

# 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 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 Analytical Protocol Specifications established by the project planning team and issued in the statement of work (SOW) (or Basic Ordering Agreement Task Order). 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. (Analytical Protocol Specifications and the relation to project measurement quality objectives (MQOs) have been 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 is cognizant of, and fully endorses, the need for an organizational quality system and a quality system, 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 system for environmental data collection activities is available from several sources including ANSI/ASQC (1994) and ISO Standard 9001 (1994).

34 The QA requirements have been developed by several Federal Agencies and consensus standard  
35 organizations including the following:

- 36 • 10 CFR 830.120
- 37 • 10 CFR 50, Appendix B
- 38 • ANSI N42.23-1996
- 39 • ASME NQA-1-1989
- 40 • DOE Order 4.14.1 on QA
- 41 • EPA Order 5360.1 on Quality Systems (1998c)
- 42 • DOD QA requirement MIL-Q-9858A

## 43 **4.2 The Importance of Project Plan Documents**

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

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

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

- 53 • Full documentation for legal, regulatory, and historical use of the information;
- 54 • Specification of data collection and quality control;
- 55 • Documentation of analytical requirements through the incorporation of an Analytical  
56 Protocol Specifications;
- 57 • Implementation of planned data collection activities (through internal and external  
58 assessment and oversight activities); and
- 59 • Meeting project-specific criteria (i.e., MQOs, DQOs) through data validation and usability  
60 assessment.

### 4.3 A Graded Approach to Project Plan Documents

A graded approach is the process of basing 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, 1994). 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 their 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 may also be desirable when Office of Management and Budget (OMB) clearance and approval is needed to carry out the project (e.g., NRC/EPA proposed Publicly Owned Treatment Works Survey).

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. (Other titles used for project narrative statements are “QA narrative statement” and “proposal QA plan” (EPA, 1998a). 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.

90 **4.4 Project Plan Documents**

91 The ANSI/ASQC (1994) definition for a QA Project Plan (QAPP), which is also applicable to  
92 other integrated project plan documents, is “a formal document describing in comprehensive  
93 detail the necessary QA, QC and other technical activities that must be implemented to ensure  
94 that the results of the work performed will satisfy the stated performance criteria.” The project  
95 plan documents should contain this information in a clear and integrated manner so that all  
96 implementation teams can understand their role and the project objectives.

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

104 **4.4.1 Guidance on Project Plan Documents**

105 National standards guidance on project plan documents is available in:

- 106 • ASTM Standard Practice (D5283) for Generation of Environmental Data Related to Waste  
107 Management Activities: Quality Assurance and Quality Control Planning and  
108 Implementation (ASTM, 1992);
- 109 • Standard Guide (D5612), Quality Planning and Field Implementation of a Water Quality  
110 Measurements Program (ASTM, 1994); and
- 111 • Standard Provisional Guide (PS85) for Expedited Site Characterization of Hazardous Waste  
112 Contaminated Sites (ASTM, 1996).

113 Guidance on project plans for environmental data collection activities in the federal sector is also  
114 available (EPA, 1998a; 40 CFR 300.430; NRC, 1989; and USACE, 1994 and 1997). Other  
115 Federal Agency guidance may follow EPA guidance for QAPPs (EPA, 1998a).

116 **4.4.2 Approaches to Project Plan Documents**

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

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

133 Traditional site investigations are generally based on a phased engineering approach, which  
134 collects samples based on a pre-specified grid pattern and does not provide the framework for  
135 making changes in the plan in the field. The work plan (the project plan document) for the site  
136 investigation typically will specify the number of samples to be collected, the location of each  
137 sample and the analyses to be performed. A newer concept is to develop a dynamic work plan  
138 (the project plan document), which, rather than specifying the number of samples to be collected  
139 and the location of each sample, would specify the decision making logic that will be used in the  
140 field to determine where the samples will be collected, when the sampling will stop, and what  
141 analyses will be performed. Guidance on dynamic work plans is available in the Standard  
142 Provisional Guide (PS85) for Expedited Site Characterization of Hazardous Waste Contaminated  
143 Sites (ASTM, 1996).

144 MARLAP does not recommend a particular project plan document approach, title or arrange-  
145 ment. Federal and state agencies have different requirements for the various environmental data  
146 collection activities. In certain cases there are regulatory requirements. If an organization has  
147 successful experience addressing the essential content of plan documents (Section 4.5) in a well  
148 integrated, document format, it is usually unnecessary and wasteful of time and monies to change

149 a proven approach. The project plan document should reflect, and be consistent with, the  
150 organization's QA policies and procedures.

151 *MARLAP recommends a primary project plan document that includes other documents by*  
152 *citation or as appendices.* The primary project plan document serves to integrate the multi-  
153 disciplinary sections, other management plans, and stand alone documents into a coherent plan.  
154 Appropriate management plans may include the Health and Safety Plan, Waste Management  
155 Plan, Risk Analysis Plan, Community Relations Plan, or Records Management Plan. If a detailed  
156 discussion of the project already exists in another document, which is available to project  
157 participants, then a brief description of site history and incorporation of the document into the  
158 project plan document by reference may be appropriate. Incorporation by citation may also be  
159 appropriate when the complexity of the project requires an extensive discussion of background  
160 issues. Other documents that should be integrated, if available, are the report on the planning  
161 process, the Data Validation Plan (Chapter 8), and the DQA Plan (Chapter 9). If stand alone  
162 documents are not immediately available to project participants, they should be appended to the  
163 (primary) project plan document.

## 164 **4.5 Elements of Project Plan Documents**

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

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

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

177 **4.5.1 Content of Project Plan Documents**

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

- 182 • The project description and objectives;
- 183 • Identification of those involved in the data collection and their responsibilities and  
 184 authorities;
- 185 • Enumeration of the QC procedures to be followed;
- 186 • Reference to specific SOPs that will be followed for all aspects of the projects; and
- 187 • Health and Safety protocols.

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

193 **TABLE 4.1—Elements of Project Plan Documents**

Project Plan (ASTM D5283, 1992 and ASTM D5612, 1994)	Dynamic Work Plan (ASTM PS 85, 1996)	QAPP (EPA, 1998a)
<b>Project Management</b> 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.		<b>A. Project Management</b> A1 Approval Sheet A2 Table of Contents A3 Distribution List A4 Project Organization
<b>Background Information</b> Reasons for data collection. Identify regulatory programs governing data collection.	<ol style="list-style-type: none"> <li>1. <b>Regulatory Framework</b></li> <li>2. <b>Site Descriptions and History of Analyte Use and Discovery</b></li> <li>3. <b>Analysis of Prior Data and Preliminary Conceptual Site Model</b></li> </ol>	A5 Problem Definition and Background

*Project Plan Documents*

	<b>Project Plan (ASTM D5283, 1992 and ASTM D5612, 1994)</b>	<b>Dynamic Work Plan (ASTM PS 85, 1996)</b>	<b>QAPP (EPA, 1998a)</b>
208 209 210 211 212 213	<b>Project Objectives</b> <ul style="list-style-type: none"> <li>Clearly define objectives of field and laboratory work.</li> <li>Define specific objectives for the sampling location.</li> <li>Describe intended use of data.</li> </ul>	<b>Dynamic Technical Program</b> <ul style="list-style-type: none"> <li>Essential questions to be answered or specific objectives.</li> <li>Identify the investigation methods and the areas in which they may be applied.</li> <li>Provide clear criteria for determining when the project objectives have been met.</li> </ul>	A6 Project Description. A7 Quality Objectives and Criteria for Measurement Data. A8 Special Training Requirements/Certifications. A9 Documentation and Records.
214 215 216 217 218 219	<b>Sampling Requirements</b> Sample requirements are specified, including: <ul style="list-style-type: none"> <li>Sampling locations.</li> <li>Equipment and Procedures (SOPs).</li> <li>Sample preservation and handling .</li> </ul>	<b>Field Protocols and Standard Operating Procedures</b> (this section may be attached as a separate document)  [* see footnote]	<b>B. Measurement/Data Acquisition</b> B1 Sampling Process Designs. B2 Sampling Method Requirements. B3 Sample Handling and Custody Requirements. B4 Analytical Methods Requirements.
220 221 222 223 224 225 226 227 228	<b>Analytical Requirements</b> The analytical requirements are specified, including: <ul style="list-style-type: none"> <li>Analytical procedures (SOPs).</li> <li>Analyte list.</li> <li>Required method uncertainty.</li> <li>Required detection limits.</li> <li>Regulatory requirements and DQO specifications are considered.</li> </ul>		
229 230 231 232 233 234 235 236 237 238 239 240	<b>Quality Assurance and Quality Control Requirements</b> <ul style="list-style-type: none"> <li>QA/QC requirements are addressed for both field and laboratory activities.</li> <li>Type and frequency of QC samples will be specified.</li> <li>Control parameters for field activities will be described.</li> <li>Performance criteria for laboratory analysis will be specified.</li> <li>Data validation criteria (for laboratory analysis) will be specified.</li> </ul>	<b>Quality Assurance and Quality Control Plan</b>	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 Plan (ASTM D5283, 1992 and ASTM D5612, 1994)	Dynamic Work Plan (ASTM PS 85, 1996)	QAPP (EPA, 1998a)
<p><b>Project Documentation</b> All documents required for planning, implementating, and evaluating the data collection efforts are specified, may include:</p> <ul style="list-style-type: none"> <li>• SOW, Work Plan, SAP, QAPP, H&amp;S Plan, Community Relations Plan.</li> <li>• Technical reports assessing data.</li> <li>• Requirements for field and analytical records.</li> </ul>	<ol style="list-style-type: none"> <li>1. <b>Data Management Plan</b></li> <li>2. <b>Health and Safety Plan</b></li> <li>3. <b>Community Relations Plan</b></li> </ol>	<p><b>C. Assessment/Oversight</b> C1 Assessments and response Actions. C2 Reports to Management. <b>D. Data Validation and Usability</b> D1 Data Review, Verifications and Validation Requirements. D2 Verification and Validation Methods. D3 Reconciliation with DQO.</p>

[\* 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 provides more detailed guidance on the content of project plan documents following the outline developed by EPA requirements (EPA, 1998b) and guidance (EPA, 1998a) for Quality Assurance Project Plans 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.

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

### 276 **4.5.3 Plan Content for Small Projects**

277 The project plan documents for small projects and basic studies (Section 4.3) generally consist of  
278 three elements: the Title and Approval Sheet, the Distribution List, and a Project Narrative. The  
279 Project Narrative should discuss in a concise manner the majority of issues that are normally  
280 addressed in a project plan document, such as a QAPP. A typical Project Narrative (EPA, 1998b)  
281 may be a concise and brief description of:

- 282 • Problem and site history (A5)
- 283 • Project/task organization (A4)
- 284 • Project tasks, including a schedule and key deliverables (A6)
- 285 • Anticipated use of the data (A5, A6)
- 286 • MQOs (A7)
- 287 • Sampling process design requirements and description (B1)
- 288 • Sample type and sampling location requirements (B2)
- 289 • Sample handling and custody requirements (B3)
- 290 • Analytical protocols (B4)
- 291 • QC and calibration requirements for sampling and analysis (B5, B7)
- 292 • Inspection and maintenance of analytical instrumentation (B6)
- 293 • Plans for peer or readiness reviews prior to data collection (C1)
- 294 • Assessments to be conducted during actual operation (C1)
- 295 • Procedure for data review (D2)
- 296 • Identification of any special reports on QA/QC activities, as appropriate (C2)
- 297 • Reconciliation with DQOs or other objectives (D3)

298 Table 4.2 or Appendix D gives information on what is addressed in each bullet above, using the  
299 element identifier shown in parenthesis.

### 300 **4.6 Linking the Project Plan Documents and the Project Planning Process**

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

**TABLE 4.2–Crosswalk Between Project Plan Document Elements and Directed Planning Process**

ID	Project Plan Document Elements (QAPP, EPA QA/R-5, 1998b)*	Content	Directed Planning Process Input
<b>PROJECT MANAGEMENT</b>			
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.	<ul style="list-style-type: none"> <li>• Include the members of the project planning team and stakeholders.</li> </ul>
A4	Project/Task Organization	1) Identify individuals or organizations participating in the project and discuss their roles and responsibilities. 2) Provide an organizational chart showing relationships and communication lines.	The directed planning process: <ul style="list-style-type: none"> <li>• Identified the stakeholders, data users, decision makers.</li> <li>• Identified the core planning team and the technical planning team members who will often be responsible for technical oversight.</li> <li>• Will often identify the specific persons/organizations that will be responsible for project implementation (sampling and analysis).</li> </ul>
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"> <li>• Documented the problem, site history, existing data, regulatory concerns, background levels and thresholds.</li> <li>• Developed a decision statement.</li> </ul>
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 identified: <ul style="list-style-type: none"> <li>• Deadlines and other constraints that can impact scheduling.</li> <li>• Existing and needed data inputs.</li> </ul> Project planning team established: <ul style="list-style-type: none"> <li>• Action levels and tolerable decision error rates that will be the basis for the decision rule.</li> <li>• The optimized sampling and analytical design as well as quality criteria.</li> </ul>
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	Project planning team: <ul style="list-style-type: none"> <li>• Identified the regulatory standards and the action level(s).</li> <li>• Established the decision rule.</li> <li>• Described the existing and needed data inputs.</li> <li>• Described practical constraints and</li> </ul>

Project Plan Documents

ID	Project Plan Document Elements (QAPP, EPA QA/R-5, 1998b)*	Content	Directed Planning Process Input
		analysis to the user's quality objectives.	<p>the domain.</p> <ul style="list-style-type: none"> <li>Established the statistical parameter that is compared to the action level.</li> <li>Established tolerable decision error rates used to choose quality criteria.</li> <li>Established quality criteria linked to the optimized design.</li> <li>Establish data verification, validation and assessment criteria and procedures.</li> <li>Establish APS and MQOs.</li> </ul>
317	A8 Special Training Requirements/ Certification	Identify and discuss special training/certificates required to perform work.	<p>Project planning team:</p> <ul style="list-style-type: none"> <li>Identified training, certification, accreditation requirements for field and laboratory.</li> <li>Identified Federal and state requirements for certification for laboratories.</li> <li>Identified Federal and state requirements for activities, such as disposal of field-generated residuals.</li> </ul>
318	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.	<p>Project planning team:</p> <ul style="list-style-type: none"> <li>Indicated whether documents will be controlled and the distribution list incomplete.</li> <li>Identified documents that must be archived.</li> <li>Specified period of time that documents must be archived.</li> <li>Specified procedures for error corrections (for hard copy and electronic files).</li> </ul>
319	<b>MEASUREMENT/DATA ACQUISITION</b>		
320	B1 Sampling Process Designs (Experimental Designs)	<p>(1) Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest.</p> <p>(2) Identify non-standard methods and validation process.</p>	<ul style="list-style-type: none"> <li>Project planning team established the rationale for and details of the sampling design.</li> </ul>
321	B2 Sampling Methods Requirements	Describe sampling procedures, needed materials and facilities, decontamination procedures, waste handling and disposal procedures,	<ul style="list-style-type: none"> <li>Project planning team specified the preliminary details of the optimized sampling method.</li> </ul>

ID	Project Plan Document Elements (QAPP, EPA QA/R-5, 1998b)*	Content	Directed Planning Process Input
		and include a tabular description of sample containers, sample volumes, preservation and holding time requirements.	
322	B3 Sample Handling and Custody Requirements	Describe the provisions for sample labeling, shipment, sample tracking forms, procedures for transferring and maintaining custody of samples.	<ul style="list-style-type: none"> <li>Project planning team described the regulatory situation and site history, which can be used to identify the appropriate sample tracking level.</li> </ul>
323	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"> <li>Identified inputs to the decision (nuclide of interest, matrix, etc.).</li> <li>Established the allowable measurement uncertainty that will drive choice of the analytical protocols.</li> <li>Specified the optimized sampling and analytical design.</li> </ul>
324	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"> <li>Established the allowable measurement uncertainty, which will drive QC acceptance criteria.</li> <li>Established the optimized analytical protocols and desired MQOs.</li> </ul>
325	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.	
326	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.	<ul style="list-style-type: none"> <li>Project planning team established the desired MQOs, which will drive acceptance criteria for instrumentation performance.</li> </ul>
327	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.	

*Project Plan Documents*

ID	Project Plan Document Elements (QAPP, EPA QA/R-5, 1998b)*	Content	Directed Planning Process Input
328	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"> <li>Identified the types of existing data that are needed or would be useful.</li> <li>Established the desired MQOs that would also be applicable to archived data.</li> </ul>
329 330	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.	
<b>ASSESSMENT/OVERSIGHT</b>			
331 332	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 will receive reports and procedures for corrective actions.	<ul style="list-style-type: none"> <li>The project planning team established the MQOs and developed statements of the Analytical Protocol Specifications, which are used in the selection of the analytical protocols and in the ongoing evaluation of the protocols.</li> </ul>
333	C2 Reports to Management	Identify the frequency, content and distribution of reports issued to keep management informed.	
<b>DATA VALIDATION AND USABILITY</b>			
334 335	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.	<ul style="list-style-type: none"> <li>Project planning team established.</li> <li>Established the MQOs for the sample analysis, and may also have discussed completeness and representativeness requirements that will be the basis of validation.</li> <li>Established the action level(s) relevant to the project DQOs.</li> <li>Established the data validation criteria.</li> </ul>
336	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"> <li>Determines appropriate level of custody.</li> <li>May develop a Validation Plan.</li> </ul>

ID	Project Plan Document Elements (QAPP, EPA QA/R-5, 1998b)*	Content	Directed Planning Process Input
337 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"> <li>• Defined the necessary data input needs.</li> <li>• Defined the constraints and boundaries with which the project would have had to comply.</li> <li>• Defined the decision rule.</li> <li>• Identified the hypothesis and tolerable decision error rates.</li> <li>• Defined MQOs for achieving the project DQOs.</li> </ul>

338 [Adapted from: EPA, 1998a]  
339 [\* EPA QAPP elements are discussed in Appendix D]

340 The project plan should be a dynamic document, used and updated over the life of the project.  
341 For example, the analytical methods requirements in the project plan documents (B4) will  
342 initially reflect the Analytical Protocol Specifications established by the project planning team  
343 (Chapter 3) and issued in the SOW or BOA Task Order (Chapter 5). When the analytical  
344 laboratory has been selected (Chapter 7), the project plan document should be updated to reflect  
345 the specific analytical protocols: the actual protocols to be used, which should be included by  
346 citation or inclusion of the SOPs as appendices.

#### 347 **4.6.1 Planning Process Report**

348 MARLAP recommends the inclusion, by citation or as an appendix, of the directed planning  
349 process report in the project plan documents. If the planning process was not documented in a  
350 report, MARLAP recommends that a summary of the planning process addressing, for example,  
351 the assumptions and decisions, the established action levels, the DQO statement, and the  
352 Analytical Protocol Specifications, which include the established MQOs and any specific  
353 analytical process requirements, be included in the project plan document section on Problem  
354 Definition/Background (A5). Additional detailed information on the analytical protocol  
355 specifications including the MQOs will be presented in the project plan document sections on  
356 Project/Task Description (A6), Quality Objectives and Criteria for Measurement Data (A7), and  
357 Analytical Methods Requirements (B4).

358 MARLAP views the project plan documents as the principal product of the planning process. To  
359 illustrate how to capture and integrate the outputs of the planning process into the plan docu-

360 ment(s), Table 4.2 presents a crosswalk of the elements of the EPA QAPP Document and outputs  
361 of a directed planning process.

## 362 **4.6.2 Data Assessment**

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

### 371 4.6.2.1 Data Verification

372 Analytical data verification assures that laboratory conditions and operations were compliant  
373 with the contractual SOW and the project plan. Verification compares the data package to these  
374 requirements (contract compliance) and checks for consistency and comparability of the data  
375 throughout the data package and completeness of the results to ensure all necessary documen-  
376 tation is available. Performance criteria for verification should be documented in the contract and  
377 in the project plan document in the sections that address Data Review, Verification, and  
378 Validation Requirements (D1), and Verification and Validation Methods (D2).

### 379 4.6.2.2 Data Validation

380 Validation addresses the reliability of the data. During validation, the technical reliability and the  
381 degree of confidence in reported analytical data are considered. Data validation criteria and  
382 procedures should be established during the planning process and captured in the project plan  
383 document (and the SOW for the validation contractor). Performance criteria for data validation  
384 can be documented directly in the project plan document in Data Review, Verifications, and  
385 Validation Requirements (D1) and Verifications and Validation Methods (D2) or in a separate  
386 plan, which is included by citation or as an appendix in the project plan document.

387 Guidance on Data Validation Plans is provided in Chapter 8, Section 8.3. The data validation  
388 plan should contain the following information:

- 389 • A summary of the project, which provides sufficient detail about the project's Analytical  
390 Protocol Specifications, including the MQOs;

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

#### 398 4.6.2.3 Data Quality Assessment

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

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

- 409 • A summary of the project, which provides sufficient detail about the project's DQOs and  
410 tolerable decision error rates;
- 411 • Identification of what issues will be addressed by the DQA;
- 412 • Identification of any statistical tests that will be used to evaluate the data;
- 413 • Description of how the representativeness of the data will be evaluated (for example, review  
414 the sampling strategy, the suitability of sampling devices, subsampling procedures,  
415 assessment findings);
- 416 • Description of how the accuracy of the data, including potential impact of non-measurable  
417 factors (for example, subsampling bias) will be considered (for example, review the

- 418 Analytical Protocol Specifications and the analytical plan, the suitability of analytical  
419 protocols, subsampling procedures, assessment findings);
- 420 • Description of how the MQOs will be used to determine the usability of measurement data  
421 (that is, did the uncertainty in the data significantly affect confidence in the decision);
  - 422 • Identification of what will be included in the DQA report; and
  - 423 • Identification of who will receive the report and the mechanism for its archival.

### 424 **Summary of Recommendations**

- 425 • A graded approach to project plan writing because of the diversity of environmental data  
426 collection activities.
- 427 • A primary integrating project plan that includes other documents by citation or as  
428 appendices.
- 429 • Project plan documents that integrate all technical and quality aspects for the life-cycle of  
430 the project, including planning, implementation, and assessment.
- 431 • Inclusion, by citation or as an appendix, of the report on the directed planning process in  
432 the project plan documents. If the planning process was not documented in a report,  
433 MARLAP recommends that a summary of the planning process addressing assumptions  
434 and decisions, established action levels, DQO statement and established MQOs, and  
435 Analytical Protocol Specifications be included in the project plan documents.

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