

2 PROJECT PLANNING PROCESS

2.1 Introduction

Efficient environmental data collection activities depend on successfully identifying the type, quantity, and quality of data needed, as well as how the data will be used to support the decision making process. MARLAP recommends the use of a directed or systematic planning process. These planning processes provide a logic and framework for setting well-defined, achievable objectives and developing a cost-effective, technically sound and defensible sampling and analysis design that balances the data user's tolerance for uncertainty in the decision process and the available resources for obtaining data to support a decision. *MARLAP has chosen to use the term "directed planning" to emphasize that the planning process, in addition to having a framework or structure (i.e., it is systematic), is focused of defining the data needed to achieve an informed decision for a specific project.*

The objective of this MARLAP chapter is to promote:

1. Directed project planning as a tool for project management to identify and document the data quality objectives (DQOs)—that is, qualitative and quantitative statements that define the project objectives and the tolerable rate of making decision errors that will be used as the basis for establishing the quality and quantity of data needed to support the decision—and the measurement quality objectives (MQOs) that define the analytical data requirements appropriate for decision making;
2. The involvement of technical experts in particular radioanalytical specialists in the planning process; and
3. Integration of the outputs from the directed planning process into the implementation and assessment phases of the project through documentation in project plan documents, the analytical SOW, and the data assessment plans (e.g., for data validation, data verification, and data and data quality assessment—DQA).

MARLAP will use the terms "DQOs" and "MQOs," as defined above and in Chapter 1, throughout this document because of their widespread use in environmental data collection activities. These concepts may be expressed by other terms, such as "decision performance criteria" or "project quality objectives" for DQOs and "measurement performance criteria" or "data quality requirements" for MQOs.

31 This chapter provides an overview of the directed planning process. Additional discussion on the
32 planning process in Chapter 3, *Key Analytical Planning Issues and Developing Analytical*
33 *Protocol Specifications*, will focus on project planning from the perspective of the analytical
34 process and the development of Analytical Protocol Specifications (APSs). Section 2.2 will
35 discuss the importance of directed project planning. The approach, guidance and common
36 elements of directed planning are discussed in Section 2.3. The project planning team is
37 discussed in Section 2.4, and the role of the radioanalytical specialists is highlighted in Section
38 2.5. The results of the planning process are discussed in Section 2.6. Section 2.7 presents the next
39 steps of the planning phase of the project, which will document the results of the planning
40 process and will link the results of the planning process to the implementation and assessment
41 phases of data collection activities.

42 The environmental data collection process consists of a series of elements: planning, developing,
43 and updating project plan documents; contracting for services; sampling; analysis; data
44 verification; data validation; and data quality assessment (see Section 1.4.7, “Data Life Cycle,” of
45 Chapter 1, *Introduction to MARLAP*). These elements are interrelated (sampling and analysis
46 cannot be performed efficiently or resources allocated effectively without first identifying data
47 needs during planning). Linkage and integration of the data collection process elements are
48 essential to the success of the environmental data collection activity.

49 **2.2 The Importance of Directed Project Planning**

50 A directed planning process has several notable strengths. It brings together the stakeholders (see
51 box), decision makers, and technical experts at the beginning of the project to gain commitment
52 to the project and a consensus on the nature of the problem and the desired decision. MARLAP
53 recognizes the need for a directed planning process that involves radioanalytical and other
54 technical experts as principals to ensure the decision makers’ data requirements and the results
55 from the field and radioanalytical laboratory are linked effectively. Directed planning enables
56 each participant to play a constructive role in clearly defining:

- 57 • The problem that requires resolution;
- 58 • What type, quantity, and quality of data the decision maker needs to resolve that problem;
- 59 • Why the decision maker needs that type and quality of data;
- 60 • What are the tolerable decision error rates; and
- 61 • How the decision maker will use the data to make a defensible decision.

Example of Stakeholders for a Cleanup Project

A stakeholder is anyone with an interest in the outcome of an activity. For a cleanup project, some of the stakeholders could be:

- *Federal, regional, State, and tribal environmental agencies* with regulatory interests (e.g., NRC and EPA).
- *States* with direct interest in transportation, storage and disposition of wastes, and a range of other issues.
- *City and County Governments* with interest in the operations and safety at sites as well as economic development and site transition.
- *Site Advisory Boards, citizens groups, licensees, special interest groups, and other members of the public* with interest in cleanup activities at the site.

A directed planning process encourages efficient planning by providing a framework for organizing complex issues. The process promotes timely, open, and effective communication among the stakeholders resulting in well-conceived and documented plans. Because of the emphasis on documentation, directed planning also provides project management with a more efficient and consistent transfer of knowledge to new project members.

A directed planning process focuses on collection of only those data needed to address the appropriate questions and support defensible decisions. Directed planning helps to eliminate poor or inadequate sampling and analysis designs that require analysis of (1) too few or too many samples, (2) samples that will not meet the needs of the project, or (3) inappropriate QC samples. During directed planning, which is an iterative process, the sufficiency of existing data is evaluated, and the need for additional data to fill the gaps, as well as the desired quality of the additional data, is determined. By defining the MQOs, directed planning provides input for obtaining appropriate radioanalytical services, which balance constraints and the required data quality.

The time invested in preliminary planning can greatly reduce resource expenditure in the more resource-intensive execution phase of the project. Less overall time (and money) is expended when early efforts are focused on defining (and documenting) the project's objectives (DQOs), technically based, project-specific analytical data needs (MQOs and any specific analytical

91 process requirements), and measures of performance for the assessment phase of the data
92 collection activity.

93 **2.3 Directed Project Planning Processes**

94 The recognition of the importance of project planning has resulted in the development of a
95 variety of directed planning approaches. MARLAP does not endorse any one planning approach.
96 Users of this manual are encouraged to consider the available approaches and choose a directed
97 planning process that is appropriate to their project and agency. Appendix A, *Directed Planning*
98 *Approaches*, provides brief descriptions of several directed planning processes.

99 A graded approach to project planning will be discussed in Section 2.3.1. Standards and guidance
100 on project planning are presented in Section 2.3.2. An overview of common elements of project
101 planning is discussed in Section 2.3.3. The elements of project planning will be discussed in
102 detail in Section 2.5.

103 **2.3.1 A Graded Approach to Project Planning**

104 The sophistication, the level of QC and oversight, and the resources applied should be appropri-
105 ate to the project (i.e., a “graded approach”). Directed planning for small or less complex
106 projects follows the logic of the process but will proceed faster and involve fewer people. The
107 goal still will be to (1) plan properly to collect only the data needed to meet the objectives of the
108 project and (2) establish the measures of performance for the implementation and assessment
109 phases of the data life cycle of the project.

110 **2.3.2 Guidance on Directed Planning Processes**

111 The following national standards related to directed project planning for environmental data
112 collection are available:

- 113 • Standard Practice (D5792) for Generation of Environmental Data Related to Waste
114 Management Activities: Development of Data Quality Objectives (American Society for
115 Testing and Materials (ASTM, 1995a), which addresses the process of development of data
116 quality objectives for the acquisition of environmental data. This standard describes the DQO
117 process in detail.
- 118 • Standard Provisional Guide (PS85) for Expedited Site Characterization of Hazardous Waste
119 Contaminated Sites (ASTM, 1996a), which describes the Expedited Site Characterization

120 (ESC) process used to identify all relevant contaminant migration pathways and determine
121 the distribution, concentration and fate of the contaminants for the purpose of evaluating risk,
122 determining regulatory compliance, and designing remediation systems.

123 • Standard Guide (D5730) Site Characteristics for Environmental Purposes with Emphasis on
124 Soil, Rock, the Vadose Zone and Ground Water (ASTM, 1996b), which covers a general
125 approach to planning field investigations using the process of defining one or more
126 conceptual site models that is useful for any type of environmental reconnaissance or
127 investigation plan with a primary focus on the surface and subsurface environment.

128 • Standard Guide (D5612) Quality Planning and Field Implementation of a Water Quality
129 Measurements Program (ASTM, 1994), which defines criteria and identifies activities that
130 may be required based on the DQOs.

131 • Standard Guide (D5851) Planning and Implementing a Water Monitoring Program (ASTM,
132 1995b), which provides a procedural flowchart for planning the monitoring of point and non-
133 point sources of pollution of water resources (surface or ground water, rivers, lakes or
134 estuaries).

135 Several directed planning approaches have been implemented by the federal sector for
136 environmental data collection activities. MARLAP does not endorse a single planning approach
137 and project planners should be cognizant of their agency's requirements for planning. The
138 following guidance is available:

139 • EPA developed the DQO Process (EPA, 2000) and has tailored DQO Process guidance for
140 specific programmatic needs of project planning under the Comprehensive Environmental
141 Response, Compensation, and Liability Act of 1980 (CERCLA/Superfund) (EPA, 1993) and
142 for site-specific remedial investigation feasibility study activities (EPA, 2000).

143 • The U. S. Army Corps of Engineers (ACE) Technical Project Planning (TPP) Process (ACE,
144 1998) was developed for technical projects planning for hazardous, toxic and radioactive
145 waste sites.

146 • DOE has developed the Streamlined Approach for Environmental Restoration (SAFER)
147 (DOE, 1993) for its environmental restoration activities.

148 • Planning guidance, including decision frameworks, for projects demonstrating compliance
149 with a dose- or risk-based regulation is available for final status radiological surveys

150 (MARSSIM, 2000) and radiological criteria for license termination (NRC, 1998a; NRC,
151 1998b).

152 Additional information on the DQO Process (ASTM, 1995a; EPA, 2000) is presented in
153 Appendix B, *The Data Quality Objectives Process*.

154 **2.3.3 Elements of Directed Planning Processes**

155 Environmental data collection activities require planning for the use of data in decision making.
156 The various directed planning approaches, when applied to environmental data collection
157 activities, address common planning considerations. Some common elements of the planning
158 processes are:

- 159 1. *Define the problem*: Identifying the problem(s) facing the stakeholder/customer that requires
160 attention, or the concern that requires streamlining.
- 161 2. *Identify the Decision*: Defining the decision(s) or the alternative actions that will address the
162 problem(s) or concern and satisfy the stakeholder/customer, and determine if new data are
163 required to make the decision.
- 164 3. *Specify the Decision Rule and the Tolerable Decision Error Rates*: Develop a decision rule to
165 get from the problem or concern to the desired decision and define the limits on the decision
166 error rates that will be acceptable to the stakeholder/customer. The decision rule can take the
167 form of “if ...then...” statements for choosing among decisions or alternative actions.
- 168 4. *Optimize the Strategy for Obtaining Data*: Determine the optimum, cost-effective way to
169 reach the decision while satisfying the desired quality of the decision. Define the quality of
170 the data that will be required for the decision by establishing specific, quantitative and
171 qualitative analytical performance measures (e.g, MQOs). Define the process and criteria to
172 evaluate the suitability of the data to support their intended use (DQA).

173 The objective of the directed project planning process for environmental data collection activities
174 is to reach consensus among the stakeholders on defining the problem, the full range of possible
175 solutions, the desired decision, the optimal data collection strategy, and performance measures
176 for implementation and assessment phases of the project. If a cursory job is done defining the
177 problem or the desired results, the consequence will be the development of a design that may be
178 technically sound but answers the wrong question, may answer the question only after the

179 collection of significant quantities of unnecessary data, or may collect insufficient data to answer
180 the question.

181 The key outputs of the directed planning process are DQOs: qualitative and quantitative
182 statements that define the project objectives and the tolerable decision error rates that will be
183 used as the basis for establishing the quality and quantity of data needed to support the decision.
184 *The MQOs and the decisions on key analytical planning issues will provide the framework for*
185 *Analytical Protocol Specifications.* The MQOs and the tolerable decision error rates will provide
186 the basis for the data assessment phase (data validation and DQA). The elements of project
187 planning will be discussed in detail in Section 2.5 from the perspective of the radioanalytical
188 specialists after introducing the concepts of the project planning team and radioanalytical
189 specialists in Section 2.4. Key analytical planning issues and Analytical Protocol Specifications
190 are discussed in Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol*
191 *Specifications.*

192 **2.4 The Project Planning Team**

193 Participants in the project planning process will vary depending on the nature of the project, but
194 in most cases a multi-disciplinary team will be required. The project planning team should
195 consist of all the parties who have a vested interest or can influence the outcome (stakeholders).
196 A key to successful directed planning of environmental projects is getting the data users and data
197 suppliers to work together early in the process to understand each other's needs and require-
198 ments, to agree on the desired end product, and to establish lines of communication. Equally
199 important is having integrated teams of operational and technical experts. These experts will
200 determine whether the problem has been sufficiently defined and if the desired outcomes are
201 achievable. With technical expert input early in the planning process, efforts are focused on
202 feasible solutions, and resources are not wasted pursuing unworkable solutions.

203 **2.4.1 Team Representation**

204 Thus, members of the project planning team may include program and project managers,
205 regulators, public representatives, project engineers, health and safety advisors, and specialists in
206 statistics, health physics, chemical analysis, radiochemical analysis, field sampling, quality
207 assurance/quality control (QA/QC), data assessment, contract and data management, field
208 operation, and other technical specialists. The program or project manager(s) may be a Remedial
209 Project Manager (RPM), a Site Assessment Manager (SAM), or a Technical Project Officer
210 (TPO). Some systematic planning processes, such as Expedited Site Characterization, utilize a
211 core technical team supported as needed by members of larger technical and operational teams.

212 Throughout this document, the combined group of decision makers and technical experts is
213 referred to as the “project planning team.”

214 The duration of service for the project planning team members can vary, as can the level of
215 participation required of each member during the various planning phases. While the project
216 planning team may not meet as frequently once the project objectives and the sampling and
217 analysis design have been established, a key point to recognize is that the project planning team
218 should not disband. Rather, the team or a “core group” of the team (including the project
219 manager and other key members) should continue to meet at agreed upon intervals to review the
220 project’s progress and to deal with actual project conditions that require changes to the original
221 plan. The availability of a core team also provides the mechanism for the radioanalytical
222 laboratory to receive needed information to clarify questions as they arise.

223 A key concept built into directed planning approaches is the ability to revisit previous decisions
224 after the initial planning is completed (i.e., during the implementation phases of the
225 environmental data collection process). Even when objectives are clearly established by the
226 project planning team and contingency planning was included in the plan development, the next
227 phases of the project may uncover new information or situations, which require alterations to the
228 data collection strategy. For example, finding significantly different levels of analytes or different
229 analytes than were anticipated based on existing information may require changes in the process.
230 To respond to unexpected events, the project planning team (or the core group) should remain
231 accessible during other phases of the data collection process to respond to questions raised,
232 revisit and revise project requirements as necessary, and communicate the basis for previous
233 assumptions.

234 **2.4.2 The Radioanalytical Specialists**

235 Depending on the size and complexity of the project, MARLAP recognizes that a number of key
236 technical experts should participate on the project planning team and be involved throughout the
237 project as needed. When the problem or concern involves radioactive analytes, it is important
238 that the radioanalytical specialist(s) are part of the project planning team, in addition to radiation
239 health and safety specialists. MARLAP recommends that the radioanalytical specialists be a part
240 of the integrated effort of the project planning team. Throughout this manual, the term
241 “radioanalytical specialists” will be used to refer to the radioanalytical expertise needed.

242 *Radioanalytical specialists may provide expertise in (1) radiochemistry and radiation/nuclide*
243 *measurement systems and (2) the knowledge of the chemical characteristics of the analyte of*
244 *concern. In particular, the radioanalytical specialist plays a key role in the development of*

245 MQOs. The radioanalytical specialists may also provide knowledge about sample transportation
246 issues, preparation, preservation, sample size, subsampling, available analytical protocols and
247 achievable analytical data quality. If more than one person is needed, the specialists members
248 need not be from the same organization. The radioanalytical specialists need not be from the
249 contractual radioanalytical laboratory. *The participation of the radioanalytical specialists is*
250 *critical to the success of the planning process and the effective use of resources available to the*
251 *project.*

252 **2.5 Direct Planning Process and Role of the Radioanalytical Specialists**

253 The importance of technical input in a directed planning process becomes apparent when one
254 examines the common difficulties facing the radioanalytical laboratory. Without sufficient input,
255 there is often a disconnect in translating the project planning team's analytical data requirements
256 into laboratory requirements and products. Radioanalytical advice and input during planning,
257 however, help to assure that the analytical protocol(s) selected will satisfy the data requirements,
258 including consideration of time, cost and relevance to the data requirements and budget. The role
259 of the radioanalytical specialists during the early stage of the directed planning process is to focus
260 on whether the desired radionuclides can be measured and the practicality of obtaining the
261 desired analytical data. During the latter part of the process, the radioanalytical specialists can
262 provide specific direction and fine tuning for defining the analytical performance requirements
263 (MQOs) and other items of the Analytical Protocol Specifications.

264 Planning with input from radioanalytical specialists can help ensure that the data received by the
265 data users will meet the project's DQOs. Common areas that are improved with radioanalytical
266 specialists' participation in project planning include:

- 267 • The correct radionuclide is measured;
- 268 • MQOs are adequately established and achievable;
- 269 • Consideration is given to the impact of half-life and parent/progeny factors;
- 270 • The data analysis is not compromised by interferences;
- 271 • Unnecessary or overly sophisticated analytical techniques are avoided in favor of analytical
272 techniques appropriate to the required level of measurement uncertainty;
- 273 • Optimum radioanalytical variables, such as count time and sample volume, are considered;

- 274 • Environmental background levels are considered;
- 275 • Chemical speciation is addressed; and
- 276 • Consideration is given to lab operations (e.g., turnaround time, resources).

277 These improvements result in an appropriate data collection design with specified MQOs and any
 278 specific analytical process requirements to be documented in the project plan documents and
 279 SOWs.

280 The following sections, using the common planning elements outlined in Section 2.3.3, will
 281 discuss the process and results of directed planning in more detail and emphasize the input of
 282 radioanalytical specialists. Table 2.1 provides a summary of (1) the information needed by the
 283 project planning team, (2) how the radioanalytical specialists participate, and (3) the output or
 284 product for each element of the directed planning process. It must be emphasized that a directed
 285 planning process is an *iterative*, rather than step-wise, process. Although the process is presented
 286 in discrete sections, the project planning may not progress in such an orderly fashion. The
 287 planning team will more precisely define decisions and data needs as the planning progresses and
 288 use new information to modify or change earlier decisions until the planning team has
 289 determined the most resource effective approach to the problem. The common planning elements
 290 are used for ease of presentation and to delineate what should be covered in planning, not the
 291 order of discussion.

292 **TABLE 2.1 Summary of the Directed Planning Process and Radioanalytical Specialists Participation**

Element	Information Needed by The Project Planning Team	Radioanalytical Specialists Participation/Input	Output/Product
294 1. State the problem 295	<ul style="list-style-type: none"> • Key stakeholders and their concerns. • Facts relevant to current situation (e.g., site history, ongoing studies). • Analytes of concern or analytes driving risk. • Matrix of concern. • Regulatory requirements and related issues. • Existing data and the reliability of the information. • Known sampling constraints. • Resources and relevant deadlines. 	<ul style="list-style-type: none"> • Evaluate existing radiological data for use in defining the issues (e.g., analytes of concern). • Assure that the perceived problem is really a concern by reviewing the underlying data that is the basis for the problem definition. • Consider how resource limitations and deadlines will impact measurement choices. • Use existing data to begin to define the analyte of concern and the potential range of concentrations. 	<ul style="list-style-type: none"> • Define the problem with specificity. • Identify the primary decision maker, the available resources, and constraints.

Element	Information Needed by The Project Planning Team	Radioanalytical Specialists Participation/Input	Output/Product	
296 297 298	2a. Identify the decision(s)	<ul style="list-style-type: none"> Analytical aspects related to the decision. Possible alternative actions. Sequence and priority for addressing the problem. 	<ul style="list-style-type: none"> Provide focus on what analytes need to be measured considering analyte relationships and background. Begin to address the feasibility of different analytical protocols. Begin to identify the items of the Analytical Protocol Specifications. Begin to determine how sample collection and handling will affect MQOs. 	<ul style="list-style-type: none"> Statements that link the defined problem to the associated decision(s) and alternative actions.
299 300 301 302	2b. Identify inputs to the decision(s)	<ul style="list-style-type: none"> All useful existing data. The general basis for establishing an action level. Acquisition strategy options (if new data is needed). 	<ul style="list-style-type: none"> Review the quality and sufficiency of the existing radiological data. Identify alternate analytes. 	<ul style="list-style-type: none"> Defined list of needed new data. Define the characteristic or parameter of interest (analyte/matrix). Define the action level. Identify estimated concentration range for analyte(s) of interest.
303 304 305 306 307 308	2c. Define the decision boundaries	<ul style="list-style-type: none"> Sampling or measurement timeframe. Sampling areas and boundaries. Subpopulations. Practical constraints on data collection (season, equipment, turnaround time, etc.). Available protocols. 	<ul style="list-style-type: none"> Identify temporal trends and spatial heterogeneity using existing data. With the sampling specialists, identify practical constraints that impact sampling and analysis. Determine feasibility of obtaining new data with current methodology. Identify limitations of available protocols. 	<ul style="list-style-type: none"> Temporal and spatial boundaries. The scale of decision.
309 310 311 312	3a. Develop a decision rule	<ul style="list-style-type: none"> Statistical parameter to be used to describe the parameter of interest and to be compared to the action level. The action level (quantitative). The scale of decision making. 	<ul style="list-style-type: none"> Potentially useful methods. Estimates of measurement uncertainty and detection limits of available analytical protocols. 	<ul style="list-style-type: none"> A logical, sequential series of steps (“if...then”) to resolve the problem.
313 314 315 316 317 318 319 320	3b. Specify limits on decision error rates	<ul style="list-style-type: none"> Potential consequences of making wrong decisions. Possible range of the parameter of interest. Allowable differences between the action level and the actual value. Acceptable level of decision 	<ul style="list-style-type: none"> Assess variability in existing data for decisions on hypothesis testing or statistical decision theory. Evaluate whether the tolerable decision error rates can be met with available laboratory protocols or the error tolerance needs to be relaxed or new 	<ul style="list-style-type: none"> Definition of the baseline condition (null hypothesis) and quantitative estimates of acceptable decision error rates. Define the range of possible parameter

Element	Information Needed by The Project Planning Team	Radioanalytical Specialists Participation/Input	Output/Product
	errors or confidence.	methods developed.	values where the consequence of a Type II decision error is relatively minor (gray region).
<p>323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341</p> <p>4. Optimize the Strategy for Obtaining Data</p>	<ul style="list-style-type: none"> All outputs from all previous elements including parameters (analytes and matrix) of concern, action levels, anticipated range of concentration, tolerable decision error rates, boundaries, resources and practical constraints. Available protocols for sampling and analysis. 	<p>With sampling specialists, consider the potential combinations of sampling and analytical methods, in relation to:</p> <ul style="list-style-type: none"> Sample preparation, compositing, subsampling. Available protocols. Method requirement by regulations (if any). Detection and quantitation capability. MQOs achievable by method, matrix and analyte. Quality control sample types, frequencies, and evaluation criteria. Sample volume, field processing, preservatives, and container requirements. Assure that the MQOs for sample analysis are realistic. Assure that the parameters for the Analytical Protocol Specifications are complete. Resources and time frame to develop and validate new method(s), if required. 	<ul style="list-style-type: none"> The most resource-effective sampling and analysis design that meets the established constraints (i.e., number of samples needed to satisfy the DQOs and the tolerable decision error rates). A method for testing the hypothesis. The MQOs and the statement(s) of the Analytical Protocol Specifications. The process and criteria for data assessment.

2.5.1 Define the Problem

The first and most important step of the project planning process is a clear statement of the fundamental issue to be addressed by the project. Correctly implemented, directed planning ensures that a clear definition of the problem is developed before any additional resources are committed. The project planning team should understand clearly the conditions or circumstances that are causing the problem and the reason for making a decision (e.g., threat to human health or environment).

Many projects present a complex interaction of technical, economic and political factors. The problem definition should include a summary of the study objectives, regulatory context, funding and other resources available, relevant deadlines, previous study results, and any obvious data

352 collection design constraints. By participating in the initial stages of the project planning, the
353 radioanalytical specialists will understand the context of the facts and logic used to define the
354 problem and begin to formulate information on applicable protocols based on the projects's
355 resources (time and budget).

356 Existing data (e.g., monitoring data, radioactive materials license, emergency actions, site permit
357 files, operating records) may provide specific details about the identity, concentrations, and
358 geographic, spatial, or temporal distribution of analytes. However, these data should be examined
359 carefully. Conditions may have changed since the data were collected. For example, additional
360 waste disposal may have occurred, the contaminant may have been released or migrated, or
361 decontamination may have been performed. In some cases, a careful review of the historical data
362 by the project planning team will show that a concern is not a problem or the problem can be
363 adequately addressed using the available data.

364 **2.5.2 Identify the Decision**

365 The project planning team will define the decision(s) to be made (or the question the project will
366 attempt to resolve) and the inputs and boundaries to the decision. There may also be multiple
367 decision criteria that have to be met and each should be clearly defined. For example, the
368 decision may be for an individual survey area rather than the site as a whole, or a phase of the site
369 closure project (scoping, characterization, operation or final status survey) rather than the project
370 as a whole because of the different objectives and data requirements.

371 The decision should be clear and unambiguous. It may be useful to state specifically what
372 conclusions may and may not be drawn from the data. If the study is to be designed, for example,
373 to investigate whether or not a site may be released for use by the general public, then the project
374 planning team may want to specifically exclude other possible uses for the data.

375 **2.5.2.1 Action Level**

376 The term "action level" is used in this document to denote the numerical value that will cause the
377 decision maker to choose one of the alternative actions. The action level may be a derived
378 concentration guideline level, background level, release criteria, regulatory decision limit, etc.
379 The action level is often associated with the type of medium, analyte and concentration limit.

380 Some action levels, such as the release criteria for license termination, are expressed in terms of
381 dose or risk. The release criterion is typically based on the total effective dose equivalent
382 (TEDE), the committed effective dose equivalent (CEDE), risk of cancer incidence (morbidity)

383 or risk of cancer death (mortality) and generally cannot be measured directly. For example, in site
384 cleanup, a radionuclide-specific predicted concentration or surface area concentration of specific
385 nuclides that can result in a dose (TEDE or CEDE) or specific risk equal to the release criterion
386 is called the “derived concentration guideline level” (DCGL). A direct comparison can be made
387 between the project’s analytical measurements and the DCGL (MARSSIM, 2000). For drinking
388 water analysis, an example of an action level would probably be a radionuclide specific
389 concentration based on the Maximum Contaminant Level under the Safe Drinking Water Act.

390 The project planning team should also determine possible alternative actions that may be taken.
391 Consideration should also be given to the option of taking no action, as this option is frequently
392 overlooked (e.g., no technology available, too costly, relocation will create problems).

393 During these discussions of the directed planning process, the role of the radioanalytical
394 specialists is to ensure that the analytical aspects of the project have been clearly defined and
395 incorporated into the decision(s). The radioanalytical specialists focus on defining: (1) the
396 parameter (analyte/matrix) of interest; (2) what analytical information could resolve the problem;
397 and (3) the practicality of obtaining the desired field and laboratory data. Sections 3.3.1 through
398 3.3.7 of Chapter 3 discuss in more detail the analytical aspects of the decision (or question) and
399 determining the characteristic or parameter of concern. This information is incorporated into the
400 Analytical Protocol Specifications.

401 2.5.2.2 Scale of the Decision

402 The project planning team clearly should define the geographical area(s) to which the decision
403 will apply. The scale of the decision selected should be the smallest, most appropriate subset of
404 the population for which decisions will be made based on the spatial or temporal boundaries. For
405 example, at a remediation site, a survey unit is generally formed by grouping contiguous site
406 areas with a similar use history and the same classification of potential concentration of the
407 analyte of interest. The survey unit will be defined with a specified size and shape for which a
408 separate decision will be made as to whether the unit attains the site-specific reference-based
409 cleanup standard for the designated analyte of interest (MARSSIM, 2000; NRC, 1998c).

410 The survey unit is established to delineate areas or volumes of similar composition and history
411 for which a single decision can be made based on the statistical analysis of the data. The
412 variability in the measurement data for a survey unit is a combination of the imprecision of the
413 measurement process and the real spatial and temporal variability of the analyte concentration. If
414 the measurement data include a background contribution, the spatial variability of the
415 background adds to the overall measurement variability.

416 2.5.2.3 Inputs and Boundaries to the Decision

417 The project planning team determines the specific information and data required for decision
418 making. The statistical parameter (e.g., mean) that will be used in the comparison to the action
419 level should be established. Typically, the study boundaries are discussed when the project
420 planning team defines the problem. Changing conditions (e.g., weather, temperature, humidity)
421 that could impact the success of sampling or analysis or data interpretation should be considered
422 as well. The radioanalytical specialists can provide input during the determination of the
423 appropriate action level and the appropriate parameter of interest (e.g., mean concentration).

424 2.5.2.4 Data Needs

425 The project planning team should develop a list of the specific data (number and type) and data
426 requirements (quality). An estimate of the expected variability of the data will be needed.
427 Existing data, experience and scientific judgement can be used to establish the estimate.
428 Information on environmental background levels and variability may be needed (see Chapter 3
429 for a discussion of background). The project planning team establishes whether the existing data
430 are sufficient or whether new data are needed to resolve the problem.

431 **2.5.3 Specify the Decision Rule and the Tolerable Decision Error Rates**

432 A decision statement or rule is developed by combining the decisions and the alternative actions.
433 The decision rule presents the strategy or logical basis for choosing among the alternative
434 decisions, generally by use of a series of “if...then” statements. For a complex problem, it may be
435 helpful to develop a logic flow diagram (called a decision tree or decision framework), arraying
436 each element of the issue in its proper sequence along with the possible actions. The decision
437 rule identifies (1) the action level that will be a basis for decision and (2) the statistical parameter
438 that is to be compared to the action level.

439 **Example of a Decision Rule:**

440 If the mean concentration in the survey unit is less than the action level, then the
441 survey unit is in compliance with the release criterion.

442 The radioanalytical specialists play a key role in the development of alternative technical actions
443 that are realistic and quantifiable and that satisfy the programmatic and regulatory needs. The
444 results of the technical actions must be measurable: the protocols suggested will be able to detect

445 the radionuclide of interest. (see Chapter 3, *Critical Analytical Planning Issues and Developing*
446 *Analytical Protocol Specifications*, for additional discussion on background.)

447 For each proposed alternative technical action, the radioanalytical specialists can:

- 448 • Focus the project planning team on what radionuclides will need to be measured and what
449 types of analytical techniques are available;
- 450 • Address whether it is feasible to obtain the necessary analytical results;
- 451 • Present the technical limitations (i.e., the minimum detectable concentrations—MDCs) of
452 available measurement systems; and
- 453 • Address how sample collection and handling will affect what measurement techniques can be
454 used.

455 The project planning team also assesses the potential consequences of making a wrong decision.
456 While the possibility of a decision error can never be totally eliminated, it can be controlled. The
457 potential consequences of a decisions error are used to establish tolerable limits on the
458 probability that the data will mislead the decision maker into making an incorrect decision. (see
459 Appendix B for a discussion of hypothesis testing, action levels, and Type I and Type II decision
460 errors). The decision rule and decision makers' limits on the decision error rates are used to
461 establish performance criteria for a data collection design.

462 In developing the tolerable decision error rate, the team needs to look at alternative measurement
463 approaches, the sources of error in field and laboratory handling of samples and analysis, factors
464 that would influence the likelihood of a Type I or Type II error, estimates of the cost of analysis,
465 and judicious use of resources. Determining realistic levels of tolerable decision error rates for
466 the decision rule will reduce or eliminate attempts by the project planning team in developing
467 and optimizing the sampling and analysis design that later will have to be re-designed to attain
468 more realistic decision error rates.

469 **2.5.4 Optimize the Strategy for Obtaining Data**

470 During the process of developing and optimizing the options for the sampling and analysis of
471 data, the technical team members should determine the most resource effective analytical
472 protocols and associated quality control that will meet all the requirements (desired outputs)

473 established by the project planning team. Optimizing the data collection design generally requires
474 extensive coordination between the radioanalytical specialists and the sampling specialists.

475 Typical issues that require consideration in the development of the analysis design include the
476 number of samples required, the analytical protocol specifications, which include the MQOs
477 (e.g., a statement of the required method uncertainty) required of the analytical procedures. The
478 analytical protocol specifications, which include the MQOs, will be discussed in Sections 2.5.4.1
479 and 2.5.4.2 below. In general, the more certainty required in the DQOs, the greater the number of
480 samples or the more precise and unbiased the measurements need to be. During planning, the
481 costs and time for field and analytical procedures must be balanced against the level of certainty
482 that is needed to arrive at an acceptable decision.

483 The radioanalytical specialists are involved in evaluating the technical options and their effect on
484 the sources of decision error, their resource requirements and the ability to meet the project's
485 objectives. The radioanalytical specialists can identify an array of potential analytical methods,
486 which can be combined in analytical protocols to meet the defined data needs and MQOs.
487 Working with the sampling specialists, potential sampling methods are identified based on the
488 sample requirements of the potential analytical protocols and other sampling constraints. The
489 planning team specialists need to consider sources of bias and imprecision that will impact the
490 representativeness of the samples and the accuracy of the data collected. Appropriate
491 combinations of sampling methods, analytical protocols and sampling constraints can then be
492 assessed with regard to resource effectiveness.

493 It may be useful at this point for the project planning team to perform a sensitivity analysis on the
494 input parameters that contribute to the final analytical result. The final analytical result directly
495 impacts the decision, so this sensitivity analysis will allow the project planning team to identify
496 the portions of the analytical protocols, which potentially have the most impact on the decision.
497 Once identified, these portions of the analytical protocols can be targeted to receive a propor-
498 tionally larger share of the resources available for developing the protocols.

499 2.5.4.1 Analytical Protocol Specifications

500 Requirements of the desired analytical protocol(s) should be based on the intended use of the
501 data. That is, project-specific critical parameters should be considered, including the type of
502 radioactivity and the nuclides of concern, the anticipated range of concentrations, the media type
503 and complexity, regulatory required methods and customer method preferences, the measurement
504 uncertainty required at some activity concentration, detection limits required, necessary chemical
505 separation, qualification or quantification requirements, QC requirements and turnaround time

506 needed. MQOs are a key component of the Analytical Protocol Specifications and are discussed
507 in Section 2.5.4.2. Chapter 3, *Key Analytical Planning Issues and Developing Analytical*
508 *Protocol Specifications*, contains more detailed discussion on some of the key decisions and
509 needed input to successfully optimize the sampling and analysis design and develop Analytical
510 Protocol Specifications. Chapter 6 discusses the selection of an analytical protocol from the
511 laboratory's perspective.

512 The project planning team should ensure that there are analytical methods available to provide
513 acceptable measurements. If analytical methods do not exist, the project planning team will need
514 to consider the resources needed to develop a new method, reconsider the approach for providing
515 input data, or perhaps reformulate the decision statement.

516 2.5.4.2 Measurement Quality Objectives

517 When additional data are to be obtained, the project planning process should establish measures
518 of performance for the analysis (MQOs) and evaluation of the data. Without these measures of
519 performance, data assessment is difficult and arbitrary.

520 A MQO is a statement of a performance objective or requirement for a particular method
521 performance characteristic such as the required method uncertainty at some concentration. MQOs
522 can be both quantitative and qualitative performance objectives. Quantitative and qualitative
523 MQOs are used for real-time compliance monitoring by field and lab staff and during subsequent
524 assessments and data usability determinations. Quantitative MQOs provide numerical criteria for
525 field and laboratory QC samples or procedure performance (*e.g.*, specifications for MDC, yield,
526 efficiency, laboratory control sample precision and recovery, blank levels, lab duplicate
527 precision, collocated sample precision). Precision, bias, completeness, and sensitivity are
528 common data quality indicators for which quantitative MQOs could be developed during the
529 planning process (ANSI/ASQC, 1994). Thus, quantitative MQOs are statements that contain
530 specific units of measure, such as: x percent recovery, x percent relative standard uncertainty, a
531 standard deviation of x Bq/L, or a MDC of x Bq/g. The specificity of the MQOs allows specific
532 comparisons of the data to an MQO. Chapter 3 provides detailed guidance on developing MQOs
533 for select method performance characteristics.

534 A graded approach should be taken to the selection of the MQOs. For example, from a project
535 viewpoint, it is highly practical and economical to establish MQOs on a graded basis that are in
536 concert with the anticipated range of the analytes concentration compared to the action level. For
537 example, the required method uncertainty, when the analyte concentration is much greater than

538 the action level, can be less restrictive than when the analyte concentration approaches the action
539 level. These decisions are extremely important in the protocol selection process.

540 The MQOs for the analytical data should be documented in the project plan documents (e.g., the
541 QA Project Plan). MQOs are also the basis for the data verification and validation criteria (see
542 Appendix D, Section 2.7, for discussion of MQOs and QA Project Plans).

543 **2.6 Results of the Directed Planning Process**

544 By the end of the directed planning process, the project planning team has established their
545 priority of concerns, the definition of the problem, the decision(s) or outcome to address the
546 posed problem, the inputs and boundaries to the decision(s), and the tolerable decision error
547 rates. They have also agreed on decision rules that incorporate all this information into a logic
548 statement about what must be done to obtain the desired answer. The key output of the planning
549 process is the DQOs: qualitative and quantitative statements that clarify study objectives, define
550 the appropriate type of data, and specify the tolerable rate of making decision errors that will be
551 used as the basis for establishing the quantity and quality of data needed to support the decisions
552 and the criteria for data assessment.

553 If new data are required, then the project planning team has defined the desired analytical quality
554 of the data (MQOs). That is, the project planning team has determined the type, quantity, and
555 quality of data needed to support a decision. The directed planning process has clearly linked
556 sampling and analysis efforts to an action and a decision. This linkage allows the project
557 planning team to determine when enough data have been collected.

558 If new data are to be obtained, the project planning team has developed the most resource-
559 effective sampling and analysis design that will provide adequate data for decision making.
560 Based on the DQOs, the project planning team specifies the sampling collection design and
561 Analytical Protocol Specifications, including:

- 562 • The type and quantity of samples to be collected;
- 563 • Where, when, and under what conditions they should be collected;
- 564 • What radionuclides are to be measured; and
- 565 • The MQOs to ensure that the analytical errors are controlled sufficiently to meet the tolerable
566 decision error rates specified in the DQOs.

567 **2.6.1 Output Required by the Radioanalytical Laboratory: The Analytical Protocol**
568 **Specifications**

569 As a result of directed planning, the description of the DQOs for the project and the Analytical
570 Protocol Specifications, which contain the MQOs and any specific analytical process require-
571 ments for additional data will provide the radioanalytical laboratory with a clear and definitive
572 description of the desired data, as well as the purpose and use of the data. This information will
573 be provided to the project implementation team through the SOW and the project plan
574 documents. Precise statements of analytical needs may prevent the radioanalytical laboratory
575 from:

- 576 • Having to make a “best guess” as to what data are really required;
- 577 • Using the least costly or most routine protocol, which may not meet the needed data quality;
- 578 • Independently developing solutions for unresolved issues without direction from the project
579 planning team; and
- 580 • Having “moving targets” and “scope creep” that stem from ambiguous statements of work.

581 The output of the planning process, from the perspective of the radioanalytical laboratory, is the
582 Analytical Protocol Specifications. The Analytical Protocol Specifications should contain the
583 minimum level of specificity required to meet the project data requirements. In accordance with a
584 performance based measurement approach the laboratory will use this information to select or
585 develop (specific) analytical protocols that will meet the MQOs. The Analytical Protocol
586 Specifications should present the resolution of the project planning team on both general issues
587 and matrix-specific issues. Chapter 3, *Key Analytical Planning Issues and Developing Analytical*
588 *Protocol Specifications*, addresses some of the common radioanalytical planning issues.

589 The Analytical Protocol Specifications should include, but not be limited to:

- 590 • The radionuclide(s) of concern;
- 591 • The media of concern with information on chemical, explosive and other hazardous
592 components;
- 593 • The anticipated concentration range (estimate, maximum or detection capability);
- 594 • The MQOs desired for the radionuclides of concern;
- 595 • The sample preparation and preservation requirements (laboratory and field);
- 596 • The type and frequency of QC samples required of each radionuclide of concern;
- 597 • The sample transport, tracking and custody requirements;
- 598 • The required analytical turnaround time for the project and the anticipated budget for the
599 analysis; and

- 600 • The data reporting requirements.

601 **2.6.2 Chain of Custody**

602 Requirements for formal Chain of Custody (COC) should be specified in the Analytical Protocol
603 Specifications if required. COC procedures provide the means to trace possession and handling
604 of the sample from collection to data reporting. The data report requires a number of items, not
605 all of which can be listed here. COC will impact how the field and lab components handle the
606 sample. COC is discussed in Chapter 10 and Chapter 11.

607 **2.7 Project Planning and Project Implementation and Assessment**

608 A directed planning process generally is considered complete with the approval of an optimal
609 data collection design approach or when historical data are deemed sufficient to support the
610 desired decision. However to complete the process, the project planning team clearly should
611 document the results of the planning process and link DQOs and MQOs to the implementation
612 and assessment processes. The directed planning process is the first activity in the project's
613 planning phase (see Figure 1.1, "The Data Life Cycle"). The planning process outputs are key
614 inputs to the implementation and assessment processes of the data collection activities. That is,
615 the outputs of the directed planning process are the starting point for developing plan documents,
616 obtaining analytical services, selecting specific analytical protocols and assessing the data
617 collected. This section will provide an overview of the next steps of the planning phase and the
618 linkage to the implementation and assessment phases and to other chapters in MARLAP, Part I.

619 **2.7.1 Documenting the Planning Process**

620 A concept inherent in directed planning approaches is the establishment of a formal process to
621 document both the decisions and supporting logic established by the team during the project
622 planning process. Establishing this documentation process is not only good management practice,
623 but also tends to prevent situations where new team members recreate the past logic for activities
624 being performed upon the departure of their predecessors. As actual field conditions or other
625 situations force changes to the original plans, the documentation can then be updated through a
626 change control process to continue to maintain the technically defensible basis for the actions
627 being taken.

628 When properly documented, the directed planning process:

- 629 • Provides a background narrative of the project;

- 630 • Defines the necessary input needed (nuclides, matrices, estimate of concentration range, etc.);
- 631 • Defines the constraints and boundaries within which the project would have to operate;
- 632 • Defines the decision rule, which states the action level that will be the basis for the decision
- 633 and the parameter that is to be compared to the action level;
- 634 • Identifies the tolerable decision error rates;
- 635 • Identifies MQOs for new analytical data; and
- 636 • Identifies processes and criteria for usability of the data.

637 The results of the project planning process are also needed for the development of project plan
638 documents required for implementing the sampling and analysis activities. These project plan
639 documents may include a Quality Assurance Project Plan (QAPP), Work Plan, or Sampling and
640 Analysis Plan (SAP). The format and naming of plan documents are usually a function of the
641 authoring organization's experience, the controlling federal or state regulations, or the controlling
642 Agency. Project plan documents are discussed in Chapter 4, *Project Plan Documents*, and in
643 Appendix D, *Content of Project Plan Documents*. The project plan documents will rely on the
644 planning process outputs, including the MQOs, to describe in comprehensive detail the necessary
645 QA, QC, and other technical activities that must be implemented to ensure that the results of the
646 work performed will satisfy the stated DQOs. The project plan documents should also document
647 the processes and criteria developed for data assessment. MARLAP recommends that the
648 planning process rationale is documented and the documentation integrated with the project plan
649 documents. Documentation of the planning process can be incorporated directly in the project
650 plan documents or through citation to a separate report on the planning process.

651 **2.7.2 Obtaining Analytical Services**

652 If contractual laboratory services are required, the contracting office or Sample Management
653 Office (SMO) should rely on the planning process statements of required data and data quality,
654 the Analytical Protocol Specifications, to develop the Statement of Work (SOW) for the
655 laboratory. The SOW is the contractual agreement, which describes the project scope and
656 requirements (i.e., what work is to be accomplished). Contracting laboratory services is discussed
657 in Chapter 5, *Obtaining Laboratory Services*, and Chapter 7, *Evaluating Methods and*
658 *Laboratories*. MARLAP recommends that a SOW be developed even if a contract is not
659 involved, for example, when an agency employs one of its own labs.

660 **2.7.3 Selecting Analytical Protocols**

661 From an analytical perspective, one of the most important functions of a directed planning
662 process is the identification and resolution of key analytical planning issues for a project. A key

663 analytical planning issue may be defined as one that has the potential to be a significant contribu-
664 tor of uncertainty to the analytical process and ultimately the resulting data. Identifying key
665 analytical issues for a particular process requires a clear understanding of the analytical process.
666 It is the role of the radioanalytical specialist on the project planning team to ensure that key
667 analytical planning issues have been clearly defined and articulated and incorporated into the
668 principal decision or principal study question. Chapter 3 discusses the key analytical planning
669 issues.

670 The selection of radioanalytical protocols by the laboratory is made in response to the Analytical
671 Protocol Specifications (for each analyte/matrix) developed by the project planning team as
672 documented in the SOW. Unless required by regulatory policy, rarely will a radioanalytical
673 method be specifically stated. A number of radioanalytical methods are available but no one
674 method provides a general solution; all have advantages and disadvantages. The selection of a
675 method is related to a broad range of consideration, including analyte and matrix characteristics,
676 technical complexity and practicality of the method, quality requirements, availability of
677 equipment, facility and staff resources, regulatory and economic considerations, and practicality
678 and previous use of the method. Chapter 6 discusses the selection of a protocol, as well as, the
679 modification of an existing protocol to account for changes in sample substrate.

680 **2.7.4 Assessment Plans**

681 Concurrent with the development of MQOs and other specifications of the optimized analytical
682 design, is the development of the data assessment plans. *Data assessment is difficult and*
683 *arbitrary when attempted at the end of the project without planning and well defined, project*
684 *specific criteria.* The development of these plans during the project planning process should
685 ensure that the appropriate documentation will be available for assessment and that those
686 implementing and assessing data will be aware of how the data will be assessed. Assessment of
687 environmental data consists of three separate and identifiable phases: data verification, data
688 validation, and data quality assessment (DQA). Verification and validation pertain to evaluation
689 of analytical data generated by the laboratory. DQA considers all sampling, analytical, and data
690 handling details, and other historical project data when determining the usability of data in the
691 context of the decisions to be made. *The focus of verification and validation is on the analytical*
692 *process and a data point by data point review, while DQA considers the entire data collection*
693 *process and the entire data set as it assesses data quality.* Verification, validation, and DQA
694 assure the technical strengths and weaknesses of the overall project data are known, and
695 therefore, establishes the technical defensibility of the data. Assessment plan documents are
696 discussed in detail in Chapters 8 and 9.

697 2.7.4.1 Data Verification

698 *The data verification process should be defined during the project planning process and*
699 *documented in a data verification plan or the project plan documents (e.g., the QAPP). The*
700 *verification plan should specify the types of documentation needed for verification. Analytical*
701 *data verification assures that laboratory conditions and operations were compliant with the*
702 *contractual SOW and project plan (i.e., SAP or QAPP). The contract for analytical services and*
703 *the project plan determine the procedures the laboratory must use to produce data of acceptable*
704 *quality (MQOs) and the content of the analytical data package. Verification compares the*
705 *material delivered by the laboratory to these requirements and checks for consistency of the data*
706 *throughout the data package, correctness of calculations, and completeness of the results to*
707 *ensure all documentation is available. Compliance, exceptions, missing documentation and the*
708 *resulting inability to verify compliance must be recorded in the data verification report. Data*
709 *verification is discussed in more detail in Chapter 8, *Radiological Data Verification and**
710 *Validation.*

711 2.7.4.2 Data Validation

712 Performance objectives and criteria for data validation should be developed during the project
713 planning process and documented in a separate plan or included in the project plan documents
714 (e.g., QAPP). Guidance on Data Validation Plans is provided in Chapter 8, *Radiological Data*
715 *Verification and Validation*. After the data are collected, data validation activities will rely on the
716 planning process statements of the MQOs to confirm whether the obtained data meet the
717 requirements of the project.

718 2.7.4.3 Data Quality Assessment

719 The DQA process evaluates whether the quality and quantity of data will support their intended
720 use. The DQA process determines whether the data meet the assumptions under which the DQOs
721 and the data collection design were developed and whether the analytical uncertainty in the data
722 will allow the decision maker to use the data to support the decision within the tolerable decision
723 error rates established during the directed planning process. Guidance on the DQA Process and
724 plan development is provided in Chapter 9, *Data Quality Assessment*. The process and criteria to
725 be used for DQA process should be developed by the project planning team and documented in
726 the project plan documents or in a stand alone plan that is cited or appended to the project plan
727 documents.

Summary of Recommendations

- MARLAP recommends the use of a directed project planning process.
- MARLAP recommends that the radioanalytical specialists be a part of the integrated effort of the project planning team.
- MARLAP recommends that the planning process rationale be documented and the documentation integrated with the project plan documents.

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