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Superfund

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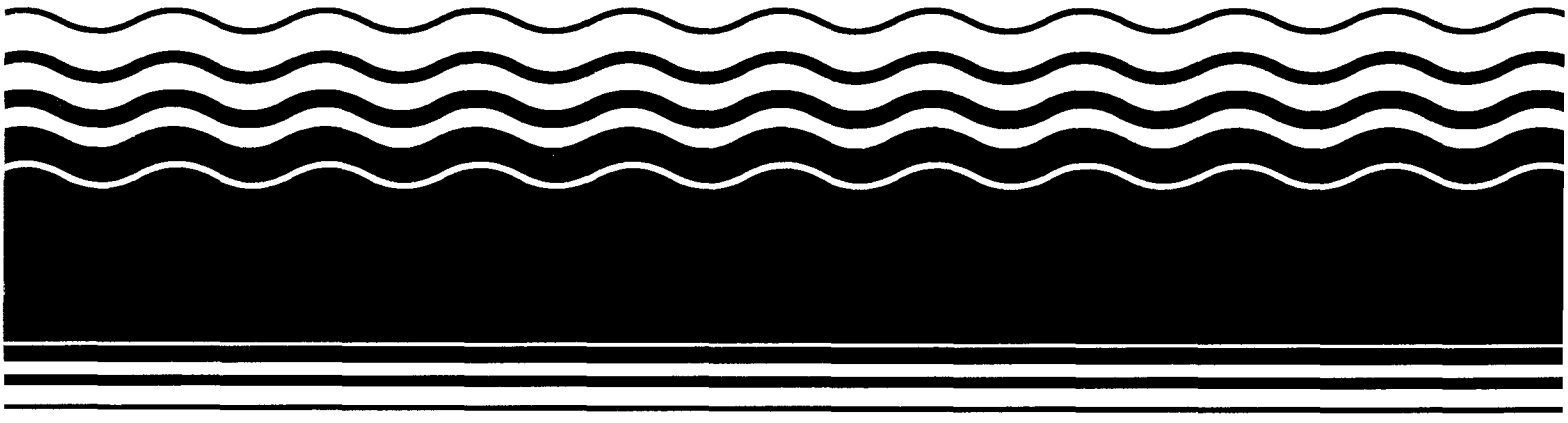
DATA QUALITY OBJECTIVES PROCESS FOR SUPERFUND

Interim Final Guidance



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DATA QUALITY OBJECTIVES PROCESS FOR SUPERFUND

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Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, DC 20460

NOTICE

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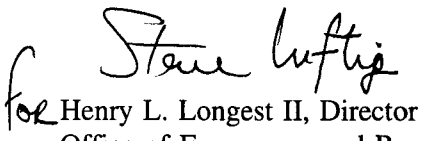
FOREWORD

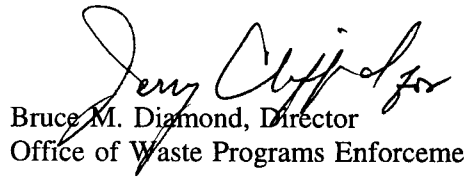
The U.S. Environmental Protection Agency (EPA) undertakes cleanup activities at abandoned hazardous waste sites under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as the Superfund program. Many of the activities involve the collection and evaluation of site-specific environmental data. EPA has developed and implemented a mandatory Agency-wide program of quality assurance for environmental data, including a process for developing Data Quality Objectives (DQOs), as an important tool for project managers and planners to determine the type, quantity, and quality of data needed to make defensible decisions.

The Office of Emergency and Remedial Response (OERR) is promoting a common understanding of the quality assurance requirements for site-specific data collection activities. The DQO Process is an effective means by which managers and technical staff can implement the mandatory Superfund quality assurance requirements. The Agency has developed this guidance on *Data Quality Objectives Process for Superfund* to replace the earlier guidance, *Data Quality Objectives for Remedial Response Activities* (EPA 540/G-87/003, OSWER Directive 9355.0-7B) and the five analytical levels introduced in that document.

It is the goal of the Superfund program and the regulated community to collect data of appropriate quality for environmental decisions while minimizing expenditures related to data collection by eliminating unnecessary duplication or unnecessarily detailed data. The most effective way to accomplish this is to implement the DQO Process.



for Henry L. Longest II, Director
Office of Emergency and Remedial Response



Bruce M. Diamond, Director
Office of Waste Programs Enforcement

LIST OF ACRONYMS

ARAR	Applicable or Relevant and Appropriate Requirement
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
DQO or DQOs	Data Quality Objectives
EE/CA	Engineering Evaluation and Cost Analysis
ESI	Expanded Site Investigation
EU	Exposure Unit
FS	Feasibility Study
HRS	Hazard Ranking System
MCL	Maximum Contaminant Level
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NPL	National Priorities List
OSC	On-Scene Coordinator
OSWER	Office of Solid Waste and Emergency Response
PA	Preliminary Assessment
PRG	Preliminary Remediation Goal
PRP	Potentially Responsible Party
QAPP	Quality Assurance Project Plan
RD	Remedial Design
RDT	Regional Decision Team
RI	Remedial Investigation
RME	Reasonable Maximum Exposure
RPM	Regional Project Manager
RU	Remediation Unit
SACM	Superfund Accelerated Cleanup Model
SAM	Site Assessment Manager
SEA	Site Evaluation Accomplished
SI	Site Inspection

INTRODUCTION

OVERVIEW AND PURPOSE OF THIS DOCUMENT

This document provides guidance on developing Data Quality Objectives (DQOs) for Superfund sites. This guidance replaces EPA/540/G-87/003, *Data Quality Objectives for Remedial Response Activities: Development Process.*

Each year the U.S. Environmental Protection Agency (EPA) and the regulated community spend approximately $5 billion collecting environmental data for scientific research, regulatory decision making, and regulatory compliance. While these activities are necessary for effective environmental protection, it is the goal of EPA and the regulated community to minimize expenditures related to data collection by eliminating unnecessary, duplicative, or overly precise data. At the same time, they would like to collect data of sufficient quantity and quality to support defensible decision making. The most efficient way to accomplish both of these goals is to begin by ascertaining the type, quality, and quantity of data necessary to address the problem before the study begins.

What is the DQO Process? The DQO Process is a series of planning steps based on the Scientific Method that is designed to ensure that the type, quantity, and quality of environmental data used in decision making are appropriate for the intended application. The steps of the DQO Process are illustrated in Figure 1.

What are DQOs? DQOs are qualitative and quantitative statements derived from the outputs of each step of the DQO Process that:

1) Clarify the study objective;
2) Define the most appropriate type of data to collect;
3) Determine the most appropriate conditions from which to collect the data; and
4) Specify acceptable levels of decision errors that will be used as the basis for establishing the quantity and quality of data needed to support the decision.

The DQOs are then used to develop a scientific and resource-effective sampling design.

The DQO Process was developed by EPA to help Agency personnel collect data that are important to decision making. The process allows decision makers to define their data requirements and acceptable levels of decision errors[1] during planning, before any data are collected. Application of the DQO Process should result in data collection designs that will yield results of appropriate quality for defensible decision making.

Why was this document developed for Superfund? Mandatory quality assurance (QA) requirements for EPA environmental data collection activities are established in EPA Order 5360.1, *Policy and Program Requirements to Implement the Quality Assurance Program.* Additionally, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP; 40 CFR Part 300) mandates specific Superfund QA requirements. Both documents emphasize that Superfund environmental data must be of known quality and require the development of Quality Assurance Project Plans (QAPPs) for all environmental data collection activities to achieve this goal. The NCP mandates the development of a

[1]Decision errors occur when variability or bias in data mislead the decision maker into choosing an incorrect course of action. Decision errors are discussed in detail in Chapter 6: SPECIFY LIMITS ON DECISION ERRORS.

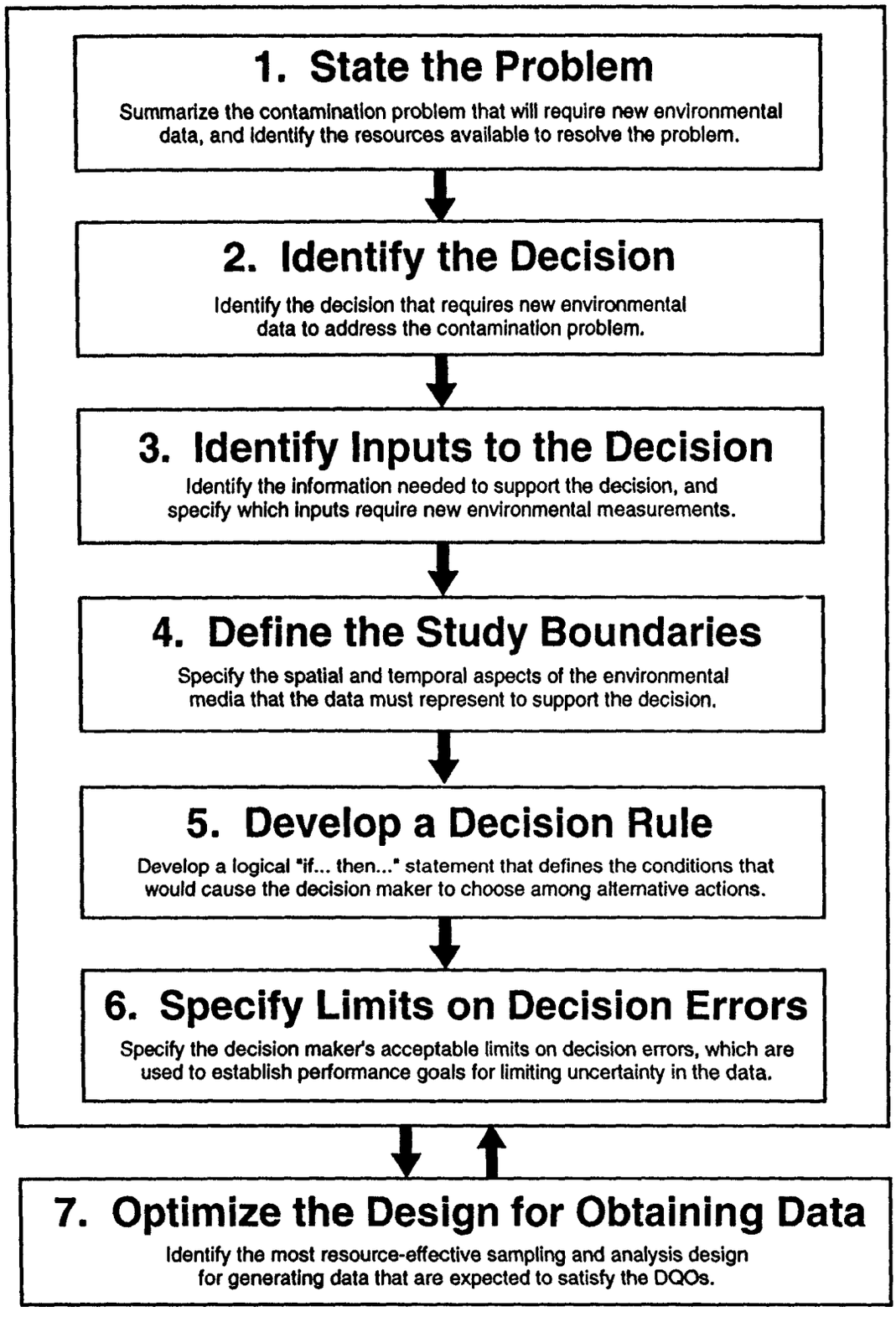


Figure 1. The Data Quality Objectives Process

Sampling and Analysis Plan (SAP), which specifies acceptable data quality goals, defines responsibility for achieving these goals, and includes as its key elements a field sampling plan and a QAPP. Figure 2 illustrates the elements of QA planning for Superfund.

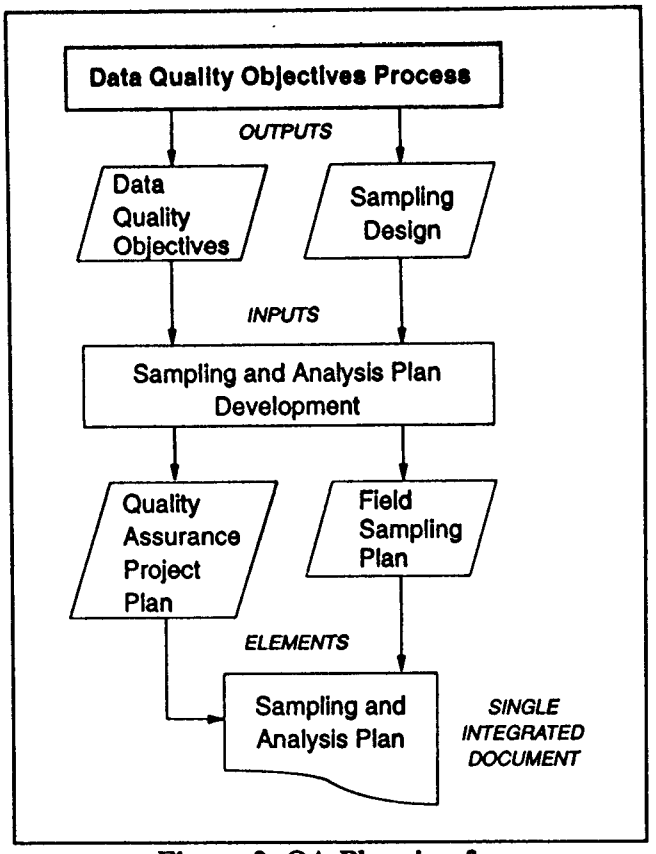


Figure 2. QA Planning for Superfund Data Collection

The DQO Process requires site managers to specify acceptable data quality goals by establishing acceptable limits on decision errors. The DQO Process outputs, including the acceptable limits on decision errors, provide the information necessary to develop the SAP. The DQO Process and the SAP requirements satisfy EPA Order 5360.1 and the NCP's mandate. This guidance document revises the Superfund program's approach to developing DQOs to be consistent with the following Agency-wide QA requirements and guidance documents:

EPA Quality System Requirements for Environmental Programs. EPA/QA/R-1. 1993.

Interim Draft EPA Requirements for Quality Management Plans. EPA/QA/R-2. 1992.

EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. EPA/QA/R-5. 1993.

Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process. EPA/QA/G-4. 1993.

Guidance for Conducting Environmental Data Quality Assessments. EPA/QA/G-9. 1993.

How is this document organized? This document is organized as follows: Chapters 1 through 7 describe procedures for implementing the DQO Process at Superfund sites. Each of these chapters describes a step of the DQO Process, and includes a background section that explains the purpose of that step, activities for developing the outputs of that step, and a list of expected outputs. Chapter 8 discusses the relationships between the DQO Process, the Sampling and Analysis Plan, and Data Quality Assessment.

This guidance is supported by several appendices. Appendix I describes in more detail selected topics relating to DQO development activities. Appendix II provides three examples of DQO development: a pre-remedial program (site inspection) ground-water example, a removal program soil example, and a remedial program soil example. Appendix III contains a glossary of terms used in this guidance document, and Appendix IV contains a bibliography of documents used in the development of this guidance.

BENEFITS OF THE DQO PROCESS

The DQO Process is a planning tool to help site managers decide what type, quality, and quantity of data will be sufficient for environmental decision making. The outputs of the DQO Process can be used to develop a statistical sampling design and to effectively plan field investigations that can stand up to rigorous review.

By using the DQO Process, a site manager provides criteria for determining when data are sufficient for site decisions. This provides a stopping rule — a way for site managers to determine when they have collected enough data. In addition, the DQO Process:

Improves Sampling and Analysis Designs	• helps site managers streamline field investigations and decide how many samples and analyses are required to support defensible decision making; • helps site managers define where and when samples should be collected; • provides the QA community with a scientific basis for defining the right type and number of quality control and quality assessment samples and associated analytical precision and recovery requirements;
Saves Money and Time	• helps field personnel identify resource-efficient sample collection methods; • helps laboratory analysts identify resource-effective analytical methods; • can drastically reduce overall project costs by improving the quality of information for decision making (for example, defining areas of the site that require remediation) and by eliminating expensive rework;
Improves Decision Making	• helps site managers develop a statistical sampling design that controls decision errors; • provides a structure for clarifying multiple study objectives into specific decisions; • encourages the participation and communication of data users and relevant technical experts in planning, implementation, and assessment.

The DQO Process is based on the scientific method, and therefore improves the legal defensibility of site decisions by providing a complete record of the decision process and criteria for arriving at conclusions.

It is important to remember that there is a tradeoff between the desire to limit decision errors and the cost of reducing decision errors. Reducing decision errors can be costly because more samples and more analyses are often required. One of the goals of the DQO Process is to help decision makers strike the best balance between acceptable limits on decision errors and the cost of meeting those decision error limits.

THE DQO PROCESS AND STATISTICS

The DQO Process has both a quantitative and a qualitative aspect. The quantitative aspect seeks to use statistics to design the most efficient field investigation that controls the possibility of making an incorrect decision. The qualitative aspect seeks to encourage good planning for field investigations and complements the statistical design. Users of this guidance are encouraged to pursue both aspects of the DQO Process. A field investigation can always benefit from good planning, even if planning does not lead to a statistical design.

Generally, the quantitative aspect and subsequent statistical design are important when site contaminant levels are close to an action level, or when variability in the data is so great that the results are inconclusive. In such cases, a statistical design can provide quantitative estimates of the level of uncertainty in the data and, therefore, help the decision maker understand and control the probability of making an incorrect decision based on the data.

The statistical procedures used in the DQO Process provide:

- a scientific basis for making inferences about a site (or a portion of a site) based on information contained in environmental samples;
- a basis for defining data quality criteria and assessing the achieved data quality for supporting integrated site assessment decisions;
- a foundation for defining meaningful quality control procedures that are based on the intended use of the data;
- quantitative criteria for knowing when site managers should stop sampling (i.e., when the site has been adequately characterized); and
- a solid foundation for planning subsequent data collection activities.

Non-probabilistic or subjective (judgmental) sampling approaches can be useful and appropriate for satisfying certain field investigation (study) objectives. For instance, if the study objective is to locate and identify potential sources of contamination, a subjective identification of sampling locations may be the most efficient method to employ.[2] If the objective is to establish that a threat exists in a complete exposure pathway by confirming the presence of a hazardous substance associated with the site or process, a judgmental sampling approach can be used. However, because of the subjective nature of the selection process, data generated from non-probabilistic samples should not be used if the goal of the study is to characterize some property of the site as a whole.

IMPLEMENTING THE DQO PROCESS

The scoping team should follow each step of the DQO Process for each medium of concern. Once the scoping team has gone through the process completely for one medium, it becomes easier and quicker to develop additional sets of DQOs in other media. For example, typically at Superfund sites the contaminants of concern identified in the early assessment phase remain the focus of subsequent field investigations in the advanced assessment, even though the decision and the action level may change. Similarly, the areas of concern that are directly related to the geographical boundaries of the study usually do not vary much through the site assessment process. Therefore, much of the DQO outputs generated in the early assessment will be applicable in advanced assessment planning.

The DQO Process is flexible and iterative. Often, especially for more complicated sites, the scoping team will need to return to earlier steps to rethink or better focus the output. These iterations through the earlier steps of the DQO Process can lead to a more focused design that can save resources in later field investigation activities.

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[2]An important caveat here is that if contamination is <u>not</u> found, then without a statistical approach very little can be said about the probability of having missed the source of contamination.

The DQO Process should be used repeatedly during the life cycle of a project. Early in the project, a more preliminary and qualitative application of the DQO Process may be appropriate to meet the site manager's needs. As more details and decisions about the site develop, a more thorough and quantitative application of the DQO Process usually is warranted. Figure 3 illustrates this point graphically. During early assessment, a site manager may decide to apply only the more qualitative aspects of the DQO Process, rely less on the quantitative aspect, and not use a statistical sampling design, especially since this is not a decision that requires a full assessment of health or environmental risks. In the advanced assessment phase, the possibility that uncertainty in environmental data may lead to incorrect decisions becomes more critical and a site manager may place more emphasis on the quantitative aspects of DQO development.

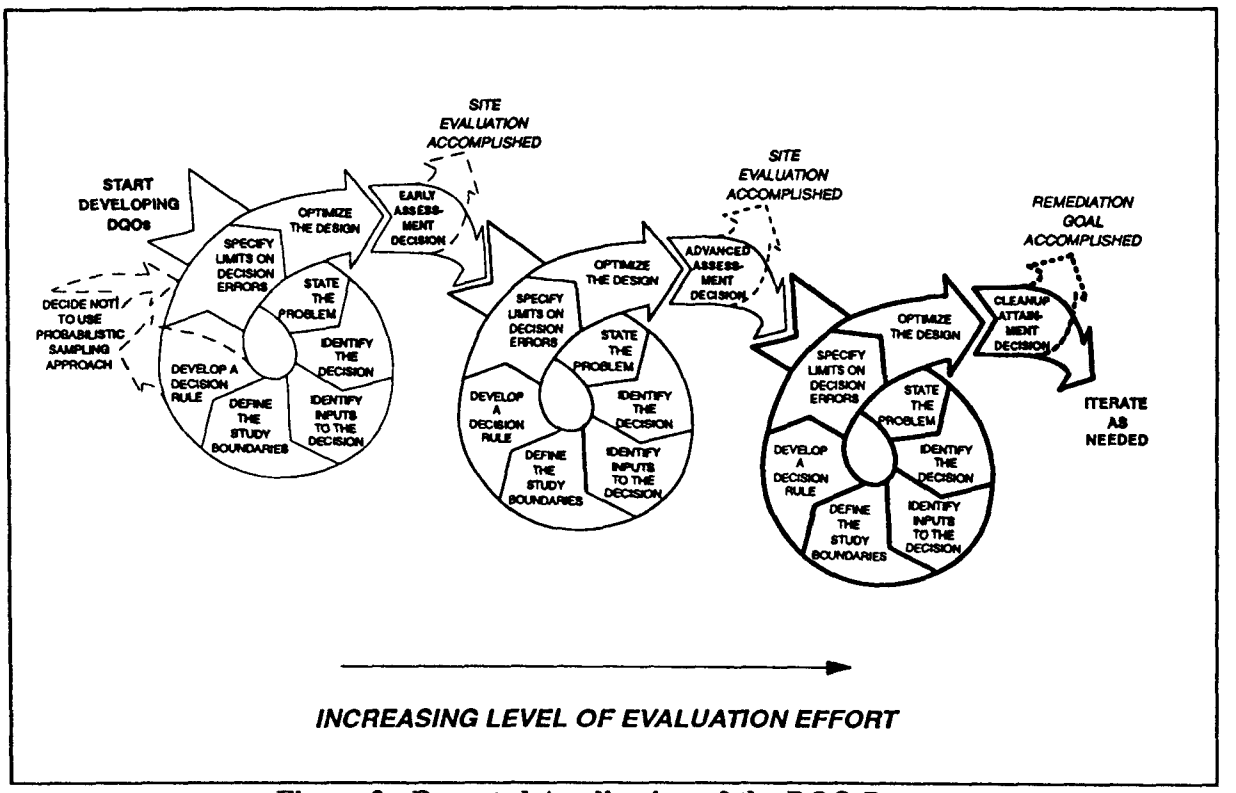


Figure 3. Repeated Application of the DQO Process

HOW THE DQO PROCESS FITS INTO INTEGRATED SITE ASSESSMENT/SACM

The DQO Process provides a logical framework for planning multiple field investigations, thereby fulfilling the integrated site assessment goal of cross-program response planning and allowing optimal cross-program data useability. By emphasizing the need to place limits on the probability of taking incorrect actions, the DQO Process complements the integrated site assessment objective of evaluating the need for action. The DQO Process places a worthwhile investment on planning, which results in timely and efficient cleanups, thereby increasing the chances of taking the correct action. For these reasons, the DQO Process is an effective approach for accomplishing and satisfying the goals of the Superfund Accelerated Cleanup Model (SACM). This guidance document is the primary document for planning site assessment field investigations. However, users should consult other relevant Superfund guidance that provide more detailed information on specific site assessment activities. Appropriate references are included throughout this guidance, and Appendix IV provides a summary of references organized by DQO topic.

WHERE TO FIND MORE INFORMATION ABOUT THE DQO PROCESS

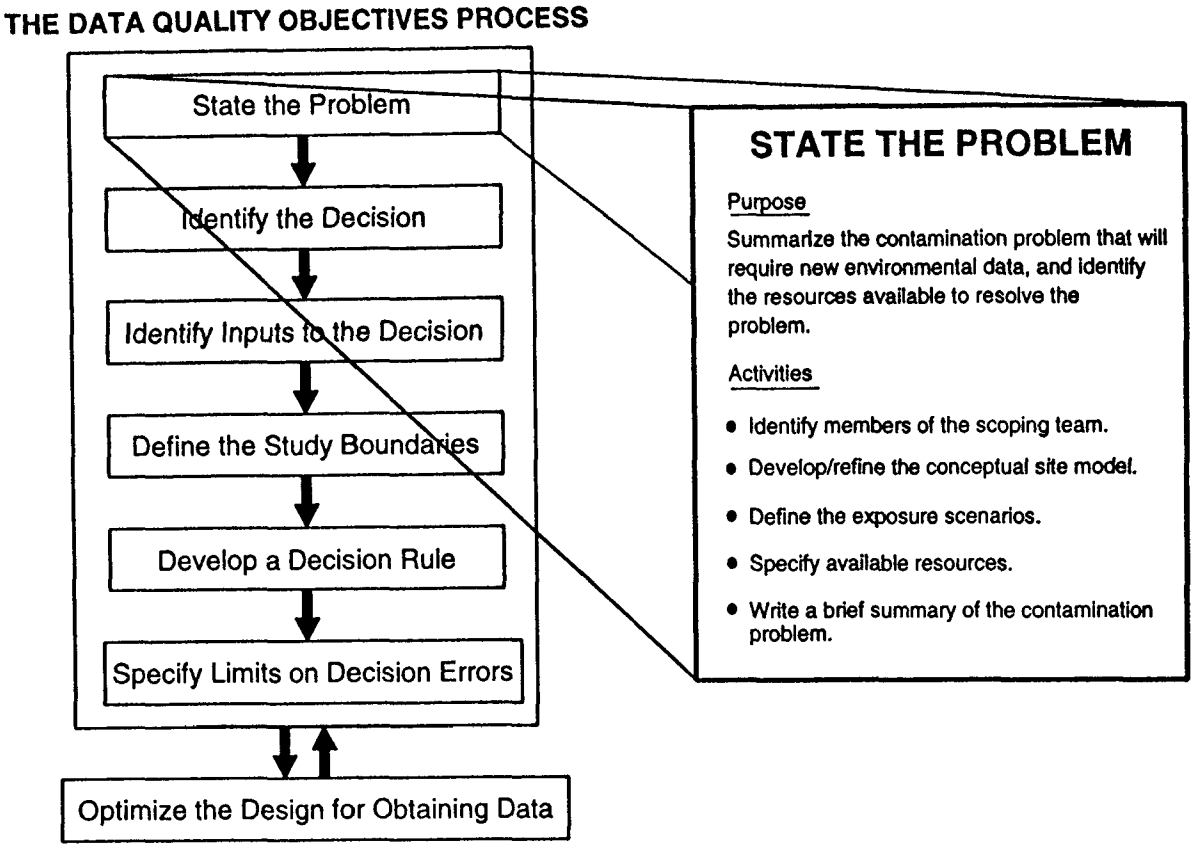
A DQO training course is available through the EPA Training Institute at U.S. EPA Headquarters in Washington, D.C.

Additional documents on DQO applications can be obtained from the Quality Assurance Management Staff at EPA Headquarters.

EPA regional and national program office quality assurance managers can provide assistance in learning more about the DQO Process.

CHAPTER 1

STEP 1: STATE THE PROBLEM



1.1 BACKGROUND

The purpose of this step is to:

- establish the DQO scoping team;
- provide a brief description of the contamination problem that presents a potential threat/unacceptable risk to human health and the environment; and
- identify resources available to address the problem.

Stating the problem typically involves a description of the source and/or location of contamination including physical and chemical factors associated with the site that could result in contaminant release or unacceptable exposures. The description should include the regulatory and programmatic context of the problem, such as the regulatory objectives and basis for the field investigation. The description of the potential contamination problem should also include appropriate action levels for evaluating and responding to releases or exposures, and appropriate response actions.

The scoping team is a multidisciplinary group of experts. They develop or refine a conceptual site model that describes and illustrates the known and suspected sources of contamination, potential migration pathways, and potential human and environmental receptors. The scoping team begins by collecting and evaluating all historical site data to formulate the conceptual site model and assess the extent to which the available historical site data support exposure scenarios that are developed later in the site assessment process. These descriptions aid in understanding the relationship among potential contaminant releases, sources of contamination, and physical and environmental targets.

1.2 ACTIVITIES

Identify Members of the Scoping Team

The creation of the scoping team is a two-step process. The first step is to identify the decision maker for the site. The decision maker (usually the site manager) and his technical staff identify the other members of the scoping team based on a preliminary understanding of the nature of the contamination problem (e.g., potentially affected media). The site manager[1] delegates responsibility for accomplishing planning tasks to the other members of the scoping team. However, the site manager makes the final decisions at the site.

The second step is to choose the members of the scoping team. The team should include representatives who are knowledgeable about several project phases, including QA specialists, samplers, chemists, modelers, technical project managers, human health and ecological risk assessors, toxicologists, biologists, ecologists, administrative and executive managers, data users, Natural Resource Trustees, and a statistician (or someone knowledgeable and experienced with environmental statistical design).

Every member of the scoping team will support or actively participate in all steps of the DQO Process. Their roles will include interpreting historical site data and preparing their team members for accomplishing DQO activities. They will also attend meetings to help generate DQO outputs that will guide the field investigation data collection designs.

Develop/Refine the Conceptual Site Model

Collect all available historical site data, including QA/QC documentation associated with previous environmental data collection activities. Use the information to develop a diagram that illustrates the relationships between:

- locations where contamination exists or contaminant/waste sources,
- types and concentrations of contaminants,
- potentially contaminated media, migration pathways,
- potential physical and environmental targets or receptors.

Presenting historical site data in this manner provides a foundation for identifying data gaps and focusing on where the problems of potentially unacceptable contamination may or may not exist.

More information on developing the conceptual site model (CSM) can be found in Appendix I, Section A. For more extensive information sources, refer to the *Guidance for Performing Site Inspections Under CERCLA*, and the *Guidance for Conducting Remedial Investigation and Feasibility Studies Under CERCLA*.

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[1]Throughout this document, the site manager is assumed to be the decision maker.

Define Exposure Pathways and Exposure Scenarios

The goal of this step is to define site conditions that indicate or could lead to an unacceptable threat or exposure at the site. Use the conceptual site model and relevant information on migration pathways as a base for accomplishing this task. For the early phases of site assessment activities, it is necessary to establish that a complete exposure pathway exists. In general, identify currently contaminated media to which individuals or sensitive ecosystems may be exposed. Following identification of the media of concern, identify potential contaminants of concern based on historical site use, analytical data, or anecdotal information. Next, define the current and future land use. Following this, determine the local/state applicable or relevant and appropriate requirements (ARARs) for the site. For cases where multiple contaminants exist and ARARs are not available for all the contaminants, develop risk-based contaminant-specific preliminary remediation goals (PRGs). Chemical-specific PRGs are concentrations based on ARARs or concentrations based on risk assessment. PRGs should also be developed even when ARARs are available for all contaminants and meeting all ARARs is not considered protective. For each medium and land use combination, identify complete exposure pathways and assemble all this information into exposure scenarios that are expected to represent the highest exposure that could reasonably occur at the site. More detailed information on accomplishing the above activities during scoping can be found in the *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals)*, EPA/540/R-92/004.

It is efficient to evaluate the potential for an unacceptable ecological threat during the human health evaluation. The following text discusses important relationships between human health and environmental evaluations:

> Environmental evaluation and human health evaluation are parallel activities in the evaluation of hazardous waste sites. Much of the data and analyses relating to the nature, fate, and transport of a site's contaminants will be used for both evaluations. At each point of these common stages, however, analysts should be sensitive to the possibility that certain contaminants and exposure pathways may be more important for the environmental evaluation than for the health evaluation, or vice versa. It is also important to recognize that each of the two evaluations can sometimes make use of the other's information. For example, the potential of a contaminant to bioaccumulate may be estimated for a health evaluation but be useful for the environmental evaluation. Similarly, measurement of contaminant levels in sport and commercial species for an environmental evaluation may yield useful information for the health evaluation.[2]

For additional information on Exposure Assessment issues and ARARs refer to the *Risk Assessment Guidance for Superfund, Volume I-Human Health Evaluation Manual, Part A and Part B; Risk Assessment Guidance for Superfund, Volume II-Environmental Evaluation Manual; Framework for Ecological Risk Assessment; EPA Risk Assessment Forum (Feb, 1992); A Review of Ecological Assessment Case Studies from A Risk Assessment Perspective; EPA Risk Assessment Forum (May, 1993); CERCLA Compliance with Other Laws Manual;* and *Guidance for Data Useability in Risk Assessment (Part A).*

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[2]*Risk Assessment Guidance for Superfund, Volume II - Environmental Evaluation Manual.* p. 3.

Specify the Available Resources

(1) **Define the budget.** Specify the approximate monetary budget for the field investigation. This estimate should account for developing DQOs and for carrying out the potential sampling and analysis activity under consideration.

(2) **Define the time constraints.** Determine the time constraints, such as the Superfund recommended time frame, for completing the various required site evaluations. Other factors to consider include political factors such as public concern and the timeliness of addressing health and ecological risks.

Write a Brief Summary of the Contamination Problem

Summarize relevant background into a concise description of the problem to be resolved.

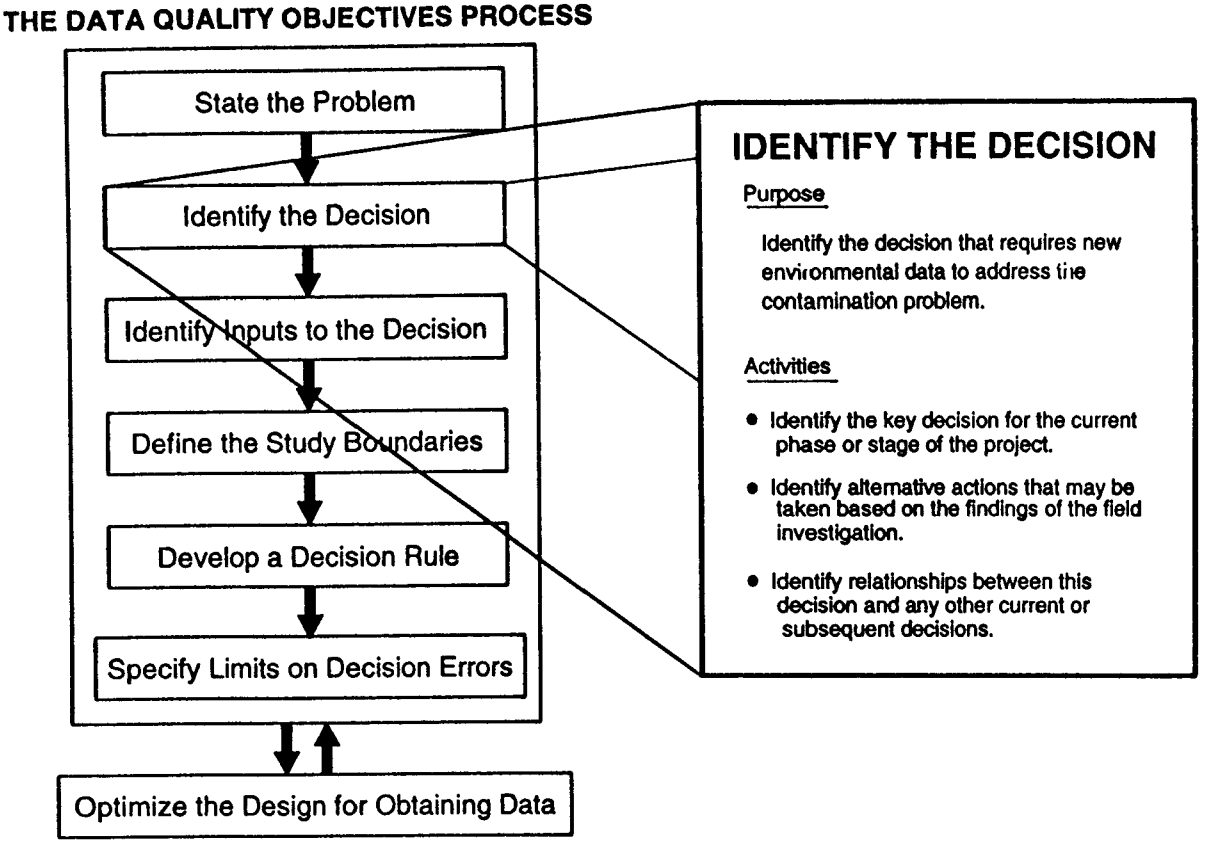
1.3 OUTPUTS

The main output of this step is a complete description of the contamination problem that includes the regulatory and programmatic context of the problem. This description typically consists of:

- a list of the known and suspected contaminants in each medium and estimates of their concentration, variability, distribution, and location;
- the conceptual site model and exposure pathways;
- a summary of the outcome and status of any previous response(s) at the site, such as early actions or previous data collection activities;
- the site's physical and chemical characteristics that influence migration and associated human, environmental, and physical target(s); and
- an estimate of the budget, schedule, and available personnel necessary to implement the appropriate response for the site.

CHAPTER 2

STEP 2: IDENTIFY THE DECISION



2.1 BACKGROUND

The purpose of this step is to identify the decision that will use environmental data to address the potential contamination problem and to state the actions that could result from the resolution of each decision statement. This is how the scoping team defines the objective of the field investigation.

Generally, environmental field investigations may be designed to satisfy a broad array of objectives, such as demonstration of regulatory compliance, research, monitoring for trends, or estimation of average characteristics. For Superfund, however, most field investigations are designed to support the site manager's selection of appropriate response actions (i.e., recommend the Site Evaluation Accomplished (SEA) or further assessment or even a removal/remedial response action). Since the field investigation objective can be viewed as a choice between alternative actions, this document describes the objectives as being synonymous with the decision and associated actions. This chapter presents four major site assessment decisions and associated actions. The site assessment decisions and associated actions listed below address the most important Removal and Remedial data collection activities. Site managers who are addressing at least one of these major site assessment decisions should proceed directly to that section below and identify the decision and corresponding actions. For site managers who are not addressing one of the major decisions, this guidance provides activities to help develop project-specific decision statements below.

Stating the decision will help focus the efforts of the scoping team toward a common objective. The actions taken will be based on the outcome of the field investigations and will lay the foundation for defining the data quality requirements. The decision statement and alternative actions together provide an initial confirmation of the assumption that environmental data are needed to help resolve the potential contamination problem.

2.2 ACTIVITIES

Identify the Key Decision for the Current Phase or Stage of the Project

Review the list of decisions presented below and select the appropriate decision for the current phase of the site assessment process.

EARLY ASSESSMENT DECISION
Determine whether the release poses a potential threat to human health or the environment.

ADVANCED ASSESSMENT DECISION, PHASE I
Determine whether the concentration of contaminants of concern exceed ARARs or exceed contaminant concentrations corresponding to the preliminary remediation goal for the site.

ADVANCED ASSESSMENT DECISION, PHASE II (EXTENT OF CONTAMINATION)
Determine the volume of media that exceeds action level(s) (i.e., ARARs, concentrations corresponding to the preliminary remediation goal, removal action levels, or final remediation levels).

CLEANUP ATTAINMENT DECISION
Determine whether the final remediation level(s) or removal action level(s) have been achieved.

If a decision other than one from the list above will be addressed, perform the following activities:

(1) Consider the actions that EPA, the potentially responsible parties, or another collective group will take based on the outcome of the field investigation. For example, what will be done to resolve the potential contamination problem? Is it necessary to collect data on contaminant concentrations in order to decide if the site-related contamination exceeds regulatory standards, including ecological screening levels?

(2) Examine the regulatory objectives for this phase of the remedial process. For example, when a site is listed on the National Priorities List (NPL), but a baseline risk assessment has not been conducted, then the regulatory objective is to determine the nature and magnitude of contamination.

(3) Perform a consistency check by assessing whether the decision will be responsive to the potential contamination problem.

Identify Alternative Actions that May Be Taken Based on the Findings of the Field Investigation

Select the actions that will be taken based on the outcome of the field investigation that correspond with the selected decision above.

Actions based on early assessment decision

(i) Recommend the site evaluation accomplished (SEA) response for the site; or
(ii) Recommend that the site warrants consideration of further assessment or a possible response action.

Actions based on advanced assessment decision, Phase I

(i) Recommend the SEA response for the site; or
(ii) Recommend that the site warrants consideration of further assessment or a possible response action.

Actions based on advanced assessment decision, Phase II

(i) Designate the area/volume for remediation; or
(ii) Do not designate the area/volume for remediation.

Actions based on cleanup attainment decision

(i) Recommend the SEA response and proceed with delisting procedures; or
(ii) Recommend that further response is appropriate for the site.

Confirm that the actions associated with the list of decisions above will help to resolve the contamination problem by determining if actions are consistent with and satisfy regulatory objectives. Also, based on the statement of the problem and decision, assess if the range of actions helps to achieve the goal of protecting human health and the environment.

Identify Relationships Between This Decision and Any Other Current or Subsequent Decisions

If several decisions will be made, identify each decision and establish the relationship among them and their order of priority. Then, identify the actions that are associated with each decision and determine a logical sequence for these actions. Use this information to determine if it would be more efficient to conduct the field investigation in stages.

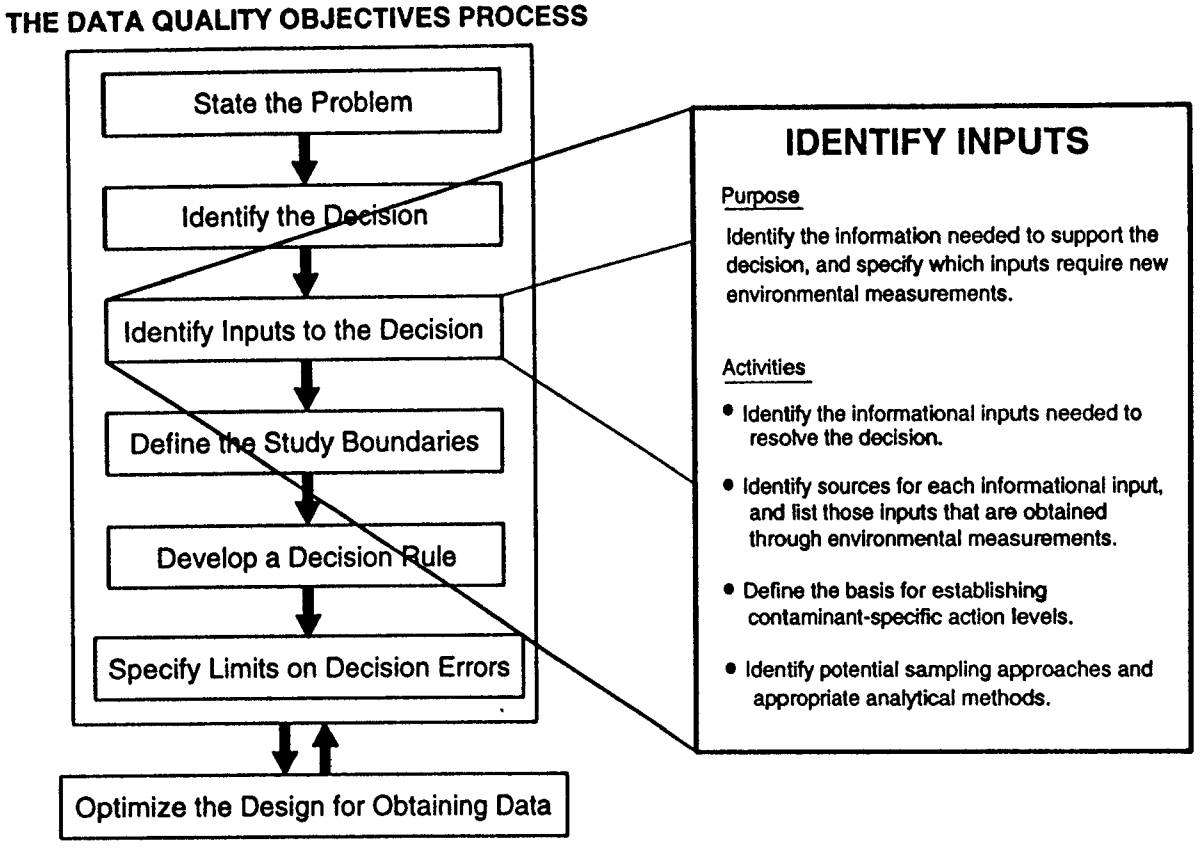
2.3 OUTPUTS

The outputs of this step are:

- a statement of the decision that will use Superfund environmental data; and
- a list of the actions that will be taken toward remediation or removal of the potential contamination problem based on the outcome of the field investigation.

CHAPTER 3

STEP 3: IDENTIFY THE INPUTS TO THE DECISION



3.1 BACKGROUND

The purpose of this step is to:

- identify the informational inputs needed to support the decision; and
- specify which inputs will require new environmental measurements.

The conceptual understanding of the site (i.e., conceptual site model), developed in Step 1: STATE THE PROBLEM, relates sources and retention or transport media to receptors. This conceptual understanding of the contamination problem and the decision statement defined in Step 2: IDENTIFY THE DECISION are previous outputs that are important to consider during this step. The action level, such as an ARAR or preliminary remediation goal(s), is another important input that will be considered during this step.

3.2 ACTIVITIES

The following subsections describe suggested activities that will help identify inputs to the decision.

Identify the Informational Inputs Needed to Resolve the Decision

It is important to determine whether monitoring, modeling, or a combination of these approaches will be used to support the decision. The decision inputs depend on the approach selected. For example, data on soil characteristics and hydrogeology could be useful for calibrating a computer model of contaminant transport and dispersion through ground water. When decisions are supported by modeling, it may be useful to consider the conceptual site model as a frame of reference. The conceptual site model summarizes how the site-related contamination may pose a risk to human health and the environment. Some components of the conceptual site model may be estimated using mathematical equations and assumptions (i.e., modeling), and other components will be estimated by directly measuring some characteristic of the site (i.e., monitoring). The conceptual site model concept was discussed in Step 1: STATE THE PROBLEM. Based on the selected approach, list all of the informational inputs needed to support the decision. Diagramming techniques may be used to help organize the list of inputs into categories and show logical or temporal relationships.

Identify Sources for Each Informational Input and List Those Inputs That are Obtained Through Environmental Measurements

Identify existing sources for information that can support the decision. Sources may include historical records, regulations, directives, engineering standards, scientific literature, previous site field investigations, or professional judgement.

Determine the Basis for Establishing Contaminant-Specific Action Level(s)

Determine if ARARs are available for the potential contaminants or if preliminary remediation goals have been developed for the site. If no regulatory threshold or standard can be identified during this step, the decision maker will need to decide how to develop a realistic concentration goal to serve as an action level for the field investigation design and evaluation. These action levels will be used as targets for developing and evaluating the study designs in the last step of the DQO Process.

Identify Potential Sampling Techniques and Appropriate Analytical Methods

Review the decision and associated regulatory objectives identified in Step 2: IDENTIFY THE DECISION. Use the list of contaminants identified earlier in this step and contaminant-specific action levels as a preliminary basis for identifying the most appropriate analytical methods. The decision on analytical methodology will be made in Step 7: OPTIMIZE THE DESIGN when more information about sampling and measurement error is available. Finally, identify potential sampling techniques and associated equipment.

Further discussion of these decision-specific activities is included in Appendix I, Section C.

3.3 OUTPUTS

The outputs that will result from the activities above include a list of informational inputs needed to make the decision and a list of environmental variables or characteristics that will be measured. There is a potential for confusion at this point because the outputs of this step are actually the inputs to the decision.

Example List of Advanced Assessment Decision, Phase I, Inputs

(1) List of Inputs Needed to Support the Decision:

- potential contaminants
  - -- concentrations in space and time
  - -- slope factors or dose/response relationships

- exposure pathways
  - -- media (e.g., soil, surface water, ground water, air, biota, sediments)
  - -- rates of migration (within and between media)
  - -- rates of dispersion/accumulation

- receptors
  - -- types/subpopulations
  - -- ecosystems
  - -- sensitivities
  - -- numbers/densities
  - -- activity levels/patterns

- preliminary remediation goal/ARARs

- site's physical and chemical characteristics that influence technology applicability (e.g., presence of organic components, soil permeability, and depth to impervious formation)

(2) List of Inputs That Require New Environmental Measurements:

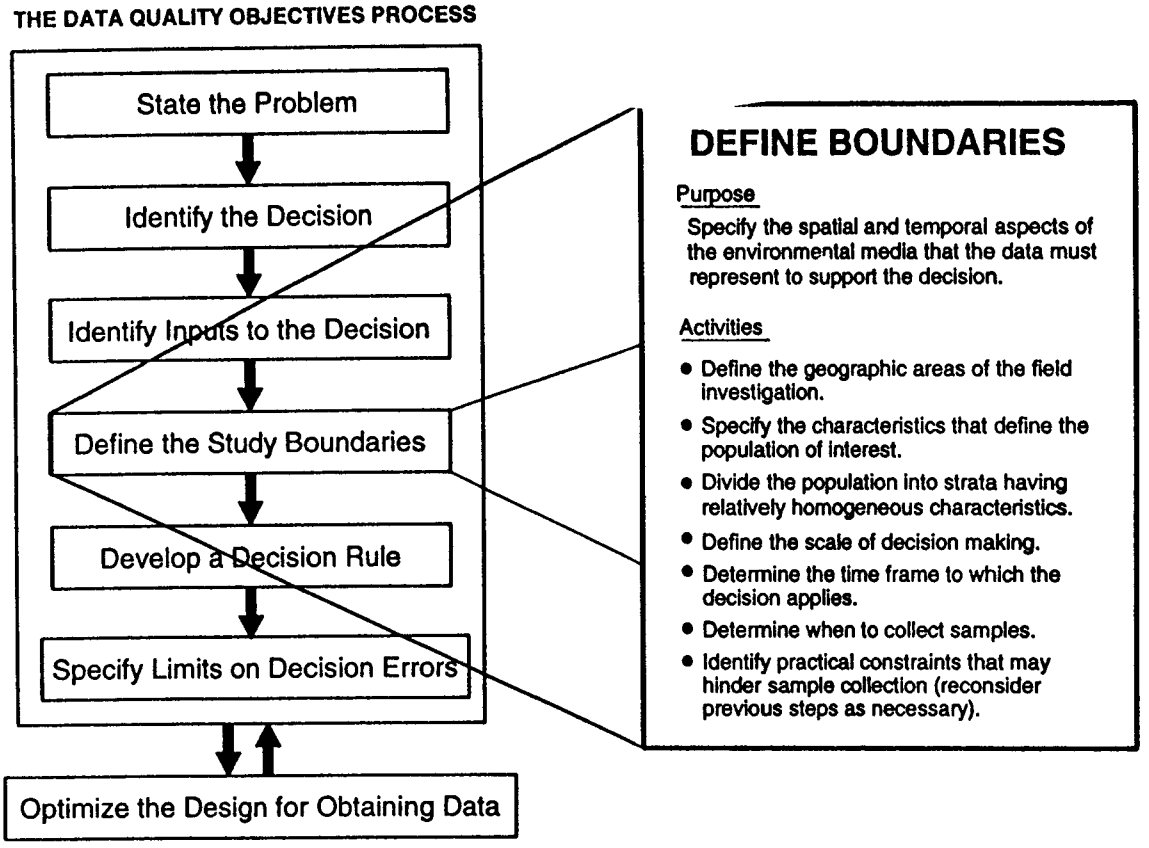
- contaminant concentrations in space and time for each media of concern

- small- and large-scale variability in potential contaminant concentrations

- other measurements related to risk assessment, such as fate and transport model parameters.

CHAPTER 4

STEP 4: DEFINE THE BOUNDARIES OF THE STUDY



4.1 BACKGROUND

The purpose of this step is to define the spatial and temporal boundaries of the study, so as to clarify the domain of what the samples are intended to represent. In addition, Step 4: DEFINE THE BOUNDARIES provides guidance on how to partition a site so as to prevent inappropriately pooling and averaging data in a way that could mask potentially useful information.

In order for samples to be representative of the domain or area for which the decision will be made, the boundaries of the study must be precisely defined. The purpose of this step is to clearly define the set of circumstances (boundaries) that will be covered by the decision. These include:

- Spatial boundaries that define what should be studied and where the samples should be taken; and
- Temporal boundaries that describe when samples should be taken and what time frame the study data should represent.

These boundaries will be used to ensure that the study design incorporates the time periods in which the study should be implemented, areas that should be sampled, and the time period to which the study results should apply. This will help ensure that the study data are representative of the objects or people being studied.

Practical constraints that could interfere with sampling are also identified in this step. A practical constraint is any hinderance or obstacle that may interfere with the full implementation of the study design.

Applicable information from previous DQO steps that will be necessary to develop boundaries includes:

- site contaminant(s) identification;
- potential migration pathways and exposure routes and potential receptors;
- the site's physical and chemical characteristics that enhance or decrease the likelihood of contaminant distribution movement within and among media;
- future use of the site;
- the decision(s) identified in the Step 2: IDENTIFY THE DECISION; and
- the "sampling and analysis action level" or "final remediation/removal action level."

4.2 ACTIVITIES

Define the Spatial Boundary of the Decision.

Figure 4-1 is a representation of this step.

(1) *Define the domain or geographic area within which all decisions must apply.* The domain or geographic area is a region distinctively marked by some physical features (i.e., volume, length, width, boundary) to which the decision will apply. Some examples are property boundaries, operable units, and exposure areas.

(2) *Specify the characteristics that define the population of interest.* The "population" is a term that refers to the total collection of objects or people to be studied, and from which the sample is to be drawn. For instance, a population may be PCB concentrations in soil at a Superfund site, or blood lead levels in the exposed human population. Clearly define the attributes that make up the population by stating them in a way that makes the focus of the study unambiguous. For example, "the top 12 inches of soil" is less ambiguous than merely "surface soil".

Some of the considerations in defining the media of concern are:

- What medium was originally contaminated?
- What inter-media transfer of cross-contamination is likely to have occurred (i.e., leaching, transport, etc.)?

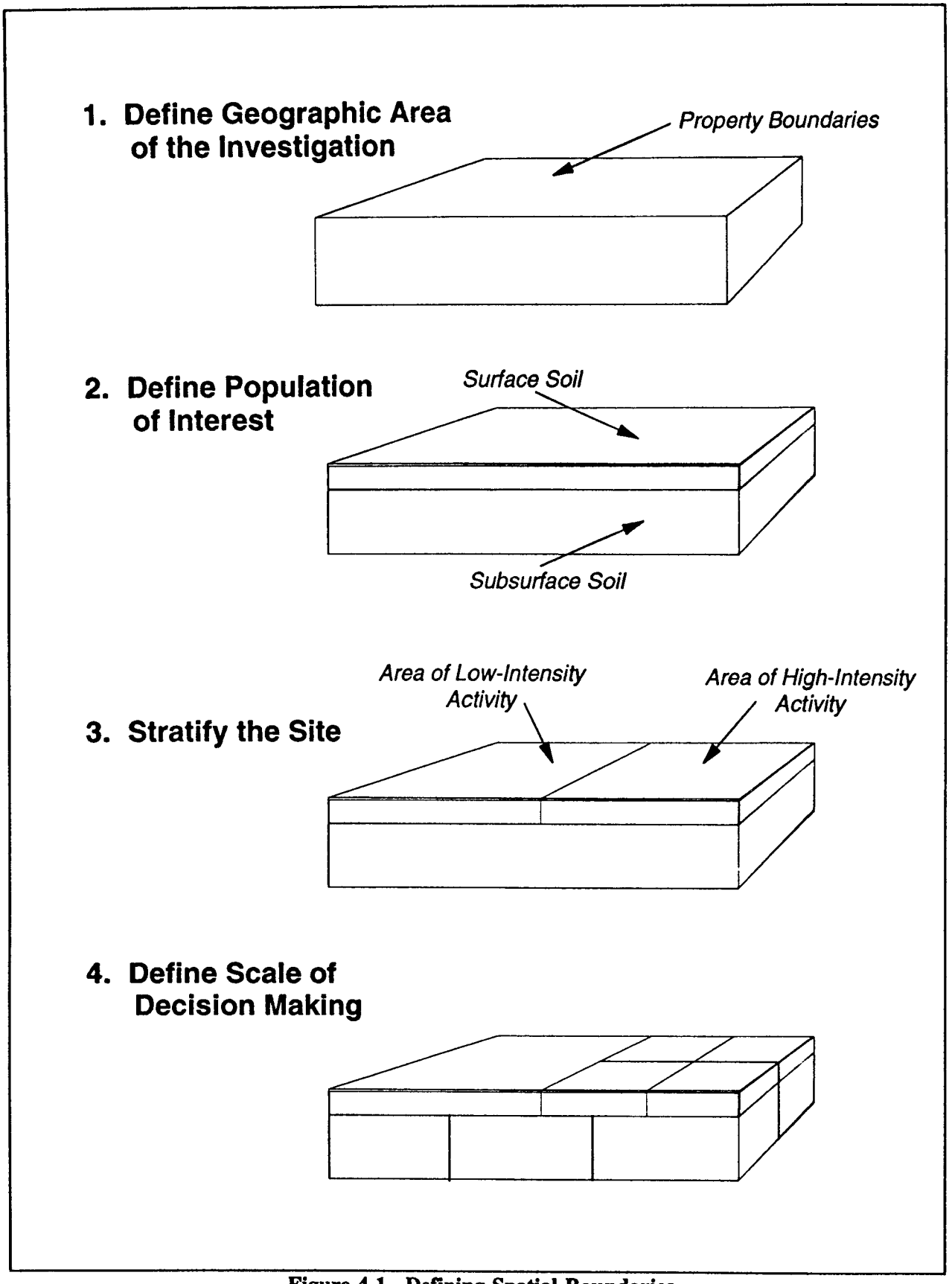


Figure 4-1. Defining Spatial Boundaries.

(3) *When appropriate, divide the population into strata that have relatively homogeneous characteristics.* Using existing information, stratify[1] each medium or set of objects into subsets of categories that exhibit relatively homogeneous properties, such as contaminant concentrations. Stratification is desirable for studying sub-populations or reducing the complexity of the problem by breaking it into more manageable pieces. The decision maker can choose to make separate decisions about each stratum or the entire population.

(4) *Define the scale of decision making.* The scale of decision making is the smallest area, volume, or time frame of the media in which the scoping team wishes to control decision errors. The goal of this activity is to define subsets of media that the scoping team will make decisions about in order to evaluate health and environmental risks and the cleanup goals of the site, and, at the same time, meet the constraints of the DQOs. The size may range from the entire geographic boundaries of the site to the smallest size area that presents an exposure to the receptor. The size of the scale of decision making is generally based on:

(A) *Risk*: Here, the scale of decision making is determined by the relative risk that exposure presents to the receptor (i.e., the size of the scale is correlated with the risks that it poses to the receptor). The scale of decision making that is based on risk is referred to as an "Exposure Unit" (EU). An example of an EU could be a ½-acre potential homestead on a remediated site.

(B) *Technological considerations*: Here, the scale of decision making is based on the most efficient area or volume of medium that can be removed or remediated with the selected technology. These areas or volumes are called Remediation Units (RUs). An example of an RU is the area of topsoil that can be removed by one pass of a bulldozer.

(C) *Other considerations*: Here, the scale of decision making is based on practical factors or a combination of risk and technological factors that dictate a specific size. These factors may include "hot spots" whose size should be based on historical site use.

As an example, consider a study of contaminated soil where the goal is to protect future residents from exposure and where the future land use is residential. The planning team may set the scale of decision making to a 14' by 14' area (EU) if the children derive most of their exposure from an outdoor play area of this size. Consequently, the decision that will be made at the site would be protective of children, a sensitive population in exposure assessment.

Define the Temporal Boundaries of the Decision.

(1) *Determine the time frame to which the study data apply.* It may not be possible to collect data over the full time period to which the decision will apply. Therefore the scoping team must determine the most appropriate time frame that the data should reflect (e.g., the study data will reflect the condition of contaminant leaching into ground water over a period of a hundred years).

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[1]Stratification is used to reduce the variability of contaminant concentrations and therefore reduce the number of samples needed to meet the limits of decision error that will be defined in Chapter 7. Decisions are generally made about an area the size of the stratum or smaller.

(2) *Determine when to collect samples.* Conditions may vary over the course of a study due to weather or other factors. Moreover, the study decision may be influenced by the seasons. For example, a study to measure exposure to volatile organic compounds from a contaminated site may give misleading information if the sampling is conducted in the colder winter months rather than the warmer summer months. Therefore the scoping team must determine the most appropriate time period to collect data that will reflect the conditions that are of interest.

Identify any Practical Constraints on Data Collection.

These constraints include seasonal or meteorological conditions when sampling is not possible and the unavailability of personnel, time, or equipment. For example, it could occur that surface soil samples could not be taken beyond the east boundaries of a site under investigation because access to that area had not been granted by the owner of the adjacent property.

Further discussion of the scale of decision making, including examples, is included in Appendix I, Section D.

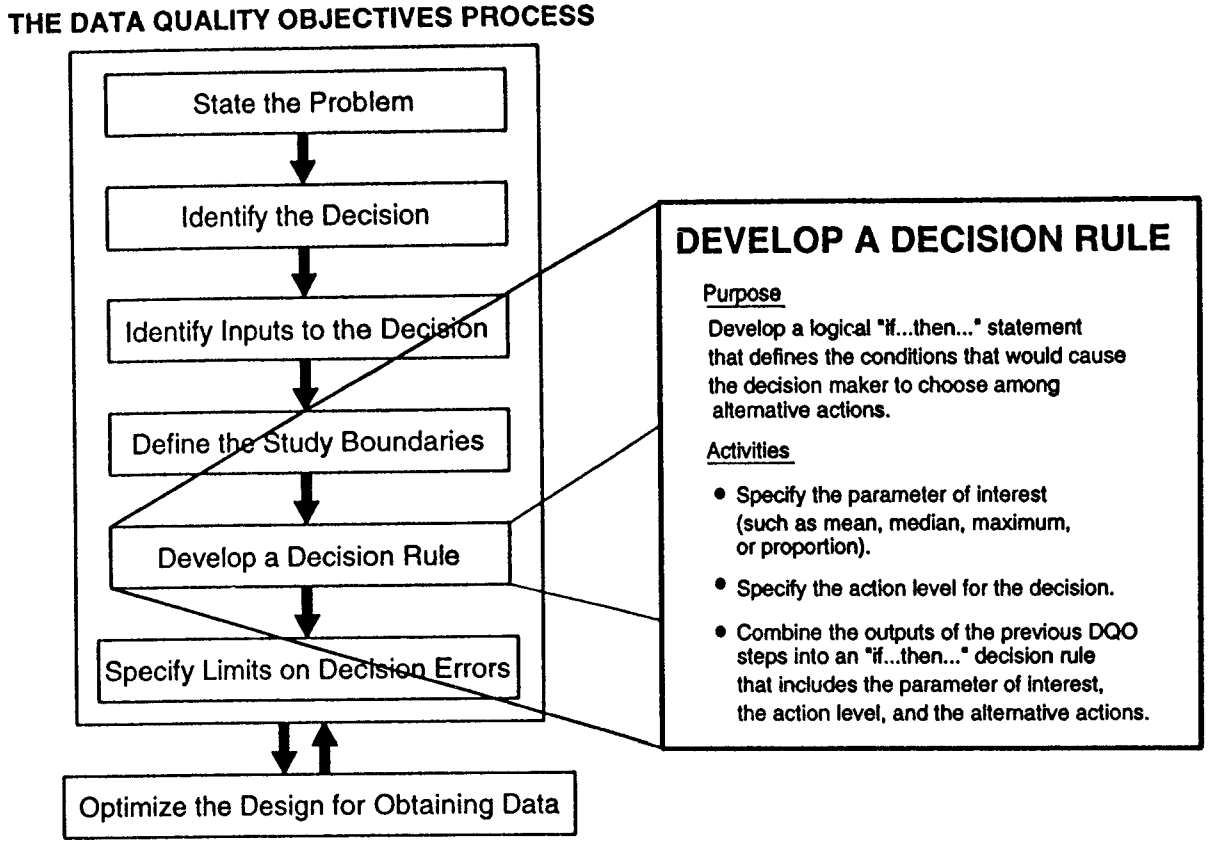
4.3 OUTPUTS

The outputs of this step are:

- a detailed description and physical representation (map) of the geographic limits (boundaries) of each environmental medium (soil, water, air, etc.) within which the decision(s) will be made;
- a detailed description of the characteristics that define the population of interest;
- definition of the time period in which samples will be taken and to which decisions will apply;
- the most appropriate scale of decision making for each medium of concern; and
- description of practical constraints that may impede sampling.

CHAPTER 5

STEP 5: DEVELOP A DECISION RULE



5.1 BACKGROUND

The purpose of this step is to integrate the output from the previous steps of the DQO Process into a statement that defines the conditions that would cause the decision maker to choose among alternative actions. The outputs from earlier steps include the actions and the decision from Step 2: IDENTIFY THE DECISION, the action level from Step 3: IDENTIFY THE INPUTS TO THE DECISION, and the scale of decision making from Step 4: DEFINE THE STUDY BOUNDARIES.

5.2 ACTIVITIES

Specify the Statistical Parameter that Characterizes the Population of Interest

The statistical parameter of interest is a descriptive measure (such as a mean, median, proportion, or maximum) that specifies the characteristic or attribute that the decision maker would like to know about the statistical population. Review the study objectives to determine if a particular statistical parameter is implied or stated. Consult other members of the planning team, such as a risk

assessor or person with statistical training, to determine the most appropriate statistical parameter for the problem.

Appendix I, Section E, contains additional information on choosing a population parameter.

Specify the Action Level (Final Remediation Level or Removal Action Level) for the Decision

The action level is the contaminant concentration which, if exceeded, would indicate that action should be taken at the site (the action prescribed in Step 2: IDENTIFY THE DECISION).[1]

If the decision maker believes that the final remediation level could be one of two different levels, then the more stringent one should be chosen for the action level. A more stringent action level will require analytical methods (detection limits) that would satisfy the less stringent action level as well. If multiple contaminants are of concern and ARARs are not available or not sufficiently protective, risk-based PRGs need to be developed. Refer to the *Risk Assessment Guidance for Superfund, Volume I-Human Health Evaluation Manual, Part B, Development of Preliminary Remediation Goals.*

Combine the Outputs from the Previous DQO Steps and Develop a Decision Rule

Recall the actions specified in Step 2: IDENTIFY THE DECISION. Combine the actions, sampling and analysis action level, and the parameter of interest (including the scale of decision making) in a statement that describes the conditions that would lead to a specific course of action. An example of a decision rule for a Superfund site is, "If the mean PCE concentration of each downgradient well is greater than the upgradient well, then further assessment and response is required; otherwise recommend SEA."

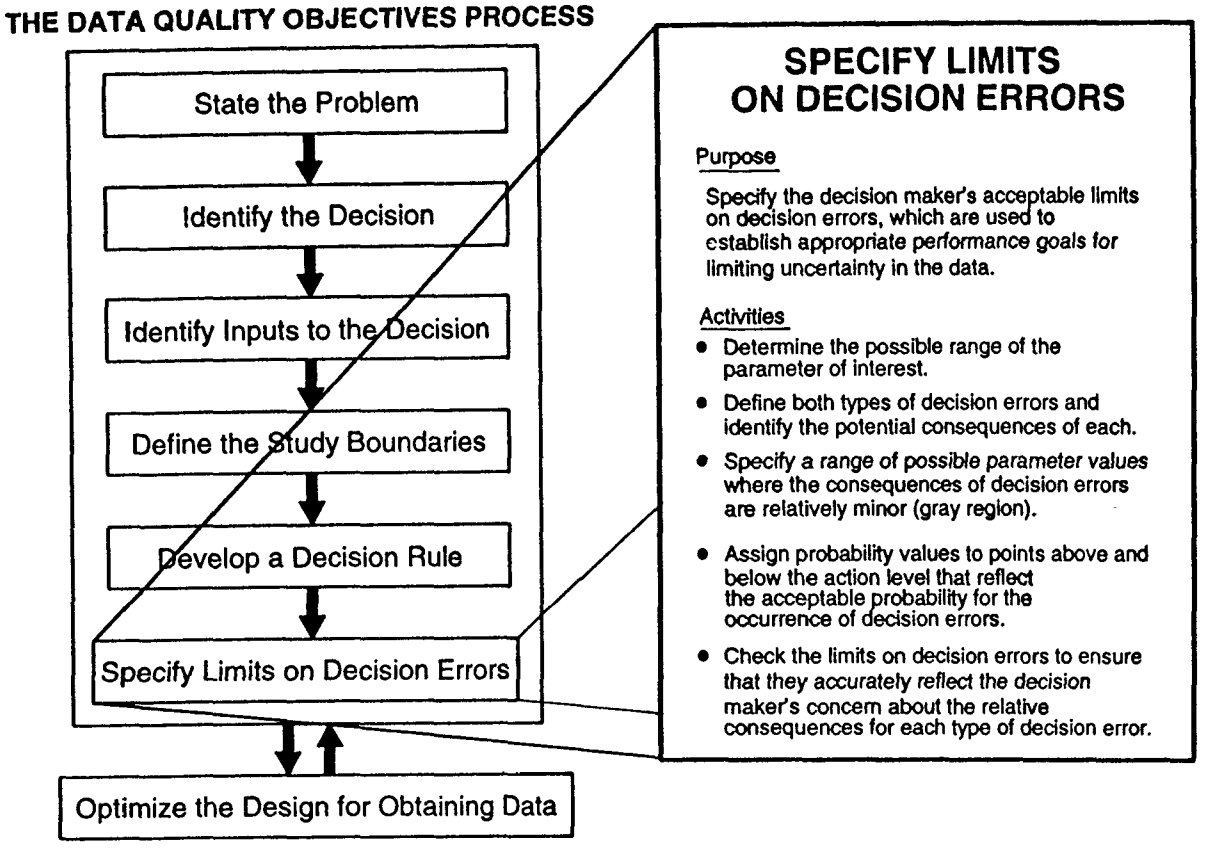
5.3 OUTPUTS

The output for this step is an "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative courses of action. It should include the decision, the actions, the parameter of interest, the action level, and the scale of decision making. For example, if the mean concentration of contaminants in sediments within the stream reach the ecological screening level(s), then recommend that the site warrants consideration of further assessment on a response action.

[1]This action level is not the final remediation level. The final remediation level is not determined until the ROD. Rather, this action level is an assumption made during planning based on the decision maker's expectation of the final remediation level. The action level is only an assumption, and does not bind the decision maker to a specific value for the final remediation level.

CHAPTER 6

STEP 6: SPECIFY LIMITS ON DECISION ERRORS



6.1 BACKGROUND

The purpose of this step is to specify the site manager's acceptable decision error rates based on a consideration of the consequences of making an incorrect decision. These limits will be used in Step 7: OPTIMIZE THE DESIGN to generate the most resource-effective sampling design.

Site managers are interested in knowing the true state of some feature of a site. Since measurement data can only estimate this state, however, decisions that are based on measurement data could be in error (decision error). Therefore, the goal of the scoping team is to design a sampling plan that limits the chance of making a decision error to an acceptable level. This step of the DQO Process will help the site manager define what constitutes acceptable limits on the probability of making a decision error.

There are two reasons why the site manager cannot know the true value of a population parameter:

(1) The population of interest almost always varies over time and space. Limited sampling will miss some features of this natural variation because it is usually impossible or impractical to measure every point of a population or to measure over all time frames. Sampling error

occurs when sampling is unable to capture the complete scope of natural variability that exists in the true state of the environment.

(2) A combination of random and systematic errors inevitably arises during the various steps of the measurement process, such as sample collection, sample handling, sample preparation, sample analysis, data reduction, and data handling. These errors are called measurement errors because they are introduced during measurement process activities.

The combination of sampling error and measurement error is called total study error, which is directly related to decision error.

The probability of making decision errors can be controlled by adopting a scientific approach. The scientific method employs a system of decision making that controls decision errors through the use of hypothesis testing. In hypothesis testing, the data are used to select between one condition of the environment (the baseline condition or null hypothesis, H_o) and the alternative condition (the alternative hypothesis, H_a). For example, the site manager may decide that a site is contaminated (the baseline condition) in the absence of strong evidence (study data) that indicates that the site is clean (alternative hypothesis). Hypothesis testing places the greater weight of evidence on disproving the null hypothesis or baseline condition. Therefore, the site manager can guard against making the decision error that has the greatest undesirable consequence by setting the null hypothesis equal to the condition that, if true, has the greatest consequence of decision error.

A decision error occurs when the measurement data lead the site manager to reject the null hypothesis when it is true, or to fail to reject the null hypothesis when it is false. These two types of decision errors are classified as false positive errors and false negative errors, respectively.

False Positive Error — A false positive error occurs when sampling data mislead the site manager into believing that the burden of proof has been satisfied and that the null hypothesis (H_o or baseline condition) should be rejected. Consider an example where the site manager presumes that concentrations of contaminants of concern exceed the action level (i.e., the baseline condition or null hypothesis is: concentrations of contaminants of concern exceed the action level). If the sampling data lead the site manager to incorrectly conclude that the concentrations of contaminants of concern do not exceed the action level when they actually do exceed the action level, then the site manager would be making a false positive error. A statistician usually refers to the false positive error as alpha (α), the level of significance, the size of the critical region, or a Type I error.

False Negative Error — A false negative error occurs when the data mislead the site manager into wrongly concluding that the burden of proof has not been satisfied so that the null hypothesis (H_o) is not rejected when it should be. A false negative error in the previous example occurs when the data lead the site manager to wrongly conclude that the site is contaminated when it truly is not. A statistician usually refers to a false negative error as beta (β), or a Type II error. It is also known as the complement of the power of a test.

While the possibility of making decision errors can never be totally eliminated, it can be reduced. To reduce decision errors, the scoping team must develop an acceptable estimate of the population parameter. This can be accomplished by collecting a large number of samples (to reduce sampling error) and by analyzing individual samples several times using more precise laboratory methods (to reduce measurement error). Better sampling designs can also be developed to collect data that more accurately and efficiently represent the population of interest. Reducing decision errors, however, generally increases costs. In some cases, reducing decision errors is unnecessary for making

a reasonable decision. For instance, if the consequences of decision errors are minor, a reasonable decision could be made based on relatively crude data. Similarly, if the consequences of decision errors are severe, the site manager will want to develop a sampling design that eliminates as much sampling and measurement error as possible (within budget constraints).

A site manager must balance the desire to limit decision errors to acceptable levels with the cost of reducing decision errors. To find the best balance and thereby efficiently determine whether to reduce sampling and/or measurement error, the site manager must define acceptable probabilities of decision errors. Once the acceptable probabilities of decision errors are defined, then the effort necessary to reduce sampling and measurement errors to meet these limits can be quantified in Step 7: OPTIMIZE THE DESIGN. It may be necessary to iterate between Step 6 and Step 7 more than once before an acceptable balance between limits on decision errors and the cost of a sampling design can be achieved.

6.2 ACTIVITIES

The combined information from the activities section of this chapter can be graphically displayed onto a "Design Performance Goal Diagram" (Figures 6-1 and 6-2), or charted in a "Decision Error Limits Table" (Tables 6-1 and 6-2). The activities section will refer to these figures and tables to help the reader understand the relationships between the activities and the outputs of this step.

Determine the possible range of the parameter of interest.

Establish the possible range of the parameter of interest by estimating its upper and lower bounds. This means defining the lowest (typically zero in environmental studies) and highest concentrations at which the contaminant(s) is expected to exist at the site. This will help focus the remaining activities of this step on only the relevant values of the parameter. Use historical data, including analytical data, if available. For example, the range of the parameter shown in Figures 6-1 and 6-2 and Tables 6-1 and 6-2 is between 0 and 210 ppm. Note that when interpreting the Design Performance Goal Diagram, the concentration values on the horizontal axis represent the true concentration of the parameter of interest.

Define both types of decision errors and identify the potential consequences of each.

Using the action level specified in Step 5: DEVELOP A DECISION RULE, designate the areas above and below the action level as the range where the two types of decision errors could occur. The process of defining the decision errors has four steps:

(1) *Define both types of decision errors and establish which decision error has more severe consequences near the action level.* For instance, the threat of health effects from a contaminated hazardous waste site may be considered more serious than spending extra resources to remediate the site. Therefore, a site manager may judge that the consequences of incorrectly concluding that the concentrations of site-related contaminants do not exceed the action level are more severe than the consequences of incorrectly concluding that the concentrations of site-related contaminants exceed the action level.

(2) *Establish the true state of nature for each decision error.* In the example above, from the site manager's perspective, the true state of the site for the more severe decision error will be that the concentrations of site-related contaminants exceed the action level. The true state of nature for the less severe decision error is that the concentrations of site-related contaminants do not exceed the action level.

(3) *Define the true state of nature for the more severe decision error as the baseline condition or null hypothesis* (H_0= the site is contaminated), *and define the true state of nature for the less severe decision error as the alternative hypothesis* (H_a= the site is not contaminated). Since the burden of proof rests on the alternative hypothesis, the data must demonstrate enough information to authoritatively reject the null hypothesis and conclude the alternative. Therefore by setting the null hypothesis equal to the true state of nature that exists when the more severe decision error occurs, the site manager is guarding against making the more severe decision error.

(4) *Assign the terms "false positive" and "false negative" to the proper decision errors.* A false positive decision error corresponds to the more severe decision error and a false negative decision error corresponds to the less severe decision error. The definition of false positive and false negative errors depends on the viewpoint of the decision maker and the actions that are taken. Consider the viewpoint where a person has been presumed to be "innocent until proven guilty" (i.e., H_0 is: innocent; H_a is: guilty). A false positive error would be convicting an innocent person; a false negative error would be not convicting the guilty person. From a decision maker's viewpoint the errors are reversed when a person is presumed to be "guilty until proven innocent" (i.e., H_0 is: guilty; H_a is: innocent). Here, the false positive error would be not convicting the guilty person and the false negative error would be convicting the innocent person.

Define and evaluate the potential consequences of decision errors at several points within the false positive and false negative ranges. For example, the consequences of a false positive decision error when the true parameter value is merely 10% above the action level may be minimal because it would cause only a moderate increase in the risk to human health. On the other hand, the consequences of a false positive error when the true parameter is ten times the action level may be severe because it could greatly increase the exposure risk to humans as well as cause severe damage to a local ecosystem. In this case, site managers would want to have less control (tolerate higher probabilities) of decision errors of relatively small magnitudes and would want to have more control (tolerate small probabilities) of decision errors of relatively large magnitudes.

The action level has been set at 100 ppm in Figures 6-1 and 6-2. (Note that the action level is represented by a vertical dashed line at 100 ppm.) Figure 6-1 shows the case where a site manager considers the more severe decision errors to occur above the action level. Figure 6-2 shows the case where the site manager considers the more severe decision error to occur below the action level. The hypothesis test for the second case is the reverse of the first case, so the false positive and false negative errors are on opposite sides of the action level. This chapter will focus on Figure 6-1 for illustrative purposes.

Specify a range of possible parameter values where the consequences of decision errors are relatively minor (gray region).

The gray region is a range of points (bounded on one side by the action level) where the consequences of a false negative decision error are relatively minor. Establish the general location of the gray region by evaluating the consequences of wrongly concluding that the baseline condition (the null hypothesis) is true.

The gray region establishes the minimum distance from the action level to which the site manager would like to control decision errors. In statistics, this distance is called delta (δ), and is an essential part of the calculations needed to determine the number of samples that need to be collected. The width of the gray region reflects the site manager's concern for decision errors. A more narrow gray region implies a desire to conclusively detect the condition when the true parameter value is close to the action level. When the sample estimate of the parameter falls within the gray region, the site manager may have a high probability of making a decision error (i.e., the data may be "too close to call"), and may wrongly conclude that the baseline condition is true.

The gray region is an area where it will not be feasible or reasonable to control the false negative decision error rate to low levels because the resources that would be required would exceed the expected costs of the consequences of making that decision error. In order to determine with confidence whether the true value of the parameter is above or below the action level (depending on the more severe decision error), the site manager would need to collect a large amount of data, increase the precision of the measurements, or both. If taken to an extreme, the cost of collecting data can exceed the cost of making a decision error, especially where the consequences of the decision error may be relatively minor. Therefore, the site manager should establish the gray region by balancing the resources needed to "make a close call" versus the consequences of making that decision error.

In Figure 6-1, the gray region has been set below the action level in the area where the site manager has determined that the decision errors have the least consequence. The width of the gray region indicates that the site manager does not wish to control decision errors when the true concentration at the site is between 80 and 100 ppm.

Assign probability values to points above and below the action level that reflect the acceptable probability for the occurrence of decision errors.

Assign probability values to points above and below the action level that reflect the site manager's acceptable limits for making an incorrect decision. The most stringent limits on decision errors that are typically encountered for environmental data are .01 (1%) for both the false positive and false negative decision errors (α and β). This guidance recommends using .01 as the starting point for setting decision error rates.[1] The most frequent reasons for setting limits greater than .01 are that the consequences of the decision errors may not be severe enough to warrant setting decision error rates that are this stringent. If the decision is made to relax the decision error rates from .01 for false positive and false negative decision errors, the scoping team should document the rationale for setting the decision error rate. This rationale may include potential impacts on cost, human health, and ecological conditions.

[1] The value of .01 should not be considered a prescriptive value for setting decision error rates, nor should it be considered as the policy of EPA to encourage the use of any particular decision error rate.

Repeat this activity for both sides of the gray region. Generally, the acceptable limits for making a decision error should decrease as the consequences of a decision error become more severe further away from the action level.

Figure 6-1 shows that from the action level to a true value of 150 ppm for the parameter of interest, the site manager will tolerate a 5% chance of deciding that the true value is below the action level, based on field investigation data. If the true value is greater than 150 ppm, the site manager will tolerate only a 1% chance of deciding the true value is really below the action level. Below the action level, from 60-80 ppm the site manager will tolerate deciding the true value is above the action level 10% of the time, and between 40-60 ppm the site manager will allow a false negative decision error rate of 5%.

Check the limits on decision errors to ensure that they accurately reflect the site manager's concerns about the relative consequences for each type of decision error.

The acceptable limits on decision errors should be smallest (i.e., have the lowest probability of error) for cases where the site manager has greatest concern for decision errors. This means that if one type of error is more serious than another, then its acceptable limits should be smaller (more restrictive). In addition, the limits on decision errors are usually largest (high probability of error can be tolerated) near the action level, since the consequences of decision errors are generally less severe as the action level is approached. Verify that the site manager's acceptable limits on decision errors are consistent with these principles.

The Design Performance Goal Diagram (which is sometimes called a "Decision Performance Curve") can be refined by breaking the "steps" of decision errors into smaller units. This would have the effect of adding rows of information to its corresponding Decision Error Limits Table. The information from the diagram will be used in the final step of the DQO Process (Step 7: OPTIMIZE THE DESIGN) in order to construct a statistically based evaluation of how well the sampling design will meet the DQOs. This evaluation involves the construction of a power curve, which is a graphical description of a sampling design's expected performance. If the power curve lies within the acceptable regions of the Design Performance Goal Diagram, then the corresponding sampling design satisfies the site manager's acceptable limits on decision errors.

Appendix I, Section F, contains additional information on specifying limits on decision errors.

6.3 OUTPUTS

The outputs from this step are the site manager's acceptable decision error rates based on a consideration of the consequences of making an incorrect decision. These limits on decision errors can be expressed in a Decision Error Limits Table or in a Design Performance Goal Diagram.

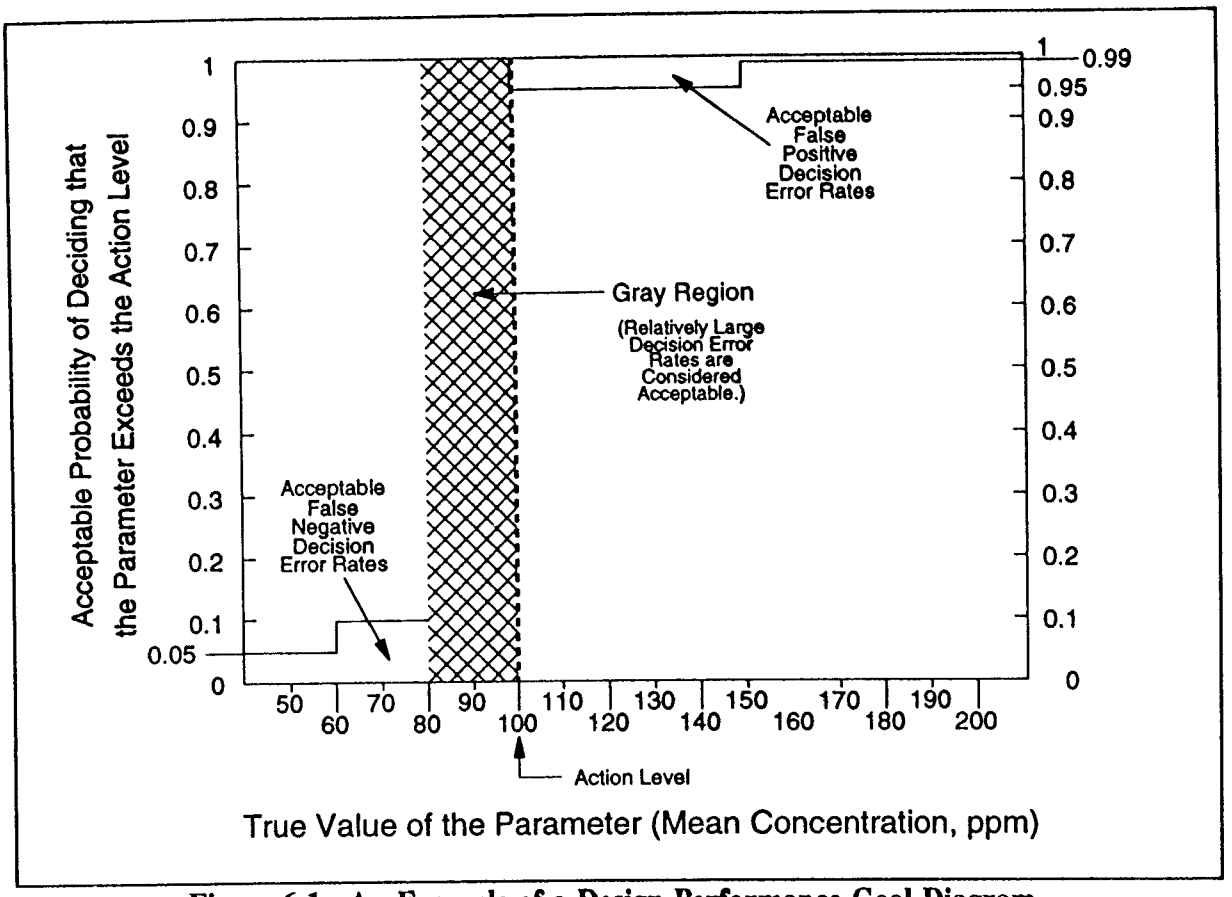


Figure 6-1. An Example of a Design Performance Goal Diagram (Baseline condition: parameter exceeds action level)

True concentration	Correct decision	Acceptable probability of making an incorrect decision (a decision error)
50 to 60 ppm	does not exceed action level	5%
60 to 80	"	10%
80 to 100	"	gray region—no probability specified
100 to 150	exceeds action level	5%
150 to 200	"	1%

Table 6-1. Decision Error Limits Table Corresponding to Figure 6-1

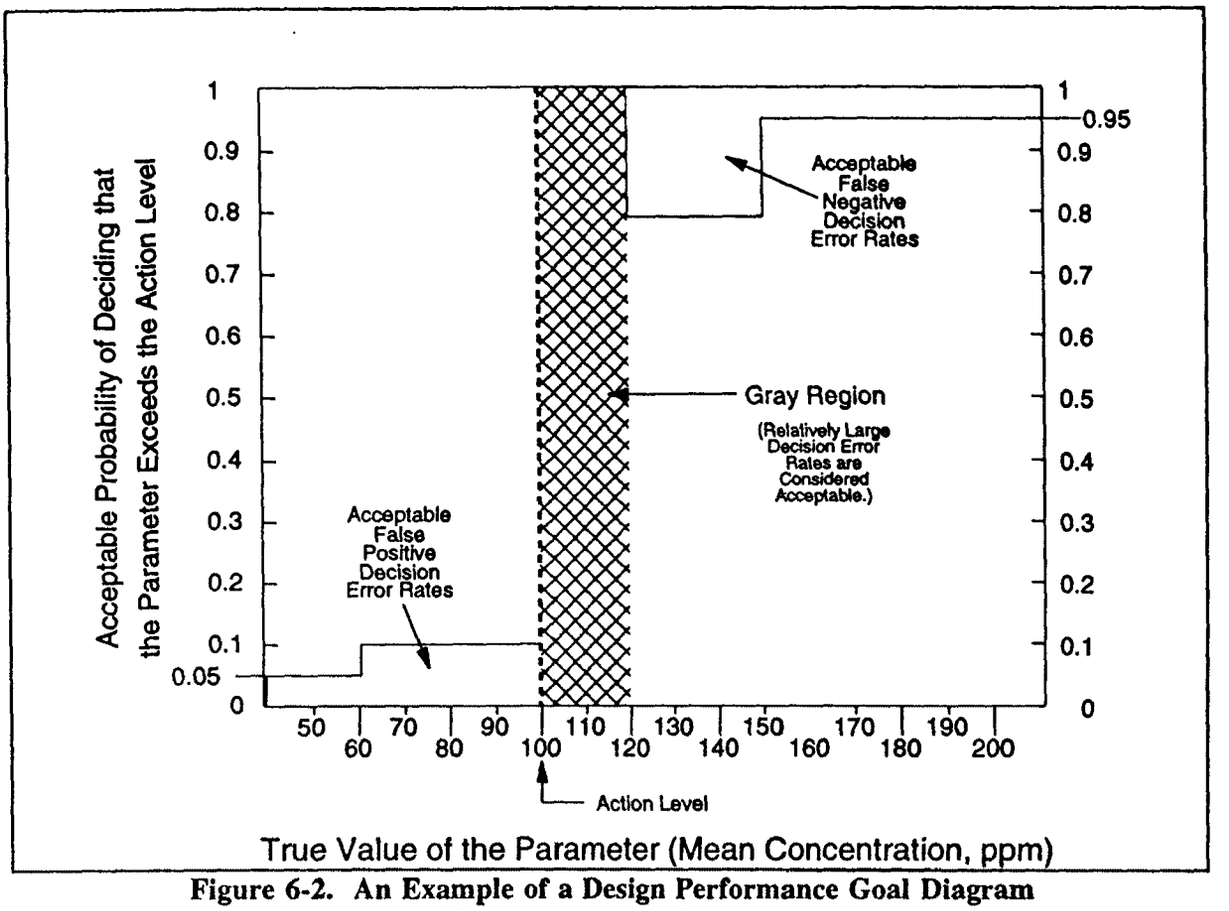


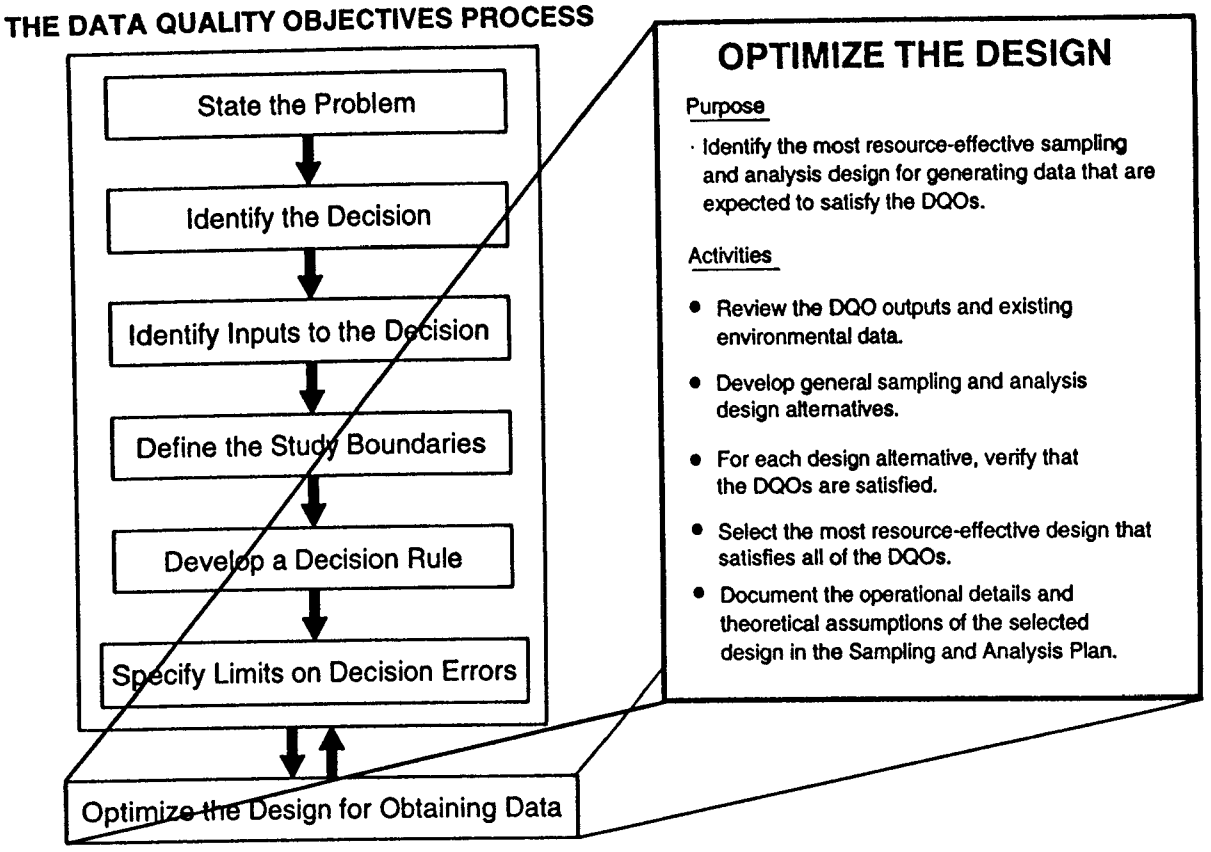
Figure 6-2. An Example of a Design Performance Goal Diagram (Baseline condition: parameter less than action level)

True concentration	Correct decision	Acceptable probability of making an incorrect decision (a decision error)
50 to 60 ppm	does not exceed action level	5%
60 to 100	"	10%
100 to 120	"	gray region—no probability specified
120 to 150	exceeds action level	20%
150 to 200	"	5%

Table 6-2. Decision Error Limits Table Corresponding to Figure 6-2

CHAPTER 7

STEP 7: OPTIMIZE THE DESIGN



7.1 BACKGROUND

The purpose of this step is to identify the most resource-effective sampling design that generates data which satisfy the DQOs specified in the preceding steps. To develop the optimal design for this study, it may be necessary to work through this step more than once after revisiting previous steps of the DQO Process.

This step provides a general description of the activities necessary to generate and select sampling designs that satisfy the DQOs. In addition, it contains information about how the outputs from the previous six steps of the DQO Process are used in developing a statistical design. Appendix I, Section G, discusses the basic principles of developing a statistical design and some basic design options. This document, however, does not give detailed guidance on the mathematical procedures involved in developing a statistical sampling design; for this type of guidance, see the references cited in Appendix I, Section G, or consult with a statistician. Site managers also may want to use EPA's DQO Decision Error Feasibility Trials software,[1] which provides a first-pass rough estimate of sample

[1] U.S. EPA. 1993. *Data Quality Objectives Decision Error Feasibility Trials Software for Personal Computers.*

sizes required to satisfy the DQOs. This user-friendly PC software can help speed up the first iteration through the DQO process.

For most field investigations, a probabilistic sampling approach is necessary for extrapolating results from a set of samples to the entire site. By combining an efficient probabilistic sampling design with a statistical hypothesis test, the decision maker will be able to optimize resources such as funding, personnel, and temporal constraints while still meeting the DQOs. The hypothesis test used in analyzing the data is an extremely important part of the statistical design, since it provides the theoretical underpinnings for selecting the number, type, location, and timing of environmental samples. While it may be true that the hypothesis test may be refined or changed later in the light of what is discovered when collecting and examining the data, it is essential to have a plan for the statistical analysis of the data *before* collecting samples so that the data are more likely to support the ultimate decision.

For some field investigations, a non-probabilistic (judgmental) sampling approach is acceptable. A judgmental sampling design consists of directed samples where the decision maker (or technical expert) selects the specific sampling locations.[2] Typically this occurs when the site manager wants to confirm the existence of contamination at specific locations, based on visual or historical information. However, when non-probabilistic sampling approaches are used, quantitative statements about data quality are limited to the measurement error component of total study error. If the site manager wishes to draw conclusions about areas of the site beyond the exact locations where samples were taken, then a probabilistic approach should be used. This will allow the site manager to make quantitative statement about the sampling error component of total study error, and thus determine the probability of making a decision error regarding larger areas of the site.

Even if a judgmental sampling design is chosen, it is important to implement all applicable activities of this step. This will ensure that the qualitative data quality objectives, such as budget, schedule, and the temporal and spatial constraints (boundaries) are met. In addition, this step will help the scoping team document:

1. the reasons for selecting a non-probabilistic sampling approach;
2. the reasons for selecting specific sampling locations; and
3. the expected performance of the sampling design with respect to the qualitative DQOs.

7.2 ACTIVITIES

Review the DQO Outputs and Existing Environmental Data

The outputs from the previous steps of the DQO Process provide a succinct collection of information that is used to develop the sampling design in the following way:

- The limits on decision errors provide crucial information for selecting the number of samples to be collected, the number of analyses per sample, and the hypotheses to be tested.

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[2]Grid samples or transect samples contain an element of randomization because the initial sampling point is chosen randomly. Therefore they are considered probabilistic designs, not judgmental.

- The inputs, boundaries, and decision rule are used in deciding the location and timing of samples.

Therefore, the scoping team should review the previous DQO outputs and confirm the budget for sampling and analysis, and the project schedule (especially deadlines). List any logistical or administrative limitations, such as weather, equipment, and personnel availability identified in Step 4: DEFINE THE BOUNDARIES. Site characteristics, previous sample locations, quality control data, and audit reports from earlier field investigations also provide valuable information to the sampling design team (or statistician).

For probabilistic sampling designs, additional information will be needed regarding the expected variability of contaminants. Consequently, any existing environmental data from the site (or from similar sites) should be reviewed. Information about existing environmental data may have been identified during Step 1: STATE THE PROBLEM and Step 3: IDENTIFY THE INPUTS. If no existing data are available, it may be necessary to conduct a limited field investigation to develop an adequate estimate of variability.

Develop General Sampling and Analysis Design Alternatives

The sampling design team will develop alternative sampling and analysis designs that could generate data needed to test the hypothesis. To generate alternative designs, the statistician may vary several different aspects of the design, such as the number and locations of samples collected in the field, the types of samples collected, or the number of replicate analyses performed on samples.

For each sampling design, a statistical model should then be developed that describes the relationship of the measured value to the "true" value. This mathematical formulation clarifies how data generated from a design is to be interpreted and processed in testing the hypothesis. A tentative analytic form for analyzing the resulting data (for example, a student's t-test or a tolerance interval) should also be specified. Use this information to solve for the minimum sample size that satisfies the decision maker's limits on decision errors. If the design involves multiple subsample sizes (e.g., for stratification schemes), then select the optimal mix of subsample sizes.

It is important not to rule out any alternative analytical or field sampling methods due to preconceptions about whether or not the method is "good enough." It must be remembered that the objectives of the statistical design are to limit the *total* error, which is a combination of sampling and measurement error, to acceptable levels. Traditional laboratory methods tend to minimize measurement error, but they can be so expensive that only a limited number of samples can be analyzed within the budget. There often may be advantages to using less precise methods that are relatively inexpensive, thereby allowing a significantly larger number of samples to be taken. Such a design would trade off an increase in measurement error for a decrease in sampling error. Given the large amount of natural variability in many environmental studies, this approach may reduce overall costs while limiting the total decision error rates to acceptable levels just as well as a design based on traditional laboratory methods.

For Each Design Alternative, Verify that the DQOs are Satisfied

Verify that each design alternative satisfies all of the DQOs, including limits on decision errors, budget, schedule, and practical constraints. If none of the designs satisfy the DQOs, the scoping team may need to:

- increase the acceptable decision errors rates;
- increase the width of the gray region;
- relax other project constraints, such as available personnel;
- increase funding for sampling and analysis; or
- change the boundaries; it may be possible to reduce sampling and analysis costs by changing or eliminating subgroups that will require separate decisions.

Select the Most Resource-Effective Design that Satisfies All of the DQOs

The design team should perform a sensitivity analysis on the alternative designs to see how each design performs when the assumptions are changed, together with the impact on costs and resources. Typically, this means changing certain parameters within some reasonable range, and seeing how each of these changes influences the expected decision error rates. For example, if the contaminant variability is higher or lower than assumed for the design, what happens to the design performance? Or, if the final remedial level is more/less stringent than the assumed action level, what happens to the design performance? A Statistical Power Curve is a useful statistical tool used to evaluate whether a sampling design has the ability to meet the DQOs.[3] An example of a Power Curve is shown in Figure 7-1.

Evaluate the design options based on cost and ability to meet the DQO constraints and select the most resource-effective design among the alternatives. The "most resource-effective" may be the lowest cost alternative that meets the DQOs, or it may be a relatively low-cost design that still performs well when the design assumptions change.

Document the Operational Details and Theoretical Assumptions of the Selected Design in the Sampling and Analysis Plan

Once the final design has been selected, it is important to ensure that the design is properly documented. This will improve efficiency and effectiveness of later stages of the data collection and analysis process, such as the development of field sampling procedures, quality control procedures, and statistical procedures for analysis of the data. The key to successful design documentation is in drawing the link between the statistical assumptions on which the design is based and the practical activities that ensure that these assumptions generally hold true.

The operational requirements for implementing the sampling design are documented in the Field Sampling Plan and the Quality Assurance Project Plan, both of which are included in the Sampling and Analysis Plan. Design elements that must be documented include:

- sample types (e.g., composite vs. grab samples);

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[3]A Power Curve provides a graphical depiction of the sensitivity of a design; the steeper the curve, the more sensitive the design will be in detecting conditions when the baseline (null) hypothesis should be rejected.

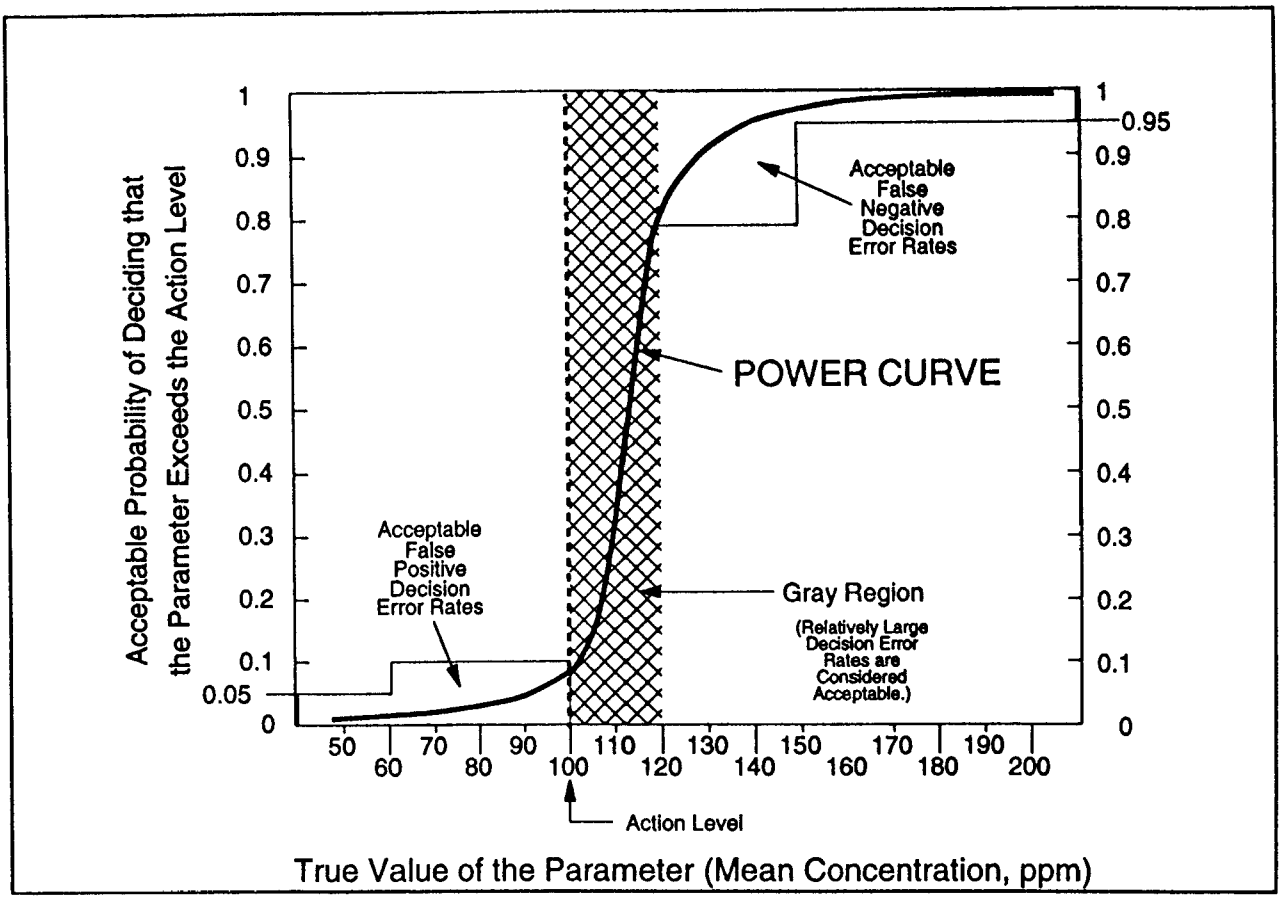

Figure 7-1. An Example of a Power Curve

- general collection techniques (e.g., split spoon vs. core drill, or activated charcoal media vs. evacuated canister);
- sample support (i.e., the amount of material to be collected for each sample);
- sample locations (surface coordinates and depth) and how the locations were selected;
- timing issues for sample collection, handling, and analysis;
- analytical methods (or performance standards); and
- quality assurance and quality control needs.

For probabilistic sampling designs, the statistical model and assumptions must also be documented. This item is often omitted, yet it can be one of the most important aspects of the design documentation. If the theoretical basis for the design is documented, then the project team has a basis for handling unexpected problems that inevitably arise in the field. This will help maintain the overall validity of the study in the face of unavoidable deviations from the original design.

7.3 OUTPUTS

The outputs for this step include the optimal (most resource-effective) sampling design for the field investigation, along with documentation of the key assumptions underlying the design. The data collected using this design are expected to be "adequate" for the site manager's or other decision maker's needs.

7.4 SUPERFUND DATA CATEGORIES

During the sampling design step, the design team identified design elements that relate to QA/QC procedures. As explained later in Chapter 8, these QA/QC-related design elements are combined with other required QA/QC procedures, and the complete set of QA/QC requirements for the project are incorporated into the quality assurance project plan (QAPP). The DQO Process provides a logical basis for linking QA/QC procedures to the intended use of the data, primarily through the decision maker's acceptable limits on decision errors. The translation of the site manager's acceptable limits on decision errors into specific QA/QC requirements is done during Step 7: OPTIMIZE THE DESIGN and completed in the QAPP development process.[4]

To assist in the interpretation of data, the Superfund program has developed the following two descriptive data categories:

- Screening data with definitive confirmation;
- Definitive data.

These two data categories are associated with specific quality assurance and quality control elements, and may be generated using a wide range of analytical methods. The particular type of data to be generated depends on the qualitative and quantitative DQOs developed during application of the DQO Process. The decision on the type of data to be collected should not be made prior to completion of the entire DQO Process.

Screening Data with Definitive Confirmation

Definition of Screening Data

Screening data are generated by rapid, less precise methods of analysis with less rigorous sample preparation. Sample preparation steps may be restricted to simple procedures such as dilution with a solvent, instead of elaborate extraction/digestion and cleanup. Screening data provide analyte identification and quantification, although the quantification may be relatively imprecise. At least 10% of the screening data are confirmed using analytical methods and QA/QC procedures and criteria associated with definitive data. Screening data without associated confirmation data are not considered to be data of known quality.

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[4] For more information about the QAPP development process, see *Guidance for Preparing, Reviewing, and Implementing Quality Assurance Project Plans for Environmental Programs*, EPA/QA/G-5 (Draft).

Screening Data QA/QC Elements

- Sample documentation (location, date and time collected, batch, etc.);
- Chain of custody (when appropriate);
- Sampling design approach (systematic, simple or stratified random, judgmental, etc.);
- Initial and continuing calibration;
- Determination and documentation of detection limits;
- Analyte(s) identification;
- Analyte(s) quantification;
- Analytical error determination:[5] An appropriate number of replicate aliquots, as specified in the QAPP, are taken from at least one thoroughly homogenized sample, the replicate aliquots are analyzed, and standard laboratory QC parameters (such as variance, mean, and coefficient of variation) are calculated and compared to method-specific performance requirements specified in the QAPP;
- Definitive confirmation: at least 10% of the screening data must be confirmed with definitive data as described below. As a minimum, at least three screening samples reported above the action level (if any) and three screening samples reported below the action level (or as non-detects, ND) should be randomly selected from the appropriate group and confirmed.

Definitive Data

Definition of Definitive Data

Definitive data are generated using rigorous analytical methods, such as approved EPA reference methods. Data are analyte-specific, with confirmation of analyte identity and concentration. Methods produce tangible raw data (e.g., chromatograms, spectra, digital values) in the form of paper printouts or computer-generated electronic files. Data may be generated at the site or at an off-site location, as long as the QA/QC requirements are satisfied. For the data to be definitive, either analytical or total measurement error must be determined.

Definitive Data QA/QC Elements

- Sample documentation (location, date and time collected, batch, etc.);
- Chain of custody (when appropriate);
- Sampling design approach (systematic, simple or stratified random, judgmental, etc.);
- Initial and continuing calibration;
- Determination and documentation of detection limits;
- Analyte(s) identification;
- Analyte(s) quantification;
- QC blanks (trip, method, rinsate);
- Matrix spike recoveries;
- Performance Evaluation (PE) samples (when specified);

[5] The procedures identified here measure the precision of the analytical method, and are required when total measurement error is not determined under confirmation step.

- Analytical error determination (measures precision of analytical method): An appropriate number of replicate aliquots, as specified in the QAPP, are taken from at least one thoroughly homogenized sample, the replicate aliquots are analyzed, and standard laboratory QC parameters (such as variance, mean, and coefficient of variation) are calculated and compared to method-specific performance requirements defined in the QAPP;
- Total measurement error determination (measures overall precision of measurement system, from sample acquisition through analysis): An appropriate number of co-located samples as determined by the QAPP are independently collected from the same location and analyzed following standard operating procedures. Based on these analytical results, standard laboratory QC parameters such as variance, mean, and coefficient of variation should be calculated and compared to established measurement error goals. This procedure may be required for each matrix under investigation, and may be repeated for a given matrix at more than one location at the site.

Impact of Data Categories on Existing Superfund Guidance

These Data Categories replace references to analytical levels, quality assurance objectives, and data use categories. The major documents impacted by the Data Categories are:

- *Data Quality Objective Guidance for Remedial Response Activities: Development Process and Case Studies*: EPA/540/G-87/003 and 004, OSWER Directive 9355.0-7B;
- *Quality Assurance/Quality Control Guidance for Removal Activities: Sampling QA/QC Plan and Data Validation Procedures:* EPA/540/G-90/004, OSWER Directive 9360.4-01 April 1990; and
- *Guidance for Performing Site Inspections Under CERCLA*, OSWER Directive 9[illegible] August 1992.

CHAPTER 8

BEYOND THE DQO PROCESS:
The Sampling and Analysis Plan and Data Quality Assessment

8.1 OVERVIEW

This chapter explains some important QA management steps that occur after the DQO Process has been completed. The DQO Process is part of the planning phase of the data collection life cycle, as illustrated in Figure 8-1. At the completion of the DQO Process, the site manager will have documented the project objectives and key performance requirements for the data operations in the DQOs, and will have identified a sampling design that is expected to achieve the DQOs. The sampling design and DQOs are used to develop the Quality Assurance Project Plan (QAPP) and the Field Sampling Plan (FSP), both of which are included in the Sampling and Analysis Plan (SAP). The SAP provides the detailed site-specific objectives, specifications, and procedures needed to conduct a successful field investigation. During the implementation phase of the data collection life cycle, the SAP is executed and the samples are collected and analyzed. During the assessment phase, Data Quality Assessment (DQA) is performed on the data to determine if the DQOs have been satisfied. The relationships between the DQO Process and these subsequent activities is explained in more detail below.

8.2 SAMPLING AND ANALYSIS PLAN DEVELOPMENT

The SAP is a formal Superfund project document that specifies the process for obtaining environmental data of sufficient quantity and quality to satisfy the project objectives. The DQO Process can be viewed as a preliminary step in the SAP development process, since it logically precedes the actual development of the SAP document, as shown in the right half of Figure 8-1. The outputs of the DQO Process feed directly into the development of the QAPP and the FSP, which are the two main elements of the SAP. Thus, the SAP is a single document that integrates the DQOs, QAPP, and FSP into a coherent plan for collecting defensible data that are of known quality adequate for the data's intended use.

The Quality Assurance Project Plan

The QAPP is required for all EPA data collection activities. The QAPP contains information on project management, measurement and data acquisition, assessment and oversight, and data validation and useability. DQOs are a formal element of the QAPP, yet information contained in the DQOs relates indirectly to many other elements of the QAPP. In essence, the DQOs provide statements about the expectations and requirements of the data *user* (such as a site manager). In the QAPP, these requirements are translated into measurement performance specifications and QA/QC procedures for the data *suppliers*, to provide them with the information they need to satisfy the data user's needs.

The Field Sampling Plan

The FSP specifies how to conduct field activities to obtain the environmental data needed for the project. Whereas the DQO Process generates a sampling design based on the data user's needs, the FSP provides the operational plan for executing that sampling design. The FSP identifies

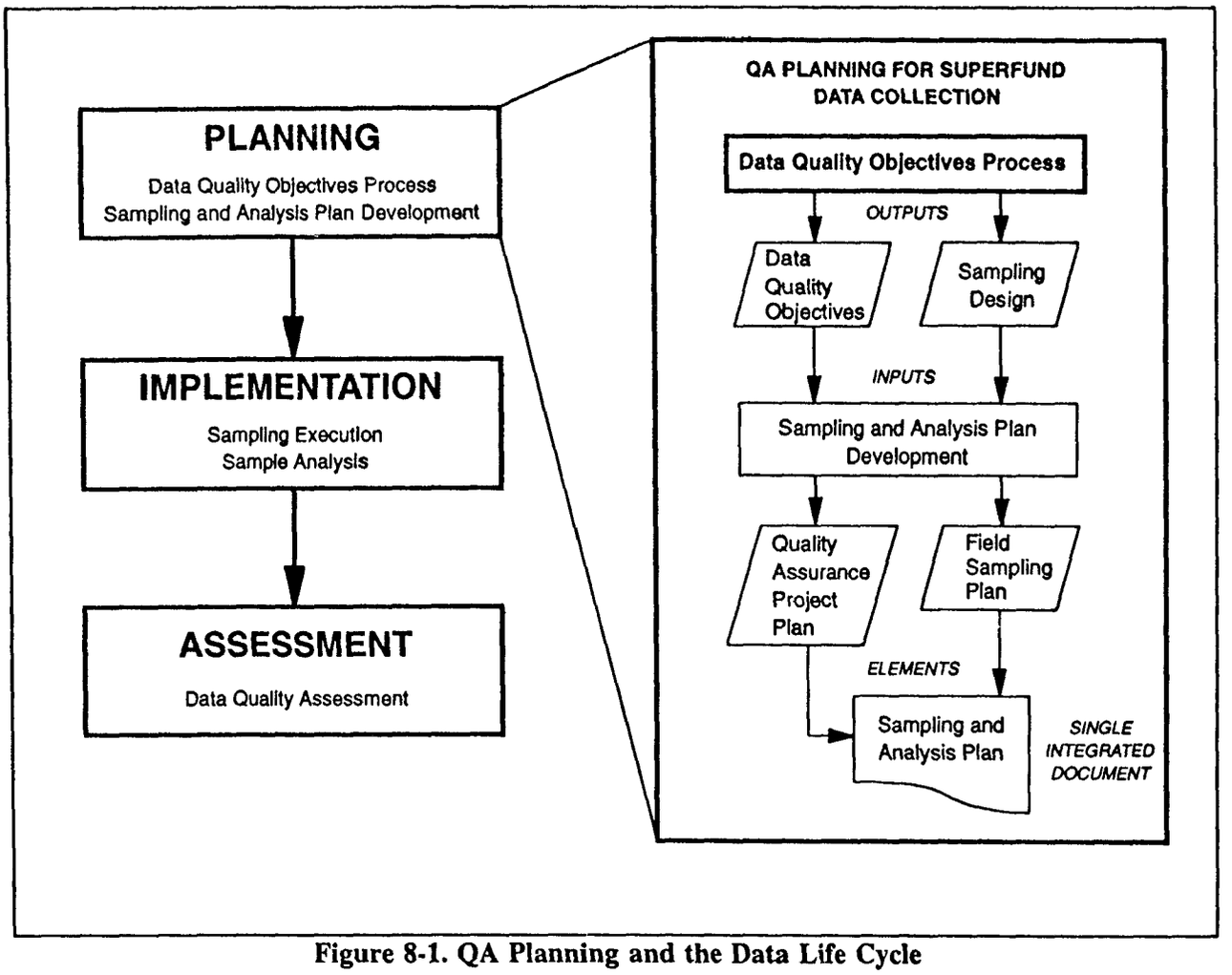

Figure 8-1. QA Planning and the Data Life Cycle

procedures for collecting samples in a manner that is consistent with the underlying theory and assumptions upon which the sampling design is based. This, along with the QA/QC procedures specified in the QAPP, helps ensure that the resulting data will be valid and appropriate for their intended use.

8.3 DATA QUALITY ASSESSMENT

After the environmental data have been collected and validated in accordance with the SAP, the data must be evaluated to determine whether the DQOs have been satisfied. EPA has developed guidance on Data Quality Assessment (DQA) to address this need.[1] DQA involves the application of statistical tools to determine whether the variability and bias in the data are small enough to allow the site manager to use the data to support the decision with acceptable confidence. The five main steps of the DQA process are illustrated in Figure 8-2.

[1] U. S. Environmental Protection Agency (EPA). 1993. *Guidance for Conducting Environmental Data Quality Assessments*. EPA/QA/G-9.

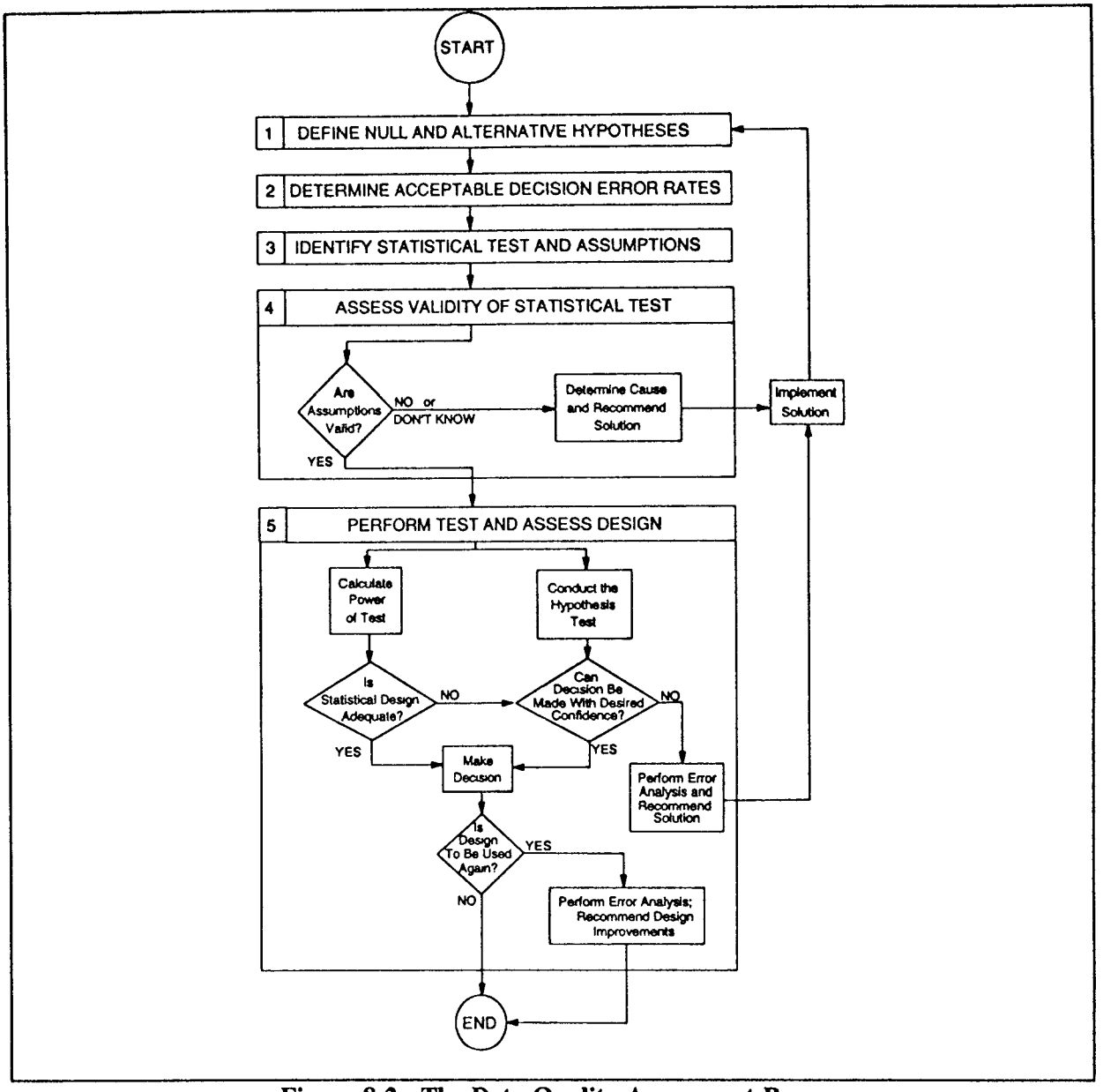

Figure 8-2. The Data Quality Assessment Process

For DQA to be effective and efficient, the crucial groundwork must have been laid in the planning phase. The DQOs provide the evaluation criteria by which the data will be assessed, and the SAP provides the blueprint by which the data will be generated. If the planning has been carried out thoughtfully, and the plans are executed successfully, then the DQA will provide answers that are useful for the site manager.

APPENDIX I

TECHNICAL SUPPLEMENT TO THE DATA QUALITY OBJECTIVES PROCESS

SECTION A: STATE THE PROBLEM

THE CONCEPTUAL SITE MODEL AND THE DQO PROCESS

This discussion focuses on the relationship between the conceptual site model (CSM) and the DQO process for Phase I of the advanced assessment decision. The DQO process involves a series of steps that gradually narrows, focuses, and divides a potentially complex problem into manageable pieces. Site problems can be very complex, especially in cases where contamination is present in several media or when cross-media contamination exists.

The CSM is developed using readily available (existing) data and illustrates the relationship between contaminants, retention/transport media, and receptors. The relationship between contaminants, retention/transport media, potential receptors, and the possibility for exposure to occur is central to a description of the problem, which is required in the first step of the DQO process.

The CSM also facilitates understanding of why new environmental data may be needed to resolve the contamination problem. The need for new environmental data may be confirmed by using the DQO process.

The CSM also serves as a framework for identifying data gaps. Data gaps identified in the CSM can be addressed by listing them as inputs to the decision in the third step of the DQO process. Information in the CSM about the location of contamination and potential receptors, as well as contaminant fate and transport, can be used to establish spatial and temporal boundaries for the field investigation in the fourth step of the DQO process. In summary, the development of the CSM directly influences the generation of the outputs of the first four steps of the DQO process.

The following discussion provides more information on developing the CSM and on defining exposure scenarios.

DEVELOP/REFINE THE CONCEPTUAL SITE MODEL

The following series of tasks are most appropriate for scoping site inspections and Phase I remedial investigations. In the later phases of the Superfund process, it is most important to confirm the exposure scenarios and generate a diagram depicting contaminant concentrations superimposed on a site map.

(1) **Collect existing site data.** Gather all historical site data and other pertinent information and compile an up-to-date data base on the site. Use this information to prepare written descriptions and graphic illustrations (diagrams) of contaminant sources, migration and exposure pathways, and potential physical and environmental targets or receptors. These illustrations and diagrams condense and document the important elements of exposure, and facilitate identification of the data needed to assess the potential risks of exposure associated with the site.

(2) **Organize, analyze, and interpret existing site data.** Organize site data according to:

- information on sources and source types (e.g., landfills, impoundments, lagoons, or ditches);
- affected media;
- site's physical and waste characteristics that can influence migration or containment; and
- potential migration and exposure pathways and receptors.

Summarize the analytical results of previous data collection activities with respect to:

- contaminants of interest;
- contaminant concentrations in each media and the practical concentration ranges of concern;
- anticipated analytical methods; and
- analytical method performance characteristics such as precision, bias, and method detection limits.

Perform a site reconnaissance with photographic equipment to document and gather current information to determine whether observations are consistent with the current understanding of the site. During the site visit, search for signs of contamination, such as the appearance of surface water, stressed vegetation, or discolored soil. Use topographic maps to mark well locations and estimate the extent of source areas or the presence of sensitive environs. Try to uncover information that will help assess the apparent stability of the site, such as leaking containment structures or weakening beams. Conduct limited sampling with portable equipment and gather additional anecdotal information from local sources that may reveal disposal areas or practices that were previously unknown and may affect contaminant migration.

(3) **Determine if existing data can support the conceptual site model.** Assess whether a limited field investigation is needed to adequately define the conceptual site model. This assessment helps determine whether or not samples need to be collected and, if so, if they will be used to supplement or verify existing data.

(4) **Define the conceptual site model.** The compilation, organization, and interpretation of historical site data now can be used to develop a diagram that illustrates the conceptual site model. Representing the linkages among contaminant sources, release mechanisms, pathways, exposure routes, and receptors in a diagram is a very useful and efficient technique for summarizing the current understanding of the contamination problem.

The written description should be supported with maps and cross-sections depicting contaminants and contaminant distribution, as appropriate.

DEFINE EXPOSURE SCENARIOS

(1) **Identify media of concern.** Use historical site data including analytical data to identify media that is currently contaminated or that can become contaminated through migration.

(2) **Identify the contaminants of concern.** Develop a broad list of contaminants known or suspected to be at the site. A comprehensive approach to identifying contaminants minimizes missing chemicals that may contribute to overall risk at the site or those that may not contribute to risk significantly, but are present in large quantities.

(3) **Define future land use.** Currently, a formula for determining the probable future land use for a site is unavailable. Therefore, begin by considering the current site land use and determine if factors such as zoning laws, renovation projects, and anticipated population growth may influence the future land use for a site. The "Risk Assessment Guidance for Superfund (RAGS) Human Health Evaluation Manual, Part A" (U.S. EPA, July 1989) provides more detailed support for defining future land use.

(4) **Define Applicable or Relevant and Appropriate Requirements (ARARs).** Identify the ARARs for the site. Start with the current list of contaminants and list all the chemical-specific ARARs from all the environmental statutes. Along with the standard, note the jurisdictional prerequisites under which the ARAR was established. This information will be used to determine the applicability, relevancy, and appropriateness of the standard for CERCLA. The search continues beyond chemical-specific ARARs. It should also include location- and action-specific ARARs. Further assistance in identifying ARARs for the site is provided in the "CERCLA Compliance with Other Laws Manual" (U.S. EPA, August 1988).

(5) **Assemble exposure scenarios.** Identify all available exposure pathways associated with the site. An exposure pathway describes a unique mechanism by which a receptor is exposed to site-related contaminants. Each exposure pathway includes:

- a source and release mechanism;
- a retention and transport medium;
- an exposure point; and
- an exposure route.

For each medium and land-use combination, identify the most appropriate exposure scenarios.

At this point, several components of an exposure scenario have already been identified and should be brought forward. One of these components is the potential receptor identified in the conceptual site model. Use the potential receptors and characterize the exposure setting as it relates to receptor locations and average daily activity patterns. The scoping team also considers those physical site characteristics and waste characteristics that influence contaminant migration. Other components of the conceptual site model that assist this effort are the

identified sources and affected or potentially contaminated media. Once these exposure-related elements have been identified, consider receptor locations and activity patterns and any point of potential contact with these media. After defining all potential exposure points, identify probable exposure routes (i.e., ingestion, inhalation, dermal contact).

Next, assemble all of the information collected above into complete exposure pathways and combine exposure pathways as appropriate.

SECTION B: IDENTIFY THE DECISION

RELATIONSHIPS BETWEEN THE DECISION STATEMENTS AND PRE-SACM SUPERFUND PROCESS

The purpose of the following information is to help users correlate the first three decisions presented in the guidance to the pre-SACM Superfund process.

Superfund site assessment encompasses identification, evaluation, and response to uncontrolled releases of hazardous substances and determination of the level of post-cleanup risks to human health and the environment. To evaluate a site efficiently and minimize unnecessary expenditure of resources, site assessment activities are performed in stages or tiers.

According to the Office of Solid Waste and Emergency Response Interim Guidance on "SACM Regional Decision Teams" (Publication 9203.1-0-51, December 1992), site response action options that are based on information or data generated in the early assessment stage (i.e, site inspection[1]) include recommending the initiation of RI activities. Therefore, in general, site inspection and removal data collection activities and the decisions they support occur in the early assessment stage timeframe. A statement of the early assessment decision is, "Determine whether the release (or potential release) poses a threat to human health or the environment." Recognize that a removal action can occur at any time during site assessment.

The Advanced Assessment Stage activities follow the early assessment. As stated in the previous paragraph, a remedial investigation[2]data collection activity and the decision it supports occurs in the Advanced Assessment Phase I timeframe. A statement of the Advanced Assessment Phase I decision is, "Determine whether contaminant of concern concentrations exceed ARARs or contaminant concentrations corresponding to the target risk level for the site."

The Advanced Assessment Phase II data collection activity is conducted only if a determination is made that contaminant concentrations exceed ARARs or concentrations corresponding to the target risk level and, as a result, the site warrants a further response action. The Advanced Assessment Phase II data collection activity occurs in the remedial investigation/feasibility study timeframe.

SACM Decisions in the Context of the DQO Process

This guidance specifically discusses four site decisions that often require field investigations. Three are site assessment decisions and the fourth is the cleanup verification decision after the remedial response action has been completed. This subsection discusses these SACM decisions in the

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[1]The Interim guidance also references Preliminary Assessment/Removal Assessment as part of the Early Assessment Stage activities. However, this guidance focuses on activities that involve collection of new environmental data. Typically, new environmental data are not collected during the preliminary assessment. Therefore, this guidance is most concerned with data collection activities in support of site inspections and removal assessment during the early assessment stage.

[2]A combined focused or expanded SI/RI data collection can also be conducted during the advanced assessment Phase I.

context of the DQO process, along with notations that relate the SACM decisions to the corresponding phase of the pre-remedial and remedial programs.

Early Assessment (Pre-Remedial) Stage

The early assessment (i.e., removal preliminary assessment or remedial preliminary assessment) allows site managers to screen sites and select those that warrant further assessment and possible response action using either the removal and/or remedial authorities.[3] These preliminary assessments typically are executed without the collection of waste or environmental samples. Instead, they rely on the collection of readily available information and therefore are unlikely to realize the full benefit of DQO application. The assessment may result in a decision to recommend the site evaluation accomplished (SEA) designation or to recommend further assessment and possible response action for the site. The further assessment recommendation may involve collection of additional data to perform a focused site inspection (SI) or an expanded site inspection/remedial investigation (ESI/RI), if the site has a high likelihood of remedial action. The SI and ESI/RI field investigations usually require the collection of waste or environmental samples and would benefit from a full application of the DQO process. A possible response action recommendation may involve an emergency/time-critical removal action, a non-timecritical early action (removal or early/interim remedial), the initiation of the NPL listing process concurrent with the early response action or ESI/RI, and/or initiation of enforcement activities. Generally, it may not be expedient to apply the DQO process to emergency/time-critical removal action field investigations. On the other hand, DQOs should be developed for non-time-critical early action field investigations.[4]

Advanced Assessment Stage (Remedial Investigation Phase I)

The field investigations in the advanced assessment stage field investigations are conducted in phases. The primary purpose of the first phase is to support the risk assessment, which is an input to the decision on whether the site warrants an additional response action. In this advanced site assessment stage, the response action recommendation typically involves a non-time-critical removal or early and/or long-term remedial action. Sites that require a response action enter the second phase of the advanced assessment.

Advanced Assessment (Remedial Investigation Phase II)

The purpose of the second phase of the advanced assessment is to determine the extent of contamination that exceeds ARARs or contaminant concentrations corresponding to the target risk level. Consistent with SACM and streamlining initiatives, this extent of contamination determination is performed concurrently with the first phase of the advanced assessment.[5] The extent of contamination determination supports alternative development processes of both removal engineering evaluation and cost analysis (EE/CA) and remedial feasibility studies (FS).[6]

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[3]SACM Publication 9203.1-051, September 1992: "SACM Program Management Update, Assessing Sites Under the SACM," page 2.

[4]SACM Directive 9203.1-051, September 1992: "SACM Program Management Update, Early Action and Long-Term Action Under SACM".

[5]SACM Publication 9203.1-051, September 1992: "SACM Program Management Update, Assessing Sites Under the SACM," page 3.

[6]The extent of contamination decision may also support presumptive remedy and lightning ROD streamlining initiatives.

Cleanup Attainment Stage

The final SACM decision that will require new data and be the focus of DQO development is the cleanup attainment decision. This decision addresses whether final response actions achieved final remediation levels or removal action levels.

SECTION C: IDENTIFY THE INPUTS TO THE DECISION

DECISION-SPECIFIC ACTIVITIES

EARLY ASSESSMENT DECISION

The objective of this field investigation is to evaluate the degree to which the site presents a threat to human health and the environment.

List the Inputs Needed to Support the Decision

Gather the following information during this phase:

- historical waste generation and disposal practices;
- hazardous substances associated with the site;
- potential sources of hazardous substances;
- important migration pathways and affected media;
- a comprehensive survey of targets;
- critical sample locations for the SI;
- contaminants or waste; and
- PA results.

Identify Informational Sources for Each Decision Input

Compile any readily available information about the site and its surroundings. PA documentation, records that indicate the contaminants at the site, site photographs, and anecdotal evidence are all potential informational sources. For more involved assessments, documentation of observed releases, observed contamination, and levels of actual contamination at the site will be required.

Identify the Inputs that will Require New Environmental Measurements

Some of the information identified in the previous activity may require environmental measurements. List those inputs requiring environmental measurements that cannot be satisfied by existing data from previous field investigations.

The following lists summarize the outputs for each decision.

List of Early Assessment Inputs

(1) List of Inputs Needed to Support the Decision:

- contaminant or waste migration pathway
- waste
- contaminants

- action level[1]

(2) List of Inputs That Require New Environmental Measurements:

- contaminant concentrations
- background concentrations[1]

ADVANCED ASSESSMENT DECISION: PHASE I

List the Inputs Needed to Support the Decision

This stage of the cleanup process will involve determining the nature and magnitude of contamination. To do so, it is necessary to identify potential contaminants and determine whether or not their concentrations exceed ARARs or levels that pose an unacceptable risk. Therefore, the relevant information includes:

- records indicating the contaminants that might be found at the site;
- information that identifies contaminants actually present at the site;
- information about how contaminant concentrations are distributed among media across the site;
- ARARs (if they exist) or exposure assumptions that will be used in the preliminary remediation goal (PRG) calculation;
- toxicity information for each contaminant;
- fate and transport information to be used in assessing exposure; and
- a target risk that provides a preliminary definition of the threshold of unacceptable risk.

Determine whether or not contaminant concentrations exceed ARARs or concentrations corresponding to the target risk level. If ARARs exist, the decision involves determining if the site complies with explicit regulatory criteria, such as a Maximum Concentration Limit (MCL) for ground water near a drinking water well. If ARARs do not exist, and the decision will be based on estimates of the risks posed by the site, then there may be several alternative methods by which site risks can be estimated. Each method will require different informational inputs. The following suggested activities apply to this latter, more complicated case.

- Consider each exposure pathway of concern.
- Identify the variables in the risk calculation for each pathway.
- Decide which variables will be estimated using site-specific information and which variables will be assigned default values.
- For each variable that will be estimated using site-specific information, determine whether the estimate will be based primarily on modeling or direct measurement, or both.

[1]This applies when a comparison of site contamination levels to background levels is the basis for decision making.

List the sampling and analysis action level.[2] If the decision is based on ARARs, then list the ARARs; if the decision is based on site-specific risk, then list the target risk level.

List all of the decision inputs needed to determine if the site fails to comply with ARARs or exceeds the acceptable target risk. In both cases, information on concentrations of contaminants will be required. If the decision is based on site-specific risk, then information on each input to the PRG calculation for each exposure pathway will be needed (the work done in developing the decision support strategy should provide a good starting point). This will include the contaminant potency factors, exposure pathways, fate and transport information, receptor types and activity levels or patterns, and intake parameters.

Identify Informational Sources for Each Decision Input

For ARARs, identify the specific regulation. For risk-based decisions, identify informational sources for the target risk and each input to the PRG calculation. Sources may include default values derived from written guidance, historical records, census data, field measurements or observations, or professional judgement. If the decision support strategy requires site-specific modeling to estimate any of the variables in the risk calculation, then identify any key model parameters that need to be estimated using site-specific information.

Determine if existing data from this site or similar sites exist. If the data do exist, evaluate them qualitatively to see if they appear to be the type that are appropriate for the decision.

List the Inputs That Will Require New Environmental Measurements

Some of the sources identified in the previous activity will include field measurements. List those inputs that require environmental measurements and that cannot be satisfied by existing data from previous field investigations.

List of Advanced Assessment Decision, Phase I, Inputs

(1) List of Inputs Needed to Support the Decision:

- potential contaminants
  - concentrations in space and perhaps time
  - potency factors or dose/response relationships
- exposure pathways
  - media (e.g., soil, surface water, ground water, air)
  - rates of migration (within and between media)
  - rates of dispersion/accumulation

[2]This is the contaminant concentration that corresponds to the target risk level, given various assumptions about exposure and contaminant fate, transport, and dispersion mechanisms.

- receptors
  - types/subpopulations
  - sensitivities
  - numbers/densities
  - activity levels/patterns
- target risk/ARARs
- site's physical and chemical characteristics that influence technology applicability (e.g., presence of organic components, soil permeability, and depth to impervious formation)

(2) List of Inputs That Require New Environmental Measurements:

- contaminant concentrations in space (and perhaps time) for each media of concern
- small- and large-scale variability in potential contaminant concentrations
- other measurements related to risk assessment, such as fate and transport model parameters

ADVANCED ASSESSMENT DECISION: PHASE II (EXTENT OF CONTAMINATION)

Much of the information developed at this stage of the cleanup process builds on the foundation laid in the previous stage (if DQOs were not developed for Advanced Assessment Phase I, then it will be necessary to develop some of that information as part of Phase II). This decision addresses the extent of contamination that will require remediation. Consequently, the information at this stage will be similar in character to Phase I, but will be more specific or refined.

List the Inputs Needed to Support the Decision

To calculate the volume of media that will require remediation, information will be needed about the specific locations where contaminant concentrations exceed ARARs or the sampling and analysis action levels. Information on remedial alternative effectiveness, efficiency, and cost also will be needed.

- List the contaminants with concentrations that exceed ARARs or the target risk. If the decision is based on ARARs, then confirm the list of information required to determine compliance with the ARARs for each contaminant. If the decision is based on site-specific risk, then confirm the list of inputs to the PRG calculation that will be required to determine the extent of contamination that exceeds the PRG.

- List the engineering information required to determine the effectiveness, efficiency, and cost of each remedial alternative.

- If the removal action level or final remediation level differs from the sampling and analysis action level,[3] then identify the new inputs required to determine the location and volume of media that exceed the removal action level or final remediation level.

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[3]If decision inputs were not developed for the Phase I advanced assessment decision, then conduct the activities described above for that phase, except use the final remediation level and the selected remedy in place of the preliminary action level and remedial alternatives, respectively.

- List the inputs needed to determine the volume of media that exceeds ARARs or the sampling and analysis action level.

- This phase focuses on the extent of contamination that will require remediation. The approach for determining contaminant concentrations usually will follow directly from the approach taken in Phase II. For decisions based on site-specific risks, the approach to estimating risk variables also should be consistent with the approach taken in Phase II.

Identify Sources for Each Decision Input

These sources should be similar to those identified in Phase I, unless the removal action level or final remediation level differs greatly from the sampling and analysis action level.

Identify the Inputs that will Require New Environmental Measurements

Examine the inputs derived from environmental measurements and list those inputs that will not be satisfied by existing data.

List of Advanced Assessment Decision, Phase II, Inputs

(1) List of Inputs Needed to Support the Decision:

- removal/remedial technologies or alternatives
- contaminants
- refined exposure assumptions or baseline risk assessment assumptions
- sampling and analysis action level or final remediation level

(2) List of Inputs That Require New Environmental Measurements:

- contaminant concentrations

CLEANUP ATTAINMENT DECISION

This stage addresses a question much different than the previous two stages: Do contaminant concentrations remaining after the remedial action exceed the final remediation level? Nonetheless, the information required to answer this question closely parallels the information required in the first two stages.

List the Inputs Needed to Support the Decision

The removal action level or the final remediation level serves as the criterion for deciding if the response action is complete; hence the scope of information needed at this stage is less than that

required in previous stages.[4] For the cleanup attainment decision, the primary focus is on the distribution of contaminant residual concentrations across the site.

- List the removal action level or final remediation level for each contaminant and identify any other decision criteria that may be specified in the Engineering Evaluation/Cost Analysis (EE/CA) or the ROD (for example, the ROD may require that a specific statistical test be performed to determine if the site has attained the final remediation levels).

- List the inputs required to determine if the contaminant concentrations exceed the removal action level or final remediation levels.

- Identify any special concerns, such as the desire to ensure that no hot spots above a certain size and concentration are left behind.

- List the cleanup attainment decision inputs that require field measurements that will not be satisfied by existing data.

Identify Sources for Each Decision Input

Identify the information sources for each of the cleanup attainment decision inputs. It is unlikely that any existing data will satisfy this need, unless the data were collected during the remedial action timeframe (such as monitoring data).

List the Inputs that will Require New Environmental Measurements

List the cleanup attainment decision inputs that require field measurements that will not be satisfied by existing data.

List of Cleanup Attainment Decision Inputs

(1) List of Inputs Needed to Support the Decision:

- removal action levels or final remediation levels for each contaminant
- distribution of contaminant (or surrogate) concentrations

(2) List of Inputs That Require New Environmental Measurements:

- contaminant (or surrogate) concentrations

[4]In previous stages, information about the risk calculation may have been included; however, this information is now subsumed within the removal action level or the final remediation level. Likewise, Advanced Assessment Phase I required information about remedial technologies and alternatives; after the ROD, the remedy has been selected, which reduces the scope of information required to make subsequent decisions.

SECTION D: DEFINE THE STUDY BOUNDARIES

Section D provides the scoping team with relevant information about how to develop risk-based, technology-based, and other scales of decision making. In addition, this section will focus on defining spatial boundaries and scales of decision making for four media of concern: surface soil, subsurface soil, surface water, and ground water.

1. SCALES OF DECISION MAKING

The following section provides relevant information about how to develop risk-based, technology-based, and other scales of decision making.

RISK-BASED SCALES OF DECISION MAKING

Development of risk-based scales requires substantial input from and relies on the professional judgement of the risk assessment member of the scoping team. In order to develop risk-based scales of decision making, the scoping team must evaluate: (1) the daily activity and behavior pattern of the most sensitive receptor; (2) the exposure pathway and route(s); (3) the current and future media use designation; and (4) contaminant toxicity values. In some cases, ARARs or a target risk level may be required to define the scale of decision making.

To make a risk-based decision, the sampling data should be representative of well-defined areas, volumes, and time periods which the scoping team determines a receptor could be exposed to given the anticipated use of the site. Since this scale is based on exposure assumptions, they are referred to as "Exposure Units" (EUs). If possible, the EU should represent a direct correlation between the area of contamination and the exposure that the receptor is likely to receive. Each media will have its own unique type of EU. As an example, surface soil has an EU that is defined by length, width, and depth of the surface soil layer.

TECHNOLOGY-BASED SCALES OF DECISION MAKING

If the Advanced Assessment Decision (Phase I) has already been made, the scoping team may define a scale of decision making based on the technology that was chosen to remediate the site. Scales of decision making that correspond to these areas are called Remediation Units (RUs). An RU is defined as the subset of a medium that can reasonably be remediated with the selected remediation technology (e.g., the minimum volume of soil that can be efficiently removed with a backhoe). RUs are defined by the scoping team in order to design the most cost-effective remediation design. The size of the RU will determine the scale of resolution that will be necessary for the sampling plan and also the amount of material that will ultimately be remediated. For each medium, the optimal size of an RU can be determined using a relative cost analysis and an estimate of (or assumptions about) the variability and distribution of contaminants in the media. When the "relative cost" of remediation is high compared to sample and analysis costs, and the variability of contaminants is fairly high (e.g., a patchy distribution), studying each RU and remediating only those that are contributing to risk may substantially reduce costs without decreasing the level of protection of the public. When the level of variability is very low, the optimal RU size will most likely be the same as the EU.

OTHER SCALES OF DECISION MAKING

In some instances it will be difficult or impossible to directly relate the size or volume of the media to the exposure of a receptor and there may not be a technological approach that can be translated into RUs. In these cases, the scoping team must select the scale of decision making that combines the consideration of risk from exposure with practical considerations about an EU or RU size. Again, the evaluation of the size or volume of an EU should be based on the future use of the site (residential, light industrial, recreational, etc.) and the receptors' activity pattern at the site.

EXAMPLES OF SCALES OF DECISION MAKING

In order to explain the process of setting a scale of decision making, three short examples have been provided. These examples are only meant to illustrate the concept of the scale of decision making.

Example #1: Risk-Based Scale of Decision Making

> *Background — The fictitious site is situated in Montana where a lead smelter has operated over the past 25 years and contaminated a site of approximately 35 acres with lead tailings and ash from the smelter. The smelter site is surrounded by residential homes and it seems likely that the site could be used as residential lots in the future. The primary contaminant of concern on the site is lead in the soil. The exposure pathway is ingestion of soil and the primary target receptor is small children. One of the primary activities of children that exposes them to soil is playing in their backyard around areas that are devoid of vegetation. In this case the risk assessor postulates that the majority of the soil exposure received by a small child is in an area of the backyard that encompasses the sandbox and swing set.*

Given this scenario, it would be reasonable for the scoping team to want to control uncertainty in the sampling data related to the area or volume where children get the majority of their exposure. Therefore the scoping team would set the scale of decision making to the 14'-14' area which is equal to the average size of a backyard play area. This is a risk based scale of decision making because it is possible to correlate the scale of decision making with the exposure of the most sensitive receptor.

Example #2: Technology-Based Scale of Decision Making

> *Lagoon Remediation — A Midwestern Coke Plant discharged process waste water into lagoons on their property. This resulted in the contamination of sediments with organic chemicals. Solid wastes from the same process were disposed of in several other lagoons and landfill areas. These contained organic chemicals as well as inorganic contaminants. The lagoons and landfill areas are surrounded by a wetland area which is the primary concern as a receptor for the contamination. There are no human receptors nearby. The site manager recognizes that the cleanup of the lagoons will involve more than one type of remediation practice and is most likely to involve bioremediation and incineration to reduce the influence of the organic chemicals.*

The scoping team at this site choose to evaluate each lagoon separately based on the assumption that each lagoon would have homogeneous contamination which could be remediated by a single, but possibly separate, remediation process. Therefore, each lagoon is considered to be a distinct RU.

Example #3: Other Scales of Decision Making

Carolina Transformer — The soil at an abandoned transformer production and reclamation facility has been contaminated with PCBs (polychlorinated biphenyls). The expected future use of the site is light industrial and the major route of exposure is through soil ingestion. The RPM is most concerned with exposure to children trespassers who play on the site.

In this scenario, the scoping team does not believe that there is a strong correlation between the size of a soil area and the relative "amount" of exposure that the children will receive. However, from the anticipated site activities of the children, they can select a size area (scale) that would be protective under the RME if that area had an average concentration of PCBs below the sampling and analysis action level. For this site, the scale of 1/2 acre was chosen as the Scale of Decision Making. While this decision was based on some assumptions or risk and the consideration of the receptor's activities, the scoping team had to finally make an estimate of the size area that would be protective of the children rather than rely on a direct correlation between soil area and risk. This is what differentiates this example from example #1, the risk-based scale of decision making.

2. MEDIA-SPECIFIC BOUNDARY DEVELOPMENT

This section provides specific information or considerations that are useful for the development of boundaries for specific media. Each medium is treated as a separate chapter. It is useful to have defined the geographic area of the investigation before using this section.

Surface soil and subsurface soil are treated separately in this guidance. Direct contact exposure to contaminants in surface soil through ingestion, inhalation of airborne particulate and dermal absorption exposure routes is the primary focus of the subsequent discussion. Subsurface soil discussions, on the other hand, primarily focus on indirect exposure routes through other media such as ground water.

(a) SURFACE SOIL

The media-specific boundary development for surface soil will provide relevant information to help the scoping team define spatial boundaries and the scale of decision making for surface soil.

DEFINING THE MEDIA

The physical attributes that define surface soil include grain size, depth, relationship to water (i.e., sand or sediment), organic material content, etc. The scoping team should consider how to classify objects that appear in surface soil, such as rocks or debris, and whether or not they should be sampled and/or remediated. The depth of soil that is classified as "surface soil" may be regulated or standardized in some states or regions. Be sure to check with the proper offices and obtain the necessary approval before making this decision.

DEFINE THE SCALE OF DECISION MAKING FOR SURFACE SOIL

Below are descriptions of how to define the scale of decision making for surface soil.

Risk-Based Scales of Decision Making

(1) Identify the future land-use designation and exposure route and determine if it provides a basis for defining an exposure area or volume.

(2) Define an area or volume of media within which the receptor is expected to limit his daily activities or to which the receptor is expected to come into contact during the period of exposure.

(3) Integrate the information from Steps 1 and 2 with the professional judgement of the risk assessor in order to define an exposure area or volume. For example, for residential land use where soil ingestion is determined to be the primary pathway of exposure, young children may get the majority of their exposure from a typical yard area. A case where a typical plot size was recommended as such an exposure area can be found in the *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual* (EPA July 1989) in Chapter 6, Section 6.5.3, page 6-28. If the site-specific plot size is ⅓-acre, then the ⅓-acre should be considered an estimate for the scale of decision making.

(4) Modify any estimated scales of decision making with information collected during the site visit and information that may have been collected by the Agency for Toxic Substances and Disease Registry if human monitoring was conducted. These scales may provide additional clues about the activity patterns of the receptors.

Where it is difficult to establish a scale of decision making based on land use and receptor behavior patterns, rely on standard default exposure area values that are available for media-specific pathways in the *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A*. Contact the Risk Assessment Workgroup in the Toxics Integration Branch of EPA for their current work on this topic or use a technology-based approach to define the scale of interest.

Technology-Based Scales of Decision Making

There are two types of technology-based scales of decision making. The first relies on physical features of a site to suggest the scale. These may be features that divide the site into smaller units, such as roads, buildings, or other physical impediments, or features that suggest the location of contaminants, such as lagoons, trenches, or waste pits.

The second technological approach for defining the scale of decision making is driven by the technology used to remove or clean up the contamination. This approach involves the identification of the most efficient subset of media or minimum volume of contaminated material that can be removed (i.e., the minimum amount of soil that can be removed with a backhoe) or remediated with the selected technology during an operation of the equipment or treatment cycle.

(b) SUBSURFACE SOIL

This section will describe relevant information to aid the scoping team to develop spatial boundaries and scale of decision making for subsurface soil.

Because subsurface soil has the potential to distribute contaminants along several exposure pathways, the development of boundaries must be based on exposure pathways that have been defined in Step 1: STATE THE PROBLEM. This section will evaluate methods of developing boundaries for subsurface soil by concentrating on two exposure pathways: 1) Direct Exposure — when the subsurface soil becomes surface soil through routine building and landscaping operations; and 2) Indirect Exposure — when the contaminants from the subsurface soil leach into the ground water and present an exposure through surface or drinking water.

Subsurface soil boundaries must be defined in three dimensions. They should be defined based on the possible exposure scenario. For example, if exposure to subsurfaces soil is expected to occur as a result of routine building or landscaping, the scoping team may define the subsurface boundary as the average depth and width of a building foundation. In other cases, the regional Superfund office may have a standard definition for subsurface soil that includes dimensions and other attributes. This definition should be reviewed by the scoping team to determine if it is appropriate for its circumstances.

DEFINING THE MEDIA

The physical features that describe subsurface soil are similar to those that define surface soil. Refer to the section on surface soil. The depth of soil that is classified as "subsurface soil" may be regulated in some states or regions. Be sure to check with the proper offices and to obtain the necessary approval before making this decision.

DEFINE SCALE OF DECISION MAKING FOR SUBSURFACE SOIL — EVALUATION OF SURFACE SOIL CONTAMINATION BY SUBSURFACE SOIL

Risk-Based Scales of Decision Making

Currently the Risk Assessment Group of the Toxics Integration Branch of EPA is developing risk-based approaches for studying subsurface soil. Contact their office for the latest developments in this area.

Technology-Based Scales of Decision Making

The scale of decision making for subsurface soil brought to the surface during building or landscaping operations is equal to the volume of subsurface soil that could potentially reach the surface. In order to determine a scale of decision making for subsurface soil, the scoping team must understand what potential building and landscaping operations might occur based on the future use of the site. This information, along with the size and depth of the foundation, basement, or soil removal will give the scoping team a good estimate of the volume of soil that will be removed. This subsurface volume becomes the scale of decision making. The scoping team will then evaluate the potential health risks that this volume of soil presents when it is removed.

Once the scale has been set, the scoping team will evaluate how each volume presents exposure as surface soil based on possible exposure scenarios. For example, the scoping team would evaluate the possible exposure that the contaminated soil presents by evaluating the range of surface soil contamination (thickness and extent) and possible contact of receptors spread on the surface.

DEFINE THE SCALE OF DECISION MAKING FOR SUBSURFACE SOIL — EVALUATION OF GROUND WATER CONTAMINATED BY SUBSURFACE SOIL

Risk-Based Scales of Decision Making

Currently the Risk Assessment Group of the Toxics Integration Branch of EPA is developing risk-based approaches for studying subsurface soil. Contact their office for the latest developments in this area.

Technology-Based Scales of Decision Making

A technology-based scale of decision making would be one that is defined as the smallest unit of subsurface soil that could efficiently be remediated to limit the contamination of ground water using current technology.

(c) SURFACE WATER AND ASSOCIATED MEDIA

Developing boundaries for surface water is particularly difficult because a surface water body may be either static or dynamic. The dynamic systems can have inputs from non-contaminated and contaminated sources. Under dynamic or static conditions, the concentration of contaminant of the water body can be reduced due to dilution or increase through contaminant inputs from other media such as surface soil, sediment, and ground water. Defining the boundaries of surface water will not only involve defining the bodies that are contaminated, but also defining the media that have the potential to contaminate surface water in the future.

This section will describe relevant information to aid the scoping team to develop spatial and temporal boundaries and scales of decision making for surface water bodies.

DEFINE THE MEDIA

Some of the physical features that describe surface water are depth, breadth, width, and volume. In the case where a flowing body of water is being evaluated, the scoping team should determine the extent (run) where they feel contamination is possible. Use historical information and existing analytical data to divide the surface water into areas that are relatively homogeneous within the geographic area of the investigation. Consider making separate decisions about surface water based on the sources of contamination or concentration of contamination. Surface water such as lakes and ponds may be stratified based on depth where contaminants may concentrate. Alternatively, flowing bodies such as rivers and streams may be stratified based on their proximity to contaminant sources.

DEFINE THE SCALE OF DECISION MAKING FOR SURFACE WATER

The scale of decision making for surface water is defined as the smallest unit (volume, depth, etc.) of surface water or associted media for which the scoping team wishes to limit the probability of a decision error. For surface water, there are many potential sources of contamination from associated media. Therefore, this section will help the scoping team define the scale of decision making for the associated media as well as the surface water.

Risk-Based Scales of Decision Making

Currently the Risk Assessment Group of the Toxics Integration Branch of EPA is developing risk-based approaches for studying surface water. Contact their office for the latest developments on this topic.

Technology-Based Scales of Decision Making

The technology scale of decision making for surface soil is defined as the smallest unit of surface water or other contaminated media that could efficiently be remediated to limit contaminant exposure to the receptor.

Scales of Decision Making for Surface Water By Source of Contamination

Surface Soil Contamination of Surface Water

It may be useful to delineate watershed areas within the site in order to define areas where soil contamination may impact the surface water quality. Evaluate both the dissolved and suspended portions of soil (runoff as well as leachate). In order to evaluate contaminant leaching, it is essential to have a good understanding of the physical and chemical properties of both the soil and the contaminant(s). In addition, the scoping team should evaluate the normal and the extreme conditions on the site such as extreme rain events, flooding, spring runoff, etc.

Ground-Water Contamination of Surface Water

Ground-water contamination of surface water is particularly difficult to study because contaminant concentration and flow volume are difficult to measure or model with accuracy. In addition, these parameters may vary over time. It may not be possible in this case to develop a scale of decision making. In this event, the goal of the scoping team will be to locate the sources of contamination and to estimate the extent of ground-water contamination.

Sediment Contamination of Surface Water

In evaluating sediment contamination of ground water, the goal of the scoping team is to determine the quantity of sediment that already exists in the river or lake that could possibly contaminate the surface water through leaching, or the mobilization of the sediment into the surface water.

(d) GROUND WATER

Ground water is the most difficult media to evaluate primarily because it exists within a soil matrix which is difficult to sample and evaluate. In addition, many of the techniques that are used in the boundary section such as exposure units do not apply well to the ground-water system.

DEFINE THE MEDIA

This guidance defines boundaries of ground water to include the overall spatial features of ground-water depth and range, and the temporal aspects of flow, including rate, water table height, and variation.

DEFINE THE SCALE OF DECISION MAKING

Consult the hydrogeologist and ground-water specialist when considering scales of decision making for ground water.

SECTION E: DEVELOP A DECISION RULE

CHOOSING A POPULATION PARAMETER

The first activity in developing a decision rule is choosing the parameter to characterize the population of interest. Choosing the parameter of interest involves several considerations that are discussed below.

AVOIDING PREMATURE CONCLUSIONS ABOUT THE STATISTICAL DESIGN

It is important to remember in the discussion that follows that the decision rule is not intended to constrain the statistical design. Therefore, the decision maker need only specify the population parameter that corresponds to the decision, instead of specifying a summary statistic. For instance, instead of specifying "a geometric average", the decision maker should only specify "a mean". This will allow the statistician to choose a summary statistic, either to conform to the assumptions of the statistical model that underlies the design, or in response to an analysis of the actual data if the design assumptions are not supported by the data.

CLARIFYING WHAT THE DECISION MAKER REALLY WOULD LIKE TO KNOW

When specifying an appropriate population parameter, the best guideline to follow is to ask the question, "What would the decision maker really like to know?" If it is an 'average' condition across an area or time interval at the site, then this will be important information in developing the sampling design. If it is a peak value at the site, then the sampling strategy may be quite different. If the decision maker wants to know where the "hot spots" exist, then yet another sampling design may be appropriate. Clarifying what the decision maker would like to know if the true conditions at the site could be known will help focus the discussion on matters most relevant to the decision rule.

UNDERSTANDING THE IMPLICATIONS OF DIFFERENT STATISTICAL PARAMETERS

Data may be summarized in a variety of ways, and each statistical parameter will have certain implications regarding the site. Consequently, it is important to specify a parameter that logically corresponds to the decision at hand. The following examples illustrate this point.

Mean

The mean is a measure of central tendency of a distribution. The mean concentration of a contaminant often is used by risk assessors as a mathematical model of long-term exposure. It usually requires fewer samples than other parameters to achieve a similar level of confidence, and is useful when the contaminated medium is relatively uniform with a small variance. The mean may be sensitive to extreme values; hence a few high concentrations can significantly raise a mean, while a number of low values (such as "non-detects") can reduce the mean. This sometimes gives rise to concerns about "averaging away" a contamination problem at a site. In addition, the mean is not representative of a site when there are a large proportion of non-detects.

Median

The median is another measure of central tendency that is used to estimate the 50th percentile of a distribution. The median is less sensitive to extreme values, and may be appropriate to use when the contaminants are distributed in a manner that violates the usual assumptions of a bell-shaped (normal) or lognormal curve.

Percentiles

Percentiles describe conditions where x percent of the distribution is less than or equal to the percentile value. For example, if a 95th percentile of a contaminant distribution is equal to 400 parts per million, then 95% of the concentration levels are less than or equal to 400 ppm. Percentiles may be used to ensure that the "tails" of a distribution are factored into a decision so that, for instance, "almost all" of the contamination falls below a certain threshold value.

SECTION F: SPECIFY LIMITS ON DECISION ERRORS

ESTABLISHING PROBABILITY LIMITS ON DECISION ERRORS

After defining the gray region, the decision maker will need to determine the acceptable probabilities of each decision error. In some non-Superfund applications, one or more of these probabilities will be established by regulation. For example, the RCRA rule for determining whether a waste is hazardous because of lead contamination specifies that an upper 90% confidence limit on the mean lead concentration be compared to the standard; this is comparable to specifying a 0.10 probability limit for the false positive decision error. In the Superfund program, however, these types of explicit standards usually are not pre-set.

If the acceptable probabilities for decision errors are not established by regulation, the decision maker will need to set them. Setting the probability limits on decision errors will depend on two main factors: the relative consequences of each decision error, and the cost of attaining the decision error rates. When setting the decision error rates, the decision maker must keep in mind that the cost of attaining the decision error rates should not exceed the consequences of the decision error. Usually this will require professional judgments about the likelihood of different consequences and the magnitudes of their corresponding costs and benefits. By using judgment to balance the costs and benefits of reducing the probability of decision errors versus the costs and benefits of their potential consequences, the decision maker establishes how definitive or conclusive the data must be in supporting the decision.

By defining the limits on decision errors for both the null hypothesis and alternative hypothesis, the decision maker is actually setting limits on two different aspects of the problem. One of the limits will restrict the decision errors that could cause risk of exposure to inhabitants and the environment. The other limit will restrict the decision error that would cause unnecessary cleanup of the site when the actual risks are below regulated standards.

SECTION G: OPTIMIZE THE DESIGN

This appendix discusses some basic concepts involved in creating a sampling design. Probability sampling designs and statistical models are discussed and examples of these concepts are included in the DQO applications at Superfund sites contained in Appendix II. In addition, a discussion on confidence intervals and hypothesis tests is also included to demonstrate the difference in these techniques. However, methods for creating and analyzing sampling designs and building statistical models are beyond the scope of this guidance. The reader is referred to Cochran (1977), Gilbert (1987), and U.S. EPA (1989) for more information. It is recommended that those unfamiliar with statistical sampling techniques consult a statistician or someone familiar with statistical sampling designs. If certain critical statistical design assumptions are violated, the data may become unusable for the specified purpose.

1. SAMPLING DESIGNS

NON-PROBABILISTIC SAMPLING

Non-probabilistic sampling (judgmental sampling) involves an expert selecting sample locations based on experience and knowledge of the site. The results from these samples cannot be extrapolated to the entire site, and it is difficult to measure the accuracy of any estimates using the data. However, judgmental samples can be used subjectively to provide information about specific areas of the site, which is generally useful during the preliminary assessment and site investigation stages if there is substantial information on the contamination sources and history. For instance, judgmental sampling is useful when the sampling objective is to confirm specific locations of contamination that have already been identified through visual or historical information. If any statistical conclusions are desired, however, judgmental sampling is not applicable.

PROBABILISTIC SAMPLING

Probability sampling designs allow the results from a set of samples to be generalized to the entire site. All probability sampling designs have an element of randomization which allows probability statements to be made about the quality of estimates derived from the data. Every potential sampling point within the sampling unit has a positive probability of being sampled. Therefore, probability samples are useful for testing hypotheses about whether a site is contaminated, the level of contamination, and other common problems that occur with Superfund sites.

There are many different probability sampling designs, each with advantages and disadvantages. A few of the most basic designs include simple random sampling, sequential sampling, systematic sampling, and stratified sampling. Other probability designs, such as multistage probability sampling and search sampling, are too complicated to be explained in this guidance. It is recommended that a statistician be consulted to determine the best design and the most appropriate analysis.

Simple Random Sampling

The simplest probability sample is the simple random sample. With a random sample, every possible sampling point has an equal probability of being selected and each sample point is selected independently from all other sample points. Random sample locations are usually generated using a random number table or through computer generation of pseudo-random numbers. Simple random

sampling is appropriate when little or no information is available for a site, and the population does not contain any trends. If some information is available, simple random sampling may not be the most cost-effective sampling design available.

Sequential Random Sampling

Sequential random sampling is a variation of simple random sampling. As before, every possible sampling point has an equal probability of being selected, and sample locations are selected randomly. However, instead of conducting a hypothesis test with all the data, a decision is made after each sampling round is collected and measured. This decision can have three possible results: reject the hypothesis, accept the hypothesis, or continue collecting data. Therefore, it may not be necessary to collect and analyze all the samples required for a simple random sample.

Sequential sampling designs are useful when analyses are very expensive and not much information is known about sampling and/or measurement variability. However, this method can only be used when the contaminant distribution is stable over the sampling time frame.

Systematic Sampling

Systematic sampling achieves a more uniform spread of sampling points than simple random sampling by selecting sample locations using a spatial grid, such as a square, rectangle, or triangle, in two or three dimensions. To determine sample locations, a random starting point is chosen, the grid is laid out using this starting point as a guide, then all points on the grid (grid nodes) are sampled.

Since sampling locations are located at equally spaced points, they may be easier to locate in the field than simple random samples or other probability samples. However, a systematic sampling design should not be used if the contamination exhibits any cyclical patterns.

Stratification

Stratified random sampling is used to improve the precision of a sampling design. To create a stratified sample, divide the study area into two or more non-overlapping subsets (strata) that cover the entire site. Strata should be defined so that physical samples within a stratum are more similar to each other than to samples from other strata. Sampling depth, concentration level, previous cleanup attempts, and confounding contaminants can be used as the basis for creating strata. Once the strata have been defined, each stratum is then sampled separately using one of the above methods.

A stratified sample can control the variability due to media, terrain characteristics, etc., if the strata are homogenous. Therefore, a stratified random sample may provide more precise estimates of contaminant levels than those obtained from a simple random sample. Even with imperfect information, a stratified sample can be more cost-effective. In addition, stratification can be used to ensure that important areas of the site are represented in the sample. However, analysis of the data is more complicated than for other sampling designs.

The purpose of defining strata for a stratified random sample is different from the purpose of defining strata for a scale of decision making. The strata in a stratified random sample are sampled separately, then the data are combined to create estimates for the entire site or scale of decision making. Stratum estimates are also available; however, decisions based on individual stratum estimates will not have the same decision error rates as those defined in Step 6: SPECIFY LIMITS

ON DECISION ERRORS.

Composite Sampling

If analysis costs are high compared to sampling costs and the parameter of interest is the mean, then the use of composite samples should be considered. Composite sampling involves physically mixing two or more samples before analysis. This method must be used in conjunction with a sample design in order to determine sample locations (for instance, random composite sampling). Compositing samples can be a cost-effective way to select a large number of sampling units and provides better coverage of the site without analyzing each unit.

Composite sampling is useful for estimating or testing the mean when information about variability is not necessary. It is also useful if the samples are to be used as a screening device. Additionally, since the amount of contamination in a composite sample should be larger than in an individual sample, there are times when a contaminant may be more easily detected in a composite sample. However, information on extreme values and variability is lost with composite data. The population of interest must be relatively homogeneous for compositing to be feasible. Sometimes individual samples are changed by the mixing process; for instance, volatile chemicals may evaporate. In addition, when the action level is close to the limit of detection, the potential dilution caused by compositing makes the use of composite sampling infeasible. Therefore, composite sampling designs should be considered with caution.

2. STATISTICAL MODELS

Statistical models describe how the observed responses are expected to behave by relating a measured value to the true parameter of interest and any sources of uncontrolled variation. Estimates can then be derived for the parameter of interest and these sources of variation using the model. The model is very important for understanding the assumptions underlying a proposed test statistic and sampling design. Thus, it will later serve as the basis for the data quality assessment.

A statistical model consists of fixed components and random components. What is regarded as fixed or random will be determined by the test of interest and by the inherent structure of the survey design. Usually, the parameter of interest (for instance, a mean) is considered fixed while the sources of uncontrolled variation are considered random. These sources include analytic/measurement errors, temporal and spatial components, and any other factors that may affect the data collection.

The model should:

1. Specify distributional characteristics of the random components; for instance, their means are usually assumed to be zero and the variances are assumed to be stable.

2. Identify which components are independent of one another. This information is usually based on historical information, pilot data, or professional judgement.

3. Specify the relationship between the various components; for instance, if they behave in an additive or multiplicative fashion (or some combination).

4. Identify any correlation structure if temporal or spatial autocorrelations are considered present.

3. CONFIDENCE INTERVALS AND HYPOTHESIS TESTS

Confidence intervals and formal hypothesis tests are two statistical methods that can be used for decision making. A hypothesis test controls both the false positive decision error rate (α) and false negative decision error rate (β). A confidence interval only controls the probability of making a false positive decision error (α) (for example, concluding that a site is clean when it is truly dirty). However, the probability of making a false negative decision error (β) is fixed at 50% for confidence intervals (i.e., $\beta = .5$).

A confidence interval and a hypothesis test can be very similar. Consider the problem of determining whether the mean concentration (μ) of a site exceeds a cleanup standard (CS), where the contaminant is normally distributed. A confidence interval could be constructed for the mean, or a t-test could be used to test the statistical hypothesis:

$$H_0: \mu > CS \quad \text{vs.} \quad H_a: \mu < CS.$$

If the site manager's false negative decision error rate is .5 (i.e., β=.5) then these methods are the same. Additionally, with a fixed α, the sample size of a confidence interval only influences the width of the interval (since β=.5). Similarly, the sample size of a t-test influences β and δ (where δ = upper value of the gray region minus the lower value of the gray region). However, by solving for the sample size using a t-test, one can substitute back into the sample size equation for a confidence interval and compute a width corresponding to this sample size. Then the results of the two methods will be identical.

Although the results of the hypothesis test and the confidence interval may be identical, the hypothesis test has the added advantage of a power curve. The power curve is defined as the probability of rejecting the null hypothesis. An ideal power curve is 1 for those values corresponding to the alternative hypothesis (all $\mu < CS$, in the example above) and 0 for those values corresponding to the null hypothesis (all $\mu > CS$, in the example above). The power curve is thus a way to tell how well a given test performs, and can be used to compare two or more tests. Additionally, if the null hypothesis is not rejected, the power curve gives the decision maker some idea of whether or not the design could actually reject the null hypothesis for a given level (μ).

There is no corresponding idea of a power curve in terms of confidence intervals. To derive a power curve, one would need to translate the confidence interval into the corresponding test (i.e., a t-test) and then compute the power curve. Additionally, whereas a statistical test accounts directly for the false negative decision error, a confidence interval does not ($\beta = .5$). Finally, a confidence interval and a statistical test almost always are based on distributional assumptions, independence assumptions, etc. If these assumptions are violated, it may be easier to select an alternative test (for example, a non-parametric test) than it is to derive an alternative confidence interval. For these reasons, this document concentrates its discussion on hypothesis testing.

SECTION H: THE DQO PROCESS AND THE SUPERFUND ACCELERATED CLEANUP MODEL

OVERVIEW OF THE SUPERFUND ACCELERATED CLEANUP MODEL

The Office of Solid Waste and Emergency Response has introduced an initiative that is designed to streamline and accelerate Superfund cleanups. This initiative is called the Superfund Accelerated Cleanup Model (SACM). The goals of SACM are to make hazardous waste cleanups more timely and efficient through better planning and integration of all Superfund programs (within existing statutory and regulatory requirements). The DQO process provides a framework for planning field investigations under SACM.

SACM eliminates certain distinctions between the remedial and removal programs and views them as separate legal authorities under one program: the Superfund program.[1] Response actions are divided into early actions and long-term actions based primarily on the length of time the response action will take. Early actions can be taken under either removal or remedial authorities. Long-term actions will be taken under remedial authority. SACM provides a streamlined approach for non-timecritical removals and all remedial actions. This approach has six aspects:

- a continuous process for assessing site-specific conditions and the need for action;
- cross-program coordination of response planning;
- prompt risk reduction through early action (removal or remedial);
- appropriate cleanup of long-term environmental problems;
- early public notification and participation; and
- early initiation of enforcement activities.[2]

THE ROLE OF THE DQO PROCESS IN IMPLEMENTING SACM

To produce data that can be used for multiple purposes, careful planning is required. Site managers need to define the objectives of their field investigations and coordinate among different existing programs (e.g., the removal, site assessment, and remedial programs). They also will need to document planning activities well so that if the site manager or Regional Decision Team (RDT) determines later that a further assessment or different response action is appropriate, the planning information and data collected in the earlier field investigation can be used by others within Superfund.

The DQO process provides a framework for planning multiple field investigations and documenting those planning activities. The DQO process encourages the participation of all those people involved in generating or using site data. If there is a reasonable chance that the site could require response actions under different legal authorities (removal/remedial) or different programs under the same authority (site assessment/remedial), then representatives from these programs are encouraged to participate on the DQO planning team. The DQO process provides a logical, step-by-step procedure for organizing the complex issues that cut across different programs and project phases and for keeping the team focused on the issues most relevant to planning the field investigation.

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[1]U.S. EPA, "Superfund Accelerated Cleanup Model (SACM)," Publication No. 9203.1-01, Memo from Don R. Clay, April 7, 1992, p. 3.

[2]OSWER Publication 9203.1-051, *Status of Key SACM Program Management Issues — Interim Guidance*, December 1992, p. 1.

APPENDIX II

APPLICATION OF DATA QUALITY OBJECTIVES TO SUPERFUND SITES

EXAMPLES

SECTION A

GROUND-WATER EXAMPLE

THE WATERVILLE MUNICIPAL LANDFILL SUPERFUND SITE

1.0 BACKGROUND

The Waterville Municipal Landfill was in operation from 1967 to 1985. During this time, the facility accepted residential and commercial waste. Historical information indicates that waste solvent was disposed of at the Waterville Municipal Landfill. One chemical in particular, perchloroethylene (PCE), was disposed of in large quantities. PCE is a class C, possible human carcinogen which mainly targets the kidney. Ingestion and inhalation of drinking water from contaminated ground water are considered viable exposure routes.

The Waterville Municipal Landfill is situated in the Atlantic coastal plain overlying an unconfined aquifer that serves as a drinking water source for nearby residents via domestic wells (see Figure A-1). Local residents are concerned that the landfill may be releasing contaminants into the ground water. EPA has initiated an Expanded Site Investigation (ESI) because of the potential for exposure to PCE through drinking water.

The aquifer underlying the landfill site was previously contaminated by PCE from a leaking tank at a dry cleaning facility, which is hydraulically upgradient from the landfill site. The leaking tank was removed in 1990. PCE was detected during quarterly sampling in 1991 and 1992, but was detected below levels of concern. Well A is hydraulically upgradient from the landfill and is located at the site boundary. Two drinking water wells — wells B and C — are within ¼ mile and are hydraulically downgradient from the site (see Figure A-2). Any leakage from the landfill will affect only the downgradient wells.

2.0 DQO DEVELOPMENT

The following is an example of the output from each step of the DQO process.

Step 1: State the Problem — a description of the problem and specifications of available resources and relevant deadlines for the study.

(1) Identify the members of the DQO scoping team — The members of the scoping team will include the Site Assessment Manager (SAM), a field sampling expert, a chemist, a hydrogeologist, a QA Officer, and a statistician. The SAM is the decision maker.

(2) Define/refine the conceptual site model — Figure A-1 illustrates some of the main elements of the conceptual site model, such as the source of contamination, routes of migration, and potential receptors (humans living in households connected to the domestic water supply fed by wells B and C). Additional information needed to

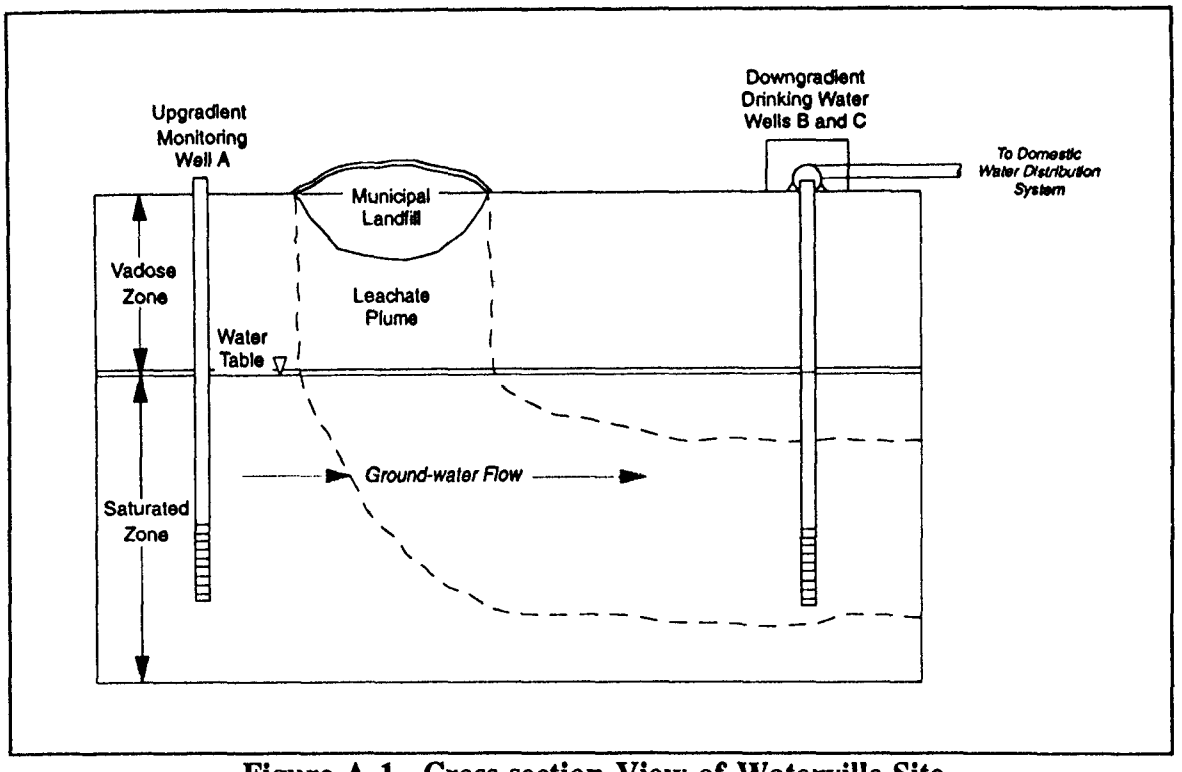

Figure A-1. Cross-section View of Waterville Site

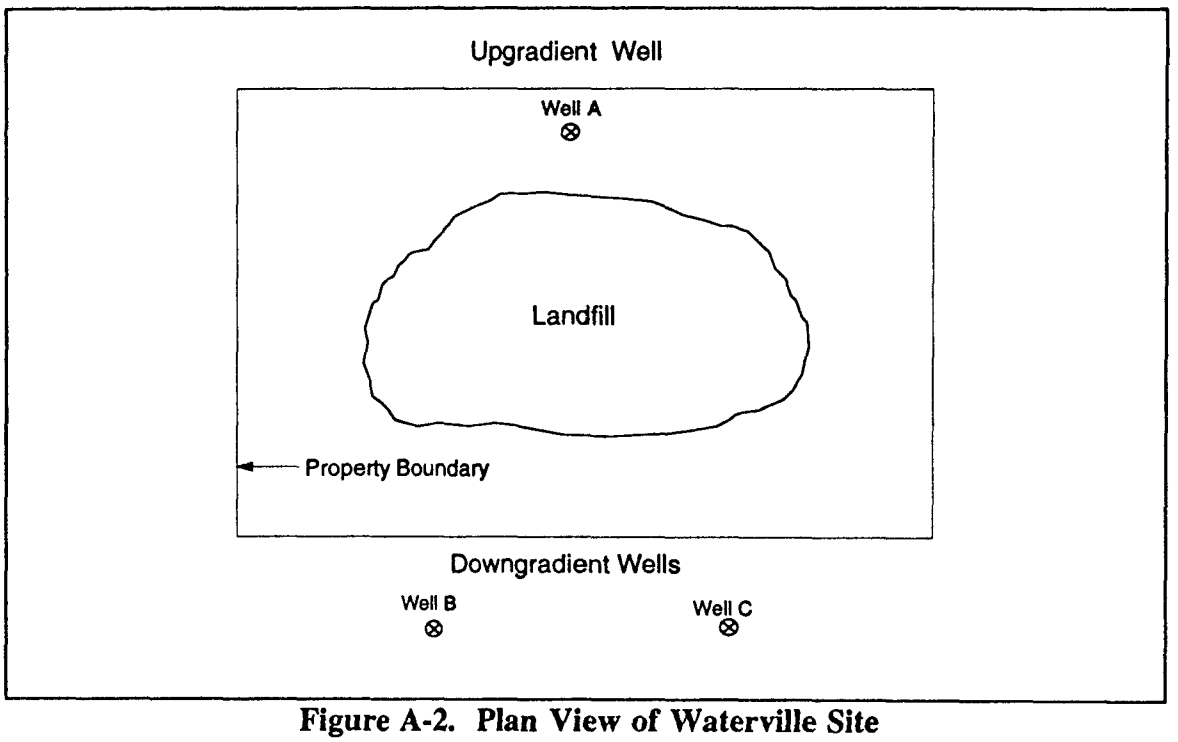

Figure A-2. Plan View of Waterville Site

complete the conceptual site model includes the type of contaminant (PCE) and a range of expected concentrations.

(3) Define exposure scenario — PCE located in the landfill can be released from decaying containers, escape from the unlined landfill, and migrate into the ground-water aquifer which is the drinking water supply for the town. Residents may be exposed to PCE contamination through dermal contact, inhalation, and ingestion of drinking water during routine daily activities in their homes, such as cooking and showering.

(4) Specify the available resources — EPA would like to take the minimum samples necessary that would still provide adequate data quality to support a defensible decision. There are adequate resources to collect and analyze a few samples from each of the three wells.

(A) *Time* — Residents with wells near the site are concerned about the safety of their drinking water. Local representatives would like this problem addressed within 6 months.

(B) *Identify project constraints* — In the pre-remedial phase of the Superfund process, financial resources are limited.

(5) Write a brief summary of the contamination problem — The Waterville Municipal Landfill is known to have accepted large quantities of PCE, and now residents of the town are concerned that the PCE may be leaking and contaminating their domestic water supply via two drinking water wells located near the landfill.

Step 2: Identify the Decision — a statement of the decision that will use environmental data and the actions that could result from this decision.

(1) State the decision — Determine whether there has been a release of PCE from the Waterville Municipal Landfill into the drinking water aquifer of Waterville.

(2) State the actions that could result from the decision —

(a) Recommend Site Evaluation Accomplished (SEA); or
(b) Recommend further assessment or a response action.

Step 3: Identify the Inputs to the Decision — a list of the environmental variables or characteristics that will be measured and other information needed to make the decision.

(1) Identify the informational inputs needed to resolve the decision — Concentrations of PCE in ground water are needed from at least one upgradient location and at least one downgradient location near the landfill.

(2) Identify sources for each informational input — The information on PCE concentrations in ground water can be obtained through analytical measurements performed on water samples drawn from upgradient well A and downgradient wells B and C. There are existing data for well A gathered during 1991 and 1992.

During 1991 and 1992, quarterly PCE data were collected from well A, the upgradient well. The SAM is concerned that the upgradient level of PCE contamination may have changed over the course of the sampling which began two years ago. If the contamination problem has changed during the two years, the previously collected data may not be appropriate and new data may need to be collected. Therefore, the SAM needs to verify that there are no temporal trends in the data for well A. A plot of the eight observations shows no visible trends. The SAM, however, has decided to compare the data from 1991 and 1992 to verify that the distribution of PCE contamination has not changed.

	Observations of PCE Concentrations (ppb)						
Year	*Jan. 1*	*April 1*	*July 1*	*Oct. 1*	*Mean*	*Std. Dev.*	*Variance*
1991	0.406	0.399	0.340	0.383	0.382	0.0296	8.767E-04
1992	0.434	0.347	0.422	0.383	0.397	0.0395	1.563E-03
Differences (1991 minus 1992)	-0.028	0.052	-0.082	0.0	-0.0145	0.0559	3.124E-03

Evaluation of changes in the PCE concentration over the sampling period 1991-1992

Comparison of Sample Variance: An F-test can be used to test the uniformity of two variances by comparing the ratio of the two variances with critical values from an F-distribution. The ratio of 1991 and 1992 variances is:

$$F = \frac{1.563E\text{-}03}{8.767E\text{-}04} = 1.783$$

Since the SAM wishes to test $H_0 : \sigma^2_{1991} = \sigma^2_{1992}$ versus $H_1 : \sigma^2_{1991} \neq \sigma^2_{1992}$, the critical region (with $\alpha = .1$) is given by:

$$F < F_{(1-\alpha/2)} = 0.1078$$

$$F > F_{(\alpha/2)} = 9.28$$

Since $1.783 \not< 0.1078$ and $1.783 \not> 9.28$, the SAM cannot conclude that the variance in 1991 is different from the variance in 1992. Therefore, the SAM may assume these variances are equal.

Comparison of Sample Means: A t-test can be used to test the equivalence of two sample means. Since it has already been concluded that the variances are not different, a pooled t-test of the form:

$$t = \frac{|mean_1 - mean_2|}{S_p\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} = \frac{.0145}{.0346 \cdot \sqrt{\frac{1}{4}+\frac{1}{4}}} = .593$$

$$where \quad S_p = \frac{(n_1-1)s_1^2+(n_2-1)s_2^2}{n_1+n_2-2}$$

may be used. This value will be compared to the critical value of a t-distribution with 6 degrees of freedom. Since 0.593 is less than the critical value, 1.943, the SAM cannot conclude that the yearly means are different. As a result, the SAM has determined that the sampling data from 1991 and 1992 are adequate for use in the comparison with downgradient wells.

(3) Define the basis for establishing contaminant-specific action levels — The action level for this problem is the lowest possible PCE concentration that demonstrates a significant increase in comparison to the upgradient concentration.

(4) Identify potential sampling techniques and appropriate analytic methods — The bottom valve bailer (teflon or stainless steel 316) has been identified as a potential sampling technique. A dedicated sampler will be used for each well. GC/MS is the proposed analytical technique.

Step 4: Define the Boundaries of the Study — a detailed description of the spatial and temporal boundaries of the decision; characteristics that define the environmental media, objects, or people of interests; and any practical considerations for the study.

(1) Define the spatial boundaries —

(A) *Define the domain within which all decisions must apply.* The study will focus on ground water within the unconfined aquifer below the landfill.

(B) *Specify the characteristics that define the population of interest.* PCE concentrations in ground-water monitoring wells B and C. For the purposes of this study, these wells are assumed to be representative of the aquifer below the landfill.

(C) *Define the scale of decision making.* Samples will be taken from the two downgradient ground-water monitoring wells (B and C). A separate decision will be made for each drinking water well.

(2) Define the temporal boundaries —

(A) *Determine what timeframe the sampling data must represent.* Because the study is not intended to determine health risks posed by PCE, there is no specific timeframe to which the results will apply.

(B) *Determine when to collect data.* EPA is interested in characterizing the contamination at this site quickly because of the potential adverse health effects of exposure to PCE in drinking water. Because the data from the three wells will be compared, samples will be collected on the same day. Past experience at similar sites indicates that there are no systematic variations in PCE concentration over time, so samples may be taken at any time of day.

(3) Identify practical considerations that may interfere with the study — EPA does not expect to encounter any practical constraints while sampling.

Step 5: Develop a Decision Rule — an "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

(1) Specify the parameter of interest — The study is trying to quickly determine whether the downgradient concentration of PCE is significantly greater than the upgradient concentration, so the SAM has decided to specify the parameter as an observation of PCE concentration in each of the downgradient wells.

(2) Specify the action level for the study — The action level for this problem is the lowest possible PCE concentration that demonstrates a significant increase when compared with the upgradient concentration. The specific concentration will be identified during the Optimize the Design step.

(3) Develop a decision rule (an "if...then..." statement) — If any downgradient sample yields a PCE value significantly greater than the upgradient well, then there is actual contamination of the ground water and further assessment or response is required; otherwise recommend SEA.

Step 6: Specify Limits on Decision Errors — the SAM's acceptable decision error rates based on a consideration of the consequences of making an incorrect decision.

(1) Determine the possible range of the parameter of interest — The scoping team has estimated the range of the parameter of interest to be 0-10 ppb PCE in the ground water, based on the evaluation of similar PCE releases from other sites.

(2) Define both types of decision errors and identify the potential consequences of each —

(A) *Define both types of decision errors and establish which decision error has the more severe consequences.* The two decision errors are:

Decision Error 'a': Deciding that the downgradient well PCE concentration is greater than the upgradient well when it is not. The consequences of this decision error include the unnecessary costs of further study, and the possibility of unnecessary remedial or emergency removal action. Treating ground water is usually a lengthy and resource-intensive process. Other remedial options such as providing an alternate drinking water supply can be very costly also. A positive consequence of taking unnecessary action is that some environmental improvement may occur (e.g., through

removing very low levels of PCE and other contaminants), even though the improvement may be of little value when compared to the costs.

Decision Error 'b': Deciding that the downgradient well PCE concentration is not greater that the upgradient well when it is. Some consequences of this decision error include environmental damage, increased future health costs, and increased cancer illness and deaths. A positive consequence is that resources are conserved. While the resource savings may be of small consequence when weighed against the negative consequences, it is important to consider them here. A complete, balanced picture of the problem can only be developed if both positive and negative consequences of the decision error are considered. Decision Error 'b' is the more severe decision error.

(B) *Establish the true state of nature for each decision error.* The true state of nature for decision error 'a' is that the downgradient well does not have a higher concentration of PCE than the upgradient well. The true state of nature for decision error 'b' is that the downgradient well has a higher concentration of PCE than the upgradient well.

(C) *Define the true state of nature for the more severe decision error as the baseline condition (null hypothesis) and define the true state of nature for the less severe decision error as the alternative hypothesis.*

Null hypothesis, H_0 = The downgradient well has a higher concentration of PCE than the upgradient well.

Alternative hypothesis, H_a = The downgradient well does not have a higher concentration of PCE than the upgradient well.

(D) *Assign the terms "false positive" and "false negative" to the proper errors.*

False positive error = decision error 'b'
False negative error = decision error 'a'

(3) Identify Acceptable Decision Error Rates —

False Positive Error: If the downgradient concentration of PCE is greater than the upgradient concentration due to a release, the SAM desires at least a 95 percent probability of finding that a release has occurred (5% probability of a false positive error). In this example, the SAM becomes increasingly concerned the higher the downgradient PCE concentration is in comparison to the upgradient well.

False Negative Error: If there truly has been no release, the SAM wants at most a 5 percent probability that the data indicate a release.

(4) Specify the Gray Region — There will be no gray region for this problem since the decision is to determine a "significant difference" between the concentration of the downgradient wells and background concentrations rather than a fixed point (action level).

Step 7: Optimize the Design — the decision maker will analyze existing data and select the lowest cost sampling design that is expected to achieve the DQOs.

(1) Develop general sampling and analysis design alternatives — Existing data from well A were found to be useful in determining the contamination level upgradient of the site. New data will be generated for the downgradient wells and tested to determine whether they belong to the same population as the upgradient data. If the downgradient values are significantly higher, then it will be concluded that the upgradient and downgradient concentration levels come from different populations. An upper 95% tolerance limit on the population (with 95% probability that at least 95% of the distribution will be less than the limit) will be used to make this determination.

A tolerance interval may be used to prove that a well is contaminated; however, it cannot conclusively determine that a well is not contaminated; The scoping team believes, based on the past history of the site, that wells B and C are contaminated. Thus, a tolerance interval will be used to quickly verify that the wells are contaminated. If data from wells B and C fail to exceed the upper tolerance limit, then this method is inconclusive and an alternative sampling design should be developed.

The tolerance interval used will be based on a normal distribution. Hence, the assumption that the eight observations from well A follow a normal distribution should be tested. Due to the small sample size, Geary's Test for Normality will be used to test this assumption. The test statistic will be

$$a = \frac{\sum_{i=1}^{n} |x_i - \bar{x}|}{\sqrt{n\,[\sum x_i^2 - (\sum x_i)^2/n]}}$$

and an approximate test for normality will be

$$Z = \frac{(a - 0.7979)}{\left(\frac{0.2123}{\sqrt{n}}\right)} \sim N(0,1)$$

If $Z > 1.96$, the assumption of normality at a 5% level of significance will be rejected.

For the data from well A,

$$a = \frac{0.248829}{\sqrt{8 \cdot 0.007739}} = 0.835914$$

$$Z = \frac{(0.835914 - 0.7979)}{\left(\frac{0.2123}{\sqrt{8}}\right)} = 0.506459$$

Since Z < 1.96, the idea that the data are normally distributed cannot be rejected. Therefore, it will be assumed that the upgradient data are normally distributed and can be used to construct a tolerance interval.

Using the eight observations from well A, an upper tolerance interval (TL) can be constructed by:

$$TL = \text{mean} + K * \text{Std. Dev.}$$

where K is a one-sided normal tolerance factor. A table of tolerance factors can be found in the *Guidance Document on the Statistical Analysis of Ground-water Monitoring Data at RCRA Facilities*, EPA, 1993. In this case, K(0.95, 0.95, 8) = 3.188, and

$$TL = 0.389 + 3.188 * 0.03325 = 0.495$$

Any one observation over 0.495 will cause the SAM to conclude that additional contamination above the upgradient level has been observed. In other words, any one observation from either downgradient well that exceeds 0.495 will be cause for deciding that there has been a release from the landfill.

Statistical Models

For each observation y_i from the upgradient well A,

$$y_i = \mu + e_i$$

where μ represents the mean PCE concentration for the upgradient well and the e_i's represent sampling and measurement error which are assumed to be distributed with a mean of 0 and a variance equal to σ^2. Unless the data demonstrate otherwise, the observations from the downgradient wells B and C should also follow this model.

Sample Size

Ideally the SAM would like to collect just one sample from each of the two downgradient wells. Collection of one additional sample from the upgradient well is recommended to ensure that the direction of the plume from the dry cleaning facility has not changed.

(2) Select the most resource-effective design that satisfies all of the DQOs — This design is resource-effective because it requires a small number of samples (one from each well). However, if neither sample exceeds 0.495, then an alternative sampling design will be developed which would satisfy the scoping team's limits on decision errors. (A tolerance interval will only satisfy the limits of a false-positive error.)

(3) Document the details and assumptions of the selected design — This design assumes that the purpose of sampling is to verify that a release has occurred. If the data do not demonstrate that a release has occurred, the decision maker cannot conclude that the wells are not contaminated and an alternative sampling design will be developed.

SECTION B

REMOVAL PROGRAM EXAMPLE

THE LEADBURY SUPERFUND SITE

1.0 BACKGROUND

The Leadbury Superfund Site covers a large area in two counties within the State of Oklahoma. The soil within this area has elevated levels of lead. The site surrounds the town of Leadbury where the Lead Smelter Co. has been mining and smelting lead since 1933. Currently, the area of surface soil contamination extends for approximately 36 square miles surrounding the town. The lead has allegedly originated from stack emissions or possibly from improper disposal of waste materials from the smelting and mining processes. Lead concentrations exceed 500 ppm at some portions of the site.

The Environmental Protection Agency (EPA) has decided to conduct the Remedial Investigation/Feasibility Study (RI/FS) and the remedial design for this site concurrently with the removal action in observance of the Superfund Accelerated Cleanup Model (SACM) guidance. Therefore, all data collected during the removal phase will be used in later phases of the study.

The predominant threat to the public from this site comes from the inhalation and/or ingestion of lead-contaminated soil particles. Lead is known to produce many adverse health effects in humans ranging from reproductive system disorders, delays in neurological and physical development, cognitive and behavioral changes, and increased blood pressure. The main exposure pathway for lead is inhalation. Inhalation exposure is most likely to occur during dry and windy conditions that are prevalent during the summer months. Children are at special risk from lead exposure because their behavior traits result in greater intake of soil per body weight. In addition, children are more likely than adults to have nutrient deficiencies which increase the metal absorption and retention. It has also been indicated that adverse neurological effects occur at lower blood lead level thresholds in children.

An Emergency Removal Branch (ERB) assessment of the site was conducted in two phases. During Phase I, an area of 36 miles surrounding the town was sampled to determine the contaminants of concern. The samples were analyzed for 24 target compound metals and the results identified lead as the contaminant that should be addressed in more extensive sampling. In Phase II, additional surface soil locations were sampled within the Phase I area from 53 locations that were determined to be "high-access" areas for children, the target population at risk. These included school yards, playgrounds, day care centers, and church yards. Twenty-six of the high-access areas were determined to have concentrations of lead in excess of the removal program's action level of 500 ppm. These 26 areas were considered to present imminent and substantial endangerment to the public.

As part of the sampling done in Phase II, the removal program determined that the lead contamination was distributed bimodally (i.e., a graph of the distribution of lead concentrations shows two distinct peaks). The concentration of the low mode is 30 ppm while the concentration of the high mode is 700 ppm. The lower concentration of lead is thought to have come from aerial deposition

associated with the lead smelter and other mining operations. The higher concentrations are thought to be due to the use of contaminated fill material. The fill most likely came from mining tailings. It was therefore decided that a sampling plan should be initiated to locate the portions of the high-access areas that had lead contamination in excess of 500 ppm. The contaminated soils would then be removed and clean fill would replace it. The removal program has decided to use the DQO Process to help them develop the sampling plan to locate areas of excess lead contamination.

As a precursor to the DQO Process, the ERB estimated the cost of disposal for the contaminated soil. They subjected soil samples to the Toxicity Characteristic Leaching Procedure (TCLP) to determine if the contaminated soil was considered a "hazardous substance" under RCRA regulations and would therefore need to be disposed of at a more expensive hazardous waste facility. The tests showed that the contaminated soil was considered non-hazardous and could therefore be disposed of at a less costly municipal landfill.

2.0 DQO DEVELOPMENT

Step 1: State the Problem — a description of the problem(s) and specifications of available resources and relevant deadlines for the study.

(1) Identify the members of the DQO scoping team — The members of the scoping team will include the On-Scene Coordinator (OSC), the manager of the Lead Smelter Co., a Quality Assurance Officer, a representative of the Leadbury town council, a statistician who has experience with sampling design, and a chemist with field experience. The decision maker will be the OSC of the removal program.

(2) Define/refine the conceptual site model — The source of contamination is from lead found in surface soil at 26 "high-access" areas around the city. The lead has been deposited through air deposition at the high-access areas from lead smelter operations in the region over a period of 60 years. The concentration of lead is expected to be from 0 - 1000 ppm based on site preliminary site investigations. The receptors are children between the ages of 1-12 years.

(3) Define the exposure scenario — EPA is concerned about the secondary source of lead contamination existing in the surface soil at 26 high-access areas throughout the city, so the original release mechanism from the smelter is not directly relevant. However, lead will be released from the surface soil in the form of dust. The lead will be bound to soil particles. Children will be exposed through inhalation of the dust particles and through ingestion of contaminated soil at each site. The future land use is assumed to be the same as the current mixed uses.

(4) Specify available resources — The total budget for sampling, removal, and disposal is $5,560,000. Therefore approximately $200,000 is available for each of the 26 high-access areas.

(A) *Time.* All removals should be completed within 6 to 8 months.

(B) *Identify project constraints.* The OSC has requested that all stages of the operation be performed in a manner that minimizes the time and cost of sampling, analysis, and disposal.

(5) Write a brief summary of the contamination problem — Surface soil in high-access areas of Leadbury are contaminated with relatively high concentrations of lead. EPA needs to determine what portions of soil within the high-access areas need to be removed.

Step 2: Identify the Decision — a statement of the decision that will use environmental data and the actions that could result from this decision.

(1) State the decision(s) — Determine what areas within the 26 high-access areas have concentrations of lead in the soil that exceed the removal program's regulated standard.

(2) State the actions that could result from the decision —

(a) Further study will take place to delineate contamination, the surface soil will be removed, and clean fill will replace it.
(b) The surface soil will be left intact.

Step 3: Identify the Inputs to the Decision — a list of the environmental variables or characteristics that will be measured and other information needed to make the decision.

(1) Identify the informational inputs needed to resolve the decision — Concentration of lead in the soil within the 26 high-access areas.

(2) Identify sources for each informational input — The concentration of lead can be measured from soil samples.

(3) Define the basis for establishing contaminant-specific action levels — The action level for lead in soil has been set for the removal program by the Agency for Toxic Substance Disease Registry (ATSDR), based on the risk of exposure and the possibility of adverse health consequences. The action level is 500 ppm.

(4) Identify potential sampling techniques and appropriate analytic methods — The analytical method will be atomic absorption. The tulip bulb planter has been identified as a potential sample collection device.

Step 4: Define the Boundaries of the Study — a detailed description of the spatial and temporal boundaries of the decision; characteristics that define the environmental media, objects, or people of interest; and any practical considerations for the study.

(1) Define the spatial boundaries —

(A) *Define the domain within which all decisions must apply.* The boundaries of the study will be limited to the property boundaries of each separate high-access area that has been identified as having soil contamination that exceeds the removal program standard of 500 ppm for lead. Each of the 26 high-access areas will be evaluated and sampled separately.

(B) *Specify the characteristics that define the population of interest.* Surface soil (0-6 inches) associated with the site. Each of the 26 high-access areas will be considered subpopulations.

(C) *Define the scale of decision making.* Because the contaminated soil is thought to come from fill material, the sampling plan should be adequate to detect the smallest area that would reasonably have been filled within the high-access areas. The scoping team has chosen a circle with a diameter of 40 feet to a depth of 6 inches to represent the area that corresponds to the smallest area that could reasonably have been filled. This is the area that corresponds to four dump truck loads (8 tons) of fill material, spread 6 inches thick. Therefore the sampling plan must adequately detect contaminated circular areas of contaminated soil that have a diameter of 40 feet.

(2) Identify temporal boundaries — The EPA is facing public pressure to reduce the exposure risks from the site quickly.

(A) *Determine what timeframe the sampling data must represent.* Because the study is not intended to determine risk, there is no specific timeframe to which the results will apply.

(B) *Determine when to sample.* Lead in soil is stable. It will not degrade or migrate from the "high-access areas". Therefore lead can be sampled at any time. For best results, soil samples should be taken when the soil moisture is relatively low (less than 30%) so that the core samples will hold their form.

(3) Identify practical considerations that may interfere with the study — Two of the high-access areas provide a passageway between elementary school buildings. For students to avoid possible exposure, a walkway built of plywood will be installed. Additionally, it will not be possible to perform removals on these areas during regular school hours (8:00 am - 2:30 pm).

Step 5: Develop a Decision Rule — an "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

(1) Specify the parameter of interest — A hot spot can be considered as a maximum concentration. Therefore the parameter of interest is the maximum concentration.

(2) Specify the action level for the study — The removal program's action level for lead in soil is 500 ppm. The action level has been set by the ATSDR.

(3) Develop a decision rule (an "if...then..." statement) — If the maximum concentration of lead in any high-access area is greater than 500 ppm, then a second round of sampling will be implemented to delineate the extent of soil contamination. Otherwise, no action will take place.

Step 6: Specify Limits on Decision Errors — the decision maker's acceptable decision error rates based on a consideration of the consequences of making an incorrect decision.

(1) Determine the possible range of the parameter of interest — The possible range of lead concentrations is expected to be from 0-1000 ppm.

(2) Define both types of decision errors and identify the potential consequences of each —

(A) *Define both types of decision errors and determine which decision error has the more severe consequences.* The two decision errors are:

Decision Error 'a': Determining that circular areas of contaminated soil with a radius of 40 feet or greater do not exist when they actually do; i.e., determining there are no hot spots when a hot spot actually exists. The consequence of this error is that contaminated soil will not be removed and human health will be endangered. Decision Error 'a' is the more severe decision error.

Decision Error 'b': Determining that the soil is contaminated when in reality it is not; i.e., determining that a hot spot exists when in reality there are no hot spots. The consequence of this error is that time and energy will be spent on additional sampling. The public will view this error positively in that it shows that the overriding concern is for protecting human health. The consequences, therefore, are far less severe than the consequences of the other decision error.

(B) *Establish the true state of nature for each decision error.* The true state of nature for decision error 'a' is that a hot spot exists. The true state of nature for decision error 'b' is that there are no hot spots.

(C) *Define the true state of nature for the more severe decision error as the baseline condition or null hypothesis and define the true state of nature for the less severe decision error as the alternative hypothesis.*

Null Hypothesis, H_0 = A hot spot exists. (The concentration of an individual sample is above 500 ppm.)

Alternative Hypothesis, H_a = A hot spot does not exist. (The concentration of an individual sample is less than 500 ppm.)

(D) *Assign the terms "false positive" and "false negative" to the proper errors.*

False positive error = decision error 'a'
False negative error = decision error 'b'

Specify the Gray Region — The scoping team has set the gray region, which spans 100 ppm, to the left of the action level.

(4) Identify Acceptable Decision Error Rates —

(a) False Positive Error: The scoping team can accept a rate of 20% for the probability of a false positive (see Figure B-1).

(b) False Negative Error: The scoping team has set the acceptable rate of making a false negative error at 30% (see Figure B-1).

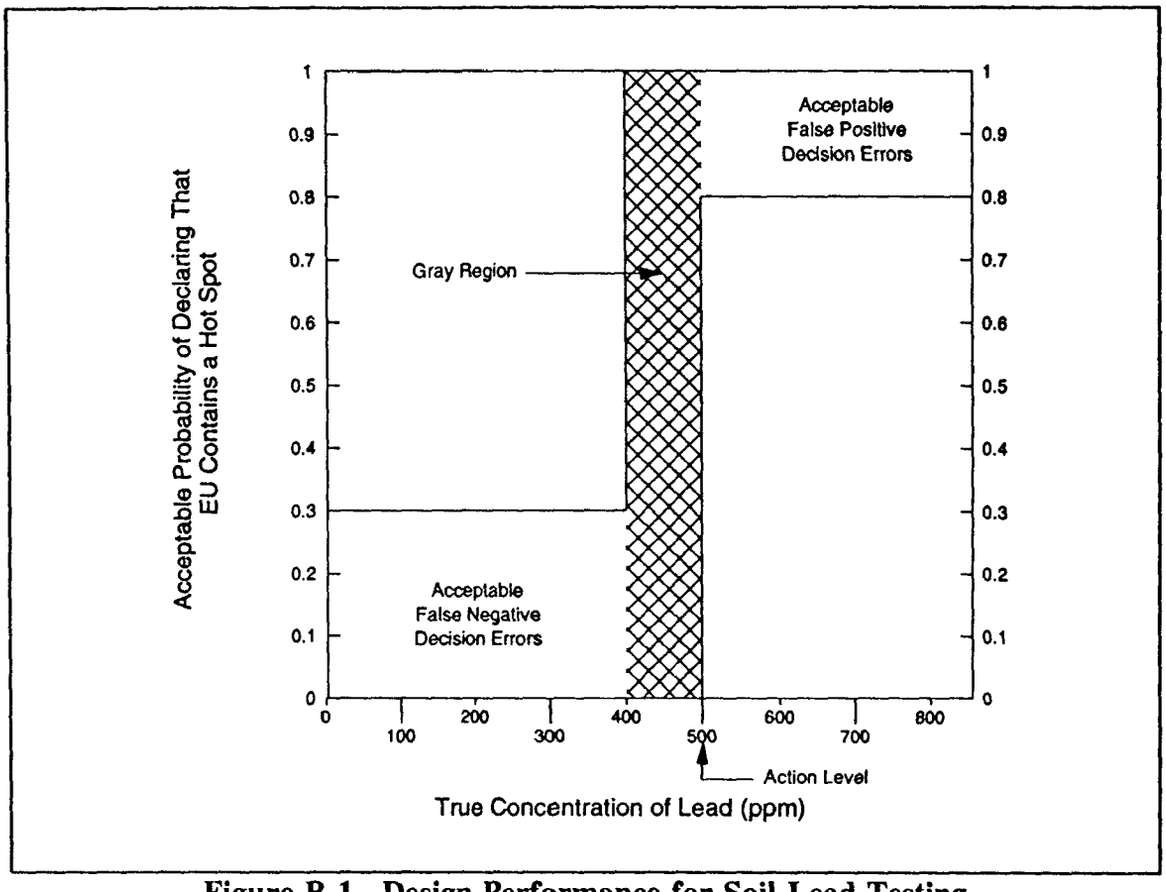

Figure B-1. Design Performance for Soil Lead Testing

Step 7: Optimize the Design — the decision maker will select the lowest cost sampling design that is expected to achieve the DQOs.

(1) Develop general sampling and analysis design alternatives — For each design alternative, the statistician must formulate a statistical model (i.e., a mathematical expression) that tests the hypothesis and select the optimal sample size that satisfies the decision maker's limits on decision errors.

A search sampling method using systematic (or grid) samples will be used to determine whether or not a "hot spot" of contamination exists. If the concentration of lead in any sample within the boundaries is significantly greater than 500 ppm, then a second round of sampling will be implemented to determine the extent of soil contamination. Otherwise, no action will take place.

The second round of sampling, sequential sampling, will characterize the extent of the area that requires removal. Additional soil samples will be taken at a point one-half the distance to the next non-contaminated sampling point. If any sample in the second round is contaminated, additional samples will continue to be collected one-half the distance to the nearest non-contaminated sampling point until a sample shows no contamination. Once this occurs, contaminated soil will be removed up to and including the last clean sample. The soil will be removed to a depth of 8 inches because this is the maximum depth that children are expected to receive exposure from soil during normal activity. Clean fill will be used to fill the depressions made during removal activity.

Samples will be taken in a triangular-shaped grid pattern. The distance between samples will be 42.5 feet (see Figure B-2). Six-inch core samples will be taken at the grid nodes, homogenized, and analyzed at each sampling location.

Because of the extreme bimodal distribution of the lead concentration, the design assumes that when a hot spot is sampled, it will not be mistaken for background and vice versa.

Statistical Models

For each observation y_i:

$$y_i = v_i + e_i$$

where v_i = true value of the i_{th} observation and
e_i = sampling error for the i_{th} observation.

The e_i's are independently and identically distributed with the mean equal to 0 and variance equal to σ^2_s.

Sample Size

Below is an explanation of a procedure that is used to determine the number of samples needed to detect hot spots of contamination within a pre-specified confidence limit. The procedure employs three common sampling patterns (square, rectangular, and triangular) to determine the optimal sample spacing and distance between samples. To determine the minimum spacing between samples that will detect an elliptical hot spot of a pre-specified size and shape with a specified confidence, the following procedure is used:

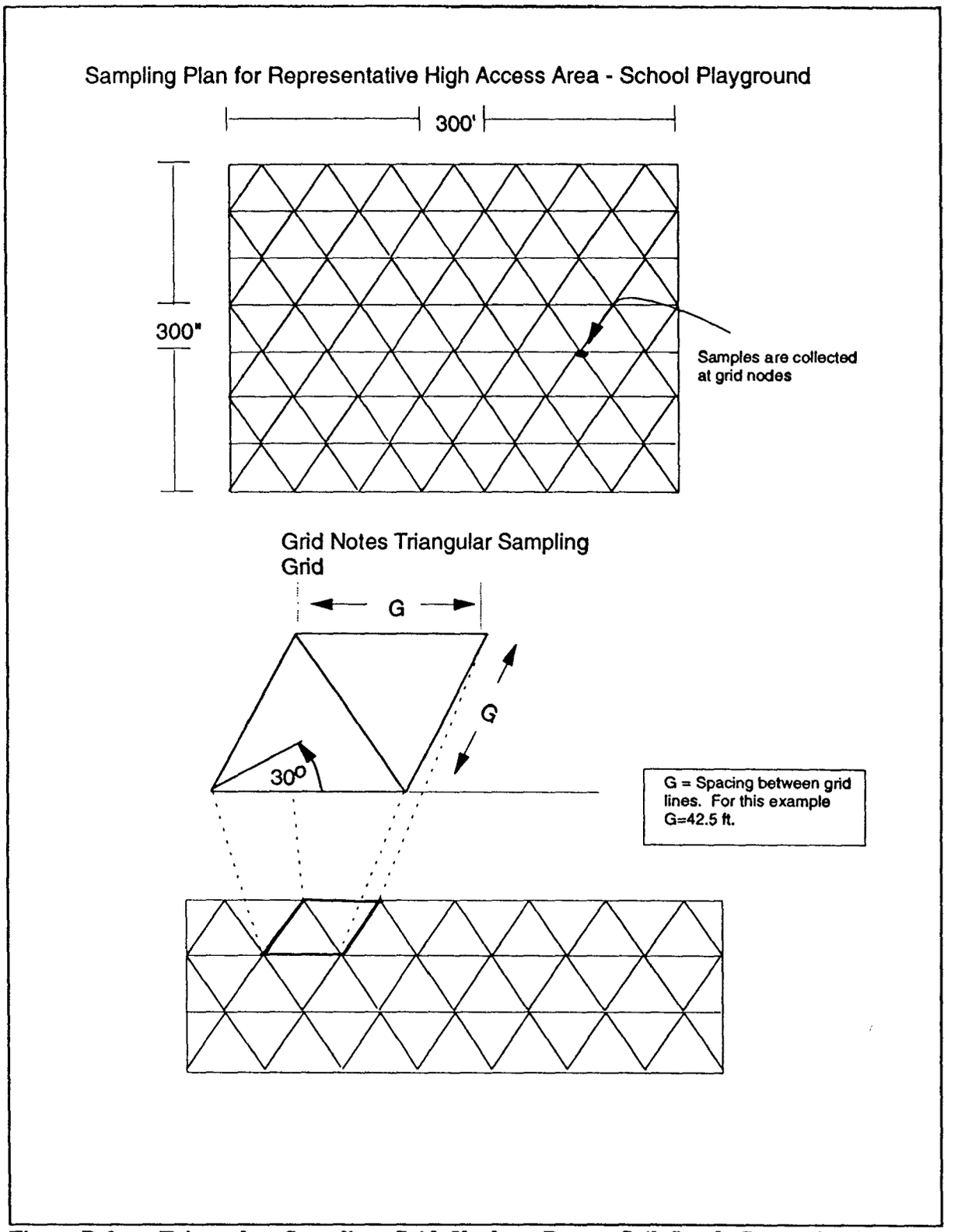

Figure B-2. Triangular Sampling Grid Used to Detect Soil Lead Contamination in a 300′ x 300′ School Playground

(A) Specify the length (L) of the long axis of the hot spot ellipse: L = 20 ft.

(B) Specify the length (R) of the short axis of the hot-spot ellipse: R = 20 ft.

(C) Divide the length of the short axis by the length of the long axis. The solution, S, is called the shape:

$$S = \frac{\text{Length of the short axis of the hot-spot ellipse}}{\text{Length of the long axis of the hot-spot ellipse}} = 1$$

(D) Specify the acceptable probability of not finding the hot spot. In our example the probability of not finding the hot spot corresponds to $\beta = .2$. (In this case, a false positive error.)

(E) Determine the distance between samples (G) using the nomograph (see Figures 2-3 and 2-4) to meet the constraints specified in the first four steps. For a square playground area with a size of 300 ft. x 300 ft., the distance between samples and the number of samples needed to meet the DQOs will be:

Using a square sampling pattern, G = 39.2 feet : 64 samples.

Using a triangular sampling pattern, G = 42.5 feet : 49 samples.

(2) Select the most resource-effective design that satisfies all of the DQOs — Sampling costs include both the cost of collecting and analyzing samples. Each soil sample tested for lead will cost $75.00. The total cost of sampling will depend on the total number of samples.

(3) Document the details and assumptions of the selected design —

- The target (hot spot) is circular. For subsurface targets, this applies to the projection of the target to the surface.
- Samples or measurements are taken on a triangular grid.
- The distance between grid points is much larger than the area sampled, measured, or cored at grid points — that is, a very small proportion of the area being studied can actually be measured.
- The definition of "hot spot" is clear and unambiguous. This definition implies that the types of measurement and the levels of contamination that constitute a hot spot are clearly defined.
- There are no measurement misclassification errors — that is, no errors are made in deciding when a hot spot has been hit.

The most efficient sampling plan is one that uses a triangular sampling grid (see Figure B-2) because it meets the constraints of the DQOs with the fewest number of samples and therefore has the lowest total cost.

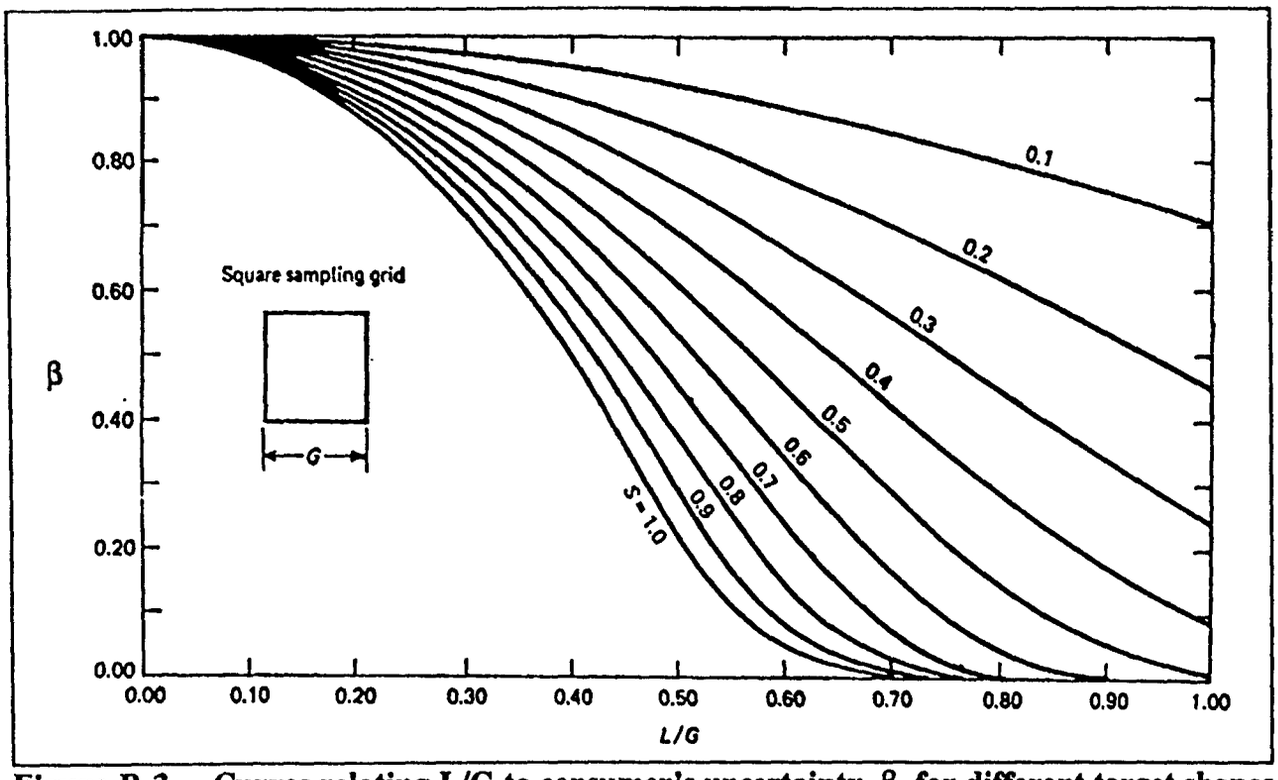

Figure B-3. Curves relating L/G to consumer's uncertainty, β, for different target shapes using a square grid (from Zirschky and Gilbert 1984, with permission)

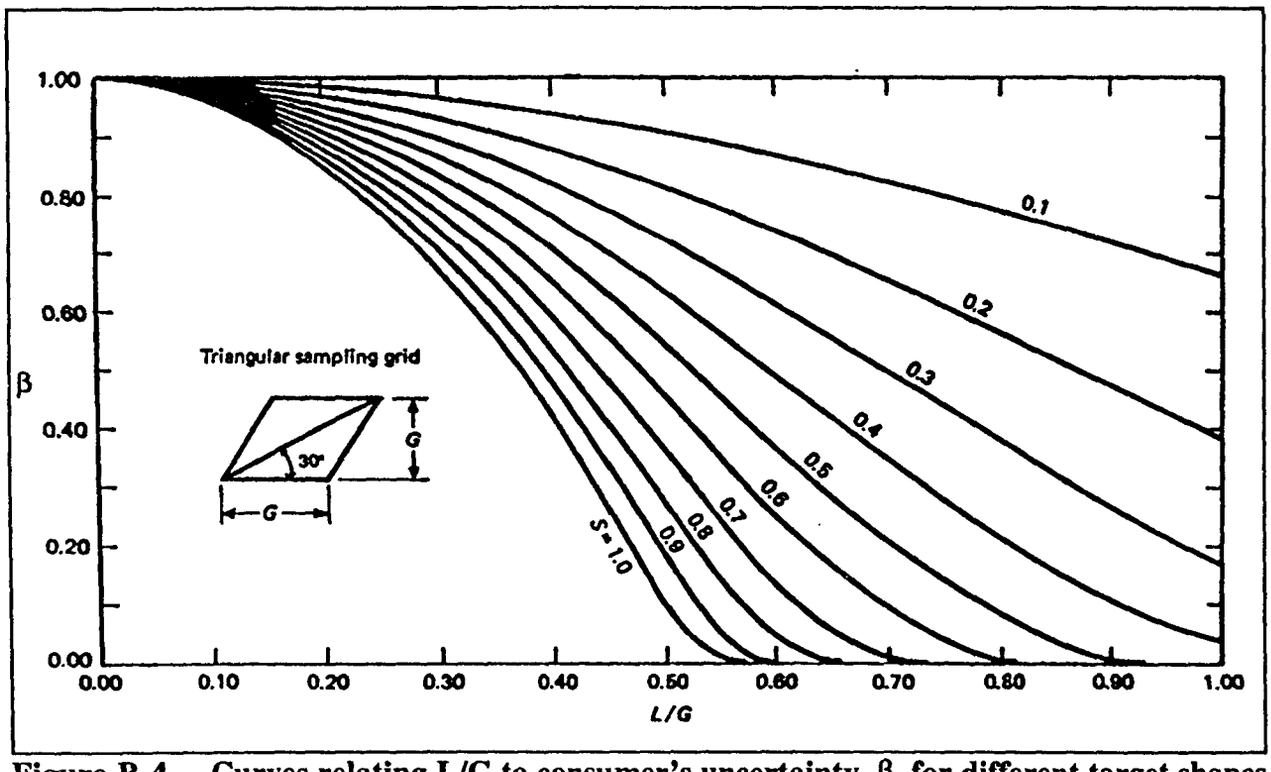

Figure B-4. Curves relating L/G to consumer's uncertainty, β, for different target shapes using a triangular grid (from Zirschky and Gilbert 1984, with permission)

SECTION C

REMEDIAL PROGRAM EXAMPLE

THE RAWHIDE SUPERFUND SITE

1.0 BACKGROUND

The Rawhide Superfund Site is a former leather tannery. Between 1982 and 1985, tannery waste sludge was landfarmed over part or all of a 29-acre pasture (see Figure C-1). "Landfarming" refers to a process of waste disposal that involves spraying or pouring waste onto the soil and then disking the waste into the soil. At this site, the sludge containing high levels of chromium compounds was disked into the soil to a depth of approximately 8 inches. Historical site information indicates that several portions of the landfarm area have received little or no waste.

High concentrations of chromium III and VI have been detected in surface soil samples at the landfarm. This may indicate that wastes were dumped on the ground, but not disked into the soil. Ground-water sampling in wells and springs within three miles of site have shown the presence of chromium and lead at levels below maximum contaminant levels (MCLs). Due to the high levels of chromium in the surface soil, the site has been placed on the National Priorities List (NPL).

The site is currently used to graze cattle. Several residences are located adjacent to the site. Potential human exposure routes identified by the site risk assessor include ingestion and inhalation of soil particulates and ingestion of ground water. Chromium VI compounds are suspected human carcinogens through the inhalation pathway only. Chromium III compounds are not considered carcinogenic. Direct contact with chromium compounds can cause a hypersensitivity reaction.

The scoping team has decided to employ the DQO process to help them determine if there are any areas of the landfarm that pose an unacceptable risk to human health and the environment and thus require further assessment or a response action. By using the DQO process, the team plans to generate a statistically valid sampling design, generate results of known confidence, make defensible decisions, and save time and resources.

2.0 DQO DEVELOPMENT

Following is an example of the output from each step of the DQO process.

Step 1: State the Problem — a description of the problem(s) and specifications of available resources and relevant deadlines for the study.

(1) Identify the members of the DQO scoping team — The members of the DQO scoping team include the RPM, a field sampling expert, a chemist, an engineer, a risk assessor, a QA Officer, a hydrogeologist, a DQO facilitator, and a statistician. The RPM is the decision maker.

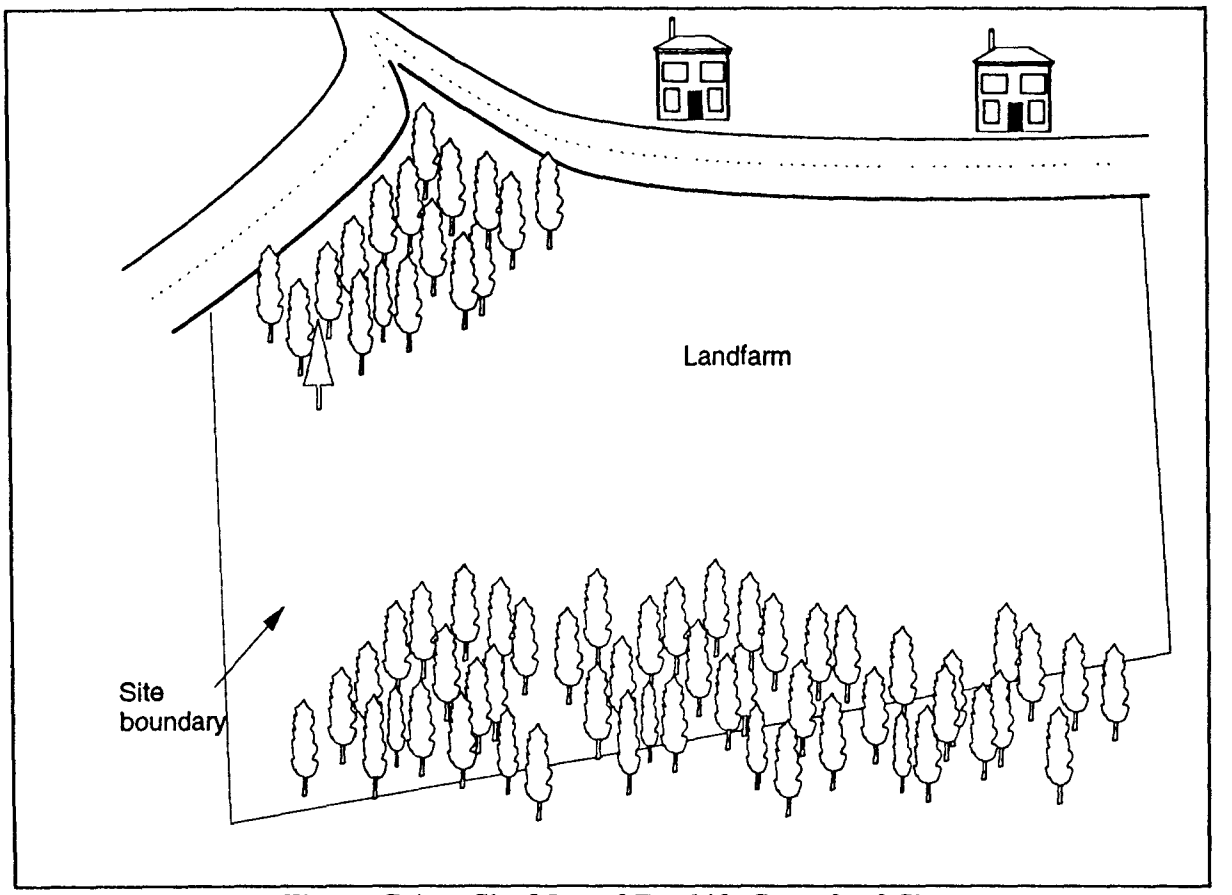

Figure C-1. Site Map of Rawhide Superfund Site

(2) Define/refine the conceptual site model — The source of the contamination is from landfarming waste disposal operations at a former leather tannery. High concentrations of chromium have been observed in soil associated with the site. Chromium and lead were detected in ground-water samples at levels below the MCLs. Contaminants are migrating from surface and subsurface soils to ground water. Contaminants may also become airborne primarily due to wind. The receptors are humans of all ages who live within a 2-mile radius and who derive their drinking water from ground-water wells which are connected to the ground-water aquifer below the site. Cattle who graze on the site are also potential receptors.

(3) Define exposure scenarios — The source of the contamination is the chromium-contaminated soil and the ground water associated with the site. Contaminants will be released through aerial transport and migration to ground water. Contaminants may also migrate through ground water to drinking water wells. The chromium will be bound to soil dust particles or dissolved in ground water. The exposure routes include ingestion of soil, inhalation of dust particles, and ingestion of ground water. The potential exposure points are the contaminated soils on-site and houses connected to drinking water supply. The land use for the site is residential.

(4) Specify the available resources — EPA is concerned about the cost of extensive sampling and analysis, but adequate data quality is a priority. EPA has allocated the funds necessary for a sampling crew of four people for only one week. All sampling must be done within that week.

(A) *Time.* The RPM wants this site addressed in a "reasonable timeframe." The RPM expects data validation to be the most time-consuming aspect of data generation. It may take up to three months after samples are collected before the data are available.

(B) *Identify project constraints.* The sampling team has a limited amount of time to collect samples due to budget constraints. This will be a major consideration during the development of the sampling and analysis design.

(5) Write a brief summary of the contamination problem — This site was placed on the NPL due to the discovery of chromium contaminated soil. Chromium was also detected in ground water associated with the site which is hydraulically connected to drinking water wells. Residents in the area can be exposed to contaminants in soil and ground water via ingestion. Residents can also be exposed to contaminated particulates via inhalation. The site manager has designated the soils associated with the site as an operable unit. Since the site is on the NPL, a remedial investigation will be performed to determine which areas of the soil pose an unacceptable risk to human health or the environment and require further assessment or a response action.

Step 2: Identify the Decision — a statement of the decision that will use environmental data and the actions that could result from this decision.

(1) State the decision(s) — Determine whether sections of the landfarm (soil) pose an unacceptable risk to human health or the environment or whether they exceed ARARs.

(2) State the actions that could result from the decision —

(a) No action.
(b) Recommend further assessment or a response action.

Step 3: Identify the Inputs to the Decision — a list of the environmental variables or characteristics that will be measured and other information needed to make the decision.

(1) Identify the informational inputs needed to resolve the decision — Surface soil samples need to be taken within the site boundaries.

(2) Identify sources for each information input — Total chromium will be measured in soil samples.

(3) Define the basis for establishing contaminant-specific action levels — Since a health-based non-carcinogenic value (600 ppm of total chromium) is lower than the risk-based carcinogenic PRG of 700 ppm for hexavalent chromium, the total chromium concentration value is considered more protective.

(4) Identify potential sampling techniques and appropriate analytic methods — A soil coring device has been identified as the potential sampling technique. Atomic absorption is the proposed analytical methodology.

Step 4: Define the Boundaries of the Study — a detailed description of the spatial and temporal boundaries of the decision; characteristics that define the environmental media, objects, or people of interests; and any practical considerations for the study.

(1) Define spatial boundaries —

(A) *Define the domain within which all decisions must apply.* Surface soil is defined as the top 12 inches of soil within the geographic boundaries of the 29-acre landfarm area, excluding forested areas where landfarming and disposal could not have taken place.

(B) *Specify the characteristics that define the population of interest.* Chromium concentrations in soil samples.

(C) *Define the scale of decision making.* Although the area is rural, future residential development is possible. Residential land use represents a reasonable worst-case scenario. The entire site has been divided into square areas that are approximately 200 x 200 feet. These areas are approximately one acre in size and correspond to the expected residential lot size. These areas are referred to as "exposure units" (EUs). EUs which overlapped the site boundaries were combined with EUs having forested areas so that 20 EUs of approximately one acre would result. A separate decision will be made for each EU.

(2) Identify temporal boundaries — EPA is facing public pressure to reduce the exposure risk from the site quickly.

(A) *Determine what time frame the sampling data must represent.* Because chromium is not migrating or degrading to any significant degree, the sampling results will apply to lifetime exposure.

(B) *Determine when to collect data.* Sampling must occur within a one-week period when EPA has made funds available.

(3) Identify practical considerations that may interfere with the study — The center of each EU will be marked with a wire flag. Because the site is currently used for grazing, there is considerable concern that the cows will ingest the wire flags. This would injure the cows and impede timely sample collection. Some background investigation has indicated that it is not likely the cows will eat the wire flags. As a precaution, the farmers will be informed of the sampling activities in order to protect the welfare of the cows.

Step 5: Develop a Decision Rule — an "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

(1) Specify the parameter of interest — The mean concentration of total chromium within each EU will be compared to the action level.

(2) Specify the action level for the study — The action level for this problem will be 600 ppm of total chromium.

(3) Develop a decision rule (an "if...then" statement) — If the average total chromium concentration in the surface soil of an EU exceeds 600 ppm, then recommend further assessment or a response action will be taken. Otherwise, no action will be taken.

Step 6: Specify Limits on Decision Errors — the decision maker's acceptable decision error rates based on a consideration of the consequences of making an incorrect decision.

(1) Determine the possible range of the parameter of interest — The possible range of chromium concentrations is 0-1000 ppm.

(2) Define both types of decision errors and identify the potential consequences of each —

(A) *Define both types of decision errors and establish which decision error has the more severe consequences.*

The two decision errors are:

Decision Error 'a': One decision error occurs when the decision maker decides an EU is not contaminated when, in truth, the mean concentration of chromium is greater than or equal to 600 ppm. If an EU that poses an unacceptable risk is not remediated, some resources may be saved, but this would be at the cost of increased human health and/or environmental risk. Increased future health costs or cancer deaths may also result. This decision error is more severe.

Decision Error 'b': The other decision error occurs when the decision maker decides, based on the data, to take action when, in truth, the mean concentration of chromium is less than 600 ppm. One possible consequence of this decision error is unnecessary further study in the EU. This would result in wasted resources and time. Offsetting this to some degree would be the marginal reduction in health risk if a response action is taken.

(B) *Establish the true state of nature for each decision error.* The true state of nature for decision error 'a' is that the mean concentration of chromium is greater than 600 ppm. The true state of nature for decision error 'b' is that the mean concentration of chromium is less than 600 ppm.

(C) *Define the true state of nature for the more severe decision error as the baseline condition or null hypothesis and define the true state of nature for the less severe decision error as the alternative hypothesis.* The hypothesis test is stated as:

Null Hypothesis (H_o): Mean concentration in the EU ≥ 600 ppm

Alternate Hypothesis (H_a): Mean concentration in the EU < 600 ppm

(D) *Assign the terms "false positive" and "false negative" to the proper errors.*

false positive error = decision error 'a'
false negative error = decision error 'b'

(3) Specify the Gray Region — The gray region corresponds to the area where the decision maker considers the consequences of making a false negative decision error to be relatively minor. In this example, the gray region is set to the left of the action level between 500 ppm and 600 ppm (see Figure C-2).

(4) Identify Acceptable Decision Error Rates — The decision maker specified the probability of deciding to take action at four different total chromium concentrations.

True Concentration of Total Chromium	Acceptable Probability of Taking Action
100 ppm	less than or equal to 1%
250 ppm	less than or equal to 10%
500 ppm	less than or equal to 25%
600 ppm	greater than or equal to 95%

Based on the above table, at a true mean of 100 ppm, the decision maker can tolerate making a false negative decision error 1% of the time. At 600 ppm (the action level), the decision maker wants to be confident of taking action 95% of the time (i.e., can tolerate making a false positive decision error 5% of the time).

Step 7: Optimize the Design — the decision maker(s) will select the lowest cost sampling design that is expected to achieve the DQOs.

(1) Develop general sampling and analysis design alternatives — For each design alternative, the statistician must formulate a statistical model (i.e., a mathematical expression) that tests the hypothesis and select the optimal sample size that satisfies the decision maker's limits on decision errors.

Several alternate designs were discussed and subsequently deemed impractical by the decision maker. One design was considered possible, however. A spatially intensive design was developed which would gather composite soil samples from each EU. Samples will be taken using a systematic grid. The sampling crew is more comfortable with this type of design than with a random sampling plan. An approximate t-test is suggested for each EU by calculating

$$t = \frac{600 - M_h}{\sqrt{v} \; / \; \sqrt{2}}$$

where M_h is the mean of the h^{th} EU and v is the pooled within-EU variance. This will be compared with the critical value of a t-distribution for $\alpha = 0.05$ and 20 degrees of freedom. If the computed value exceeds the critical value, the null hypothesis will be rejected.

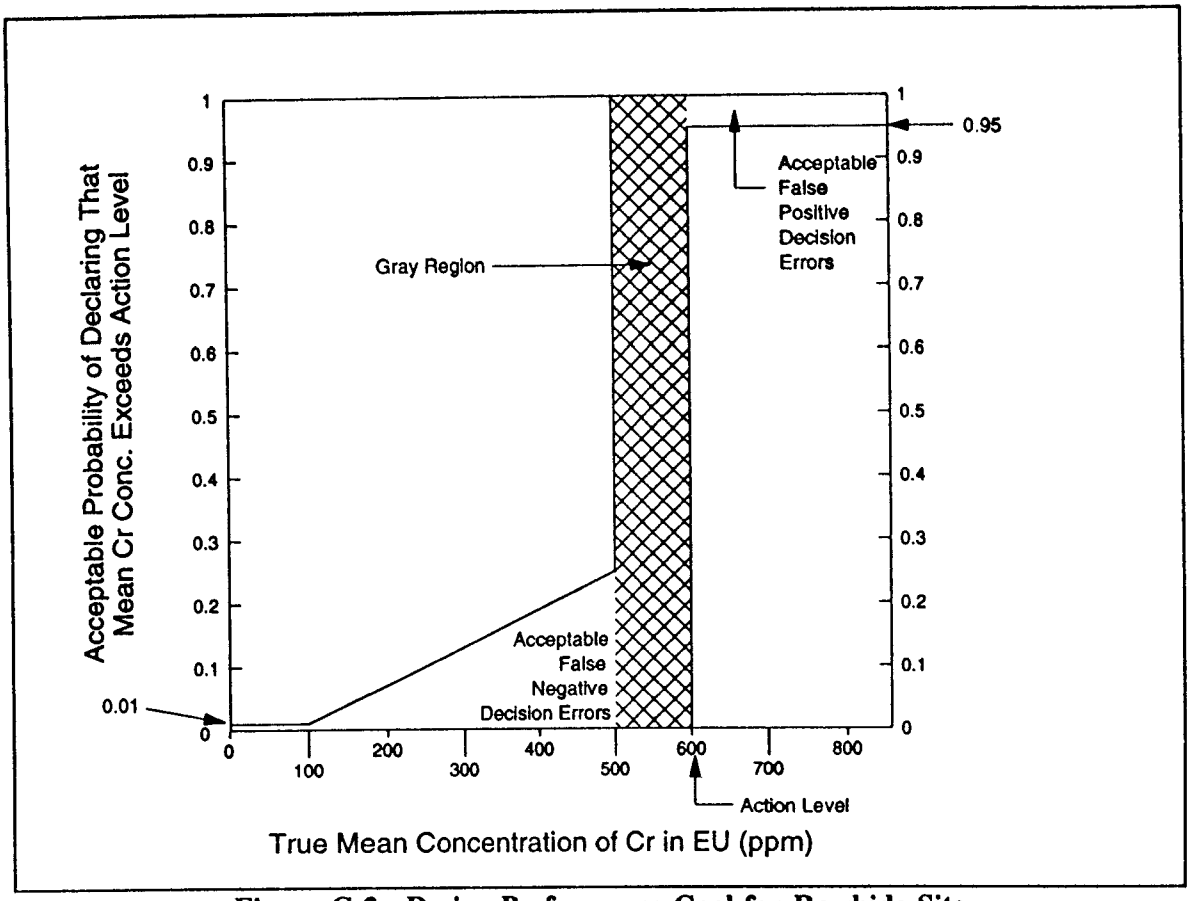

Figure C-2. Design Performance Goal for Rawhide Site

Estimate of Variance

A limited field investigation was conducted in order to develop an estimate of the expected variability of the contaminant. A preliminary estimate of the total standard deviation of the chromium is 65.70 ppm.

Statistical Model

The model proposed for the observed composite sample concentrations is

$$x_{ij} = \mu_i + \varepsilon_{ij}$$

where: x_{ij} = j^{th} composite sample of the i^{th} EU
μ_i = mean concentration of the i^{th} EU
ε_{ij} = deviation from μ_i for j^{th} composite sample of the i^{th} EU
and the ε's are distributed normally with mean zero.

Sample Size

A maximum of nine samples per composite can be realistically handled. Using this information and the prior estimate of the standard deviation, two composite samples of nine scoops each will be randomly selected from each of the 20 EUs. This sample size will provide 20 degrees of freedom, provided that the within-EU variances can be pooled.

(2) Select the most resource-effective design that satisfies all of the DQOs — Composite samples save money by reducing analysis costs, which is important for the initial study as well as for the next phase of study.

This design meets the decision maker's objectives for adequately identifying which EUs require further study or a response action. This is critical given the expected high cost of remediation.

(3) Document the details and assumptions of the selected design — Two composite samples of nine scoops each will be selected within each EU. A systematic grid with nine nodes will be used to collect the first composite sample. The second composite sample will consist of nine samples that are offset from the original grid nodes. Within each EU it is assumed that the variance is the same, regardless of the level of contamination. This assumption can be tested after the data are collected.

APPENDIX III

GLOSSARY

GLOSSARY OF TERMS

action level: the numerical value that causes the decision maker to choose one of the alternative actions (e.g., compliance or noncompliance). It may be a regulatory threshold standard, such as a Maximum Contaminant Level for drinking water, a risk-based concentration level, a technological limitation, or reference-based standard.

bias: the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different than the sample's true value).

boundaries: the area or volume (spatial boundary) and the time period (temporal boundary) to which the decision will apply. Samples are collected within these boundaries to be representative of the population of interest for the decision.

Data Quality Assessment (DQA): a process of statistical and scientific evaluation that is used to assess the validity and performance of the data collection design and statistical test, and to establish whether a data set is adequate for its intended use.

Data Quality Objectives (DQOs): qualitative and quantitative statements derived from the outputs of each step of the DQO Process which specify the study objectives, domain, limitations, the most appropriate type of data to collect, and specify the levels of decision error that will be acceptable for the decision.

Data Quality Objectives Process: a Quality Management tool based on the Scientific Method and developed by the U.S. Environmental Protection Agency to facilitate the planning of environmental data collection activities. The DQO Process enables planners to focus their planning efforts by specifying the use of the data (the decision), the decision criteria (action level), and the decision maker's acceptable decision error rates. The products of the DQO Process are the DQOs.

decision errors:

false positive error — The false positive error occurs when data mislead a decision maker into believing that the burden of proof in a hypothesis test has been satisfied, so that the null hypothesis is erroneously rejected. A statistician usually refers to the false positive error as alpha (α), the level of significance, the size of the critical region, or a Type I error.

false negative error — The false negative error occurs when data mislead the decision maker into wrongly concluding that the burden of proof in a hypothesis test has not been satisfied so that the null hypothesis is accepted. A statistician usually refers to this as beta (β), or a Type II error. It is also known as the complement of Power.

defensible: the ability to withstand any reasonable challenge related to the veracity or integrity of laboratory documents and derived data.

directed sampling: see judgmental sampling.

gray region: an area that is adjacent to or contains the action level, and where the consequences of making a decision error are relatively small.

judgmental sampling: a subjective selection of sampling locations based on experience and knowledge of the site by an expert.

limits on decision errors: the acceptable decision error rates established by the decision maker. Economic, health, ecological, political, and social consequences should be considered when setting limits on decision errors.

mean: the arithmetic average of a set of values.

measurement error: the difference between the true or actual state and that which is reported from measurements.

median: the middle value for an ordered set of n values; represented by the central value when n is odd or by the average of the two most central values when n is even.

medium: a substance (e.g., air, water, soil) which serves as a carrier of the analytes of interest.

natural variability: the variability that is inherent or natural to the media, objects, or people being studied.

parameter: a numerical descriptive measure of a population.

percentile: a value on a scale of 100 that indicates the percentage of a distribution that is equal to or below it.

population: the total collection of objects or people to be studied and from which a sample is to be drawn.

power curve: the probability of rejecting the null hypothesis (H_o) over the range of the population. The power function is used to assess the goodness of a test or to compare two competing tests.

probabilistic sampling: a random selection of sampling locations that allows the sampling results to be extrapolated to an entire site (or portion of the site).

quality assurance (QA): an integrated system of management activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service (e.g., environmental data) meets defined standards of quality with a stated level of confidence.

Quality Assurance Project Plan (QAPP): a formal technical document containing the detailed procedures for assuring the quality of environmental data prepared for each EPA environmental data collection activity and approved prior to collecting the data.

quality control (QC): the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quality Management Plan (QMP): a formal document describing the management policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation protocols of an agency, organization, or laboratory for ensuring quality in its products and utility to its users. In EPA, QMPs are submitted to QAMS for approval.

range: the numerical difference between the minimum and maximum of a set of values.

[1]sample: a single item or specimen from a larger whole or group, such as any single sample of any medium (air, water, soil, etc.).

[2]sample: a group of samples from a statistical population whose properties are studied to gain information about the whole.

sample variance: a measure of the dispersion of a set of values.

sampling: the process of obtaining a subset of measurements from a population.

sampling error: the error due to observing only a limited number of the total possible values that make up the population being studied. It should be distinguished from errors due to imperfect selection, bias in response, and errors of observation, measurement, or recording, etc.

scoping team: the group of people that will carry out the DQO Process. Members include the decision maker (senior manager), representatives of other data users, senior program and technical staff, senior managers (decision makers), someone with statistical expertise, and a QA/QC advisor (such as a QA Manager).

standard deviation: the square root of the variance.

statistic: a function of the sample measurements; e.g., the sample mean or standard deviation.

study design: a study design specifies the final configuration of the environmental monitoring effort to satisfy the DQOs. It includes the types of samples or monitoring information to be collected; where, when, and under what conditions they should be collected; what variables are to be measured; and the Quality Assurance and Quality Control (QA/QC) components that ensure acceptable sampling error and measurement error to meet the decision error rates specified in the DQOs. The study design is the principal part of the QAPP.

total study error: the sum of all the errors that are incurred during the process of sample design through data reporting. Total study error is related to decision error.

true: being in accord with the actual state of affairs.

Type I error: an error that can occur during a statistical hypothesis test. A Type I error occurs when a decision maker rejects the null hypothesis (decides that the null hypothesis is false) when it is actually true.

Type II error: an error that can occur during a statistical hypothesis test. A Type II error occurs when the decision maker accepts the null hypothesis (decides that the null hypothesis is true) when it is actually false.

uncertainty: a measure of the total variability associated with sampling and measurement that includes the two major error components: systematic error (bias) and random error (imprecision)

APPENDIX IV

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