Identify the frequency, content and distribution of reports issued to keep management informed.	
DATA VALIDATION AND USABILITY			
D1	Data Review, Verification and Validation Requirements	State the criteria including specific statistics and equations, which will be used to accept or reject data based on quality.	Project planning team: <ul style="list-style-type: none"> • Establishes the MQOs for the sample analysis, and may also discuss completeness and representativeness requirements that will be the basis of validation. • Establishes the action level(s) relevant to the project DQOs. • Establishes the data validation criteria.
D2	Verification and Validation Methods	Describe the process to be used for validating and verifying data, including COC for data throughout the lifetime of the project.	Project planning team: <ul style="list-style-type: none"> • Determines appropriate level of custody. • May develop a validation plan.
D3	Reconciliation With Data Quality Objectives	Describe how results will be evaluated to determine if DQOs are satisfied.	Project planning team: <ul style="list-style-type: none"> • Defines the necessary data input needs. • Defines the constraints and boundaries with which the project has to comply. • Defines the decision rule. • Identifies the hypothesis and tolerable decision error rates. • Defines MQOs for achieving the project DQOs.

[Adapted from: EPA, 2002]

* EPA QAPP elements are discussed in Appendix D

4.6.1 Planning Process Report

MARLAP recommends including, by citation or as an appendix, the report on the directed planning process in the project plan documents. If the planning process was not documented in a report, MARLAP recommends that a summary of the planning process be included in the project plan document section on Problem Definition/Background (A5) that addresses assumptions and decisions, established action levels, the DQO statement, and APSs (which include the established MQOs and any specific analytical process requirements). Additional detailed information on the APSs including the MQOs will be presented in the project plan document sections on project/

task description (A6), quality objectives and criteria for measurement data (A7), and analytical methods requirements (B4). MARLAP views the project plan documents as the principal product of the planning process.

4.6.2 Data Assessment

Assessment (verification, validation, and DQA) is the last step in the project's data life cycle and precedes the use of data. Assessment, and in particular DQA, is designed to evaluate the suitability of project data to answer the underlying project question or the suitability of project data to support the project decision. The project planners should define the assessment process in enough detail that achievement or failure to meet goals can be established upon project completion. An important output of the directed planning process to be captured in the project plan document is the data verification, validation and assessment criteria and procedures.

4.6.2.1 Data Verification

Analytical data verification assures that laboratory conditions and operations were compliant with the contractual SOW and the project plan. Verification compares the data package to these requirements (contract compliance) and checks for consistency and comparability of the data throughout the data package and completeness of the results to ensure all necessary documentation is available. Performance criteria for verification should be documented in the contract and in the project plan document in the sections that address data review, verification, and validation requirements (D1), and verification and validation methods (D2).

4.6.2.2 Data Validation

Validation addresses the reliability of the data. During validation, the technical reliability and the degree of confidence in reported analytical data are considered. Data validation criteria and procedures should be established during the planning process and captured in the project plan document (and the SOW for the validation contractor). Performance criteria for data validation can be documented directly in the project plan document in data review, verifications, and validation requirements (D1) and verifications and validation methods (D2) or in a separate plan, which is included by citation or as an appendix in the project plan document.

Guidance on data validation plans is provided in Section 8.3. The data validation plan should contain the following information:

- A summary of the project, which provides sufficient detail about the project's APSs, including the MQOs;

- The set of data to be validated and whether all the raw data will be reviewed and in what detail;
- The necessary validation criteria and the MQOs deemed appropriate for achieving project DQOs;
- Specifications on what qualifiers are to be used and how final qualifiers are to be assigned; and
- Information on the content of the validation report.

4.6.2.3 Data Quality Assessment

Data quality assessment consists of a scientific and statistical evaluation of project-wide knowledge to determine if the data set is of the right type, quality and quantity to support its intended use. The data quality assessor integrates the data validation report, field information, assessment reports and historical project data and compares the findings to the original project objectives and criteria (DQOs).

Performance criteria for data usability for the project should be documented in the project plan documents in a section on DQA or reconciliation of the data results with DQOs (D3) or in a separate plan, which is included by citation or as an appendix in the project plan document. Guidance on DQA plans is provided in Section 9.5. The DQA plan should contain the following information:

- A summary of the project, which provides sufficient detail about the project's DQOs and tolerable decision error rates;
- Identification of what issues will be addressed by the DQA;
- Identification of any statistical tests that will be used to evaluate the data;
- Description of how the representativeness of the data will be evaluated (for example, review the sampling strategy, the suitability of sampling devices, subsampling procedures, assessment findings);
- Description of how the accuracy of the data, including potential impact of non-measurable factors (for example, subsampling bias) will be considered (for example, review the APSs and the analytical plan, the suitability of analytical protocols, subsampling procedures, assessment findings);
- Description of how the MQOs will be used to determine the usability of measurement data (that is, did the uncertainty in the data significantly affect confidence in the decision);

- Identification of what will be included in the DQA report; and
- Identification of who will receive the report and the mechanism for its archival.

4.7 Summary of Recommendations

- MARLAP recommends using a graded approach to project plan writing because of the diversity of environmental data collection activities.
- MARLAP recommends developing a primary integrating project plan that includes other documents by citation or as appendices.
- MARLAP recommends developing project plan documents that integrate all technical and quality aspects for the life-cycle of the project, including planning, implementation, and assessment.
- MARLAP recommends including, by citation or as an appendix, the report on the directed planning process in the project plan documents.
- If the planning process was not documented in a report, MARLAP recommends that a summary of the planning process addressing assumptions and decisions, established action levels, the DQO statement, and APSs (which include the established MQOs and any specific analytical process requirements) be included in the project plan documents.
- MARLAP recommends using a formal process to control and document changes if updates of the original project plan document are needed.

4.8 References

American Society for Quality Control (ANSI/ASQC) E-4. *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. 1995. American Society for Quality Control, Milwaukee, Wisconsin.

American Society of Mechanical Engineers (ASME) NQA-1. *Quality Assurance Program Requirements for Nuclear Facilities*. New York, New York. 1989.

American Society of Testing and Materials (ASTM) D5283. *Standard Practice for Generation of Environmental Data Related to Waste Management Activities: Quality Assurance and Quality Control Planning and Implementation*. 1992. West Conshohocken, PA.

American Society of Testing and Materials (ASTM) D5612. *Standard Guide for Quality Planning and Field Implementation of a Water Quality Measurements Program*, 1994. West Conshohocken, PA.

American Society of Testing and Materials (ASTM) PS85. *Standard Provisional Guidance for Expedited Site Characterization of Hazardous Waste Contaminated Sites*. 1996. West Conshohocken, PA.

Code of Federal Regulations (CFR). 1999. 10 CFR 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

Code of Federal Regulations (CFR). 1994. 10 CFR 830.120, "Nuclear Safety Management - Quality Assurance Requirements."

Code of Federal Regulations (CFR). 1997. 40 CFR 300.430, "National Oil and Hazardous Substance Pollution Contingency Plan – Remedial Investigation/Feasibility Study and Selection of Remedy."

U.S. Department of Defense (DOD). 1963. *Quality Program Requirements*. Military Specification MIL-Q-9858A. Washington, DC.

U.S. Department of Energy (DOE). 1991. *Quality Assurance*. DOE Order 414.1A (Replaced DOE Order 5700.6C), Washington, DC.

U.S. Environmental Protection Agency (EPA). 2000. *EPA Policy and Program Requirements for the Mandatory Agency-Wide Quality System*. EPA Order 5360.1A2, Revised. Washington, DC. Available at www.epa.gov/quality/qa_docs.html.

U.S. Environmental Protection Agency (EPA). 2001. *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5). EPA/240/B-01/003. Office of Environmental Information, Washington, DC. Available at www.epa.gov/quality/qa_docs.html.

U. S. Environmental Protection Agency (EPA). 2002. *Guidance on Developing Quality Assurance Project Plans* (EPA QA/G-5). EPA/240/R-02/009. Office of Environmental Information, Washington, DC. Available at www.epa.gov/quality/qa_docs.html.

U.S. Environmental Protection Agency (EPA). 2003. *Using Dynamic Field Activities for On-Site Decision Making: A Guide for Project Managers*. EPA/540/R-03/002. Office of Solid Waste and Emergency Response, Washington, DC. Available at www.epa.gov/superfund/programs/dfa/index.htm.

International Organization for Standardization (ISO) 9001. *Quality Systems - Model for Quality Assurance in Design, Development, Installation and Servicing*. 1994.

U.S. Army Corps of Engineers (USACE). 1997. *Chemical Quality Assurance for Hazardous, Toxic and Radioactive Waste Projects*. Engineer Manual EM 200-1-6. Available at www.environmental.usace.army.mil/info/technical/chem/chemguide/chemusac/chemusac.html.

U.S. Army Corps of Engineers (USACE). 2001. *Requirements for the Preparation of Sampling and Analysis Plans*. Engineer Manual EM 200-1-3. Available at www.environmental.usace.army.mil/info/technical/chem/chemguide/chemusac/chemusac.html.

U.S. Nuclear Regulatory Commission (NRC). 1989. *Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Parts 30, 40, and 70*. Regulatory Guide 3.65.