OSWER Directive No. 9355.4-28

GUIDANCE FOR MONITORING AT HAZARDOUS WASTE SITES:

FRAMEWORK FOR MONITORING PLAN DEVELOPMENT AND IMPLEMENTATION

January 2004

ACKNOWLEDGEMENTS

The authors wish to acknowledge all the reviewers that have assisted the authors with constructive comments and assistance. We also wish to acknowledge the assistance of the Argonne National Laboratory Environmental Assessment Division task leader, Dr. Ihor Hlohowskyj, and the editorial assistance of the Argonne National Laboratory Information Publishing Division, especially primary editor Patricia Hollopeter and the staff of the Document Processing Center. We further wish to acknowledge the Monitoring working group members that assisted in the development of this guidance.

Bethany Grohs, V.M.D.
Environmental Response Team
Office of Superfund Remediation and Technology Innovation
U.S. Environmental Protection Agency

EPA Working Group Members:

Clarence Callahan, Ph.D., Region IX
James Chapman, Ph.D., Region V
Bruce Duncan, Ph.D., Region X
Stiven Foster, ORD
Bruce Pluta, Ph.D., Region III
Patti Tyler, Region VIII

Other Working Group Members:

Amy Hawkins, Naval Facilities Engineering Service Center
Jody Wireman, Ph.D., MSPH, CIH, U.S. Air Force

EXECUTIVE SUMMARY

This guidance document presents a framework for developing and implementing technically defensible Monitoring Plans for hazardous waste sites. In support of the One Hazardous Waste Cleanup Program, this document was written in direct response to, and for, site managers who are legally responsible for managing removal and remedial site activities. It is intended for use at hazardous waste sites that have completed site characterization, risk assessment, and remedy selection and are in the process of implementing a removal action or site mitigation.

This guidance presents a six-step framework for developing and documenting a Monitoring Plan that will support management decisions. The framework includes the identification of monitoring objectives and development of monitoring hypotheses to focus the monitoring program, and the development of decision rules (exit criteria) that include action levels and alternative actions for terminating or continuing the site activity and/or its monitoring program.

Within the framework, Steps 1 through 3 document the logic and rationale of the monitoring program by developing monitoring objectives that are directly related to the objectives of the site activity and by developing decision rules that will support site management decisions. Steps 4 through 6, which include the development of a Monitoring Quality Assurance Project Plan (QAPP), ensure that this logic is maintained by focusing data needs and data collection and analysis methods to directly support the monitoring objectives, decision rules, and subsequent management decisions. The framework is iterative and allows for the evaluation of the monitoring data as they are generated, thus supporting adaptive management of the site activity and the monitoring program.

This guidance document is not intended to specify the scale, complexity, protocols, data needs, or investigation methods for meeting the needs of site-specific monitoring. Rather, it presents a framework that can be used to develop and implement scientifically defensible and appropriate monitoring plans that promote national consistency and transparency in the decision-making process. This guidance is fully consistent with the Agency-Wide Quality System and may be adapted to meet the regulatory requirements of other U.S. Environmental Protection Agency programs.

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LIST OF ACRONYMS AND ABBREVIATIONS

BRA	baseline risk assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	*Code of Federal Regulations*
COC	contaminant of concern
CSM	conceptual site model
DQA	data quality assessment
DQO	data quality objective
ft	foot (feet)
ICAP	Induction Coupled Argon Plasma spectrometry
in.	inch(es)
m	meter(s)
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
OSC	On-Scene Coordinator
ppb	part(s) per billion
ppm	part(s) per million
QA	quality assurance
QAPP	Quality Assurance Project Plan
QC	quality control
RCRA	Resource Conservation and Recovery Act
RI	remedial investigation
ROD	Record of Decision
RPM	Remedial Project Manager
SMDP	Scientific Management Decision Point
U.S.C.	United State Code
U.S. EPA	U.S. Environmental Protection Agency
XRF	x-ray fluorescence

INTRODUCTION:
GUIDANCE FOR MONITORING AT HAZARDOUS WASTE SITES

PURPOSE

This guidance document presents a framework for developing and implementing technically defensible Monitoring Plans for hazardous waste sites. In support of the One Hazardous Waste Cleanup Program, this document was written in direct response to, and for, site managers (i.e., On-Scene Coordinators [OSCs] and Remedial Project Managers [RPMs]) who are legally responsible for managing removal and remedial site activities. However, risk assessors supporting Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and Resource Conservation and Recovery Act of 1976 (RCRA) activities may also use this document. Specifically, the purposes of this guidance are to:

1. Provide a framework for the development and implementation of scientifically defensible Monitoring Plans;

2. Facilitate consistency of monitoring across U.S. Environmental Protection Agency (U.S. EPA or the Agency) regions and programs; and

3. Establish procedures for identifying decision criteria prior to data collection.

The policies and procedures described in this document are intended solely as guidance. The statutory provisions and U.S. EPA regulations described in this document contain legally binding requirements. This document is not a regulation itself, nor does it change or substitute existing provisions and regulations. Thus, it does not impose legally binding requirements on the U.S. EPA, States, Tribes, or the regulated community. This guidance does not confer legal rights or impose legal obligations upon any member of the public.

The general guidelines provided in this document may not apply to a particular situation based upon the circumstances. Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of these guidelines to a particular situation. The U.S. EPA and other decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from those described in this guidance where appropriate.

This is a living document and may be revised periodically without public notice. The U.S. EPA welcomes public input on this document at any time.

SCOPE

The U.S. EPA conducts monitoring activities under many different programs (e.g., Superfund [SF], RCRA, Federal Facilities, and Underground Storage Tanks [USTs]), and the monitoring framework presented in this guidance describes a process that can be adapted to meet the regulatory requirements of these programs. Each program office may also have program-specific technical references (on data collection methods, data analysis, etc.) that may be utilized in concert with the monitoring framework. In addition, these program offices fully comply and are consistent with the Agency-Wide Quality System described in U.S. EPA Order 5360.1A2 (U.S. EPA 2000c). The U.S. EPA *Quality Manual for Environmental Programs-5360 A1* (U.S. EPA 2000b) provides the program requirements for implementing the Agency-Wide Quality System. This monitoring guidance is fully consistent with these requirements and the quality system. This monitoring guidance is intended for use at hazardous waste sites that have completed site characterization, risk assessment, and remedy selection and are in the process of implementing a remedial action or site mitigation.

This guidance document is not intended to specify the scale, complexity, protocols, data needs, or investigation methods for meeting the needs of site-specific monitoring. Rather, it presents a framework that can be used to develop and implement scientifically defensible and appropriate Monitoring Plans that promote national consistency and transparency in the decision-making process.

REQUIREMENTS FOR MONITORING

CERCLA statutory authority regarding monitoring gives the U.S. EPA authority to undertake monitoring to identify threats [42 U.S.C. § 9604(b)] and defines removal and remedial actions as inclusive of any monitoring reasonably required to ensure that such actions protect the public health, welfare, and the environment [42 U.S.C. § 9601(23) and 42 U.S.C. § 9601(24)], respectively. Section 121(c) of CERCLA [42 U.S.C. § 9621(c)], as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, together with the implementing regulation in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), requires that “if the President selects a remedial action that results in any hazardous substances, pollutants, or contaminants remaining at the site,” post-response reviews be conducted every 5 years to ensure protection of human health and the environment. The NCP states that the focus of the 5-year review should be review of monitoring data to evaluate whether the remedy continues to provide for adequate, risk-based protection of human health and the environment (40 CFR § 300.430 (f)(4)(ii)(2002)).

U.S. EPA policy for Record of Decision (ROD) development states that the lead agency can require monitoring to verify that no unacceptable exposures to potential hazards posed by site conditions will occur in the future. In corrective actions conducted under RCRA, as amended, properly designed performance monitoring programs are considered integral to remedy success and are to be considered throughout the corrective action process (U.S. EPA 1996). Detailed guidance regarding RCRA performance monitoring is available in U.S. EPA 1992 and 2001a. Additional monitoring regulations in support of RCRA include those pertaining to groundwater and landfill standards. 40 CFR 264.90 (f), 264.98, and 265 delineate detection monitoring requirements and monitoring system specifications for groundwater. 40 CFR 258.54 and 258.55 delineate detection and assessment monitoring program requirements for landfills.

OVERVIEW OF MONITORING

Definition

The scientific literature provides a variety of definitions of monitoring. Among these, the definition presented by Elizinga et al. (1998) most closely approximates monitoring at hazardous waste sites: "The collection and analysis of repeated observations or measurements to evaluate changes in condition and progress toward meeting a management objective." Within this definition, monitoring is driven by management objectives and is implemented within a management context. For example, monitoring under CERCLA may have the objectives of collecting and evaluating data to determine whether the selected remedy meets the CERCLA management objective of providing adequate risk-based protection of human health and the environment.

Monitoring is the collection and analysis of data (chemical, physical, and/or biological) over a sufficient period of time and frequency to determine the status and/or trend in one or more environmental parameters or characteristics. Monitoring should not produce a "snapshot in time" measurement, but rather should involve repeated sampling over time in order to define the trends in the parameters of interest relative to clearly defined management objectives. Monitoring may collect abiotic and/or biotic data using well-defined methods and/or endpoints. These data, methods, and endpoints should be directly related to the management objectives for the site in question.

Monitoring and Its Objectives

Many types of monitoring may be conducted at a site, such as detection monitoring (to detect changes in ambient conditions), compliance monitoring (to evaluate compliance with regulatory requirements), and remedial monitoring (to evaluate remedy effectiveness). Depending on the nature of the site, one or more types of monitoring may be necessary and each type will have its own monitoring objectives.

As previously stated, the objectives of a Monitoring Plan will depend directly on the specific site activity and associated management objectives. Monitoring objectives may therefore address the following:

- Evaluation of remedy effectiveness and protection of human health and the environment;
- Evaluation of contaminant migration;
- Evaluation of effectiveness of habitat mitigation; or
- Compliance with regulatory requirements.

At a project location, the monitoring, objectives and study design may also vary, depending on the physical, chemical, and biological nature of the site (such as a freshwater polychlorinated biphenyl compound [PCB] site, a soil lead site, or a prairie restoration site). In all instances, the associated Monitoring Plan objectives ultimately should support a management objective for the site and its activity.

> **HIGHLIGHT I-1**
> **Site Activities**
>
> Site activities may include any number of activities that could occur at a hazardous waste site, including, but not limited to, implementation and/or operation of a removal action, remedial action, institutional controls, or habitat mitigation.

Monitoring Outcome

Upon completion of the specified monitoring activities, the results normally will point toward one of three general conclusions, which in turn should be used to support a management decision for the site. These conclusions will typically be related to the success of the site activity being addressed by the Monitoring Plan. First, if the monitoring results indicate that the site activity has been successful, the management decision may be to terminate monitoring and the site activity and proceed with the relevant regulatory process or program under which the site activity is being conducted. For example, CERCLA and the NCP require 5-year reviews conducted in perpetuity whenever contaminants remain in place. This regulation remains regardless of the outcome of the Monitoring Plan. Second, if the monitoring data indicate that the activity is trending toward success, then the decision may be to continue monitoring. Finally, if the monitoring data do not indicate activity success, clearly show activity failure, or are equivocal, the management decision may be to evaluate both the site activity and the Monitoring Plan to determine the factors responsible for the monitoring results, and to revise the Monitoring Plan and/or the site activity accordingly. Management decisions may also be made earlier during monitoring (e.g., prior to conclusion of monitoring) as monitoring data are generated. These decisions may be to terminate the monitoring process sooner than planned, continue monitoring as planned, or modify the monitoring program to guide ongoing activities toward their eventual success.

MONITORING PLAN DEVELOPMENT

Monitoring Team Formation

The overall site decision rests with site management (e.g., the OSC and RPM). In order to assist management with the development and implementation of a Monitoring Plan, a monitoring team may be formed. This team may include the site manager, supporting technical staff (e.g., Biological Technical Assistance Groups [BTAGs], risk assessors, analytical chemists, environmental engineers), and appropriate stakeholders (e.g., natural resource trustees and the public). The role of this team is to provide input into the development and implementation of the Monitoring Plan. The formation of the team, as well as its involvement in the Monitoring Plan, is site-specific and as requested, and/or directed by, site management.

Process for Developing the Monitoring Plan

This guidance document presents a six-step process that can be used to develop clear-cut monitoring objectives; develop scientifically defensible study designs and data interpretation methods; and support management decisions based on decision criteria for continuing, revising, or concluding monitoring and site activities. This six-step process (depicted in Figure I-1) may be utilized to develop Monitoring Plans for various types of monitoring, including but not restricted to those intended to evaluate remedy effectiveness and habitat mitigation. This process may also be employed to develop a Monitoring Plan for conducting 5-year reviews at sites where, upon completion of remedial activities, some form of restricted land use remains.

Framework Scientific Management Decision Points (SMDPs)

Step 1: Monitoring objectives
Step 2: Monitoring hypotheses, questions, and conceptual site models
Step 3: Preliminary decision rules
Step 4: Monitoring QAPP
Step 5: Revisions to the Monitoring Implementation Plan
Step 6: Decision Document

This guidance focuses on the components critical to developing a Monitoring Plan with clearly identified and appropriate objectives, methods, and decision criteria. This guidance does not provide recommendations on individual data collection methods, analyses, or other data collection and analysis aspects of monitoring. The selection of specific data collection and analysis methods, which occurs within Step 4 of this monitoring framework, would occur on a site-specific basis and follow the procedures and requirements specified in the U.S. EPA Quality Manual (U.S. EPA 2000b). The monitoring guidance calls for the development of a monitoring-specific Quality Assurance Project Plan (QAPP) that is consistent with and satisfies the requirements of the U.S. EPA Agency-Wide Quality System (U.S. EPA 2000c). The Monitoring Plan must also identify the monitoring-specific quality assurance (QA) and quality control (QC) policies and procedures (as identified in Chapter 5 of the U.S. EPA Quality Manual [U.S. EPA 2000b]) needed to achieve the monitoring objectives.

At the conclusion of each step of the six-step process, a scientific management decision point (SMDP) occurs. These SMDPs serve as points in the process where decisions are documented with regard to the Monitoring Plan objectives, hypotheses, study design, and, ultimately, the management decision. Depending on the specific step in the process, formal documentation of the SMDP may or may not be appropriate.

The development of a Monitoring Plan may go through one or more iterations, especially involving Steps 2 through 4. For example, development of the Monitoring QAPP may show that using the monitoring hypotheses and decision rules developed in Steps 2 and 3 result in a Monitoring Plan that is too expensive to implement, for which resources are not available, or too difficult to implement. In this case, one should return to Step 2 and see if the monitoring team can revise the current hypotheses or develop alternative monitoring hypotheses and decisions.

Step 1. Identify Monitoring Plan Objectives

- Evaluate the site activity
  - Identify the activity objectives
  - Identify the activity endpoints
  - Identify the activity mode of action
- Identify monitoring objectives
- Stakeholder input
- Scientific Management Decision Point (SMDP)

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Step 2. Develop Monitoring Plan Hypotheses

- Develop monitoring conceptual models
- Develop monitoring hypotheses and questions
- SMDP

↓

Step 3. Formulate Monitoring Decision Rules

- Formulate monitoring decision rules
- SMDP

↓

Step 4. Design the Monitoring Plan

- Identify data needs
- Determine Monitoring Plan boundaries
- Identify data collection methods
- Identify data analysis methods
- Finalize the decision rules
- Prepare Monitoring Quality Assurance Project Plan
- SMDP

↓

Step 5. Conduct Monitoring Analyses and Characterize Results

- Conduct data collection and analysis
- Evaluate results per the monitoring DQOs (developed in Steps 1–4), and revise data collection and analysis as necessary
- Characterize analytical results and evaluate relative to the decision rules
- SMDP

↓

Step 6. Establish the Management Decision

- Monitoring results support the decision rule for site activity success
  - Conclude the site activity and monitoring
- Monitoring results do not support the decision rule for site activity success but are trending toward support of the decision rule
  - Continue the site activity and monitoring
- Monitoring results do not support the decision rule and are not trending toward support
  - Conduct causative factor and uncertainty analysis
  - Revise site activity and/or Monitoring Plan and implement
- SMDP

Figure I-1 Six-Step Process for Developing and Implementing a Monitoring Plan

Use of the Data Quality Objectives Process

The six-step process for developing Monitoring Plans presented in this guidance relies heavily on the use of the data quality objective (DQO) process (U.S. EPA 2000a). Use of a systematic planning process such as the DQO process is a fundamental component of the U.S. EPA Agency-Wide Quality System (U.S. EPA 2000c) and associated QA/QC guidance and requirements (U.S. EPA 2000a–d; 2001b; 2002). Use of the DQO process produces qualitative and quantitative statements that define the type, quality, and quantity of data necessary to support a defensible monitoring decision by management. The DQOs identify when and where to collect monitoring samples, the number of samples to be collected, how the samples should be analyzed, the analytical performance criteria that need to be met, how the results should be interpreted relative to the monitoring objectives, the practical constraints for collecting the samples, and the level of uncertainty that is acceptable to the decision maker with regard to making a monitoring decision.

The DQO process consists of seven sequential steps that lead to the development of an optimized data collection plan. In the DQO process, the output of each step serves as input for the next step. The process may be iterative, with the output of one step resulting in the reconsideration of earlier steps.

Use of the DQO process improves project planning efficiency by promoting positive communication among stakeholders, focusing the Monitoring Plan on a clear action-oriented decision, and ensuring that decisions are made with a desired level of confidence in the results. Use of the DQO process also provides a record of what data are needed before data collection begins and the rationale for needing that data, thus establishing a logical rationale for making a monitoring decision.

The products of the DQO process should be clear, concise statements that define the data quality criteria and monitoring design performance specifications. These criteria define “how good” the data should be and the degree of acceptable uncertainty in the data. These statements identify such items as the number and locations of samples to be collected, the sampling methods, and the analytical methods. Example I-1 presents examples of how the DQO process integrates with the Monitoring Plan development framework for hypothetical bioremediation and habitat mitigation activities.

Example I-1 Integration of Data Quality Objectives into Development of Monitoring Plans, Verifying Success of Hypothetical Bioremediation and Habitat Mitigation Activities

Monitoring Framework Step	Associated DQO Step	Example 1: Bioremediation	Example 2: Habitat Mitigation
Step 1. Identify Monitoring Plan Objectives	Step 1. State the Problem. Summarize the problem that will require new environmental data (the monitoring hypothesis).	Current soil contaminant of concern (COC) levels (0–2 ft depth range) have been shown to pose unacceptable risks to plant survival. Toxicity tests identified mortality levels > 20% for exposed populations, with a lowest observed adverse effect level (LOAEL) (5% mortality) of 0.5 ppm. Bioremediation was selected to reduce this risk to acceptable levels. The Monitoring Plan objective is to determine whether the bioremediation has been successful in reducing risks to acceptable levels and can therefore be terminated.	A 50-acre portion of a brownfield site was selected for mitigation to tallgrass prairie. The Monitoring Plan objective is to determine when the mitigation activities have restored the 50-acre mitigation site to its intended condition (tallgrass prairie).
Step 2. Develop Monitoring Plan Hypotheses	Step 1. State the Problem. Summarize the problem that will require new environmental data (the monitoring hypothesis).	The monitoring hypothesis is that bioremediation will reduce risks to acceptable levels by achieving soil COC levels $\leq$ 0.5 ppm in areas with COC soil concentrations >0.5 ppm by microbial breakdown of toxic components. On the basis of the predicted rate of microbial breakdown, one or both of these bioremediation goals are expected to be attained within 7 years.	The monitoring hypothesis is that through planting, controlled burns, and herbicide application, a tallgrass prairie community will be established within 7 years that will include at least 40 native plant species that were typically present in this type of habitat in the region of the site, with 7 target species dominating (>50% vegetative cover) the community. Nonnative species will comprise <10% vegetative cover of the restored site.
Step 3. Formulate Monitoring Decision Rules	Step 2. Identify the Decision. Identify the decision that requires new data to address the problem.	Develop a preliminary decision rule to decide whether the bioremediation has met its stated objectives. If bioremediation has been successful, the management decision may be to terminate monitoring and the bioremediation and proceed with the relevant regulatory process. Alternately, the decision will be to continue bioremediation and monitoring.	Develop preliminary decision rule to decide whether the mitigation has met its stated objectives. If successful, the management decision may be to terminate monitoring and the mitigation and proceed with the relevant regulatory process. Alternately, the decision may be to continue the mitigation activities and monitoring.
Step 4. Design the Monitoring Plan	Step 3. Identify Input to the Decision. Identify information needed to support the decision; specify what input requires new data.	Data needs include COC concentrations in site soils while bioremediation is underway.	Data needs include plant community species composition, extent of vegetative cover of the preferred dominant plant species, and extent of vegetative cover of nonnative species.

Example I-1 (Cont.)

Monitoring Framework Step	Associated DQO Step	Example 1: Bioremediation	Example 2: Habitat Mitigation
	Step 4. Define the Study Boundaries. Specify the spatial and temporal aspects of the environmental media or endpoints that the data must represent to support the decision.	COC data for soils in the 0–2 ft depth range will be needed from locations where current COC concentrations are > 0.5 ppm, and these data will be needed on a quarterly basis for the next 6 years.	Monitoring activities will be limited to the 50-acre mitigation area; data collection will occur yearly in late summer-early autumn for the next 7 years.
	Step 5. Develop a Decision Rule. Develop a logical "*if...then…*" statement that defines the conditions that would cause the decision maker to choose among alternative decisions.	Finalize the decision rule *if* the measured COC concentrations are $\leq$ 0.5 ppm and remain so for three consecutive sampling rounds, *then* the remedy will be considered successful and remediation and monitoring can be stopped.	Finalize the decision rule *if* the plant community includes 40 native species, with 7 dominant species comprising >50% and nonnative vegetation <10% of the total vegetative cover of the site, *then* the mitigation will be considered successful and the mitigation and monitoring can be stopped.
	Step 6. Specify Limits on Decision Error. Specify the decision maker's acceptable limits on decision errors, which are used to establish performance goals for limiting uncertainty in the data.	A 95% confidence level will be used in all statistical evaluations of soil COC concentrations.	Reducing data uncertainty will be based on a sample size considered representative of the mitigation site. Transects with a minimum 15-m spacing interval and with plant survey locations spaced at 10-m intervals along each transect will be considered to adequately represent the restoration site.
	Step 7. Optimize the Design for Obtaining Data. Identify the most resource-effective sampling and analysis design for generating data needed to satisfy the DQOs.	Develop the Monitoring Quality Assurance Project Plan (QAPP).	Develop the Monitoring QAPP.
Step 5. Conduct Monitoring Analyses and Characterize Results	Implement design optimized in Step 7.	Implement monitoring data collection and analysis and evaluate monitoring data (per the DQOs and decision rules) as they are collected.	Implement monitoring data collection and analysis and evaluate monitoring data (per the DQOs and decision rules) as they are collected.
Step 6. Establish the Management Decision	DQO Steps 2 and 5.	Make a management decision based on the decision rules developed and finalized in framework Steps 3 and 4, respectively.	Make a management decision based on the decision rules developed and finalized in framework Steps 3 and 4, respectively.

STEP 1: IDENTIFY MONITORING OBJECTIVES

Development of a Monitoring Plan begins with the identification of monitoring objectives that are directly related to the expected outcome of the site activity (i.e., reduced soil contaminant of concern [COC] concentrations, mitigation of wetland function, or long-term stewardship of institutional controls). In Step 1, the site activity is examined and is used to identify one or more monitoring objectives.

1.1 MONITORING OBJECTIVES

Monitoring objectives can be placed into four general categories:

- Identification of changes in ambient conditions;
- Detection of movement of environmental constituents of interest (COCs, silt, temperature) from one location to another;
- Demonstration of compliance with regulatory requirements; and
- Demonstration of the effectiveness of a particular activity or action.

The monitoring objectives most applicable to a site activity will generally be determined by the nature of the activity itself. In some cases, a variety of monitoring objectives may be needed for a single site activity.

1.1.1 Examination of the Site Activity

Identification of monitoring objectives will generally be based on the examination of the site activity, which helps to identify physical, chemical, and/or ecological parameters that could be used later in developing the Monitoring Plan study design. Examination of the site activity should address:

- The outcome of the site activity (what is it intended to accomplish and what are the specific entities [e.g., biological or environmental parameters such as community structure or contaminant concentration] expected to be affected by the site activity?); and
- The mode of action of the site activity (how is the activity expected to meet its intended objectives?).

For activities related to contamination and risk issues, examination of the site activity should also address:

- The human health and ecological endpoints determined to be at risk at the site (e.g., residential child, insectivorous bird); and

- The COCs and associated cleanup criteria (what are the contaminants driving the risk, and what are the cleanup levels for reducing risks to acceptable levels?).

The time frame for implementation, operation, and completion of the site activity (such as a removal action or habitat restoration) should be identified to provide temporal bounds to the monitoring objectives and subsequent monitoring studies. Activities associated with, but not directly related to, the objectives of the site activity should be identified at this time since these may also require consideration in the Monitoring Plan. For example, mitigation measures may be needed to minimize environmental impacts associated with the implementation and operation of a remedial action. These mitigation measures should be identified and evaluated to determine whether they need to be included in the Monitoring Plan. If so, then additional monitoring objectives specific to those measures should be developed.

Available information on the site activity may be found in a variety of sources, such as risk assessments, decision documents, environmental characterization reports, engineering design documents, habitat recovery plans, wetland delineations, and natural resource management plans. For example, under CERCLA, relevant information regarding these parameters (e.g., the COCs, endpoints at risk, etc.) can often be found in the ROD and its supporting technical reports, such as the baseline risk assessment (BRA) and the feasibility study (FS). Under RCRA, similar information may be found in the Statement of Basis/Response to Comments (SB/RTC), which documents the selected corrective measure and its supporting technical reports, such as the RCRA Facility Assessment (RFA), RCRA Facility Investigation (RFI), and the Corrective Measures Study (CMS)

Example 1-1
Activity Outcome and Monitoring Objectives

An engineered cap has been installed at a site with two remedial outcomes: (1) to eliminate direct exposure of human and ecological receptors to contaminated soil and groundwater, and (2) to eliminate the potential for contaminant leaching and subsequent groundwater transport of contaminants to off-site wetlands. For this remedial action with two dissimilar outcomes, a single Monitoring Plan with two different monitoring objectives would be recommended. The first monitoring objective would address the effectiveness of the cap in reducing exposure over some designated time frame. The second monitoring objective would address the effectiveness of the cap in controlling contaminant transport via groundwater to off-site wetlands and groundwater.

Identify the Activity Outcome: Each site activity has a unique set of physical, chemical, and/or biological endpoints that are the target of the site activity, and these endpoints should be considered by the monitoring objectives. For example, the target endpoints for a grassland mitigation project may be a specified level of plant species diversity or a specific community structure, while the target endpoint for a bioremediation project may be a specified acceptable contaminant level in site soil. For the former example, the monitoring objective would likely be related to demonstrating attainment of the target species diversity or community structure. For the latter example, the monitoring objectives would be related to demonstrating attainment of a specified COC soil concentration. Information regarding the site activity outcome and its endpoints may also be useful during development of monitoring decision rules (see Step 3) and in the design of specific monitoring studies (see Step 4).

Identify the Activity Mode of Action: The mode of action of an activity defines how the activity is expected to attain its desired outcome and relates the activity endpoints to the objectives. For example, at a CERCLA soil bioremediation project the activity objective might be to reduce risks associated with the contaminated soil to acceptable levels, with the activity targeting soil COC concentrations. The mode of action of the bioremediation may be the microbial conversion of the COCs to less toxic breakdown products, thereby reducing soil COC concentrations to acceptable levels. Monitoring objectives related to this mode of action may focus on demonstrating that bioremediation is effectively reducing soil COC concentrations. Information on the activity mode of action may also be useful during development of monitoring decision rules (see Step 3) and in the design of specific monitoring studies (see Step 4). In the case of a remedial action involving implementation of a cap, the mode of action of the cap would be the elimination of exposure pathways to human and/or ecological receptors. The associated monitoring objectives would focus on ensuring cap integrity, which may include compliance with institutional controls that were established to complement the on-going physical obligations associated with maintenance of the cap, and demonstrating that exposure is not occurring at the site.

1.1.2 Identify Monitoring Objectives

The purpose of any Monitoring Plan is to demonstrate that a specific activity outcome has been or is being met within some particular time frame, and to thus support a management objective. Once information regarding the activity objectives, endpoints, and mode of action has been examined, one or more activity-specific monitoring objectives can be identified. Table 1-1 presents examples of different types of site activities and potential monitoring objectives.

Table 1-1 Example Monitoring Objectives for Different Site Activities

Site Activity	Monitoring Objectives
Sediment capping to reduce contaminant exposure and migration	Demonstrate that the cap is effective in reducing exposure — Has the desired degree of exposure reduction been attained? Demonstrate that contaminants have not migrated off site — Are contaminants at off-site locations below preliminary remediation goals? Demonstrate that mitigation measures enacted during remedy implementation are successful — Are mitigation measures effective in controlling potential impacts of remedy implementation and operation?
Wetland mitigation	Demonstrate success of wetland mitigation — Have mitigation activities achieved a desired wetland function?
Storm water outfall compliance with National Pollutant Discharge Elimination System (NPDES) permit requirements	Demonstrate that outfall water concentrations do not exceed levels specified in an NPDES Permit — Are desired water concentrations being attained?
Bioremediation to reduce soil contaminant concentrations	Demonstrate effectiveness in contaminant concentration reduction — Has a desired contaminant level been attained?
Groundwater treatment with short-term institutional controls to prohibit groundwater use until cleanup goals have been met.	Demonstrate that treatment is effective in reducing contaminant concentrations — Have contaminant groundwater concentrations been reduced to desired levels? Demonstrate that institutional controls are prohibiting groundwater use during treatment — Has groundwater use stopped?

1.2 STAKEHOLDER INPUT

Early involvement of the monitoring team serves to identify stakeholder issues and concerns before the objectives, decision rules, and study design of the Monitoring Plan are finalized and implemented. The intent of early involvement is to limit future disagreements regarding the specific design of the Monitoring Plan, thereby avoiding project delays and associated costs.

1.3 SCIENTIFIC MANAGEMENT DECISION POINT

At the conclusion of Step 1, there is an SMDP regarding the objectives of the Monitoring Plan. The purpose of the SMDP is to document a decision identifying one or more monitoring objectives that best address the site activity. While a formal deliverable is not necessary, the decision should be formally recorded as a memorandum or letter to file.

STEP 2: DEVELOP MONITORING PLAN HYPOTHESES

2.1 MONITORING HYPOTHESES

Monitoring hypotheses represent statements and/or questions about the relationship between a site activity, such as remediation or habitat mitigation, and one or more expected outcomes for that activity. The development of the monitoring hypotheses is analogous to the problem formulation step (Step 1) of the DQO process (Figure I-1). The nature of the hypotheses will strongly depend on the type of activity and the monitoring objectives previously identified (see Step 1).

The monitoring hypothesis may be generally stated as "The site activity has been successful in reaching its stated goals and objectives." The most basic monitoring question, regardless of the monitoring objectives, can be stated as "Has (is) the activity of interest reached (reaching) its stated objectives?", and the specific Monitoring Plan should focus on answering this question. The answer to this question provides support for making a management decision on the activity and associated monitoring, such as whether to cease the activity and monitoring because the activity has reached its stated objectives. Examples 2-1 and 2-2 illustrate simple monitoring hypotheses and questions for hypothetical remediation and restoration activities.

2.2 MONITORING CONCEPTUAL MODEL

Development of monitoring hypotheses may be aided by the use of a monitoring conceptual model. The monitoring conceptual model consists of a series of working hypotheses that identify the relationships between the site activity and its expected outcome. The model does not need to be highly detailed or describe all aspects of the relationships between the site activity and its expected outcome. Rather, it should describe the assumptions about the site activity and its objectives and expected outcome and serve as the basis for the monitoring hypotheses and questions. The answers to these questions provide the basis for making a decision on whether the activity has reached its stated objective.

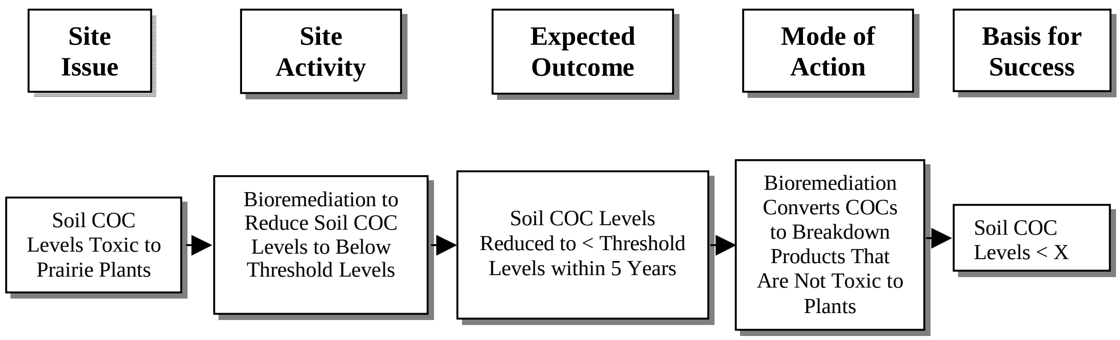
Identification of the monitoring objectives, together with the development of monitoring hypotheses (and a monitoring conceptual model), represents the outcome of Step 1 of the DQO process (State the Problem). Rather than summarizing a *problem* that requires new environmental data, it summarizes a *desired outcome* that may require new data to verify attainment of that outcome.

2.3 SCIENTIFIC MANAGEMENT DECISION POINT

The outcome of Step 2 is the identification of monitoring hypotheses and questions specific to the site activity and development of a monitoring conceptual model identifying the relationships between the site activity and its expected outcome. These comprise the SMDP for Step 2. The purpose of the SMDP is to document a decision regarding monitoring hypotheses, questions, and conceptual model. The monitoring team members should agree on any subsequent changes to these items. While a formal deliverable is not necessary, the decision should be formally recorded as a memorandum or letter to file.

Example 2-1
Monitoring Remediation Success

This example illustrates a monitoring conceptual model, a monitoring hypothesis, and associated monitoring questions for a remedial action addressing contaminated soil. The remedy involves the use of bioremediation to reduce soil COC concentrations to acceptable levels. The monitoring objectives for this activity would be to (1) evaluate the effectiveness of the remedy in reducing soil COC levels to desired levels and (2) determine whether and when remediation should stop, continue, or be revisited and possibly revised.



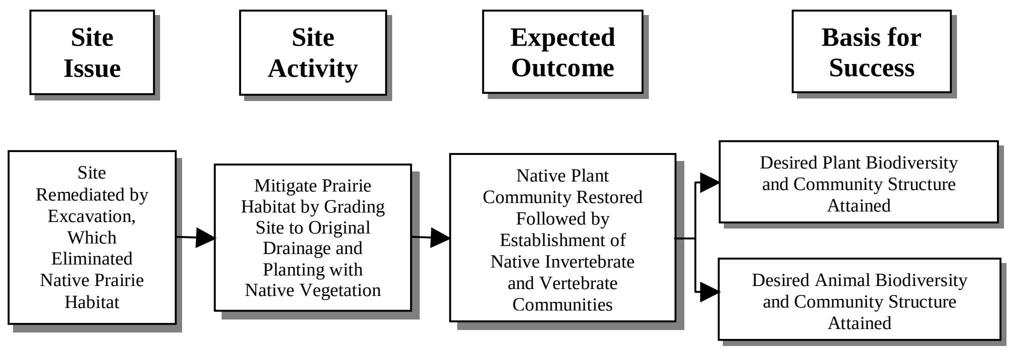
Monitoring Hypothesis: Soil COC levels are responsible for unacceptable soil toxicity to plants. Bioremediation was selected as the remedy. Bioremediation produces nontoxic breakdown products, thereby reducing soil COC concentrations to acceptable levels within 5 years of remedy implementation.

Monitoring Question:

1. Have surface soil (0–2 ft depth range) COC concentrations been reduced to acceptable levels (< 0.5 ppm)?

Example 2-2
Monitoring Habitat Mitigation Success

This example illustrates a monitoring conceptual model, a monitoring hypothesis, and associated monitoring questions for a habitat mitigation activity implemented after soil contamination was remediated by excavation and subsequent disposal of contaminated soils. The monitoring objectives for this activity would be to evaluate the effectiveness of the mitigation activity in restoring native prairie habitat and its biotic communities and determining whether and when restoration should stop, continue, or be revisited and possibly revised.



Monitoring Hypothesis: Soil excavation removed COCs but resulted in the loss of a native prairie habitat and its plant and animal communities. To mitigate the habitat loss, the site will be graded to its original contours and native prairie vegetation will be planted to reestablish native plant and animal communities.

Monitoring Questions:

1. Have native plant biodiversity and community structure been restored to a desired level or condition?
2. Have invertebrate and vertebrate biodiversity and community structure been restored to a desired level or condition?

STEP 3: FORMULATE MONITORING DECISION RULES

At the conclusion of Step 2, the monitoring objectives have been identified and site-specific monitoring hypotheses, questions, and monitoring conceptual models have been developed. In Step 3, preliminary monitoring decision rules are developed that relate the site activity and the monitoring hypotheses and questions with the monitoring results. These are refined and finalized during the development of the Monitoring Plan study design that occurs in Step 4. These monitoring decision rules are analogous to the decision rules of the DQO process. The data collected during implementation of the Monitoring Plan are evaluated with regard to these decision rules, and this evaluation supports the selection of a specific management decision (see Step 6) for the site activity and associated monitoring.

3.1 MONITORING DECISIONS

3.1.1 Formulation of Preliminary Decision Rules

In Step 3, preliminary monitoring decision rules are developed that take the form of generalized DQO decision rules. A decision rule is an "*if... then...*" statement that defines the conditions that would cause the decision maker to choose an action. In other words, it establishes the exact criteria for making a choice between taking and not taking an action. In a monitoring program, the decision rules should establish the criteria for continuing, stopping, or modifying the Monitoring Plan and/or the site activity. In general, there are four main elements to a monitoring decision rule:

- The parameter of interest;
- The expected outcome of the site activity;
- An action level (the basis on which a monitoring decision will be made); and
- Alternative actions (the monitoring decision choices for the specified action level).

The preliminary decision rules should be stated in general terms with regard to these elements. Note that the preliminary decision rule does not identify specific bounds for the action level, such as an acceptable toxicity level, a soil contaminant level, or a temporal component for the results. These specifics should be developed during design of the Monitoring Plan (see Step 4).

Example 3-1
Preliminary Decision Rules for a Bioremediation Project

A preliminary decision rule associated with a remedial action to reduce soil COC levels may be stated as "*If* the monitoring results indicate that bioremediation has reduced soil concentrations to acceptable levels, *then* the bioremediation will be considered to have reached its objectives and no further remedial action or monitoring will be necessary. Otherwise, further action in the form of continued or revised remediation and monitoring will be necessary." In this example, the preliminary decision rule identifies the parameter of interest (soil COC levels), the site activity (bioremediation), the action level that will serve as the basis for a decision (an acceptable soil COC level), and the alternative actions (conclude bioremediation and monitoring or continue remediation and monitoring).

3.1.2 Refinement of the Decision Rules

Refinement of the preliminary monitoring decision rules takes place during Step 4 (Develop Monitoring Design) (Figure I-1). During Step 4, specific studies are identified for addressing the monitoring hypotheses and questions; the results of these studies are applied to the decision rules to support a site management decision. As the monitoring study design is being developed and specific data needs and requisite studies are identified, the preliminary decision rules are revisited and refined so they specifically relate to the monitoring studies and anticipated results. This decision rule refinement may include the following for each parameter of interest:

- Identification of the specific monitoring study and its endpoint;
- Identification of specific action levels (such as a specified COC concentration);
- Identification of a time frame (the site activity duration) within which the action level is expected to be reached; and
- Identification of other monitoring study-specific factors that are directly related to the parameter of interest (such as the spatial boundaries within which the action levels are to be applied and the ability of available methods to discriminate actual responses from natural variability).

For example, the preliminary decision rule in Example 3-1 may be refined as "*If* the results of a soil COC evaluation indicate that COC levels are at or below a target level, *then* soil remediation will be considered to have reached its objectives and no further remedial action or monitoring to evaluate remedy effectiveness will be necessary." In this example, the specific monitoring study is a measurement of soil COC concentration; the study endpoint is COC concentration; the action level is a COC level at or below a target concentration; and the alternative actions are to cease or continue remediation and monitoring.

Depending on the nature of the site activity and the monitoring goals and objectives, a number of monitoring decision rules may be required. If the Monitoring Plan includes the collection of several types of dissimilar data (e.g., media contaminant levels, community structure, species diversity), the analysis of these dissimilar data may result in conflicting conclusions. In such cases, the monitoring team should strive to predetermine how dissimilar data will be interpreted (such as using weighting factors) with respect to one another in order to support a site management decision. The monitoring team should also strive to ensure that the refined decision rules are as clear and concise as possible, since these rules serve as the primary basis for a site management decision.

3.2 SCIENTIFIC MANAGEMENT DECISION POINT

At the conclusion of Step 3, preliminary monitoring decision rules have been developed that define the conditions that allow the decision maker to choose among alternative actions related to the monitoring program and the site activity. These preliminary decision criteria represent the SMDPs for Step 3. While a formal deliverable for the SMDP is not necessary, the decision should be formally recorded as a memorandum or letter to file.

STEP 4: DESIGN THE MONITORING PLAN

By the conclusion of Step 3, the monitoring objectives; the monitoring hypotheses, questions, and conceptual models; and the preliminary decision rules have been developed. This step establishes and formally documents the goals and focus of the Monitoring Plan. In Step 4, the data needs, data collection and analysis methods, QA/QC requirements, and final decision rules are developed. These components of the Monitoring Plan represent the necessary components of a U.S. EPA QAPP (as identified in the U.S EPA Quality Manual) and are fully consistent and compliant with Agency regulations. At the conclusion of Step 4, the preliminary decision rules from Step 3 are finalized and will be used in Step 6 to support a management decision. Step 4 concludes with the preparation of a Monitoring QAPP, which documents the monitoring activities that will be conducted in order to meet the monitoring objectives and support a management decision.

4.1 IDENTIFY DATA NEEDS

A variety of data may be necessary to test the monitoring hypotheses, to answer the monitoring questions, and ultimately to support a management decision. These data may be chemical, physical, and/or biological in nature, depending on the hypotheses and questions, and on the decisions to be made. Factors to consider when identifying data needs may include the following:

- Anticipated outcome of the site activity;
- Preliminary monitoring decision rules;
- Data characteristics; and
- Applicability of data (and data collection methods) from previous site investigations to the monitoring design.

4.1.1 Expected Outcome of the Site Activity

By considering the expected outcome of the site activity, the monitoring team can identify the specific chemical, physical, and/or biological parameters expected to be affected by the site activity. These parameters are the starting point for identifying the Monitoring Plan data needs. For example, phytoremediation may be selected as a remedial action for a site having unacceptable soil COC concentrations. The expected outcome of this action is a reduction in soil COC concentrations to a specified level. The associated monitoring objective is to verify that the remedial action has successfully reached that outcome. In this example, soil COC concentration is the parameter expected to be affected by the remedial action. Potential data needs for the monitoring program should focus on quantifying soil COC concentrations during and after the remediation.

4.1.2 Data Characteristics

Data characteristics refer to the nature and type of the data, such as a detection level or a taxonomic level. For example, different detection levels may apply, depending on whether the site activity involves remediation of contaminated media to reduce ecological or human health risks. As another example, a Monitoring Plan to determine the success of a prairie mitigation may require the collection of abundance data for a variety of species, or may focus on the abundance of only a single indicator species. Suppose data from previous studies indicated a plant community of about 100 species. In this example, success of the prairie mitigation may be based on the establishment of a minimum number of those species (e.g., the presence of at least 80 of the previously identified 100 species). Alternatively, success may be based on the abundance of a smaller subset of species that are considered indicators of desired species associations. In both of these examples, specific data characteristics are dependent on the site activity (i.e., remediation or mitigation) and its desired outcome (i.e., a desired media COC concentration or a plant community), the monitoring objectives (i.e., determine whether the activity has been successful), and the monitoring hypotheses and questions (i.e., the activity will reduce COC concentrations or reestablish a target plant community).

4.1.3 Evaluate Applicability of Previous Investigations

During Step 1, project reports, decision documents, and other information from previous investigations pertaining to the project site were evaluated to aid in the development of the monitoring objectives. This same information should also be evaluated during the identification of the monitoring data needs. Past investigations may include details regarding media and endpoints of concern, successful environmental data collection and analysis methods, remedy design and performance criteria, and other information that may be directly applicable to identifying monitoring data needs. For example, data collection and analysis methods that were successfully used in the remedial investigation (RI) to determine the nature and extent of sediment contamination may also be appropriate for a Monitoring Plan evaluating the effectiveness of a remedial action in reducing sediment COC concentrations. Table 4-1 provides several examples of information from previous investigations that may be applicable to designing the Monitoring Plan, including the identification of data needs.

4.2 DETERMINE MONITORING BOUNDARIES

The monitoring boundaries represent the “what, where, and when” aspects of the Monitoring Plan. In defining these boundaries, the monitoring team answers the following questions:

- What data are needed?
- How should samples be collected (discrete or composite)?
- Where should monitoring samples be collected?

Table 4-1 Potential Applicability of Previous Site Investigations to the Monitoring Design

Previous Investigation	Data Collection Objectives	Example Studies	Data Characteristics	Potential Applicability
Remedial Investigation	Characterize nature and extent of contamination	• COCs measured from groundwater wells upgradient, at, and downgradient of the site • COCs measured in soils at the site • COCs measured in groundwater surface water, soil, and sediment upgradient, at, and downgradient of the site	• Groundwater dynamics • Groundwater COC concentrations upgradient, at, and downgradient of the site • Surface water dynamics • Surface water COC concentrations upstream, at, and downstream • Underlying geology and soil associations • Soil transport and sediment dynamics • Soil and sediment COC concentrations	• Methods and sampling locations may be suitable for: • Monitoring groundwater COC transport; • Monitoring changes in groundwater quality; • Monitoring changes in surface water quality; and • Monitoring changes in soil/sediment chemistry
Baseline Ecological Risk Assessment	Characterize risks to assessment endpoints of interest	• Media-based toxicity tests • Field-based plant biomass measurements • Soil invertebrate community structure and species abundance	• Soils with different COC concentrations • Individual species and total plant biomass measurements • Numbers of individuals, by species • Number and types of soil invertebrates	• Methods and sampling locations may be suitable for: • Monitoring changes in plant biomass, diversity, and community structure; and • Monitoring recolonization of soil invertebrates
Biodiversity Survey	Identify current biological communities and resident biota	• Biotic surveys for determination of community structure and species abundance	• Physical and chemical habitat characteristics • Numbers of individuals, by species and habitat	• Methods and sampling locations may be suitable for: • Monitoring habitat mitigation • Monitoring changes in species abundance and community structure

- When should monitoring samples be collected?
- How long should sampling continue?
- How often should sampling continue?

The type of data to be sampled will be based largely on the data needs identified earlier in Step 4 (see Section 4.1). For example, the monitoring data needs may be soils in the 6–12 in. depth range, or a specific age class of fish. The geographic (spatial) area from which the monitoring data are to be collected should be a function of the nature and objectives of both the site activity and the Monitoring Plan. For example, if the site activity is groundwater remediation and the monitoring objectives are to determine whether the activity has successfully reduced groundwater COC concentrations to acceptable levels, then the Monitoring Plan would likely include groundwater sampling from on-site, upgradient, and downgradient locations. In contrast, if the site activity is a habitat mitigation, then sampling activities would likely be restricted to the immediate site boundary (and reference area if available).

Once the necessary data have been identified and the spatial boundaries selected, the temporal boundaries for the Monitoring Plan should be established. Identification of the temporal boundaries should include information on (1) when samples should be collected (e.g., spring, summer, dawn, dusk, etc.); (2) how often they should be collected (e.g., hourly, daily, weekly, etc.); and (3) how long sampling should continue (e.g., 6 months, 2 years, until a specified condition is reached).

Managers of environmental programs need to be aware that nearly all aspects of environmental monitoring are complicated by the fact that the environment is heterogeneous at both the macro and micro scales. Not only are environmental media such as soils or ecosystems naturally heterogeneous, but anthropogenic effects (such as the dispersal of contaminants into the environment) create significant spatial (and sometimes temporal) patterning and variability in the distribution of constituents of concern. This means that generic sampling designs may easily produce nonrepresentative, confusing, or misleading data. Generating representative data for heterogeneous systems includes the development of a conceptual site model (CSM), which is used to understand or hypothesize probable contaminant distributions and spatial (or temporal) patterns in relation to the intended decisions. The CSM then guides the development of sampling and analysis plans that will (1) test the validity of the assumptions used to develop the CSM and (2) gather data representative of the intended decision(s). To control for the factors that introduce variability into environmental data, sampling plans need to discuss more than just sample locations; they must also cover “sample support” issues (sample volume, dimensions, and particle size), sample homogenization, and subsampling procedures. In addition, commonly used statistical techniques are most reliable when spatial patterning of targeted analytes is not present. Since this assumption is violated under many contaminant release and migration scenarios, the CSM is the foundation for selecting proper statistical procedures (www.triadcentral.org).

4.3 IDENTIFY DATA COLLECTION METHODS

For a specific data need there may be a variety of approaches to collecting the necessary data; some may be more costly or difficult to implement than others. For example, suppose that the surface soil concentration of a particular metal was identified as a data need for the monitoring program. Determining metal concentrations in soil may be quicker and less costly using field portable x-ray fluorescence (XRF) methods than using laboratory-based Induction Coupled Argon Plasma Spectrometry (ICAP). The most appropriate analytical method for this example would depend on the expected activity outcome and on the monitoring objectives. If the monitoring objective is to determine whether soil remediation has successfully reduced the soil concentration to $\leq$100 ppm or less, the higher detection levels of the XRF may be sufficient to gather the data needed to meet the monitoring objectives. However, if the target soil concentration is $\leq$5 ppm, that level is below the capabilities of field portable XRF, and the more costly and time-consuming ICAP analysis would be needed.

It is not necessary to identify specific sampling designs at this stage of study design. Specific sampling designs are developed during optimization of the data collection design (see Section 4.5.1). Rather, at this point, data collection methods are identified that may be appropriate to collect the required data, and a preliminary determination is made of the feasibility of using those approaches to collect the data with the required characteristics and within the required time and cost restraints.

4.4 IDENTIFY DATA ANALYSIS METHODS

Monitoring, as previously defined (see Introduction), is the collection and analysis of repeated observations or measurements to evaluate changes in condition and progress toward meeting a management objective. It is critical that the study design and data analysis methods can distinguish between natural variability in the data and actual response in the parameter under evaluation. Analysis of the monitoring data may involve some form of statistical analysis. In cases where monitoring is being conducted to identify individual exceedance of some critical environmental conditions, statistical analysis may not be necessary. Use of an appropriate statistical method can help support or refute the monitoring hypotheses and thus help answer the monitoring questions. A variety of statistical tests may be employed to evaluate the monitoring data. The specific type of tests that are deemed valid depend on the nature of the monitoring hypotheses and questions, the data and its collection methods (percentage of nondetects, sample size, replication, etc.), and the desired level of decision error. The selection of the statistical approach should be based on how well the assumptions of the test are met and tied closely to the monitoring objectives, hypotheses and questions, and decision rules. In general, analysis of the monitoring data will employ some combination of descriptive and inferential statistics and time-series analysis. Some common data analysis methods are described in detail in *Guidance for Data Quality Assessment* (QA/G-9) (U.S. EPA 2000d); additional information may be found on the U.S. EPA Quality System Web site (www.epa.gov/quality).

4.4.1 Descriptive and Inferential Statistics

Descriptive statistical analysis of the monitoring data typically involves a determination of the central tendency of the data, such as the mode, median, or mean, and also identification of the dispersion (e.g., range, standard deviation) and frequency distribution (e.g., normal, bimodal) of the data. Inferential statistics examine a set of data in order to accept or reject a specific hypothesis. For a monitoring activity, there are two types of hypotheses that the analysis may support: (1) the null hypothesis that the expected outcome of the site activity has been attained, or (2) the alternative hypothesis that the expected activity outcome has not been attained. Information on descriptive and inferential statistics can be found in a variety of sources (e.g., Sokal and Rohlf 1981; U.S. EPA 2000d; Zar 1984).

Two types of errors are associated with the use of inferential statistics to evaluate a hypothesis: (1) a Type I (false positive) error, or (2) a Type II (false negative) error. With a Type I error, the analysis would indicate that the expected activity outcome has not been achieved when in fact it has. The consequences of this type of error would be that the activity (whether remediation or mitigation) would be deemed unsuccessful, and both the activity and its associated monitoring program would continue. In this case, there would be no continuing risks or impacts, but there would be a continuing expenditure of cost and effort. For a Type II error, the analysis would support the conclusion that the expected activity outcome has been achieved when in fact it has not, and both the activity and its associated monitoring should cease. The effects of such an incorrect decision would be a continued potential or actual risk or impact.

Example 4-1
Hypothesis Testing and Type I and Type II Errors

The cleanup of contaminated groundwater is being carried out through the use of a pump-and-treat system to reduce the mean groundwater concentration of lead at the site to a mean background level. In this remediation project, the groundwater lead concentration is measured monthly and statistically compared with the lead concentration in groundwater collected from designated background wells. In this example, the null hypothesis is that the mean lead concentration in the site groundwater is not significantly different than the mean background lead concentration. The alternative hypothesis is that the mean lead concentration in site groundwater is significantly greater than the mean background lead concentration.

For this example, a Type I error would occur if the analysis wrongly supported a conclusion that the mean site lead concentration was greater than the mean background lead concentration when in fact it did not significantly differ from the background level. With a Type II error, analysis of the data would support the conclusion that the mean site lead concentration was not significantly different than background when in fact it was significantly greater.

Type I and Type II errors are inversely related to one another, so that the lower the probability of a Type I error the greater the probability of a Type II error. The study design should establish significance levels that identify the acceptable probability of making a Type I error. In general, a significance level of 0.05 is usually considered sufficient to minimize the likelihood of making a Type I error while not overly increasing the likelihood of a Type II error. Although a significance level of 0.05 is among the most widely used in hypothesis testing, the consequences of both types of errors should be considered in selecting an appropriate significance level.

4.4.2 Trend Analysis

Trend analysis evaluates data collected at specified intervals over a specified period in order to determine if conditions are changing over time, and if so, how they are changing (i.e., the magnitude and direction of the change). Trend analyses can be applied to biological, chemical, or physical monitoring data. For example, trend analysis can be used to evaluate the rate of decline of groundwater COC concentrations under a particular remedial action, and it can be used to evaluate the rate at which species are recolonizing a habitat restoration site.

The amount, duration, and frequency of data needed to conduct a trend analysis depend on the nature of the data being collected and the expected outcome of the activity. For example, the collection of groundwater data is a relatively straightforward task; the frequency of collection is governed largely by such hydrogeological parameters as transmissivity and hydraulic conductivity. In this example, frequent (daily or weekly) data collection may be readily possible, and sufficient data may be collected in a relatively short period to allow for a trend analysis to be conducted. In contrast, the collection of some types of data may be limited to only a brief period each year. For example, suppose one was monitoring the success of a bird nesting in a habitat mitigation site by measuring fledging success. Since nesting and subsequent fledging may only occur yearly (i.e., during the breeding season), several years of data would be needed before any analysis of a trend in habitat recovery and fledging success could be conducted.

Trend analysis may also be employed to predict how parameters of interest might respond in the future, or how well an activity is progressing toward its stated objectives. The results of such trend analyses may be used to refine or revise site activities (e.g., operations of a particular remedial action) and thus assist future site management planning.

4.5 UNCERTAINTY ANALYSIS

Evaluation of the monitoring data must also consider the uncertainty associated with the data. The nature and magnitude of any uncertainty may strongly affect the interpretation of how well the data are meeting the DQO specifications, and whether the data support the decision rule. There may be several sources of uncertainty associated with the monitoring data, such as incomplete monitoring conceptual models, natural variation in the parameter being measured by the monitoring program, and analytical uncertainty or variability. If the monitoring program employs the same data collection methods as those used for the RI or the BRA, then the uncertainties identified during those investigations may also apply to the monitoring data.

4.6 FINALIZE THE MONITORING PLAN

At this point in designing the Monitoring Plan, the monitoring team should have:

- Developed monitoring objectives;
- Developed monitoring hypotheses, questions, and conceptual models;
- Formulated the monitoring decision rules;
- Identified data needs, including data characteristics;
- Determined the spatial and temporal boundaries for the data needs and data collection activities;
- Developed decision rules and identified acceptable decision error limits; and
- Identified data analysis methods.

This information represents the DQOs developed for the Monitoring Plan by the first six steps of the DQO process. These are the DQOs that should be met to support a defensible monitoring decision. These DQOs also represent the preliminary design parameters for the Monitoring Plan, identifying the why, what, when, and how aspects of data collection and analysis for the plan.

4.6.1 Optimize the Design

During the design optimization step (Step 7 of the DQO process), sampling and analysis alternatives are developed and reviewed with regard to satisfying the previously developed DQOs. From those alternatives determined to best satisfy the DQOs, those that are most resource (cost, effort) effective should be selected for use in monitoring. For example, both XRF and ICAP approaches can be used for determining metal concentrations in soil; XRF, however, is quicker and less costly. However, the ICAP approach provides a greatly lower level of detection. During the optimization, a decision is made on which of these approaches or combination of approaches would best meet the monitoring DQOs. Once an optimized monitoring design has been completed, the data collection methods should be evaluated to ensure that they can be successfully implemented under site conditions and within cost and budget constraints. Optimization continues with implementation of the Monitoring Plan. As Monitoring Data are generated and evaluated, the Monitoring Plan should be revisited to see if improvements, such as use of a different data collection method (i.e., a newer, cheaper, faster technology) or a revised sampling regime (i.e., a different sampling scheme) could be implemented without compromising the quality of previously collected data while continuing to meet the monitoring DQOs. Section 5.3.2 discusses evaluating and optimizing the ongoing Monitoring Plan in response to deviations from the monitoring DQOs.

4.6.2 Prepare Monitoring Quality Assurance Project Plan

The final aspect of developing the monitoring design is the preparation of a Monitoring QAPP. The following should be included in this QAPP:

- An overview and general background of the site activity for which the Monitoring Plan has been developed;
- A description of the monitoring objectives;
- The monitoring hypotheses, questions, and monitoring conceptual model;
- The data needs and characteristics;
- The data collection methods, including sampling location, timing, and frequency;
- The sampling equipment and procedures;
- The data handling requirements; and
- The data analysis methods.

U.S. EPA policy requires that all work performed by or on behalf of the U.S. EPA involving the collection of environmental data shall be implemented in accordance with an Agency-approved QAPP (U.S. EPA 2000b-c). The required components of a QAPP to be implemented by the EPA are identified in Chapter 5 of the U.S. EPA Quality Manual in Sections 5.3.2, 5.3.3, 5.3.4, and 5.3.5 (U.S. EPA 2000b), and the components of a QAPP to be implemented by external organizations (e.g., EPA contractors and grantees) are identified in EPA QA/R-5 (U.S. EPA 2001b). The Monitoring QAPP includes, and is consistent with, these requirements and thereby satisfies the requirements of the U.S. EPA Agency-Wide Quality System (U.S. EPA 2000c). Additional information on the required components of a QAPP, as well as tools for assisting in its preparation, may be found on the U.S. EPA Quality System Web site (http://www.epa.gov/quality/).

Documentation of the Monitoring QAPP may occur in a variety of ways. The QAPP that was previously prepared and implemented in support of site characterization and risk assessment data collection may be revised to incorporate the monitoring-specific QAPP components as identified above. Alternately, a monitoring-specific QAPP may be prepared that focuses only on the monitoring activities and decisions. This Monitoring QAPP may be prepared as a stand-alone document or as an addendum to the earlier project QAPP.

4.7 SCIENTIFIC MANAGEMENT DECISION POINT

The SMDP for Step 4 is the finalized Monitoring QAPP.

STEP 5: CONDUCT MONITORING ANALYSIS AND CHARACTERIZE RESULTS

At the completion of Step 4, the Monitoring Plan has been developed and documented in the Monitoring QAPP. Implementation of the plan, including data collection and analysis, occurs in Step 5. The results of the analyses in Step 5 should be used to support a management decision in Step 6 as to the success of both the monitoring program and the site activity under evaluation by the monitoring program.

5.1 DATA COLLECTION AND ANALYSIS

During Step 5, all data collection activities should strictly adhere to the study design identified in the Monitoring QAPP and be conducted at the times, locations, and frequencies specified by the DQOs. Thus, in addition to the collection and analysis of the monitoring data, a major component of Step 5 is the evaluation of the data, as they are collected, with regard to the DQOs. This evaluation assists the monitoring team in determining whether the data meet the requirements of the DQOs.

Thus, during the conduct of Step 5 the monitoring team should be continually evaluating and interpreting the data with regard to three basic questions:

1. Do the data meet the DQOs?

2. If yes, can the data collected to date support a decision rule? or

3. If the data do not meet the DQOs, why not and what changes should be made so that the data meet the specified DQOs?

These evaluations may be conducted as part of a data quality assessment (DQA), which assesses the type, quantity, and quality of data in order to verify that the planning objectives, quality requirements (consistent with the U.S. EPA Quality Manual [U.S. EPA 2000b]), and sample collection procedures were satisfied and that the data are suitable for their intended purpose. Guidance for conducting a DQA can be found in EPA QA/G-9 (U.S. EPA 2000d). Depending on how well the monitoring results meet the DQO requirements, the monitoring program may either proceed as identified in the Monitoring QAPP, be revised, or proceed to a management decision (Figure 5-1).

5.2 EVALUATION OF ANALYTICAL RESULTS

Analysis of the monitoring data should occur as the data are generated and successfully undergo the QA/QC data quality review as described in the Monitoring QAPP (see Section 4.6.2). Data analyses employ the analytical methods identified in Step 4 (see Section 4.4), and the results of these analyses should be evaluated with regard to the monitoring hypotheses, the DQOs, and the monitoring decision rules that were developed in Steps 2 and 3.

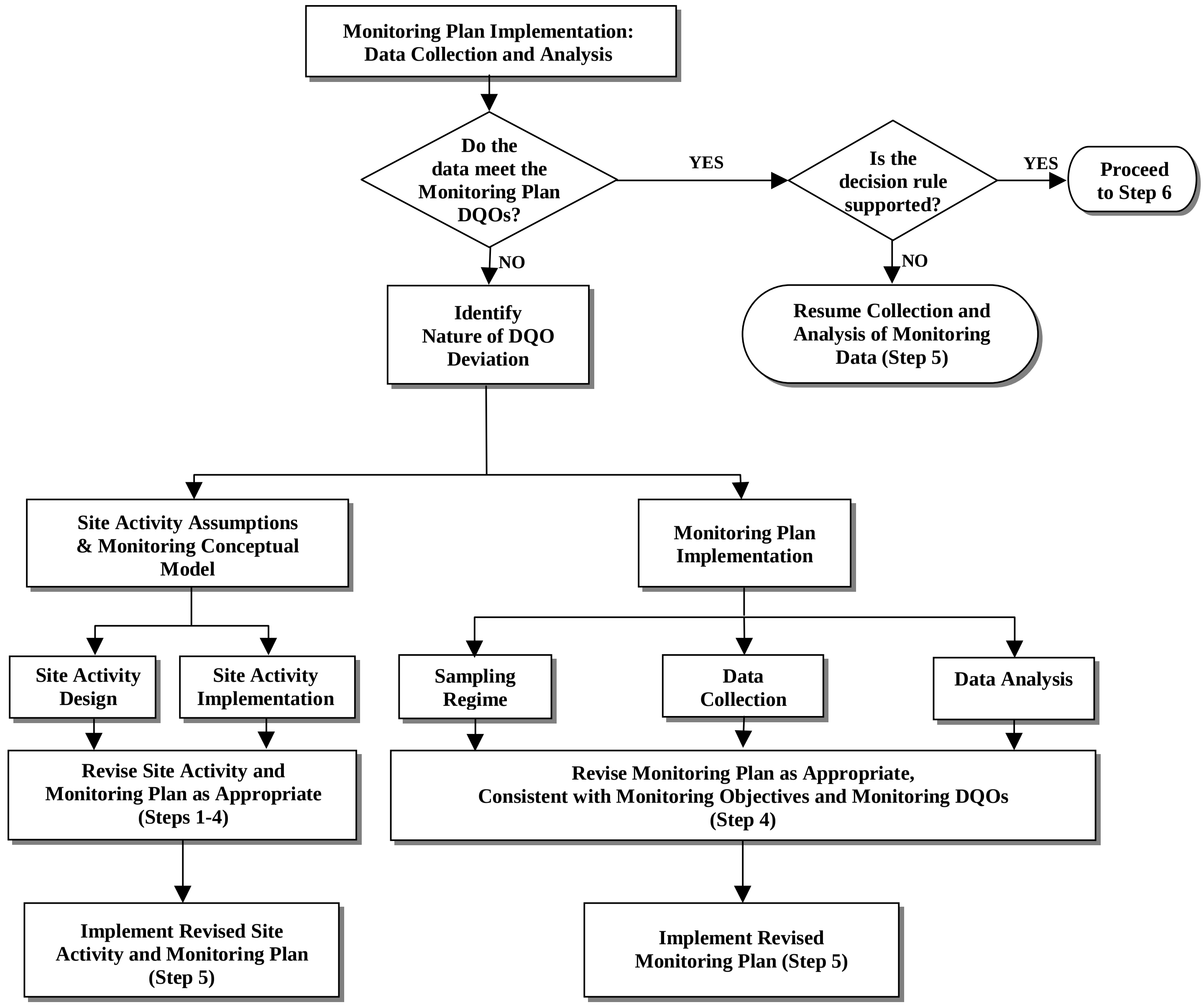


Figure 5-1 Decision Path during Monitoring Implementation and Data Collection and Analysis

5.2.1 Relationship of Analytical Results to the Monitoring Hypotheses

Recall that the basic monitoring hypothesis is "Has (is) the site activity reached (reaching) its stated objectives?" (see Step 2). This hypothesis is based, in part, on specific assumptions of how the site activity is expected to attain its outcome. As the monitoring program generates data, the monitoring team should continually analyze those data with regard to how well the data support the monitoring hypotheses and the underlying site assumptions as developed in the monitoring conceptual model. Evaluation of the data may show the site activity to be proceeding as expected, better than expected, or worse than expected. The specific outcome determines whether any modifications or adjustments to the site activity or to implementation of the Monitoring Plan may be appropriate.

For example, suppose a remedial action is initiated to address a contaminated soil problem (see Example 2-1). The monitoring hypothesis may be that the selected remedy (bioremediation) will reduce the soil contaminant concentration to <5 ppm to a specified level within 5 years of remedy implementation. If the monitoring data indicate soil concentrations are changing as expected, data collection would continue as described in the Monitoring QAPP.

If the data indicate better than expected response (i.e., soil concentrations are decreasing more rapidly than expected), then the monitoring team may consider revising the Monitoring QAPP as suggested by the data. In this case, it may be appropriate to revise not only the expected duration of the remedy and its associated monitoring program, but also aspects of the sampling regime related to sampling frequency. It may be possible to reduce the sampling frequency and/or proceed to a monitoring decision and overall site management decision sooner than was originally planned, thereby reducing overall project costs.

In contrast, if the monitoring data indicate little or no change in soil concentration, or an increase in soil contaminant levels, then it would be appropriate to evaluate implementation of the plan, the site activity assumptions, and/or the remedy assumptions and the monitoring conceptual model, and identify possible revisions to the Monitoring QAPP, the remedy, or both (Figure 5-1).

5.2.2 Data Adherence to the Data Quality Objectives

Throughout data collection and analysis, the monitoring team should pay special attention to ensuring that the specifications established by the DQOs for the monitoring design are being adequately met. These specifications include where and when the monitoring data are being collected (the spatial and temporal boundaries), how the data are being collected (the collection methods, including the sampling equipment and procedures), and how the data are being evaluated (data analysis). The monitoring team should ensure that (1) all data collection and analysis activities conform to the QA/QC policies and procedures identified in the Monitoring QAPP (see Section 4.6.2), and (2) all data validations procedures identified in the plan are carried out on all data generated by the monitoring program.

5.2.3 Data Support of the Decision Rules

As the monitoring data are collected, they should be compared with the decision rules developed in Step 3. Recall that the decision rules specify the criteria for continuing, stopping, or modifying the monitoring program and/or the site activity. For example, a monitoring decision rule associated with a soil contamination remedial action may be stated as "If the measured soil contaminant concentration is less than 0.5 ppm soil for three consecutive sampling events, then the remediation will be considered to have met its objectives." If at any point during the collection and analysis of monitoring data the data are found to support the decision rule, then the site would proceed to Step 6. Alternately, if the analysis indicates that the data do not support the decision rule, then monitoring would continue as identified in the Monitoring Plan and QAPP (Figure 5-1).

5.3 ADDRESSING DATA DEVIATIONS FROM THE MONITORING DQOs

Deviations from the DQO specifications can arise for a variety of reasons, ranging from unexpected data collection problems, to analytical errors in the laboratory, to computational errors during data analysis (Figure 5-1). Uncertainties associated with the monitoring conceptual model or assumptions regarding the expected performance and outcome of the site activity may also be the basis for deviations from the DQOs.

If deviations from the monitoring DQOs are indicated, the underlying basis for the observed deviations should be determined. The consequences of those deviations on the success of the site activity and on the continued conduct of the monitoring program should be ascertained, and actions necessary to address those deviations should be identified. In general, deviations from the monitoring DQOs may be due to (1) design and/or implementation problems of the site activity, or (2) monitoring implementation problems. Actions to address these deviations may include (1) changes to the design and/or implementation of the site activity, and/or (2) changes in the implementation of the Monitoring Plan (Figure 5-1).

5.3.1 Evaluating the Site Activity

The monitoring team should examine the implementation, expected and ongoing performance, and success of the site activity as monitoring data are collected. For example, evaluating the performance of the remedial technology may identify operational issues that are responsible for the DQO deviations. Examination of the monitoring conceptual model may greatly aid in this evaluation. Recall that during early development of the monitoring program, a monitoring conceptual model was developed to identify known and expected relationships between the site activity and the monitoring goals and objectives (see Step 2). Once developed, this conceptual model was then used to identify the monitoring data needs and develop the Monitoring Plan. If the monitoring data indicate that one or more site activity assumptions are incorrect, or that implementation of the activity is incorrect, then changes in the assumptions, design, and/or implementation of the site activity and/or the Monitoring Plan will be necessary.

Example 5-1
Revising the Site Activity

Natural attenuation was selected as the remedial action for a site having unacceptably high contaminated soil. During the development of this remedy, the site soil was assumed to have a particular biodegradation potential for the contaminant that would provide a specific attenuation rate for the remedy. Monitoring data, however, indicate that soil contaminant levels are not being attenuated at the rate expected on the basis of biodegradation potential assumptions. In this case, the original remedial assumptions would be revised to reflect the lower than expected biodegradation potential. A subsequent change to the remedy design, namely the addition of soil amendments to increase microbial activity and thus enhance biodegradation rates, was determined to be necessary to increase the attenuation rate to the level originally assumed for the action. In this example, there would be a revision to the remedy design, but the monitoring program could continue as identified in the Monitoring Plan and QAPP.

5.3.2 Evaluating Implementation of the Monitoring Plan

Evaluation of the monitoring data may indicate that the observed monitoring DQO deviations are associated with implementation of the Monitoring Plan and not with the site activity itself (Figure 5-1). Implementation problems may be associated with one or more of the following aspects of data collection: (1) the sampling regime, (2) the data collection methods, or (3) the data analysis methods (Figure 5-1).

Example 5-2
Revising Implementation of the Site Activity

A herbicide program is implemented to control and eventually eradicate invasive, non-native vegetation at a prairie mitigation site. Evaluation of the monitoring data shows that the herbicide is not effective at the current application concentration. Large individual plants survive the herbicide exposure, and seedlings continue to sprout within two weeks following herbicide application. Knowledge of the effects levels of the herbicide and its persistence in the environment suggests that success of the herbicide program can be increased to the originally desired level through an increase, consistent with Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA) requirements, in the herbicide concentration and its application frequency. In this example, both the site activity and the Monitoring Plan and QAPP would be revised.

***Sampling Regime*:** Problems with the sampling regime may be related to the spatial and temporal boundaries of the sampling design (i.e., sampling location and frequency). The monitoring team should examine the monitoring data, the current sampling regime, and the nature of the DQO deviations, and determine whether changes in the sampling design would rectify the DQO deviations. Such changes could include an increase or decrease in the number of samples collected during each sampling event from current sampling locations, an addition or a decrease in the number of locations sampled, or a change in the sampling location. Such changes should be consistent with the underlying hypotheses, DQOs, and decision rules of the Monitoring Plan and would not require changes in data collection and analysis methods.

***Data Collection Methods*:** In some cases, evaluation of the monitoring data may show that sampling methods are the basis for the observed data deviations from the monitoring DQO specifications. Such a problem could result from a variety of factors, such as unexpected environmental conditions (e.g., a greater submerged aquatic vegetation density, reducing benthic grab sampler efficiency) or insufficient biomass availability. If such problems are encountered, the monitoring team should determine how the data collection method could be revised or replaced with an alternative method. In some cases, the changes may be relatively straightforward and easy, such as simply increasing the amount of tissue collected for laboratory analysis, or changing from one type of sediment sampler to another (e.g., Eckman dredge versus core sampler). In other cases, a completely different sampling method may be required (e.g., electrofishing versus gill netting). The changes in the collection methods should provide data of sufficient quality to meet the DQO specifications and meet the needs of the decision rules. If not, additional aspects of the Monitoring Plan, such as the monitoring goals, hypotheses, and/or DQOs, may have to also be revised. Data collection methods may also be changed as new technologies become available, or as alternative methods with increased efficiency and/or reduced costs are identified.

Example 5-3
Revising the Sampling Regime

A remedial action is implemented to reduce groundwater concentrations of copper to a level < 25 ppb within 5 years (the monitoring hypothesis). The monitoring program for this action includes quarterly groundwater sampling. Trend analysis of the first four quarterly rounds of data indicates that groundwater copper concentrations are decreasing at a rate much greater than expected and may reach the target concentration (< 25 ppb) before the next sampling period. Continuing the monitoring program with the original sampling regime could result in remediation (and its associated costs) continuing beyond the actual attainment of the remediation goal. In this example, it may be appropriate to revise sampling to a bimonthly or even monthly regime until the target level has been reached and possibly for confirmatory sampling afterwards (i.e., groundwater concentration below the target level for four consecutive sampling periods). This would allow for a more real-time determination of whether the criteria specified in the monitoring decision rules have been met.

Data Analysis Methods: In some cases, inability of the monitoring data to meet their DQO specifications may be related not to sampling regime or data collection methods, but rather to the analytical methods being employed. For example, matrix interference is a commonly encountered problem in the chemical analysis of environmental media, and if not carefully considered may lead to the generation of erroneous data. Similarly, confounding factors in sediment, such as grain size or ammonia concentration, can greatly affect the outcome of sediment toxicity analyses.

Inappropriate statistical analyses may also play a role in any observed DQO deviations. For example, during development of a Monitoring Plan it may have been assumed that the monitoring data would be normally or lognormally distributed, and that parametric methods for statistical analyses would be appropriate. However, if the monitoring data are not normally distributed, then the use of parametric analyses would produce incorrect statistical results. In this case, the monitoring team would replace the parametric methods with a nonparametric (distribution-free) data analysis approach.

Documenting Revisions to the Monitoring Plan: Any changes to the Monitoring Plan, whether changes in the sampling regime, the monitoring objectives, hypotheses, the data collection methods, or decision rules should be documented as an addendum to, or a revision of, the Monitoring QAPP.

STEP 6: MANAGEMENT DECISION

6.1 MANAGEMENT DECISIONS IN THE MONITORING PLAN

In Step 6, the monitoring results are evaluated with respect to the monitoring decision rules, and a determination is made as to how well the site activity has met its stated objectives. Recall that the primary objective of any monitoring program is to demonstrate whether a specific outcome (i.e., the objective of the site activity) has been (or is being) met within a specified time frame.

If the monitoring results support the decision rules, the interpretation would be that the site activity has successfully reached its specified outcome. In this case, the management decision may be to discontinue both the activity and its monitoring program. For activities involving land use controls and/or some form of containment measure (e.g., a cap), the management decision would be to continue the activity and its associated monitoring. Alternately, if the monitoring results do not support the decision rules, the interpretation would be that the site activity has not been successful. In this case, the management decision would be to determine why the activity was unsuccessful and identify what actions are necessary in order to achieve the original site activity goals. In both cases, the management decision has consequences that affect project costs, protectiveness of human health and the environment, and ultimate site closeout.

6.2 GENERAL MANAGEMENT DECISIONS

At the end of the data collection, analysis, and characterization as specified in the Monitoring QAPP, the monitoring results will point toward one of three conclusions (Figure 6-1) relevant to the monitoring objectives and decision rules. These conclusions are:

- The monitoring decision rules have been met (results indicate site activity is successful), or

- The data are trending toward meeting the decision rules, or

- The monitoring decision rules have not been met (monitoring results indicate the site activity has not achieved its stated objective).

The management decisions associated with each of these monitoring outcomes are discussed in the following subsections. SMDPs and documentation associated with each management decision are discussed in Section 6.3.

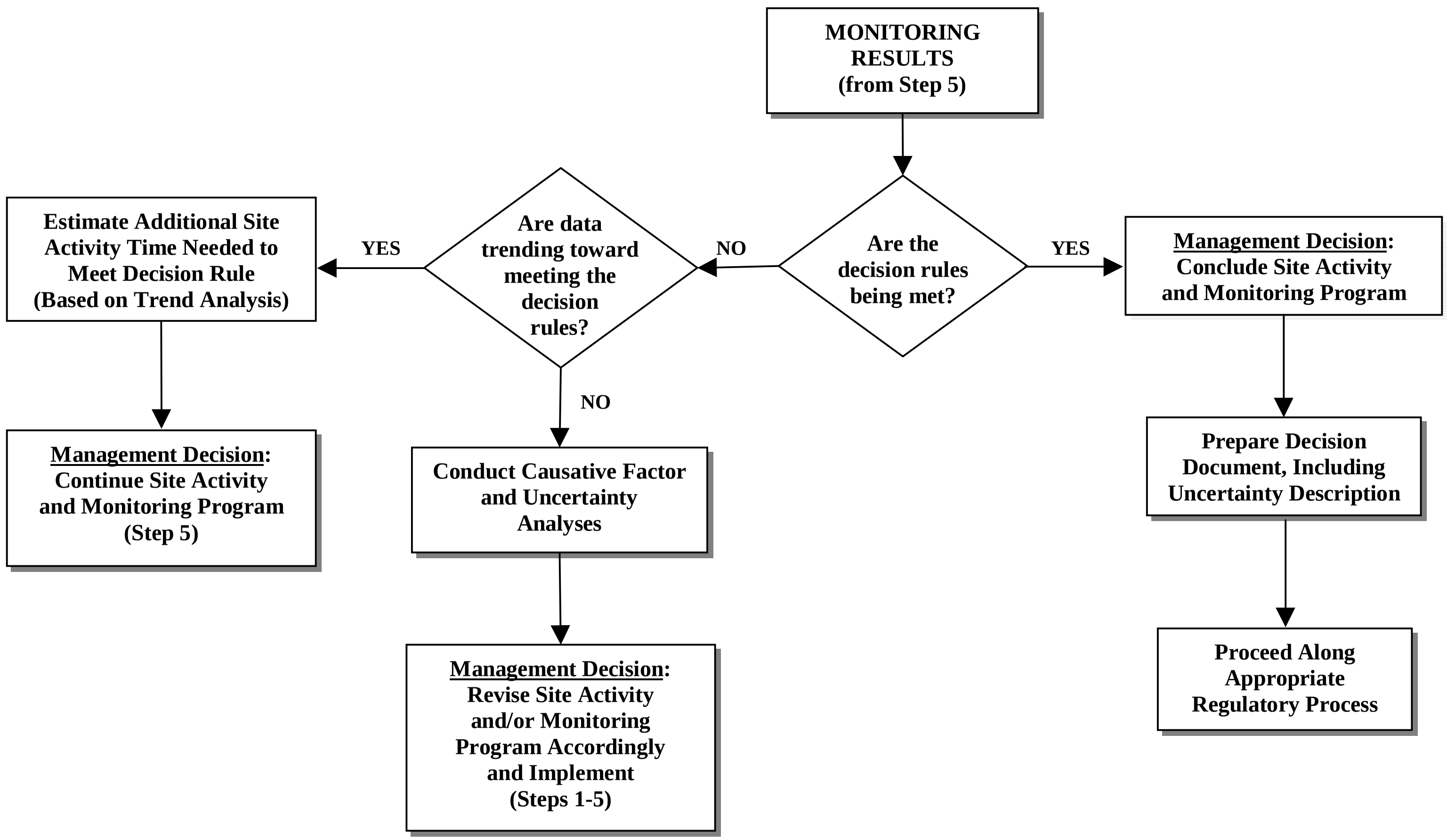


Figure 6-1 Monitoring Outcome Management Decision Path

6.2.1 Monitoring Results Indicate Site Activity Is Successful

The most desired outcome of the monitoring program would be that the results meet the monitoring decision rules (see Step 3), thus indicating that the site activity has reached its stated objectives. For this outcome, the management decision may be to conclude the site activity and associated Monitoring Plan, and move the site along in its appropriate regulatory process (Figure 6.1).

At this stage, it is critical that the monitoring results be carefully examined with regard to the monitoring decision rules, and especially with regard to how well the results met the specifications of the monitoring DQOs. Uncertainties associated with the monitoring data should be qualitatively or quantitatively identified and carefully examined. All appropriate parties should agree that the monitoring results (and the associated uncertainty) have met the decision rules.

6.2.2 Monitoring Results Indicate Site Activity Trending Toward Success

In some cases, while the monitoring data may not meet the decision rules indicating site activity success (Figure 6-1), there is a strong trend in the data indicating that activity success will likely be met sometime in the relatively near future. In this case, the site activity is simply taking longer to meet its objectives than was anticipated during development of the monitoring program. If a data trend toward timely activity success is indicated, the management decision may be to continue both the site activity and the associated monitoring program (including the Step 5 data analysis and characterization) for that time period (Figure 6-1). However, if the time to completion is deemed too lengthy, an alternate management decision (such as an additional removal action) may be appropriate.

6.2.3 Monitoring Results Indicate Site Activity Is Unsuccessful

If the monitoring results do not indicate site activity success, then the monitoring team should examine all aspects of the site activity in order to identify the causative factors responsible for the inability of the site activity to meet its stated objectives. Causative factors may be associated with site activity implementation problems or an inappropriate activity. Causative factors may also be associated with a number of non-activity-related issues, such as a previously unknown contaminant source, unexpected natural variability in environmental conditions (i.e., an extended period of drought affecting groundwater conditions or aquatic biological communities), or unexpected natural variability in biological conditions (i.e., unexpected disease outbreak). The monitoring team should also conduct an uncertainty analysis to determine to what extent the uncertainties associated with the site activity and the monitoring program may have affected the interpretation of how successful the site activity has been (based on how well the monitoring results meet the decision rules).

Once the causative factors and potentially important uncertainties have been identified, the monitoring team should identify the actions needed to address those factors and uncertainties.

The resulting management decision could be to revise the site activity as necessary, revise the monitoring program accordingly, and implement both (Figure 6-1).

Site activity revisions that involve actions to correct implementation problems may not require major changes to the existing monitoring program. The monitoring team should carefully examine the monitoring goals and objectives, decision rules, and study design to identify any changes that may be necessary because of the proposed changes to the site activity. Once the site activity and the monitoring program have been revised as appropriate, both would be implemented and Step 5 data collection and analysis would continue.

Site activity revisions that entail implementation of a different site activity may or may not require the development of an entirely new Monitoring Plan and QAPP. If the new site activity has the same or similar objectives, then a complete revision of the Monitoring Plan (e.g., going through the complete six-step process) would not be warranted. Rather, the existing plan (including the monitoring hypotheses, DQOs, and decision rules) may be revised to incorporate the new activity. A new Monitoring Plan and QAPP, including new decision rules, would be needed only if new activity objectives are developed that are completely different from the original activity objectives.

It is possible that the causative factors evaluation may also identify errors in the collection and analysis of the monitoring data. Such errors should have been identified and corrected in Step 5 as part of the DQO evaluations. However, if such errors are now found (i.e., in Step 6), the monitoring team should correct the errors and, in the case of analytical errors reexamine the monitoring data with regard to DQO compliance (Step 5) and meeting the monitoring decision rules (Step 6). A subsequent management decision would then be based on this new evaluation.

6.3 DOCUMENTATION AND SCIENTIFIC MANAGEMENT DECISION POINT

Regardless of the management decision made in Step 6, documentation of the decision will be necessary. The specific nature of the decision document will depend on the decision made (Table 6-1). This document serves as the SMDP for the outcome of Step 6.

6.3.1 Conclude Site Activity and Monitoring

If the management decision is to conclude the site activity and associated monitoring and proceed along the appropriate regulatory process, the decision document should:

- Identify the management decision and the underlying decision rules on which the decision is based;
- Summarize the monitoring data and characterization;

Table 6-1 Management Decision Documentation

Management Decision	Management Decision Document Components	New or Revised Site Activity Decision Document Needed	New or Revised Monitoring QAPP Needed
Conclude site activity and monitoring	• Management decision • Monitoring decision rules • Monitoring results • Uncertainty description	No	No
Continue site activity and monitoring	• Management decision • Monitoring decision rules • Monitoring results, including trend analyses • Uncertainty description	No	No
Revise site activity	• Management decision • Monitoring decision rules • Monitoring results • Causative factor analysis • Uncertainty description • Suggested activity revisions	Yes - revised	Yes - revised
Replace site activity	• Management decision • Monitoring decision rules • Monitoring results • Causative factor analysis • Uncertainty description	Yes - new	Yes -new

- Describe the uncertainties associated with the site activity, the Monitoring Plan, and the management decision; and

- Identify the monitoring team.

6.3.2 Continue Site Activity and Monitoring

If the management decision is to continue the site activity and monitoring, the decision document should:

- Identify the management decision and the underlying decision rules on which the decision is based;

- Summarize the monitoring data, especially the analyses indicating a trend toward activity success;

- Describe the uncertainties associated with the site activity, the Monitoring Plan, and the management decision; and

- Identify the monitoring team.

Because the decision is to continue the site activity and monitoring, no revisions would be needed to the existing site activity decision document (e.g., the ROD) or to the Monitoring Plan and QAPP.

6.3.3 Revise Site Activity

If the management decision is to revise the site activity, the decision document should:

- Identify the management decision and the underlying decision rules on which the decision is based;

- Summarize the monitoring data and characterization;

- Describe the causative factor and uncertainty analyses and summarize the results, showing as clearly as possible why the decision rules were not met and the site activity is considered to not be successful;

- Describe the actions needed to address the causative factors and uncertainties associated with the lack of activity success; and

- Identify the monitoring team.

If the need for a completely new site activity is identified, then the development of the new activity will be conducted as required by the applicable regulatory process, and any applicable documentation requirements will be applied. Development of a new monitoring program may be necessary and would follow the six-step process described in this guidance.

If only revisions to the existing site activity are necessary, these should be documented as required (e.g., a ROD addendum) by the applicable regulatory process under which the site activity is being conducted (e.g., CERCLA, RCRA). Depending on the nature of the site activity revisions, a revised Monitoring QAPP (see Step 4) may need to be prepared.

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GLOSSARY

Abiotic. Characterized by absence of life; abiotic materials include nonliving environmental media (e.g., water, soil, sediments); abiotic characteristics include such factors as light, temperature, pH, humidity, and other physical and chemical influences.

Ambient. Surrounding or background.

Assessment Endpoint. An explicit expression of the environmental value that is to be protected or that is of primary interest.

Benthic Community. The community of organisms burrowing into, or crawling upon, sediment at the bottom of a surface water body.

Benthic Grab Sampler. A mechanical sampler used to collect benthic organisms.

Bioassay. Test used to evaluate the relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation of the same type of organism.

Biodegradation. The breakdown of a compound into more elementary compounds by the action of living organisms, usually referring to microorganisms such as bacteria.

Biodiversity. The variety of life forms in a given area. Diversity can be categorized in terms of the number of species, the variety in the area's plant and animal communities, the genetic variability of the animals, or a combination of these elements.

Biomass. Any quantitative estimate of the total mass of organisms comprising all or part of a population or other specified unit, or within a given area at a given time.

Bioremediation. Use of living organisms to clean up contamination from soil, groundwater, or wastewater, either through conversion of the contaminants to less harmful forms, or by the removal of the contaminants from the abiotic environment into biological tissues.

Biotic. Living organisms, usually referring to the biological components of an ecosystem.

Brownfield. Real property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant.

Cap. A cover placed over contaminated materials in order to reduce or eliminate human or ecological exposure, prevent erosion, and/or control infiltration of water and production of contaminant leachate.

Chronic Toxicity Test. A toxicity test used to study the effects of continuous, long-term exposure to a chemical or other potentially toxic material on an organism.

Cleanup Criteria. The residual concentration of a hazardous substance in a medium that is determined to be protective of human health and the environment under specified exposure conditions, and that is the target of cleanup activities.

Community. Any group of organisms comprising a number of different species that co-occur in the same habitat or area and interact through trophic and spatial relationships.

Community Structure. Refers to the composition and abundance of species within a particular community.

Contaminant of Concern (COC). A substance detected at a hazardous waste site that has the potential to adversely affect human or ecological receptors because of its concentration, distribution, and mode of toxicity.

Contaminant Transport. The movement of contaminants from one location to another as solid particles, dissolved in water, or as separate phase liquids in response to gravity and/or movements by surface water, groundwater, or wind.

Control. A treatment in a test that duplicates all the conditions of the exposure treatments but contains no test material. The control is used to determine the response rate expected in the tested parameter in the absence of the test material.

Data Quality. A measure of the degree of acceptability and usability of data.

Data Validation. An analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set.

Data Validation Qualifier. Code applied to the data by a data validator to indicate a verifiable or potential data deficiency or bias.

Dominant Plant Species. Within a given area or plant community type, the individual species that comprise the greatest portion of the plant community, either by vegetative cover, biomass, or abundance.

Exposure. The co-occurrence of or contact between a stressor and a human or ecological receptor.

Habitat. The local environment occupied by an organism; place where a plant or animal lives.

Hazard. The likelihood that a substance will cause an adverse effect under specific conditions.

Hydraulic Conductivity. A number that describes the rate at which water can move through a permeable medium.

Hypothesis. A proposition set forth as an explanation for a specified phenomenon or group of phenomena.

Indicator Species. A species whose presence or absence is indicative of a particular habitat, community, or set of environmental conditions.

Leaching. The process by which soluble constituents are dissolved and filtered through the soil by a percolating fluid.

Lowest-Observed-Adverse-Effect-Level (LOAEL). The lowest level of a stressor evaluated in a toxicity test or biological field survey that has a statistically significant adverse affect on the exposed receptor compared with unexposed receptors in a control or reference site.

Measurement Endpoint. A measurable biotic or abiotic parameter that is related to the assessment endpoint.

Mitigation. May include but is not limited to restoration, remediation (bioremediation, phytoremediation), and other environmental improvement efforts.

Mitigation Measure. Measures taken to reduce adverse impacts on the environment.

Monitoring. The collection and analysis of repeated observations or measurements to evaluate changes in condition and progress toward meeting a management objective.

Monitoring Conceptual Model. A model that describes the relationships between the site activity and its expected outcome, as stated in the monitoring hypotheses.

Monitoring Hypothesis. One or more statements and/or questions about the relationship between a site activity, such as remediation or habitat restoration, and one or more expected outcomes for the activity.

Monitoring Team. A site-specific team under the direction of site management that may include the site manager, supporting technical staff (e.g., regional Biological Technical Assistance Groups [BTAGs], risk assessors, environmental engineers) and appropriate stakeholders (e.g., natural resource trustees and the public). The role of this team is to provide input into the development and implementation of the Monitoring Plan.

Native Species. Biota that occur naturally, not as a result of human activity, in a given area or region.

Natural Attenuation. Refers to naturally occurring processes in soil and groundwater environments that act without human intervention to reduce the mass, toxicity, mobility, volume, or concentration of contaminants in those media.

Nonnative Species. Species that humans intentionally or unintentionally introduced into an area outside of a species' natural range.

Nonparametric. Statistical methods used when the distribution of the data is not known.

On-Scene Coordinator (OSC). The federal official responsible for monitoring or directing responses to all oil spills and hazardous substance releases reported to the federal government. The On-Scene Coordinator coordinates all federal efforts with, and provides support and information to, local, state, and regional response communities.

Parametric. Statistical methods used when the distribution of the data is known.

Phytoremediation. A remediation technology using plants to remove, or to degrade to less harmful forms, contaminants in soil, sediment, and groundwater.

Population. All individuals of one species occupying a defined area and usually isolated to some degree from other similar (i.e., same species) groups.

Power of a Statistical Test. The probability of a statistical test to reject the null hypothesis when in fact it is false and the alternative hypothesis is correct.

Quality Assurance (QA). An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of a type and quality needed and expected by the customer.

Quality Assurance Project Plan (QAPP). A document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria (e.g., data quality objectives).

Quality Control (QC). The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

Record of Decision (ROD). A CERCLA document that states the decision on a selected remedial action. It typically includes a responsiveness summary and a bibliography of documents that were used to reach the decision.

Reference Site. A location as similar as possible to the site where an activity or condition of interest is present, but lacking in that activity or condition.

Remedial Project Manager (RPM). Primary point of contact involved in the cleanup of contaminated sites; coordinates, directs, and reviews the work of other agencies, responsible parties, and contractors to ensure compliance with appropriate regulatory requirements.

Removal Action. An action under CERCLA to abate, minimize, stabilize, mitigate, or eliminate the release or threat of release of a hazardous substance; such actions may be taken during any phase of the remedial action process or in the absence of a remedial action.

Sediment. Particles that have settled through a liquid, located on the bottom of surface water bodies and wetlands.

Site Activity. Any number of actions that could occur at a hazardous waste site, including but not limited to, implementation and/or operation of a removal action, remedial action, or habitat mitigation.

Soil Association. The different soil types that occur together in a specific location.

Species. A group of organisms, minerals, or other entities formally recognized as distinct from other groups.

Species Diversity. The number, types, and relative abundance of species within an ecosystem.

Stakeholder. Any party that has an interest ("stake") in a particular item.

Statistic. A computed or estimated statistical quantity such as the mean, standard deviation, or correlation coefficient.

Stressor. Any physical, chemical, or biological entity that can induce an adverse response.

Tallgrass Prairie. One of the three major types of North American Prairie, having a landscape dominated by grasses such as big bluestem and Indian grass, as well as a large number of other species of grasses and wildflowers, the latter called forbs. The vegetation sometimes reaches a height of 10 ft or more.

Taxon. Any group of organisms considered to be sufficiently distinct from other such groups to be treated as a separate unit. For example, class, order, genus, or species.

Taxonomic Level. The taxonomic category of an organism.

Toxicity. The degree of harmful effects posed by a substance to animal or plant life.

Transmissivity. The rate at which water is transmitted through a unit width of an aquifer.

Type I Error. Rejection of a true null hypothesis.

Type II Error. Acceptance of a false null hypothesis.

Uncertainty. Imperfect knowledge concerning the present or future state of the system under consideration.

Upland. High land especially at some distance from water; ground elevated above the lowlands along rivers or between hills.

Vegetative Cover. For a given area, the percentage of aerial coverage exhibited by a particular plant species or group.

Wetland. Lands transitional between terrestrial and aquatic systems where the water table is usually at or near the surface or the land is covered by shallow water, and having vegetation typically adapted for life in saturated soil conditions.

Wetland Delineation. The evaluation of an area to determine whether it meets the criteria to be classified as a wetland.

X-Ray Fluorescence (XRF). When a primary x-ray strikes a sample, the x-ray is absorbed by the atom and becomes temporarily unstable. As the atom stabilizes, it gives off a characteristic x-ray; each element produces x-rays at a unique set of energies that allow nondestructive determination of the elemental composition of a sample. The process of emissions of characteristic x-rays is called "X-ray fluorescence," or XRF.

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