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 logical framework for establishing well-defined, achievable objectives within a cost-effective, technically sound, and defensible sampling and analysis design. They also balance the data user's tolerance for uncertainty in the decision process with the available resources for obtaining data to support a decision. *MARLAP uses 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 on defining the data needed to support an informed decision for a specific project.*

This chapter provides an overview of the directed planning process. It promotes:

1. Directed planning as a tool for project management to identify and document the data quality objectives (DQOs)—qualitative and quantitative statements that define the project objectives and the tolerable rate of making decision errors, which in turn will be used to establish 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—radioanalytical specialists, in particular—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 statement of work (SOW), and the data assessment plans (e.g., for data verification, data validation, and data quality assessment).

MARLAP uses the terms "DQOs" and "MQOs," as defined above and in Section 1.4.9, 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.

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Section 2.2 discusses the importance of directed project planning. The approach, guidance, and common elements of directed planning are discussed in Section 2.3. The project planning team is addressed in Section 2.4, Section 2.5 describes the elements of project planning from the perspective of the radioanalytical specialists. The results of the planning process are discussed in Section 2.6. Section 2.7 presents the next steps of the planning phase of the project, which document the results of the planning process and link the results of the planning process to the implementation and assessment phases of data collection activities. Additional discussion on the planning process in Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*, focuses on project planning from the perspective of the analytical process and the development of Analytical Protocol Specifications (APSs).

The environmental data collection process consists of a series of elements: planning, developing, and updating project plan documents; contracting for services; sampling; analysis; data verification; data validation; and data quality assessment (see Section 1.4.1, "Data Life Cycle"). These elements are interrelated because sampling and analysis cannot be performed efficiently or resources allocated effectively without first identifying data needs during planning. Linkage and integration of the data collection process elements are essential to the success of the environmental data collection activity.

2.2 The Importance of Directed Project Planning

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

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

A directed planning process encourages efficient planning by framing and 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.

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 other related issues.
- City and county governments concerned with the operations and safety at sites as well as economic development and site transition.
- Site Advisory Boards, citizens groups, licensees, special interest groups, responsible parties, and other members of the public with interest in cleanup activities at the site.

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 quality control (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, are 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 process requirements), and measures of performance for the assessment phase of the data collection activity.

2.3 Directed Project Planning Processes

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

Section 2.3.1 discusses a graded approach to project planning, and existing standards and guidance are briefly summarized in Section 2.3.2. An overview of common elements of project planning is discussed in Section 2.3.3. The elements of project planning are discussed in detail in Section 2.5.

2.3.1 A Graded Approach to Project Planning

The sophistication, the level of QC and oversight, and the resources invested should be appropriate to the project (i.e., a "graded approach"). Directed planning for small or less complex projects follows the logic of the process but will proceed faster and involve fewer people. The goal still is to (1) plan properly to collect only the data needed to meet the objectives of the project and (2) establish the measures of performance for the implementation and assessment phases of the data life cycle of the project.

2.3.2 Guidance on Directed Planning Processes

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

- *Standard Practice for Generation of Environmental Data Related to Waste Management Activities: Development of Data Quality Objectives* (ASTM D5792), which addresses the process of development of data quality objectives for the acquisition of environmental data. This standard describes the DQO process in detail.

- *Standard Provisional Guide for Expedited Site Characterization of Hazardous Waste Contaminated Sites* (ASTM PS85), which describes the Expedited Site Characterization (ESC) process used to identify all relevant contaminant migration pathways and determine the distribution, concentration and fate of the contaminants for the purpose of evaluating risk, determining regulatory compliance, and designing remediation systems.

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

- *Standard Guide for Quality Planning and Field Implementation of a Water Quality Measurements Program* (ASTM D5612), which defines criteria and identifies activities that may be required based on the DQOs.

- *Standard Guide for Planning and Implementing a Water Monitoring Program* (ASTM D5851), which provides a procedural flowchart for planning the monitoring of point and nonpoint sources of pollution of water resources (surface or ground water, rivers, lakes or estuaries).

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

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

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

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

- Planning guidance, including decision frameworks, for projects demonstrating compliance with a dose- or risk-based regulation is available for final status radiological surveys (MARSSIM, 2000) and radiological criteria for license termination (NRC, 1998a; NRC, 1998b).

Additional information on the DQO process (ASTM D5792; EPA, 2000a) is presented in Appendix B, *The Data Quality Objectives Process*.

2.3.3 Elements of Directed Planning Processes

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

1. *State the problem*: Describe clearly the problem(s) facing the stakeholder or customer.

2. *Identify the Decision*: Define the decision(s) or the alternative actions that will address the problem(s) or concern and satisfy the stakeholder/customer, and define the inputs and boundaries to the decision.

3. *Specify the Decision Rule and the Tolerable Decision Error Rates*: Develop a decision rule to get from the problem or concern to the desired decision and define the limits on the decision error rates that are acceptable to the stakeholder/customer. The decision rule can take the form of "if ...then..." statements for choosing among decisions or alternative actions.

4. *Optimize the Strategy for Obtaining Data*: Determine the optimum, cost-effective way to reach the decision while satisfying the desired quality of the decision. Define the quality of the data that are required for the decision by establishing specific, quantitative and qualitative analytical performance measures (e.g, MQOs). Define the process and criteria to evaluate the suitability of the data to support their intended use (data quality assessment).

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

The key outputs of the directed planning process are DQOs: qualitative and quantitative statements that define the project objectives and the tolerable decision error rates that will be used as the basis for establishing the quality and quantity of data needed to support the decision. *The MQOs and the decisions on key analytical planning issues will provide the framework for Analytical Protocol Specifications*. The MQOs and the tolerable decision error rates will provide the basis for the data assessment phase (data validation and data quality assessment). Important analytical planning issues and APSs are discussed in Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*.

2.4 The Project Planning Team

The number of participants in the project planning process, and their respective disciplines, will vary depending on the nature and scope of the project, but in most cases a multidisciplinary team will be required. The project planning team should consist of all the parties who have a vested interest or can influence the outcome (stakeholders). A key to successful directed planning of environmental projects is getting the data users and data suppliers to work together early in the process to understand each other's needs and requirements, to agree on the desired end product, and to establish lines of communication. Equally important is having integrated teams of operational and technical experts. These experts will determine whether the problem has been sufficiently defined and if the desired outcomes are achievable. With the input of technical experts early in the planning process, efforts are focused on feasible solutions, and resources are not wasted pursuing unworkable solutions.

2.4.1 Team Representation

Members of the project planning team may include program and project managers, regulators, public representatives, project engineers, health and safety advisors, and specialists in statistics, health physics, chemical analysis, radiochemical analysis, field sampling, quality assurance/ quality control (QA/QC), data assessment, contract and data management, field operation, and other technical specialists. The program or project manager(s) may be a remedial project manager (RPM), a site assessment manager (SAM), or a technical project officer (TPO). Some systematic planning processes, such as Expedited Site Characterization, utilize a core technical team supported as needed by members of larger technical and operational teams. Throughout this document, the combined group of decisionmakers and technical experts is referred to as the "project planning team."

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

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

2.4.2 The Radioanalytical Specialists

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

Radioanalytical specialists may provide expertise in (1) radiochemistry and radiation/nuclide measurement systems and (2) the knowledge of the chemical characteristics of the analyte of concern. In particular, the radioanalytical specialist plays a key role in the development of MQOs. The radioanalytical specialists may also provide knowledge about sample transportation issues, preparation, preservation, sample size, subsampling, available analytical protocols and achievable analytical data quality. If more than one person is needed, the specialists members need not be from the same organization. The radioanalytical specialists need not be from the contractual radioanalytical laboratory. *The participation of the radioanalytical specialists is critical to the success of the planning process and the effective use of resources available to the project.*

2.5 Directed Planning Process and Role of the Radioanalytical Specialists

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

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

- The correct radionuclide is measured;
- MQOs are adequately established and achievable;
- Consideration is given to the impact of half-life and parent/progeny factors;
- The data analysis is not compromised by interferences;

- Unnecessary or overly sophisticated analytical techniques are avoided in favor of analytical techniques appropriate to the required level of measurement uncertainty;
- Optimum radioanalytical variables, such as count time and sample volume, are considered;
- Environmental background levels are considered;
- Chemical speciation is addressed; and
- Consideration is given to laboratory operations (e.g., turnaround time, resources).

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

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

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
1. State the problem	• 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 its reliability. • Known sampling constraints. • Resources and relevant deadlines.	• 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 are 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.	• Problem defined with specificity. • Identification of the primary decisionmaker, the available resources, and constraints.

Element	Information Needed by The Project Planning Team	Radioanalytical Specialists Participation/Input	Output/Product
2a. Identify the decision(s)	• Analytical aspects related to the decision. • Possible alternative actions. • Sequence and priority for addressing the problem.	• 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 APSs. • Begin to determine how sample collection and handling will affect MQOs.	• Statements that link the defined problem to the associated decision(s) and alternative actions.
2b. Identify inputs to the decisions	• All useful existing data. • The general basis for establishing an action level. • Acquisition strategy options (if new data is needed).	• Review the quality and sufficiency of the existing radiological data. • Identify alternate analytes.	• 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.
2c. Define the decision boundaries	• Sampling or measurement timeframe. • Sampling areas and boundaries. • Subpopulations. • Practical constraints on data collection (season, equipment, turnaround time, *etc*.). • Available protocols.	• 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.	• Temporal and spatial boundaries. • The scale of decision.
3a. Develop a decision rule	• Statistical parameter to describe the parameter of interest and to be compared to the action level. • The action level (quantitative). • The scale of decision-making.	• Identify potentially useful methods. • Estimate measurement uncertainty and detection limits of available analytical protocols.	• A logical, sequential series of steps (“if...then”) to resolve the problem.
3b. Specify limits on decision error rates	• 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 errors or confidence.	• 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 if the error tolerance needs to be relaxed or new methods developed.	• Defined baseline condition (null hypothesis) and quantitative estimates of acceptable decision error rates. • Defined range of possible parameter values where the consequence of a Type II decision error is relatively minor (gray region).

Element	Information Needed by The Project Planning Team	Radioanalytical Specialists Participation/Input	Output/Product
4. Optimize the strategy for obtaining data	• 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.	With sampling specialists, consider the potential combinations of sampling and analytical methods, in relation to: • Sample preparation, compositing, subsampling. • Available protocols. • Methods required by regulations (if any). • Detection and quantitation capability. • MQOs achievable by method, matrix and analyte. • QC 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 APSs are complete. • Resources and time frame to develop and validate new method(s), if required.	• 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 APSs. • The process and criteria for data assessment.

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

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

2.5.2 Identify the Decision

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

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

The project planning team also should determine possible alternative actions that may be taken. Consideration should be given to the option of taking no action, as this option is frequently overlooked but still may be the optimal course of action (e.g., no technology available, too costly, relocation will create problems). After examining the alternative actions, the project planning team should develop a decision statement that expresses a choice among alternative actions.

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

2.5.2.1 Define the Action Level

The term "action level" is used in this document to mean the numerical value that will cause the decisionmaker to choose one of the alternative actions. The action level may be a derived concentration guideline level (see below), background level, release criterion, regulatory decision limit, etc. The action level is often associated with the type of medium, analyte and concentration limit.

Some action levels, such as the release criteria for license termination, are expressed in terms of dose or risk. The release criterion is typically based on the total effective dose equivalent (TEDE), the committed effective dose equivalent (CEDE), risk of cancer incidence (morbidity) or risk of cancer death (mortality) and generally cannot be measured directly. For example, in site cleanup, a radionuclide-specific predicted concentration or surface area concentration of specific nuclides that can result in a dose (TEDE or CEDE) or specific risk equal to the release criterion is called the "derived concentration guideline level" (DCGL). A direct comparison can be made between the project's analytical measurements and the DCGL (MARSSIM, 2000). For drinking water analysis, an example of an action level would be a radionuclide-specific concentration based on the Maximum Contaminant Level (MCL) under the Safe Drinking Water Act (42 U.S.C. §300f-300j-26).

2.5.2.2 Identify Inputs to the Decision

The project planning team should determine the specific information required for decisionmaking and this should include a list of the specific data requirements (e.g., number, type, quality). The statistical parameter (e.g., mean concentration) that will be used in the comparison to the action level should be established. An estimate of the expected variability of the data will be needed in order to specify controls on decision-error rates. Existing data, experience and scientific judgment can be used to establish the estimate. Information on environmental background levels and variability may be needed.

The project planning team establishes whether the existing data are sufficient or whether new data are needed to resolve the problem. The radioanalytical specialist can play a key role in this effort by evaluating the quality of the existing radiological data.

2.5.2.3 Define the Decision Boundaries

The project planning team should clearly define the spatial boundaries for the project as well as the time frame for collecting data and making the decision. The spatial boundaries define the physical area to be studied and generally where samples will be collected. Temporal boundaries describe the time frame the study data will represent and when samples should be taken. Any practical constraints that could interfere with sampling should also be identified since these constraints may limit the spatial and/or temporal boundaries of the study.

During these discussions, the radioanalytical specialist can:

- Review existing data for spatial and temporal trends;
- Identify practical constraints that can impact sampling and analysis; and
- Determine feasibility of obtaining new data with current analytical methodologies.

2.5.2.4 Define the Scale of the Decision

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

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

2.5.3 Specify the Decision Rule and the Tolerable Decision Error Rates

A decision statement or rule is developed by combining the decisions and the alternative actions (see Appendix B, *The Data Quality Objectives Process*). The decision rule presents the strategy or logical basis for choosing among the alternative decisions, generally by use of a series of "if...then" statements. For a complex problem, it may be helpful to develop a logic flow diagram (also called a "decision tree" or "decision framework"), arraying each element of the issue in its proper sequence along with the possible actions. The decision rule identifies (1) the action level that will be a basis for decision, (2) the statistical parameter that is to be compared to the action level, and (3) the decision that would be made and the action that would be taken.

Example of a Decision Rule

General form: "If the value of parameter A over the area B, is greater than C, then take action D, otherwise take action D*."

Example: "If the mean concentration of *x* in the upper *y* cm of surface soil of the site is greater than *z* Bq/g, then action will be taken to remove the soil from the site; otherwise, the soil will be left in place."

The radioanalytical specialists play a key role in the development of technical alternatives that are realistic and satisfy the programmatic and regulatory needs. (See Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*, for additional discussion on background.)

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

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

The project planning team also assesses the potential consequences of making a wrong decision. While the possibility of a decision error can never be totally eliminated, it can be controlled. The potential consequences of a decision error are used to establish tolerable limits on the probability that the data will mislead the decisionmaker into making an incorrect decision. (See Appendix B, *The Data Quality Objectives Process*, for a discussion of hypothesis testing, action levels, and decision errors). The decision rule and decisionmaker's limits on the decision error rates are used to establish performance criteria for a data collection design.

In choosing the tolerable decision error rates, the team needs to look at alternative measurement approaches, the sources of error in field and laboratory handling of samples and analysis, factors that would influence the likelihood of a decision error, estimates of the cost of analysis, and judicious use of resources. Realistic decision error rates should be determined during the planning process in order to develop and optimize the sampling and analysis design process.

2.5.4 Optimize the Strategy for Obtaining Data

During the process of developing and optimizing the sampling and analysis plans, the technical team members should determine the project-specific sampling and analytical requirements and associated quality control that will meet all the requirements (desired outputs) established by the project planning team. Optimizing the data collection design generally requires extensive coordination between the radioanalytical and sampling specialists on the planning team. The technical team may not know the most effective analytical protocols at this stage.

Typical considerations during the development of the analysis portion of the data collection design include the number of samples required and the APSs, which include the MQOs (e.g., a statement of the required method uncertainty) required of the analytical procedures (see Sections 2.5.4.1 and 2.5.4.2). In general, the more certainty required in the DQOs, the greater the number of samples or the more precise and unbiased the measurements need to be. During planning, the costs and time for field and analytical procedures must be balanced against the level of certainty that is needed to arrive at an acceptable decision.

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

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

2.5.4.1 Analytical Protocol Specifications

Requirements of the desired analytical protocols should be based on the intended use of the data. That is, project-specific critical parameters should be considered, including the type of radioactivity and the nuclides of concern, the anticipated range of concentrations, the matrix type and complexity, regulatory required methods, the measurement uncertainty required at some activity concentration, detection limits required, necessary chemical separation, qualification or quantification requirements, QC requirements, and turnaround time needed. MQOs are a key component of the APSs and are discussed on the next page. Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*, contains more detailed discussion on some of the key decisions and needed input to successfully optimize the sampling and analysis design and develop APSs. Chapter 6, *Selection and Application of an Analytical Method*, discusses the selection of an analytical protocol from the laboratory's perspective.

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

2.5.4.2 Measurement Quality Objectives

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

A MQO is a statement of a performance objective or requirement for a particular method performance characteristic, such as the required method uncertainty at some concentration. MQOs can be both quantitative and qualitative performance objectives. Quantitative and qualitative MQOs are used for real-time compliance monitoring by field and laboratory staff and during subsequent assessments and data usability determinations. Quantitative MQOs provide numerical criteria for field and laboratory QC samples or procedure performance (e.g., specifications for measurement uncertainty, detection limit, yield, spikes, blanks and duplicates). Precision, bias, completeness, and sensitivity are common data quality indicators for which quantitative MQOs could be developed during the planning process (ANSI/ASQC E-4). Thus, quantitative MQOs are statements that contain specific units of measure, such as: *x* percent recovery, *x* percent relative standard uncertainty, a standard deviation of *x* Bq/L, or a MDC of *x* Bq/g. The specificity of the MQOs allows specific comparisons of the data to an MQO. Chapter 3, *Key Analytical Planning Issues and Developing Analytical Protocol Specifications*, provides detailed guidance on developing MQOs for several method performance characteristics.

The MQOs for the analytical data should be documented in the project plan documents (e.g., the QA Project Plan). MQOs are also the basis for the data verification and validation criteria (see Appendix D, Section D2.7, for a discussion of MQOs and QA project plans).

2.6 Results of the Directed Planning Process

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

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

If new data are to be obtained, the project planning team has developed the most resource-effective sampling and analysis design that will provide adequate data for decisionmaking. Based on the DQOs, the project planning team specifies the sampling collection design and APSs, including:

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

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

As a result of directed planning, the description of the DQOs for the project and the APSs (which contain the MQOs and any specific analytical process requirements for additional data) will provide the radioanalytical laboratory with a clear and definitive description of the desired data, as well as the purpose and use of the data. This information will be provided to the project implementation team through the SOW and the project plan documents. Precise statements of analytical needs may prevent the radioanalytical laboratory from:

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

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

The APSs should include, but not be limited to:

- The radionuclide(s) of concern;
- The matrix of concern, with information on chemical, explosive and other hazardous components;
- The anticipated concentration range (estimate, maximum or detection capability);
- The MQOs desired for the radionuclides of concern;
- The sample preparation and preservation requirements (laboratory and field);
- The type and frequency of QC samples required of each radionuclide of concern;
- The sample transport, tracking, and custody requirements;

- The required analytical turnaround time for the project and the anticipated budget for the analysis; and
- The data reporting requirements.

2.6.2 Chain of Custody

Requirements for formal chain of custody (COC) should be specified in the APSs if required. COC procedures provide the means to trace possession and handling of the sample from collection to data reporting. COC will impact how the field and laboratory personnel handle the sample. COC is discussed in Chapter 10 (*Field and Sampling Issues that Affect Laboratory Measurements*) and Chapter 11 (*Sample Receipt, Inspection, and Tracking*).

2.7 Project Planning and Project Implementation and Assessment

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

2.7.1 Documenting the Planning Process

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

When properly documented, the directed planning process:

- Provides a background narrative of the project;
- Defines the necessary input needed (nuclides, matrices, estimate of concentration range, etc.);

- Defines the constraints and boundaries within which the project would have to operate;
- Defines the decision rule, which states the action level that will be the basis for the decision and the statistical parameter that is to be compared to the action level;
- Identifies the tolerable decision error rates;
- Identifies MQOs for new analytical data; and
- Identifies processes and criteria for evaluating the usability of the data.

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

2.7.2 Obtaining Analytical Services

If laboratory services are required, a SOW should be developed based on the planning process statements of required data and data quality. The SOW is the contractual agreement that describes the project scope and requirements (i.e., what work is to be accomplished). MARLAP recommends that a SOW be developed even if a contract is not involved, for example when an agency employs one of its own laboratories. Contracting laboratory services is discussed in Chapter 5, *Obtaining Laboratory Services*, and Chapter 7, *Evaluating Methods and Laboratories*. Developing a SOW is discussed in Chapter 5.

2.7.3 Selecting Analytical Protocols

From an analytical perspective, one of the most important functions of a directed planning process is the identification and resolution of key analytical planning issues for a project. A key analytical planning issue may be defined as one that has the potential to be a significant contributor of uncertainty to the analytical process and ultimately the resulting data. Identifying key analytical issues for a particular process requires a clear understanding of the analytical process. It is the role of the radioanalytical specialist on the project planning team to ensure that key analytical planning issues have been clearly defined and articulated and incorporated into the principal decision or principal study question. Chapter 3 discusses the key analytical planning issues.

The selection of radioanalytical protocols by the laboratory is made in response to the APSs (for each analyte/matrix) developed by the project planning team as documented in the SOW. Unless required by regulatory policy, rarely will a radioanalytical method be specifically stated. A number of radioanalytical methods are available but no one method provides a general solution; all have advantages and disadvantages. The selection of a method involves a broad range of considerations, including analyte and matrix characteristics; technical complexity and practicality; quality requirements; availability of equipment, facility, and staff resources; regulatory and economic considerations; and previous use of the method. Chapter 6 discusses the selection of an analytical method as well as the modification of an existing analytical method to meet project requirements.

2.7.4 Assessment Plans

Concurrent with the development of MQOs and other specifications of the optimized analytical design, is the development of the data assessment plans. *Data assessment is difficult and arbitrary when attempted at the end of the project without planning and well defined, project specific criteria*. The development of these plans during the project planning process should ensure that the appropriate documentation will be available for assessment and that those implementing and assessing data will be aware of how the data will be assessed. Assessment of environmental data consists of three separate and identifiable phases: data verification, data validation, and data quality assessment (DQA). Verification and validation pertain to evaluation of analytical data generated by the laboratory. DQA considers all sampling, analytical, and data handling details, and other historical project data when determining the usability of data in the context of the decisions to be made. *The focus of verification and validation is on the analytical process and a data point by data point review, while DQA considers the data set as a whole, including the sampling and analytical protocols used to produce them.* Verification, validation, and DQA assure the technical strengths and weaknesses of the overall project data are known, and therefore, establishes the technical defensibility of the data.

2.7.4.1 Data Verification

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

2.7.4.2 Data Validation

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

2.7.4.3 Data Quality Assessment

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

2.8 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.

- MARLAP recommends using a graded approach in which the sophistication, level of QC and oversight, and resources applied are appropriate to the project.

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