Using the Data Quality Objectives Process During the Design and Conduct of Ecological Risk Assessments

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Executive Summary

U.S. Department of Energy (DOE) sites are conducting ecological risk assessments to support diverse environmental restoration and waste management programs such as land use planning, soil and groundwater remediation, waste disposal, and habitat restoration. Most of these assessments have been "one of a kind" because of the great differences that exist among DOE sites in factors such as geographic size, climate, elevation, habitats, contaminant profile, physical disturbance, and exotic species. One-of-a- kind assessments usually meet the immediate needs of the DOE. But they are often too narrow in scope to support multiple, related activities, and tend to be expensive because they are designed and conducted independently rather than built on previous efforts.

The U.S. Environmental Protection Agency (EPA) developed the Data Quality Objectives (DQO) Process to help decision makers, managers, and risk assessors determine the type, quantity, and quality of the data they need to support their programs. To date, the DQO Process has not been applied to ecological risk assessments. However, it has great potential to increase the efficiency and effectiveness of ecological risk assessments by standardizing their design and conduct. This report is the first to help DOE decision makers, managers, and risk assessors apply the DQO Process step-by-step to their ecological risk assessments. It was developed during two workshops sponsored by DOE's Office of Environmental Policy and Assistance. Combined workshop attendance was 50, including DOE staff, DOE laboratory and contractor staff, and representatives from the EPA.

This report melds the ecological risk assessment process and the DQO Process into seven steps that combine the key attributes of each. These key attributes are described by the 2-5 substeps within each step. As described in this report, the steps and substeps are

- *State the Problem*, including 1) Develop Preliminary Description of the Problem, 2) Define Planning and Decision Team, 3) Assemble Project Team, 4) Develop Detailed Description of the Problem, and 5) Define Scope and Extent of Ecological Risk Assessment

- *Identify the Decision*, including 1) Define the Management Framework, and 2) Develop a Logic Diagram of Study Questions and Answers

- *Identify Inputs to the Decision*, including 1) Determine Informational Inputs Needed to Support the Ecological Risk Assessment and Resolve the Decision Statement, 2) Determine Sources of Information for each Item of Information, and 3) List Environmental Variables or Characteristics to be Measured

- *Define the Study Boundaries*, including 1) Define the Programmatic Scale of the Decision, 2) Identify Regulatory and Institutional Considerations, 3) Define Spatial and Temporal Boundaries, and 4) Determine Areas and Timeframes for Collecting Data

- *Develop a Decision Rule*, including 1) Identify Target Species and Variables to be Measured, 2) Specify the Statistical Parameter that Characterizes the Population, 3) Specify the Action Level for the Study, and 4) Develop a Decision Rule

- *Specify Tolerable Limits on Decision Errors*, including 1) Identify the Variables that Affect the Decision, and 2) Choose the Null Hypothesis and Identify the Decision Errors

- *Optimize the Design*, including 1) Review DQO Outputs and Existing Environmental Data, 2) Develop General Data Design Alternatives, 3) Formulate the Mathematical Expressions Needed to Solve the Design Problem for Each Data Collection and Design Alternative, and 4) Develop and Document the Sampling Strategy.

Using this step-by-step process, DOE decision makers, managers, and risk assessors will be able to meet the most critical challenges that they face when designing and conducting ecological risk assessments, including

- clearly stating the decision that the assessment must support

- designing ecological risk assessments to meet existing and future natural resource management needs

- using existing data, identifying gaps in existing data, and designing the collection of new data to fill the gaps

- designing ecological risk assessments on spatial and temporal scales that are appropriate to the planning or management objective(s)

- designing ecological risk assessments to meet more than one regulatory need or application

- addressing the design needs of ecological risk assessments in the work plan phase

- using the DQO process iteratively throughout the design and conduct of ecological risk assessments.

By using the process outlined in this report, DOE decision makers, managers, and risk assessors will save time and money by designing and conducting ecological risk assessments that meet management needs, are acceptable to stakeholders, and are technically defensible.

Abbreviations and Acronyms

A	activity (as in A 5.1)
ARAR	applicable or relevant and appropriate requirements
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CWA	Clean Water Act
D	decision (as in D 5.1)
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
DQO	Data Quality Objective
DQOs	Data Quality Objectives
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act
NRDA	Natural Resource Damage Assessment
PCOC	potential contaminant of concern
RCRA	Resource Conservation and Recovery Act
RRSB	R-Reactor Seepage Basins
SQ	study question (as in SQ 3.1)

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This report is the product of two workshops sponsored by the Office of Environmental Policy and Assistance (EH-412), Assistant Secretary for Environment, Safety and Health of the U.S. Department of Energy. The first workshop was held in Augusta, Georgia from February 28 to March 2, 1995, and the second in Albuquerque, New Mexico from April 30 to May 2, 1996. The authors wish to thank the individuals who participated in these workshops, without whose participation this document could not have been written. Additionally, it should be noted that with the exception of two Pacific Northwest National Laboratory staff,(1) workshop participants were not funded by EH-412 for their participation. Hence, the authors especially thank the agencies and companies represented at the workshop for their commitments of staff and resources in this effort.

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Introduction

Ecological risk assessments (Box 1) are being conducted at most U.S. Department of Energy (DOE) sites to support the DOE's multifaceted environmental restoration and waste management mission. They are being used primarily to identify and manage ecological impacts that are occurring, or could occur, from environmental restoration and waste management activities. Assessments are being conducted to support activities as diverse as land use planning, soil and groundwater remediation, waste disposal, and habitat restoration. Because DOE's sites have a great range of contaminant profiles, sizes, climates, elevations, biomes, ecosystems, and habitat types, DOE's ecological risk assessments vary greatly in purpose, scope, approach, and implementation. The ability to increase the efficiency and effectiveness of ecological risk assessments by standardizing their design and conduct is therefore limited. However, the Data Quality Objectives (DQO) Process (Box 2) developed by the U.S. Environmental Protection Agency (EPA 1993a, 1994a) offers an effective means of achieving this objective, and is being used to assist in the design and conduct of some ecological risk assessments within and outside DOE.

Box 1. Ecological Risk Assessment

"Ecological risk assessment is defined as a process that evaluates the likelihood that adverse effects may occur or are occurring as a result of exposure to one or more stressors. A risk does not exist unless (1) the stressor has the inherent ability to cause one or more adverse effects and (2) it co-occurs with or contacts an ecological component (i.e., organisms, populations, communities, or ecosystems) long enough and at a sufficient intensity to elicit the identified adverse effect. Ecological risk assessment may evaluate one or many stressors and ecological components." (EPA 1992)

In 1994, staff from the DOE, ecologists employed by DOE contractors, and ecologists within the DOE national laboratory system recognized the potential that the DQO process has for improving ecological risk assessments. As a result, workshops were convened in Augusta, Georgia in February 1995 and in Albuquerque, New Mexico in April 1996 for the purpose of discussing how the DQO process could be applied to improve the design and conduct of ecological risk assessments being undertaken across the DOE complex. Between the two workshops, participants spent a total of four days discussing in detail how the DQO process, step by step, could be used to improve the process by which ecological risk assessments are designed and conducted. This report presents the results of those two workshops. The authors wish to thank the participants in both workshops and their employers for their commitments of time and resources to this effort. Without their support, this report would not have been possible. All participants and their employers (at the time of their participation in the workshops) are listed in the "Acknowledgments" to this report.

Purpose

The purpose of this report is to help DOE field personnel and stakeholders design and conduct effective ecological risk assessments at environmentally diverse sites through application of the EPA's DQO process. The report identifies specific points in the Framework for Ecological Risk Assessment (EPA 1992) where the DQO process can be applied iteratively (as intended by the EPA [1994a]) during the design and conduct of either quantitative or qualitative ecological risk assessments. It also discusses how to apply the DQO process at those specific points, and how to use Data Quality Objectives (DQOs, Box 3) to evaluate existing data, to identify additional data needs, and to fill those needs. The report assumes that ecological risk assessments will be conducted at environmentally diverse sites, where multiple stressors affect (or have the potential to affect) spatially and temporally variable natural resources over large spatial and temporal scales. It also assumes that ecological risk assessments across the DOE will be conducted within a wide variety of federal and state regulatory environments.

Box 2. DQO Process

"The DQO Process is a strategic planning approach based on the Scientific Method that is used to prepare for a data collection activity. It provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when to collect samples, where to collect samples, the tolerable level of decision errors for the study, and how many samples to collect." (EPA 1994a)

Diverse sites, such as many of those found throughout the DOE and U.S. Department of Defense (DoD) complexes, pose many technical challenges that are not typically associated with smaller, simpler sites (e.g., industrial and commercial sites measured in acres, sites with single contaminants, sites without radionuclide contaminants). Among the more important of these challenges are how to

- clearly articulate the decision framework that the ecological risk assessment must address
- use existing, historical data that were typically collected for reasons other than to support ecological risk assessment (e.g., routine environmental monitoring data)
- identify critical gaps in the existing data set
- design the collection of new data to fill gaps, and how to use those new data in the risk assessment process
- design ecological risk assessments on spatial and temporal scales that are appropriate to the planning or management objective (e.g., design ecological risk assessments based on ecological units, rather than regulatory units such as operable units under the Comprehensive Environmental Response, Compensation and Liability Act [CERCLA])

- design ecological risk assessments to meet management needs for existing and future natural resource profiles

- design ecological risk assessments to address more than one regulatory need or application

- address design needs specific to ecological risk assessments in the work plan phase, including the identification of benchmarks, assessment and measurement endpoints, detection limits, variables to be measured, and statistical parameters (e.g., mean values, confidence limits) to be determined

- use the DQO process iteratively throughout the design and conduct of ecological risk assessments.

This report addresses each of these challenges.

This report will be helpful to decision makers (e.g., land use planners, risk managers), site program managers (e.g., operable unit managers, remediation managers), compliance project managers (e.g., remedial investigation/feasibility study managers), risk assessors (e.g., risk assessment teams), and stakeholders (e.g., state agencies responsible for the management of natural resources; natural resource trustees under CERCLA). Because many DoD sites are large and complex, and thus pose challenges similar to those found at DOE sites, this report should also be useful to DoD field personnel and their stakeholders.

This report is intended to supplement the *Framework for Ecological Risk Assessment* (EPA 1992), the *Data Quality Objectives Process for Superfund* (EPA 1993a), and the *Guidance for the Data Quality Objectives Process* (EPA 1994a). Readers should be familiar with the information in these documents. However, summaries of the essential elements of EPA (1992) and EPA (1994a) are provided in Appendices A and B, respectively, for quick reference.

Box 3. DQOs

"DQOs are qualitative and quantitative statements derived from the outputs of the first six steps 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 tolerable limits on decision errors which 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 data collection design." (EPA 1994a)

Background

DOE owns and manages numerous sites of up to 1,350 sq. mi. (i.e., the Nevada Test Site) in different geographic and climatic regions of the country. A wide variety of ecological resources are located on these sites - for example, relatively undisturbed, sensitive habitats (e.g., wetlands, semi-arid deserts), threatened and endangered species, woodland habitats, former agricultural lands, and highly

disturbed industrialized lands. On any given DOE site, specific types of ecological resources may occur entirely within the site boundaries, or may be distributed across and beyond site boundaries. In the latter case, actions of the DOE and adjacent landowners jointly have the ability to affect ecological resources. Managing these resources responsibly, meeting the intent and letter of applicable environmental statutes, and simultaneously fulfilling the missions of the various sites requires that DOE staff be informed about 1) the resources found on their respective sites; 2) the ecological processes that occur there; 3) the functions that are preformed by those ecological resources (e.g., soil stabilization, water purification); and 4) the interactions (positive and negative) between those resources and past, present, and future human activities related to the site mission.

Ecological Risk Assessment as a Planning and Management Tool

In general, ecological information collected at each site is used to manage existing resources for present and future uses, to support interim activities needed to achieve future uses, or both. Over the past decade, DOE, DoD, EPA, and other agencies have relied increasingly on ecological risk data to fulfill these information needs. Ecological risk assessment is increasing relied upon because the derived information supports resource management decisions far more effectively and accurately than other analytical techniques (see Suter 1996). Ecological risk data provide information on three primary areas within the resource planning and management context: 1) risks associated with existing conditions; 2) risks associated with future conditions; and 3) risks associated with the interim activities that must occur to achieve future conditions.

A typical resource planning and management framework showing the relationships among resource profiles, risk profiles, activities, and activity risk profiles is shown in Figure 1. Typical resource planning and management activities include environmental remediation, environmental restoration, facility conversion, facility closure and removal, and redefinition of land uses. The solid boxes and lines indicate the general flow of planning and management activities, and the dashed boxes and lines indicate the general flow of risk assessment activities. The existing resource and risk profiles represent present conditions, while all other profiles and activities represent future conditions. Planning and management activities begin with the existing resource profile, which is derived from a characterization of the existing physical resources, biological resources, and stressors. In conjunction with the site vision (or desired facility conversion, redefined land use, etc.), a future endstate resource profile is then created to serve as the target for the planning and management activities. Achieving this target often requires that interim activities be planned and conducted. The future resource state is, therefore, dependent on both the existing resource state and the selection and timing of interim activities. Ideally, risk assessments are used to help determine and prioritize which interim activities are needed to achieve the desired endstate resource profile, and the degree to which that desired endstate is achievable.

Role of the DQO Process in Ecological Risk Assessment

Ecological risk assessments may be conducted in support of a wide variety of planning and management activities. Moreover, across the DOE complex, these activities will often be conducted on large sites that are spatially complex and temporally dynamic with respect to the distribution of ecological resources, the type and distribution of stressors, and the applicable regulatory requirements.

This high degree of variation among site conditions precludes the development of simple, step-by-step procedural guidance for the design and conduct of ecological risk assessments. Hence, each time an ecological risk assessment is needed to support planning or management activities, risk assessors are challenged to design and conduct a specific risk assessment that collects the needed data effectively and efficiently.

The DQO process offers risk assessors a standardized procedure for designing an effective, efficient risk assessment. It is a strategic planning-based approach whose objective is to ensure that "data of sufficient quality and quantity to support defensible decision making" are collected, without "unnecessary, duplicative, or overly precise data" being collected (EPA 1993a). The DQO process meets this objective through the application of seven planning steps, based on the Scientific Method, that are "designed to ensure that the type, quantity, and quality of environmental data used in decision making are appropriate for the intended application" (EPA 1993a). In so doing, it provides a means for saving time and resources by designing and conducting the risk assessment effectively and efficiently from the beginning. At present, however, only limited information is available to help risk assessors apply the DQO process effectively to ecological risk assessments.

The DQO process provides a structured approach to ecological risk assessments, particularly during its Steps 1-4. These four steps (i.e., "State the Problem", "Identify the Decision", "Identify Inputs to the Decision", and "Define the Study Boundaries") closely parallel the "Problem Formulation" phase of the ecological risk assessment process (Barnthouse and Suter, 1996; see also EPA 1992). Moreover, data collected for human health and ecological risk assessments at CERCLA sites are closely linked because they exhibit many common data requirements (e.g., data on environmental contaminants, environmental pathway analysis), and because they are constrained by the same budget and schedule requirements.

The most difficult aspects of applying the DQO process to ecological risk assessments arise in Steps 5, 6, and 7 (i.e., "Develop a Decision Rule," "Specify Tolerable Limits on Decision Errors," and "Optimize the Design," respectively) because

- officially approved environmental standards and/or goals do not exist, such that standardized ecological endpoints cannot be specified

- ecological risk assessments may be required to support complex decision rules, and hence, may require multiple endpoints

- ecological risk assessments often generate quantitative data regarding effects of stressors on various attributes of ecological systems, but use those data in evaluations of overall ecological risk that are qualitative and based primarily on weight of evidence and professional judgement (Barnthouse and Suter, 1996).

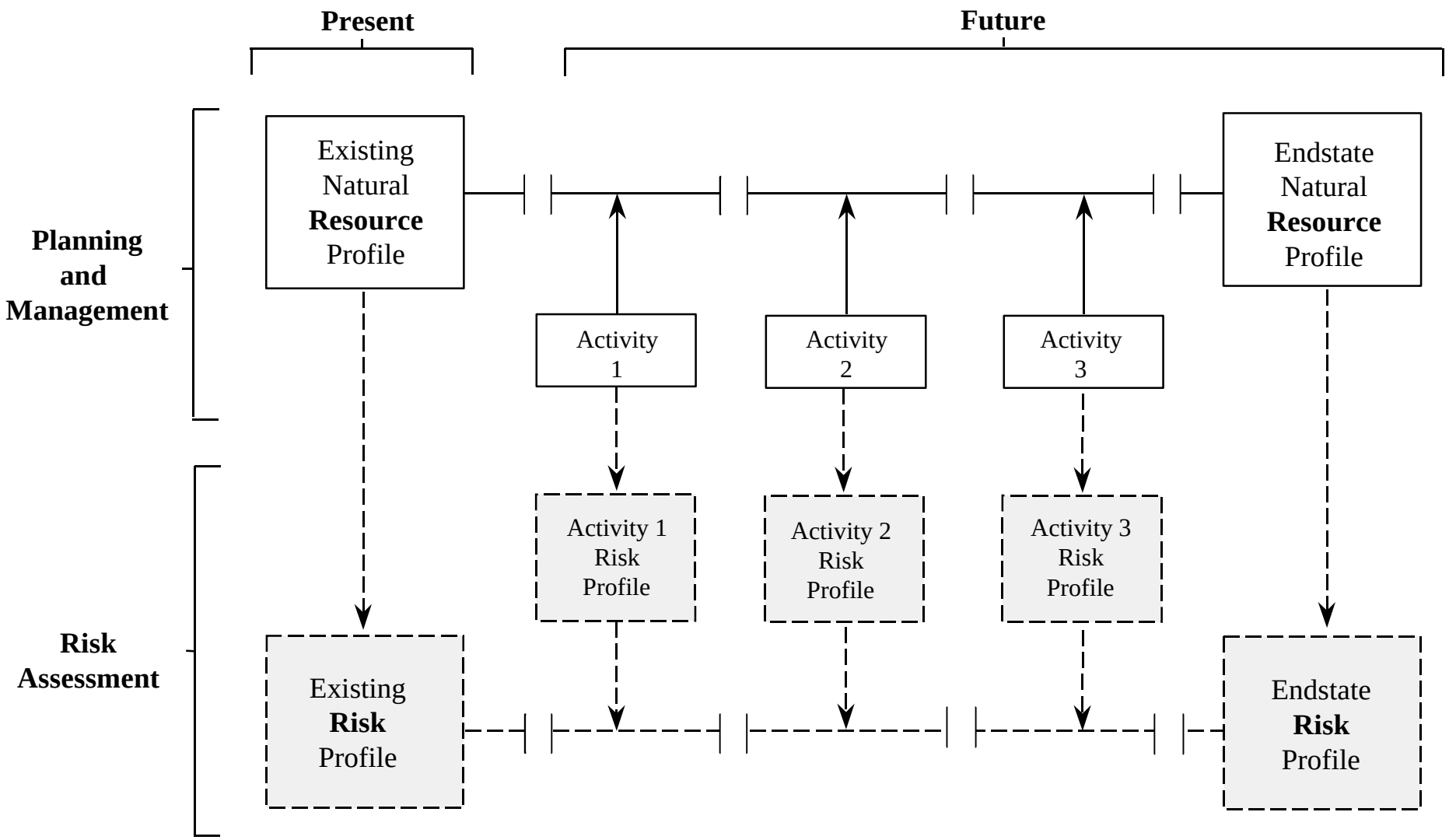

Figure 1. General Natural Resource Planning and Risk Assessment Model

In addition, to be fully developed, DQO Steps 6 and 7 require meaningful baseline information on environmental variability of the variables of interest (such information is typically not available for a site before the ecological risk assessment is conducted, and usually cannot be collected during the ecological risk assessment due to budget and/or schedule constraints). Despite these difficulties, authors and workshop participants believe that application of the DQO process to ecological risk assessments has considerable merit, as it helps ensure that ecological risk assessments are conducted as efficiently and effectively as possible. At a minimum, it helps achieve the scoping goals of EPA's (1992) *Framework for Ecological Risk Assessment*, and facilitates early, effective discussion and agreement among all participants (e.g., sponsors, regulators, other stakeholders) in the ecological risk assessment process. Reaching agreement among all participants regarding the objectives, scope, approach, cost and schedule for the ecological risk assessment builds trust among all participants and enhances the viability of the assessment. It also offers risk assessors and other participants a means for identifying and substantiating necessary changes in scope, approach, cost, and schedule change for technical reasons during the conduct of the assessment.

Organization of the Report

This report is organized around the seven steps of the DQO process, with one chapter devoted to each step. Within each step, substeps targeted to the design and conduct of ecological risk assessments are defined. In some cases, these substeps correspond directly to the activities recommended by EPA (1994a); in other cases they do not. But regardless of the degree of correspondence, each substep is cross-referenced to the relevant activities recommended by EPA (1994a). It is anticipated that the procedures recommended in this report will be applied to a great variety of environmental and ecological conditions. Hence, the report attempts to recommend activities that can be applied flexibly under a wide variety of site conditions, and that allow ecological risk assessors considerable latitude in the design and conduct of their studies.

Step 1: State the Problem

"The purpose of this step is to define the problem so that the focus of the study will be unambiguous" (EPA 1994a). Expected outputs identified by EPA (1994a) include

- "A list of the planning team members and identification of the decision maker."
- "A concise description of the problem."
- "A summary of available resources and relevant deadlines for the study."

As discussed below, recommended substeps for stating the ecological risk assessment problem are

- Substep 1.1 - Develop Preliminary Description of the Problem
- Substep 1.2 - Define Planning and Decision Team
- Substep 1.3 - Assemble Project Team
- Substep 1.4 - Develop Detailed Description of the Problem
- Substep 1.5 - Define Scope and Extent of Ecological Risk Assessment.

Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 1.

Table 1. Correspondence Between Substeps 1.1 - 1.5 and EPA Activities

Substep	**Activity A:** Identify members of the planning and decision team.	**Activity B:** Identify the primary decision maker of the planning team and define each member's role and responsibility during the DQO process.	**Activity C:** Develop a concise description of the problem.	**Activity D:** Specify the available resources and relevant deadlines for the study.
1.1			X	
1.2	X	X		
1.3	X	X		
1.4			X	
1.5				X

Substep 1.1 - Develop Preliminary Description of the Problem

The first substep is to develop a preliminary description of the problem. The most accurate and insightful preliminary problem descriptions will be prepared when the present natural resource profile (e.g., habitats, species [including threatened and endangered species and other species of concern], other environmental attributes, stressors, human uses) and the future endstate natural resource profile can be described (as per Figure 1), and when those profiles are understood within the contexts of a general conceptual site ecological model,[(a)] site management goals, associated management activities, and the applicable regulatory framework. The natural resource profiles provide descriptive information on site and resource conditions, while the conceptual site model provides information on the ecological processes, contaminants and other stressors, and pathways that are occurring on the site. Together, they provide a landscape-level understanding of present and future conditions at the appropriate spatial and temporal scales. Examples might be 1) a watershed-level understanding or an ecosystem-level understanding of the environmental media, the living resources associated with those media, the ecological processes within the watershed or ecosystem, and the potential impacts (described qualitatively) of a proposed human activity on biotic resources, abiotic resources, and ecological processes and functions; or 2) a detailed description of the present state of a facility and the surrounding ecological resources, plus a description of the desired state of that facility (e.g., transitioned to another function; closed, removed and restored) and surrounding ecological resources.

It is not the mission of the group that develops the preliminary description of the problem to determine the future state, be it the future state of a facility or future land uses. In most cases, it is also not the mission of this group to develop the conceptual site ecological model. (The most common exception would be when no conceptual site ecological model exists and it is recognized that one must be created before a project-specific ecological risk assessment can be conducted.) Rather, the group that develops the preliminary description should consider the conceptual site ecological model, site and facility planning documents, and land use plans as they have been defined by persons and groups previously tasked with those activities. These large scale descriptions and plans should be created as soon as possible at a diverse site, thereby allowing team members to describe the purpose, scope, and data quality objectives of the ecological risk assessment *as they relate to the project at hand*.

Before proceeding with a preliminary description of the problem, it is also necessary to confirm that the future facility or land use scenario (and hence, future endstate resource profile) will result in interactions with the soil, surface water, ground water, air, or biota at the site (e.g., that there are environmental media and/or biota that will be part of the scenario). Should the future scenario not

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(a) In most cases, the project team does not develop the general site conceptual model. That effort should have been undertaken earlier by a site-wide team. A good site conceptual model should define 1) the spatial and temporal boundaries of the site; 2) the major ecological actions and interactions (preferably graphically); 3) the ecological relationships of the site to adjacent areas; and 4) the interrelationships among onsite and offsite stressors. It is the job of the project team, however, to interpret the problem at hand within the context of the general site conceptual model. See American Society for Testing and Materials (1995) for information regarding the development of conceptual site models for contaminated sites.

interact with media or biota, a need may not exist to conduct an ecological risk assessment (depending on the applicable federal and/or state regulations). Alternatively, if those media and/or biota are affected, an ecological risk assessment may be needed to document the effects (both positive and negative) of the proposed activity. In cases of severe media alteration or elimination (e.g., paving over a site), a statement may be needed to document the irreconcilable damages that will occur as a result of the proposed activities. Such a statement may need to be accompanied by a mitigation plan, depending on the applicable federal and/or state regulations and the desires of the natural resource trustees.

Substep 1.2 - Define Planning and Decision Team

Members of the planning and decision team must be identified early in the risk assessment process, and must be available to work on the assessment throughout its life. The team's primary functions are to provide general direction to the ecological risk assessment and to ensure that the results of the assessment are communicated accurately to the decision makers. Because the planning and decision team guides the scope and direction of the assessment, each member of the team should have a technically sound environmental perspective. Together, they must have a reasonably comprehensive understanding of environmental processes and impacts in time and space.

Critical activities in the formation of the planning and decision team are 1) identifying the organizations (e.g., DOE, EPA) and designated persons who have actual decision-making authority, 2) identifying key contributors to the decision-making process, and 3) identifying persons whose technical skills are essential for success. Primary decision makers may include regulators, remedial project managers, trustees, operable unit managers and project managers who have a stake in the decision, and risk assessors and project engineers. Early in the formation of the planning and decision team, it will be necessary to review and confirm the regulatory requirements to which the ecological risk assessment will apply. Individuals with regulatory decision authority (i.e., the appropriate agencies and persons within those agencies) should be identified and involved early in specifying the scope and objectives of the assessment. (See Appendix C for a listing of potential regulatory compliance applications for ecological risk assessments.) Contributors to the decision(s) that the risk assessment will support will typically include others who have a stake in the decision, such as Natural Resource Damage Assessment trustees and the U.S. EPA. Persons whose technical skills may be critical for success may include regulatory analysis specialists, toxicologists, and land use planners. When team composition is finalized, members may include the DOE sponsor, ecologists, toxicologists, legal representatives and regulators, risk managers, risk assessors, external stakeholders, trustees, engineers, statisticians, and field and laboratory personnel.

The exact compositions of different teams will vary, depending on the scope of the problem, who has decision authority over the problem, the existing environmental conditions, the planned activity, and the desired outcome of that activity. Similarly, the roles and responsibilities of the various team members may also vary. However, in all cases it is optimal that decision makers and contributors to decisions be represented on the planning and decision team, and that their roles and responsibilities be commensurate with their positions of authority and interests. It is also optimal that the size of the team be manageable, and that its members remain flexible in their approach to the problems at hand.

Immediately after the composition of the planning and decision team has been finalized, its first activity should be to agree to and record, in writing, those agencies and designated persons (by name) who have authority for the decision that the ecological risk assessment will support. This is important because it establishes organizational and personal responsibility for the decision. If personnel change during the course of the assessment, continuity among the responsible agencies remains, and appropriate agency personnel may be identified to sit on the planning and decision team and participate in the decision process. A sample letter of agreement for decision authority is provided in Appendix D.

Substep 1.3 - Assemble Project Team

Once the planning and decision team defines roles and responsibilities, they must assemble a project team to plan and conduct the ecological risk assessment. The project team is responsible for designing (in detail) and conducting the ecological risk assessment in accordance with the general guidance provided by the planning and decision team. Hence, the composition of the project team must reflect the technical needs for the study. Members of the project team might include scientists, engineers, legally responsible parties, regulators, risk managers, trustees, risk assessors, risk communicators, the project manager, the program manager within which the project resides, the fiscal manager, and other interested parties (depending on the scope and objectives of the assessment).

It is the responsibility of the project team to ensure that the description of the problem and the associated risk management goals are consistent. Hence, the project team reviews for consistency 1) the scope and direction of the ecological risk assessment (as defined by the planning and decision team) and 2) the applicable risk management goals as decided in the problem formulation step of the ecological risk assessment (i.e., Substeps 1.1 above and 1.4 below). The project team should then summarize key information related to the 1) site, 2) setting, 3) stressors (in time and space), and 4) major concerns of all interested parties (i.e., regulators, trustees, sponsors), as these will eventually be considered in the decision process. An example of this key summary information is provided in Box 4.

Substep 1.4 - Develop Detailed Description of the Problem

The project team should now understand the problem sufficiently to prepare a detailed, project-specific description of the problem, and an associated problem-specific model of possible cause and effect relationships, if only qualitative in nature. A general site conceptual site model is extremely useful at this point because it helps bound the risk problem spatially and temporally. Stressors, pathways, and receptors can be identified, understood, and modelled within the larger ecosystem processes and functions. The processes and functions within the site conceptual site model also help bound the range of future endstates and land uses by defining, in general terms, the potential range of ecological endstates. In most cases, it will be possible to develop the problem-specific conceptual site model as a derivative of the general site conceptual site model, with appropriate descriptions of the stressors, pathways, and receptors of interest. Accurate estimates of ecological risk can only be obtained if the problem is understood and described from a holistic perspective, which in most cases will be provided by the general site conceptual site model. Desired future endstates are also important, as they help define acceptable levels of risk to appropriate receptors.

Box 4. Sources of Stress and Major Concerns for the R-Reactor Seepage Basins

Site:	R-Reactor Seepage Basins.
Setting:	30-acre fenced area north of reactor building; site of former R-reactor construction headquarters.
Stressors:	Radionuclides, metals, pesticides and herbicides from historical activities and accidental releases are present on the site. Other potential chemical stressors are present upgradient and downgradient of the R-Reactor Seepage Basins from sources such as the reactor building, overflow basin, and disassembly basin.
Major concerns:	Soil and groundwater are contaminated. Contamination has migrated via environmental pathways, including air, groundwater, surface water, biotic uptake, and bioturbation. Migration has been accelerated in some cases by the presence of abandoned sewer lines. Potential receptors include native fauna and flora. Federal and state species of concern that may potentially be exposed include the American alligator, wood stork, and bald eagle. A potential exists for contaminant migration offsite via the storm water runoff, biotic uptake, and groundwater pathways.

The description of the problem should begin with a succinct statement about whether the ecological risk assessment will be used to screen among alternatives (including the no-action alternative) or to provide a detailed assessment of the risks associated with a specific alternative (including the no-action alternative). This distinction is very important, as it helps determine the scope and required level of effort for the assessment. When used in a screening capacity, the large-scale ecological landscape (e.g., watershed) should be examined within the framework of the site conceptual site model (and especially the inherent processes and functions) to eliminate concerns and narrow the scope of the problem. For example, having narrowed the spatial extent of the problem to a particular habitat of concern, it is often possible to eliminate many potential impacts from consideration, even when the stressors are not well understood or documented. Problem descriptions for risks associated with specific alternatives will generally be much more focussed and specific than those for screening level assessments.

In either case, key components of problem description typically include descriptions of

- the type of assessment (i.e., screening level or specific alternative level)
- the regulatory framework within which the results of the ecological risk assessment will be used
- stakeholder concerns that should be addressed by the assessment
- risk management goals
- the ecosystem of interest, including spatial and temporal scales
- physical, chemical, and biological stressors
- site history relevant to the stressor(s)
- exposure sources and pathways
- potential receptors, receptor endpoints, and other variables of interest
- expected effects.

It is important to note that regulatory requirements and stakeholder concerns have the potential to influence the ecological risk assessment throughout the entire process, and that those requirements and concerns may change as information on stressors, resources, and risks is obtained. An example problem description is provided in Box 5.

In most cases, encoding the problem statement in a Geographic Information System can help ensure that all relevant stressors, receptors, and endpoints of interest are included in the analysis, and that all relevant cause and effect relationships are considered in the analysis. Application of geographic information systems to ecological risk assessment is discussed in Appendix E.

Substep 1.5 - Define Scope and Extent of Ecological Risk Assessment

The final activity in Step 1 is to define the scope and extent of the ecological risk assessment, including the scope, level and timing of the assessment, and the required resources. The approach must be directly tied to, and consistent with, the problem description. The description of the approach should be based on an initial discussion of how the project team plans to proceed with the assessment, the team's expectations about the need for additional data collection, and the team's initial ideas on how to obtain those data. To the extent possible, the initial description of the scope and extent of the assessment should include:

- The risk management decisions to be supported by the assessment.
- The way in which the results of the assessment will be used to meet regulatory requirements. (It is important that the applications of the results be specified as broadly as possible, anticipating future needs. For example, although the results of an ecological risk assessment

Box 5. Problem Description for R-Reactor Seepage Basins

A baseline risk assessment is being developed to assess the potential for adverse environmental effects to occur as a result of exposure to contaminants from the R-Reactor Seepage Basins (RRSB). The risk management goals for the RRSB unit are to clearly identify the risk and the uncertainties associated with the risk to ecological receptors. Baseline environmental risks are those that can be expected to occur in the absence of remedial actions. The RRSB assessment will focus on chemical stressors including radionuclides, metals, pesticides, and herbicides that historically have been released at the site. The ecosystem of interest is the area where potential adverse ecological effects may occur. Ecological receptors potentially may be exposed to stressors originating from the RRSB by exposure to soil contaminants directly through ingestion, dermal contact, and/or external radiation. Exposure may also occur as a result of secondary release of chemicals from surface and deeper soil, and subsequent migration of released chemicals through environmental media via a variety of pathways, including aeolian dispersal of particulate contaminants or contaminants adsorbed to surface soil particles; direct volatization from surface soil to air; uptake of contaminants by terrestrial organisms through the soil or by aquatic organisms through the water and/or sediments; transport of soil contaminants by storm water runoff to surface water and sediments; and chemical leaching from soil to groundwater, with subsequent discharge of groundwater into surface water and sediment streams.

Primary exposure pathways for terrestrial receptors are ingestion of soil, surface water, and sediment; exposure to direct radiation from soil and sediment; and ingestion of other animals and plants that have accumulated contaminants. Primary exposure pathways for aquatic receptors are ingestion of surface water and sediment, dermal contact, and direct radiation. Terrestrial species potentially exposed to RRSB-derived stressors include deer, raccoon, opossum, rabbits, rodents, and birds (primarily as a result of foraging activities). Burrowing species, such as rabbits, rodents, moles, and shrews would probably receive the greatest exposures among vertebrates. Invertebrates living on and within the soil could also experience significant exposures. Aquatic and semi-aquatic species potentially exposed to RRSB-derived stressors include fish, reptiles, and amphibians. Terrestrial, aquatic, and semi-aquatic species could be exposed to contaminants present in surface water and/or sediments.

This baseline risk assessment is being initiated as a result of a scheduled remedial investigation program, during which potential chemical stressors were identified. It was not initiated as a result of an unplanned release or confirmed observed effect. No effects attributable to RRSB contaminants have been observed during characterization activities.

may be used primarily to comply with the provisions of CERCLA, thought should be given to other possible applications, such as supporting related Environmental Impact Statements under NEPA. DOE considers CERCLA documentation to be part of the administrative record for NEPA.)

- The available information resources.

- The preliminary budget and schedule.

Particularly useful references for this activity are EPA (1992) and DOE (1993, 1994). Other helpful references include EPA (1993b, 1994b, 1995).

Programmatic Aids

Depending on site conditions and the specifics of the problem being considered, several programmatic aids could facilitate the activities that are conducted during Step 1. Among the more useful would be the following:

- a signed memorandum of decision responsibility for the problem being considered (see Appendix D)

- site-wide technical memoranda on various topics common to risk assessment and management, such as 1) management goals and assessment endpoints (where a potential to standardize exists), 2) a general site conceptual site model, and 3) a standard screening risk method (where data comparisons with standard benchmarks are specified)

- a standing risk planning and decision council for the site consisting of a number of individuals that is appropriate to the size and complexity of the site, and from which smaller project-specific groups can be formed for the purpose of making decisions; these individuals (including, for example, ecologists, engineers, and regulatory specialists) would request assistance from other technical experts to address specific problems

- the development of a Geographic Information System for the site that allows environmental and ecological data to be entered and analyzed in support of ecological risk assessments

- the awarding of contracts that require the contractor to use the DQO process during the conduct of the work.

Programmatic Considerations

A representative list of programmatic considerations for Step 1 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 1 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced the appropriate number(s) of the step(s).

- Can longevity be built into the DQO process, such that the final ecological risk assessment can serve multiple purposes?

- Should stakeholders and the public be involved in the DQO process? Should they be involved in setting assessment and measurement endpoints? If so, how? [3,4,7]

- Should the DQO process be used to integrate Natural Resource Damage Assessment (NRDA) concerns into the ecological risk assessment process, and if so, how? [3,4,7]

- How can the DQO process be used to better define spatial and temporal boundaries of the ecological risk assessment (e.g., ecological units versus regulatory units)? [4,7 with feedback to 4]

- How should spatial and temporal scales be considered when designing and conducting the ecological risk assessment? [4,7]

Step 2: Identify the Decision

"The purpose of this step is to define the decision statement that the study will attempt to resolve" (EPA 1994a). The expected output identified by the EPA (1994a) is "a decision statement that links the principal study question to possible actions that will solve the problem."

As discussed below, recommended substeps for identifying the decision are

- Substep 2.1 - Define the Management Framework
- Substep 2.2 - Develop a Logic Diagram of Study Questions and Actions.

Together, these substeps define where the decision resides and then the path forward. Although not specifically called for by the EPA (1994a), an understanding of the management and regulatory frameworks within which the decision resides is very important because the specific study questions and actions that are developed in this step are highly dependent on management goals and regulatory requirements. Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 2.

Table 2. Correspondence Between Substeps 2.1 - 2.2 and EPA Activities

Substep	**Activity A:** Identify the principal study question.	**Activity B:** Define the alternative actions that could result from resolution of the principal study question.	**Activity C:** Combine the principal study question and the alternative actions into a decision statement.	**Activity D:** Organize multiple decisions.
2.1				
2.2	X	X	X	X

Substep 2.1 - Define the Management Framework

The decision that will be made will be implemented within the framework of ecological risk management goals, plans, and activities, an example of which is shown in Figure 2[(a)]. An understanding of this management planning and activity structure is therefore critical to both making the decision and implementing the associated activities. For example, in the regulatory dimension, management goals will likely include compliance with applicable environmental laws and regulations. Hence, management plans will usually include compliance-directed activities. Although the decision and supporting ecological risk assessment at hand may be directed toward one compliance requirement, it is also important to identify related compliance requirements that could be served by the ecological risk assessment, so as to maximize the utility of the data that will be collected and the analyses that will conducted.

Given an understanding of how the management framework operates, it is also important to understand how well the management framework is performing. Performance can also influence the decision and implementation of associated activities. Key questions relevant to performance might include

- Is the site (or facility, etc.) achieving its management goals?
- Is the site (or facility, etc.) in compliance with regulatory requirements?
- Should the site (or facility, etc.) management framework, goals, objectives, or implementing mechanisms be altered to enhance performance?

Finally, before developing a logic diagram for the decision at hand, it is important to understand the management goal and level at which the decision will be made. The two most common goals for decisions are 1) cleanup of existing problems, and 2) management of ecological resources. These goals differ greatly, and hence greatly influence the design of the logic diagram. Moreover, a tension can exist in which environmental cleanup goals and environmental management goals are not compatible. In such cases, the logic diagrams developed to meet one goal must consider other competing goals. Within each category of goal, the level of the decision may be site-wide, programmatic, or facility-specific. The level of the decision also influences all aspects of the design of the logic diagram: the study questions, the actions, and the data needed to support them.

(a) Note, however, that other criteria will also influence the decision, depending on the regulatory framework and stakeholder interests. For example, under CERCLA the following nine criteria for evaluation of alternative remedies (Box A 2.2-7) must be considered: overall protection of human health and the environment; compliance with applicable or relevant and appropriate requirements (ARARs); long-term effectiveness and permanence; reduction of toxicity, mobility, or volume through treatment; short-term effectiveness; implementability; cost; state acceptance; community acceptance.

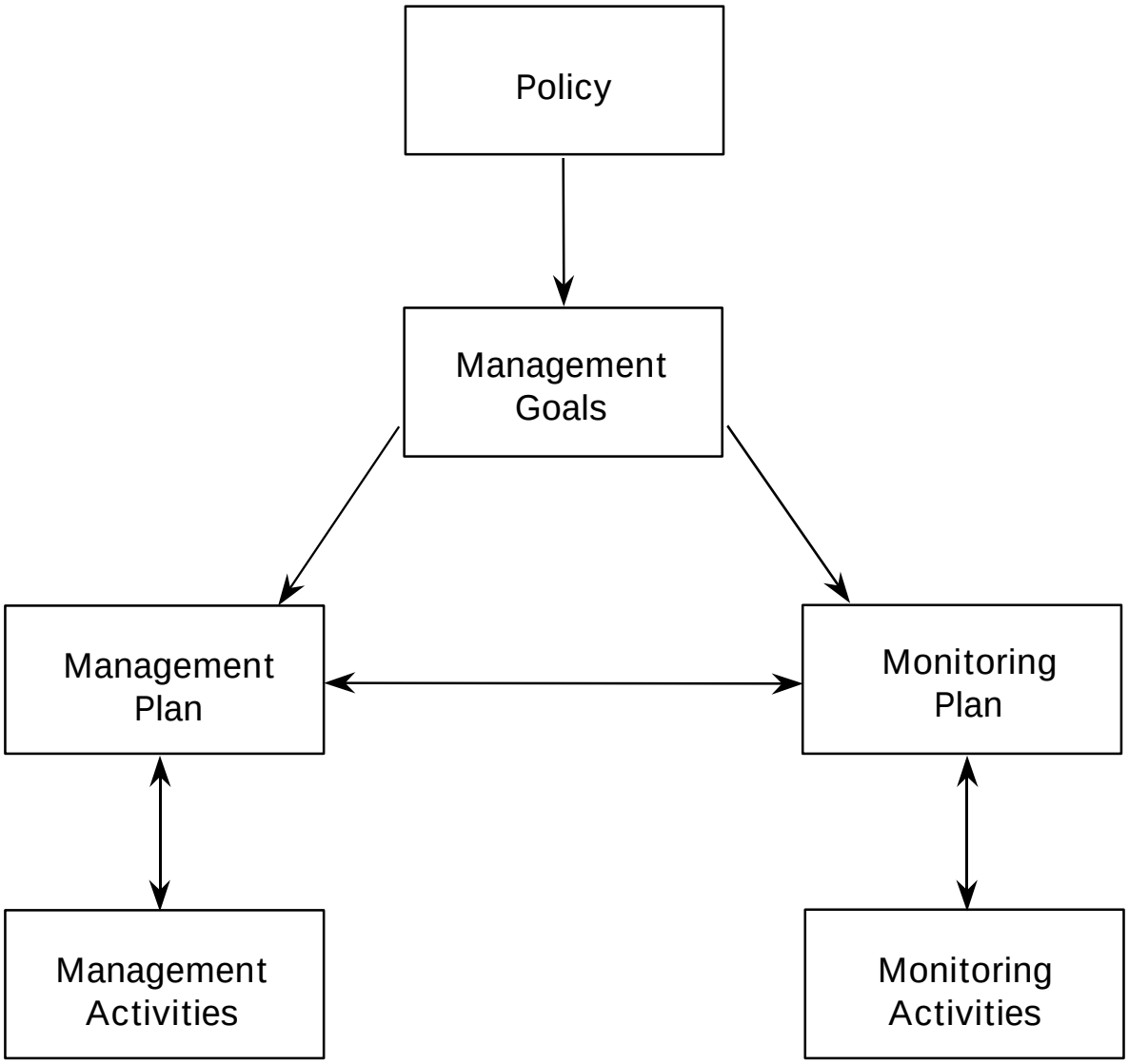

Figure 2. Typical Management Planning and Activity Structure

Substep 2.2 - Develop a Logic Diagram of Study Questions and Actions

Before developing a logic diagram for the decision at hand, it is necessary to determine whether available data are adequate to frame the decision. Specifically, a general knowledge of the local ecology and potential stressor-receptor interactions is necessary. This being the case, it is possible to develop a logic diagram of study questions and actions for the decision at hand.

For any decision involving potential ecological risk, the principal study question that must be posed in the logic diagram is

"Does the stressor(s) pose unacceptable risk(s) to any receptor(s)?"

Other study questions and actions will usually be included in the logic diagram, but the above question is the most important. If it is answered negatively, based on available information, no further action is warranted. Alternatively, if available information is insufficient to answer the question, an ecological risk assessment may be needed to make the determination and document the decision that the stressor does not pose unacceptable ecological risk. Likewise, if the question is answered affirmatively, an ecological risk assessment is usually needed.

Before developing a logic diagram that includes the principal study question, various preliminary actions and options should be explored. In some cases, taking a preliminary action or implementing an alternative option may eliminate, control, or bound the decision at hand. Example actions and options that might be considered include

- What preliminary actions might be taken to solve the problem entirely. Could the results of any such action be documented?
- What would happen, spatially and temporally, if no action were taken?
- Is interim action needed to prevent further deterioration?
- Do potential cumulative risks exist?
- Is there a need to document and communicate the benefits of current management practices instead of taking action?
- What remedial options are realistic for the situation at hand? Do these options need to be documented, evaluated, and communicated?
- Does a need exist to develop a prioritized remediation plan that specifies what to remediate, when, in what order, and when to stop?

- Does competition for resources exist? For example, is a decision needed on whether to remediate site X instead of site Y?

- Does a need exist to determine what to monitor, when to monitor, and where to monitor?

- What possible mitigation actions exist?

Below, generic logic diagrams for decisions regarding chemical and radiological stressors (Section 3.2.1) and physical and biological stressors (Section 3.2.2) are discussed. These logic diagrams propose frameworks for organizing decision and activities, and provide examples of how all four activities recommended by the EPA (1994a) can be accommodated in a logic diagram. The diagrams are not intended to be prescriptive, but rather to serve as examples that (in some cases) may be adapted to specific decisions across the DOE complex. Both logic diagrams are sufficiently robust to be implemented at a landscape level, as recommended in Step 1.

Study Questions and Actions for Chemical and Radiological Stressors

A generic logic diagram for chemical and radiological stressors is shown in Figure 3. It attempts to organize study questions (SQ) and actions (A) in a sequence that would allow ecological risks from chemical and radiological stressors to be assessed. SQ 3-4 is the "Principal Study Question" as defined by EPA (1994). Antecedent questions and subsequent questions and actions are arranged so as to provide the information needed to answer the Principal Study Question qualitatively, and then act on the preliminary finding to resolve the problem. When using this or another logic diagram to guide an assessment, it is important that the planning and decision team ensure that the scope, approach, and level of analysis is appropriate for addressing the problem at hand. Too large a scope and/or level of analysis wastes resources, while too small a scope and/or level of analysis will be insufficient to support resource management decisions.

When responding to SQ 3.1 (i.e., whether site potential contaminants of concern [PCOC] are within background), it is necessary to have some understanding of what is driving the risk, as well as what constitutes the environmental baseline for that stressor or stressors. This question may be asked for both past releases and potential future releases of contaminants.

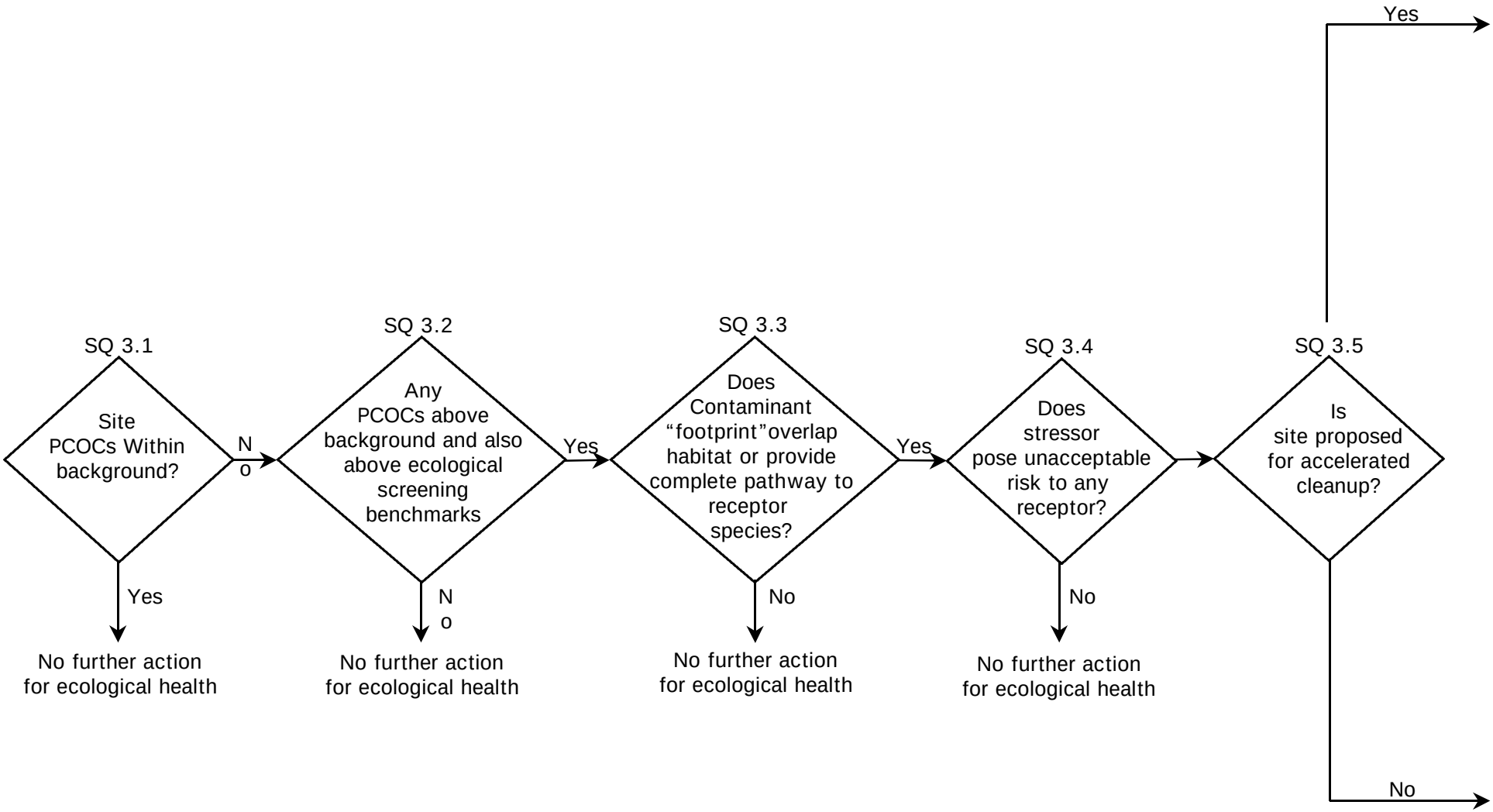

Figure 3. Study Questions (SQ) and Actions (A) for Chemical and Radiological Stressors.

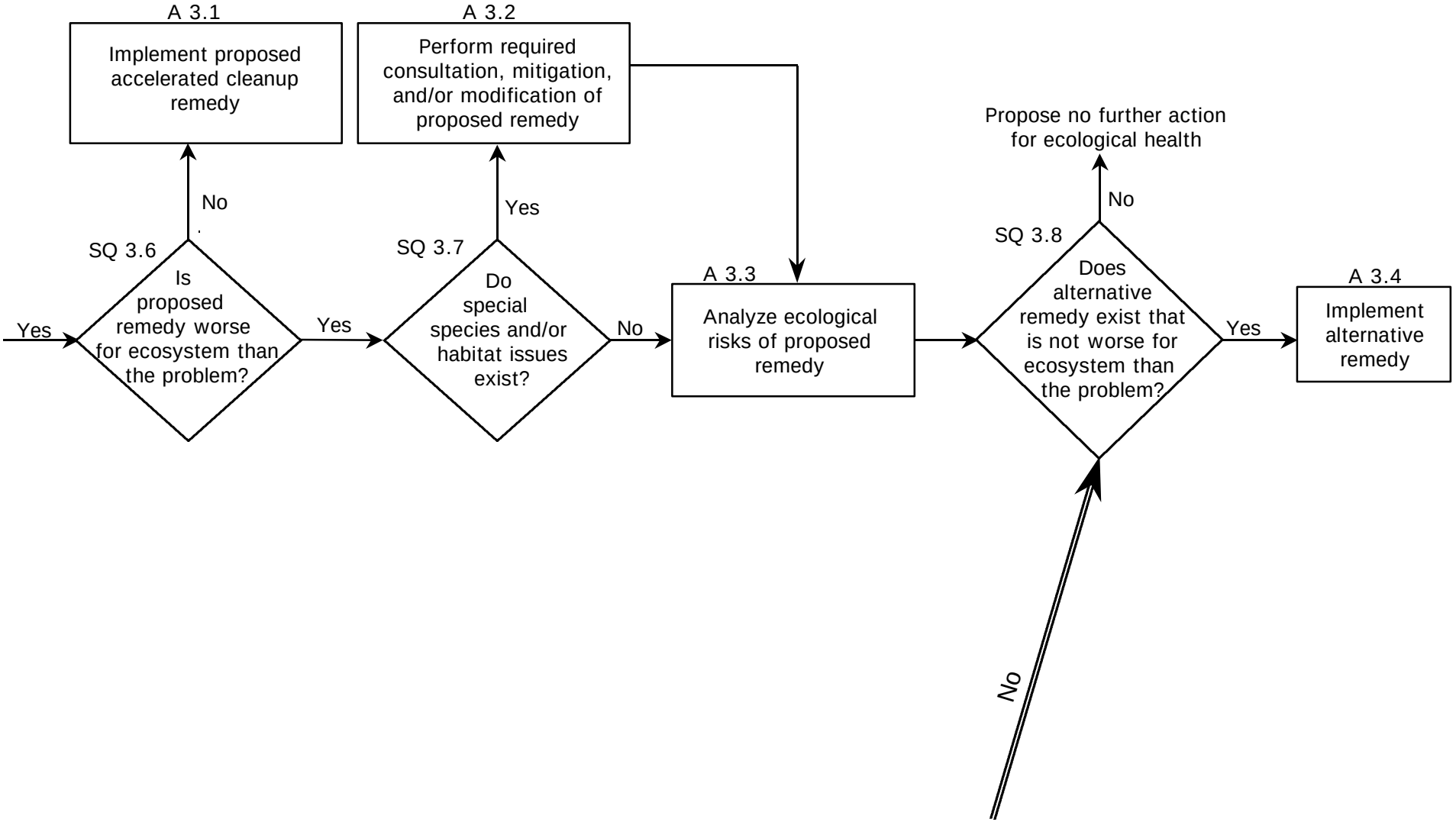

Figure 3. (continued)

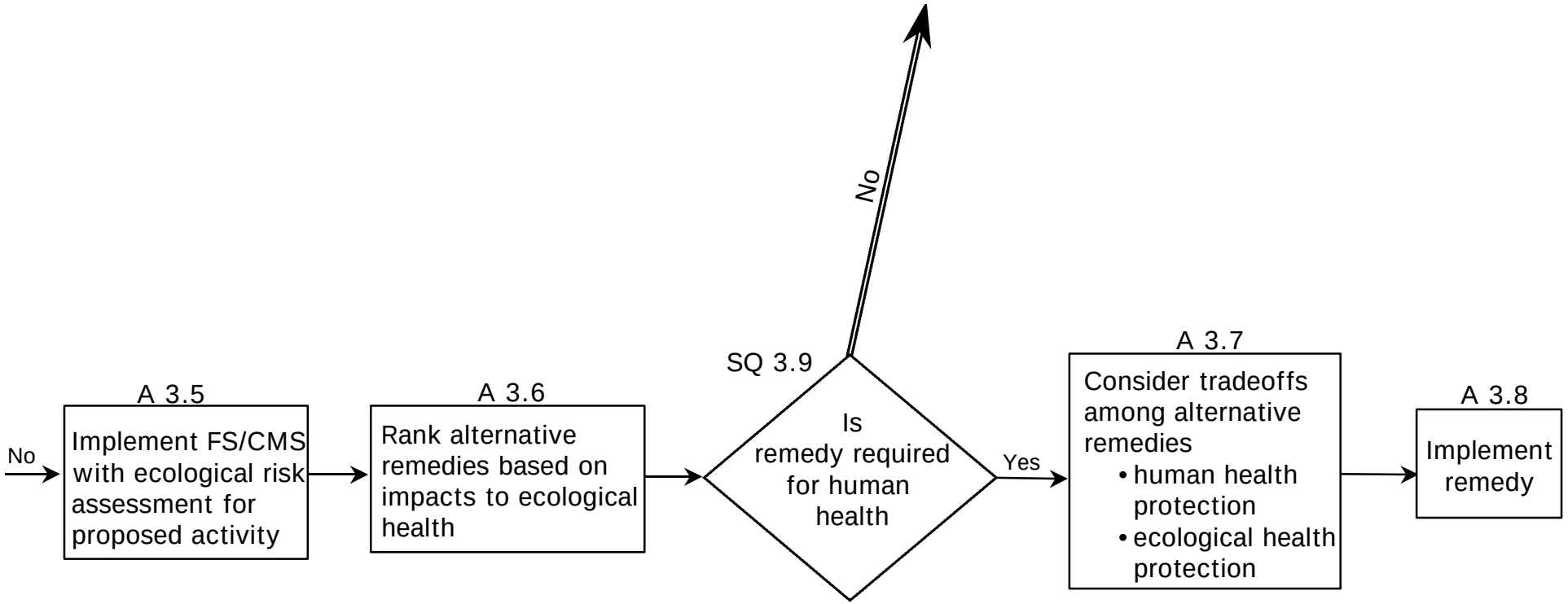

Figure 3. (continued)

Study question 2.2-2 (i.e., whether any PCOCs are above background and also above ecological screening benchmarks) assumes that assessment and measurement endpoints have been selected (e.g., receptor species), and that benchmark data are available to interpret the predicted levels of exposure. If benchmark data are not available, it may be necessary to collect site-specific toxicological or uptake data before the question can be answered. If SQ 3.2 is answered affirmatively, it is then necessary to determine whether the contaminant "footprint" (in space and time) overlaps the habitat or otherwise provides a complete pathway to receptor organisms (SQ 3.3). To answer this question, it is necessary to have a conceptual food web (at a minimum), or a general conceptual site model with associated pathway analysis routines for both terrestrial and aquatic systems.

Study question 2.2-4 is the "Principal Study Question," and must be answered at the appropriate spatial and temporal scales. If posed for ecological risks associated with a specific activity and answered affirmatively, additional study and analysis is warranted. But if posed and answered for a screening-level risk assessment, the endpoint of that assessment has been reached. For this reason, decision makers will want to minimize the probability of reaching an incorrect conclusion at this screening level, and will want the answer to SQ 3.4 substantiated by data, analytical tools, and predictive tools that exhibit a high levels of accuracy.

the highest possible levels of confidence must be associated with screening-level assessments. They must be based on the best possible information, and must employ the best possible analytical and predictive tools that meet screening-level objectives.

In general, screening-level assessments should be conducted using mean values with conservative confidence limits and realistic action levels. This approach allows different risk estimates to be compared and explained rationally. The typical alternative approach is to use maximum site values and conservative benchmarks, which results in overly conservative, unrealistic estimates of risk that cannot be compared or explained well. Moreover, the unrealistically conservative estimates of risk are often interpreted literally by risk managers and decision makers, resulting in poor decisions. That is, they consider the estimates of risk to be exact point values without any associated uncertainty. They also often ignore the conservative decisions and values imbedded in the calculation of the estimates. In reality, the estimates have statistical distributions associated with each step in their calculation, and these distributions can be used to characterize the uncertainty associated with the estimates. This uncertainty may be very large.

Study question 2.2-5 is principally a management decision, and is based on management goals and the management setting within which the decisions are made. If the action is accelerated, consideration must be given to whether the cure (i.e., solution) is worse than the disease (i.e., problem; SQ 3.6), whether special species or habitat issues exist (e.g., presence of threatened and endangered species at federal or state levels; SQ 3.7), and whether alternative remedies exist that are not worse than the disease (i.e., problem; SQ 3.8). When answering these questions, all possible combinations of receptors, habitats, ecosystems, and stressors must be considered. The key activity is A 3.3, in which the problem must be formulated and the risks analyzed in consideration of the management goals (e.g., cleanup goals, site environmental management goals), the general conceptual site model, and the ongoing monitoring programs. When considering the risks associated

with different remedial alternatives (i.e., SQ 3.6, SQ 3.8, A 3.3), the document *Risk Evaluation of Remedial Alternatives for the Hanford Site* (DOE 1995) may be useful.

If the action is not accelerated, the ecological risk assessment typically proceeds within the applicable regulatory framework (A 3.5), and alternatives are ranked (A 3.6). Consideration is then given to whether a remedy is required for the protection of human health (SQ 3.9), and if so, whether tradeoffs among alternatives should be considered (SQ 3.7). If a remedy is not required for protection of human health, consideration should be given to whether any of the alternative remedies are not worse for the ecosystem than the problem. Similar to the accelerated action track, the key activity is A 3.6, in which the problem must be formulated and the risks analyzed in consideration of the management goals (e.g., cleanup goals, site environmental management goals), the general conceptual site model, and the ongoing monitoring programs.

The final activity along both tracks is implementation of the remedy (i.e., A 3.4, A 3.8). In either case, treatability studies may be required before implementing the remedy. If so, the treatability studies will offer further opportunities to develop DQOs.

Study Questions and Actions for Physical and Biological Stressors

A generic logic diagram for physical and biological stressors is shown in Figure 4. It attempts to organize study questions (SQs) and actions (As) in a sequence that would allow ecological risks from physical and biological stressors to be assessed. Question SQ 4.2 is the "Principal Study Question" as defined by EPA (1994a). The antecedent question and subsequent questions and actions are arranged so as to provide the information needed to answer the Principal Study Question qualitatively, and then act on the preliminary finding to resolve the problem. When using this or another logic diagram to guide an assessment, it is important that the planning and decision team ensure that the scope, approach, and level of analysis is appropriate for addressing the problem at hand. Too large a scope and/or level of analysis wastes resources, while too small a scope and/or level of analysis will be insufficient to support resource management decisions.

When responding to SQ 4.1 (i.e., whether the stressor "footprint" overlaps the habitat of receptor species), it is necessary to have some understanding of what is driving the risk, as well as what constitutes the environmental baseline for that stressor or stressors.

The "Principal Study Question" (SQ 4.2) must be answered at the appropriate spatial and temporal scales. If posed for ecological risks associated with a specific activity (e.g., constructing a building) and answered affirmatively, additional study and analysis is warranted. But if posed and answered for a screening-level risk assessment (e.g., choosing among constructing a building, transporting materials offsite, and incinerating those materials), the endpoint of that assessment has been reached. For this reason, decision makers will want to minimize the probability of reaching an incorrect conclusion at this screening level, and will want the answer to SQ 4.2 substantiated by data, analytical tools, and predictive tools that exhibit a high levels of accuracy.

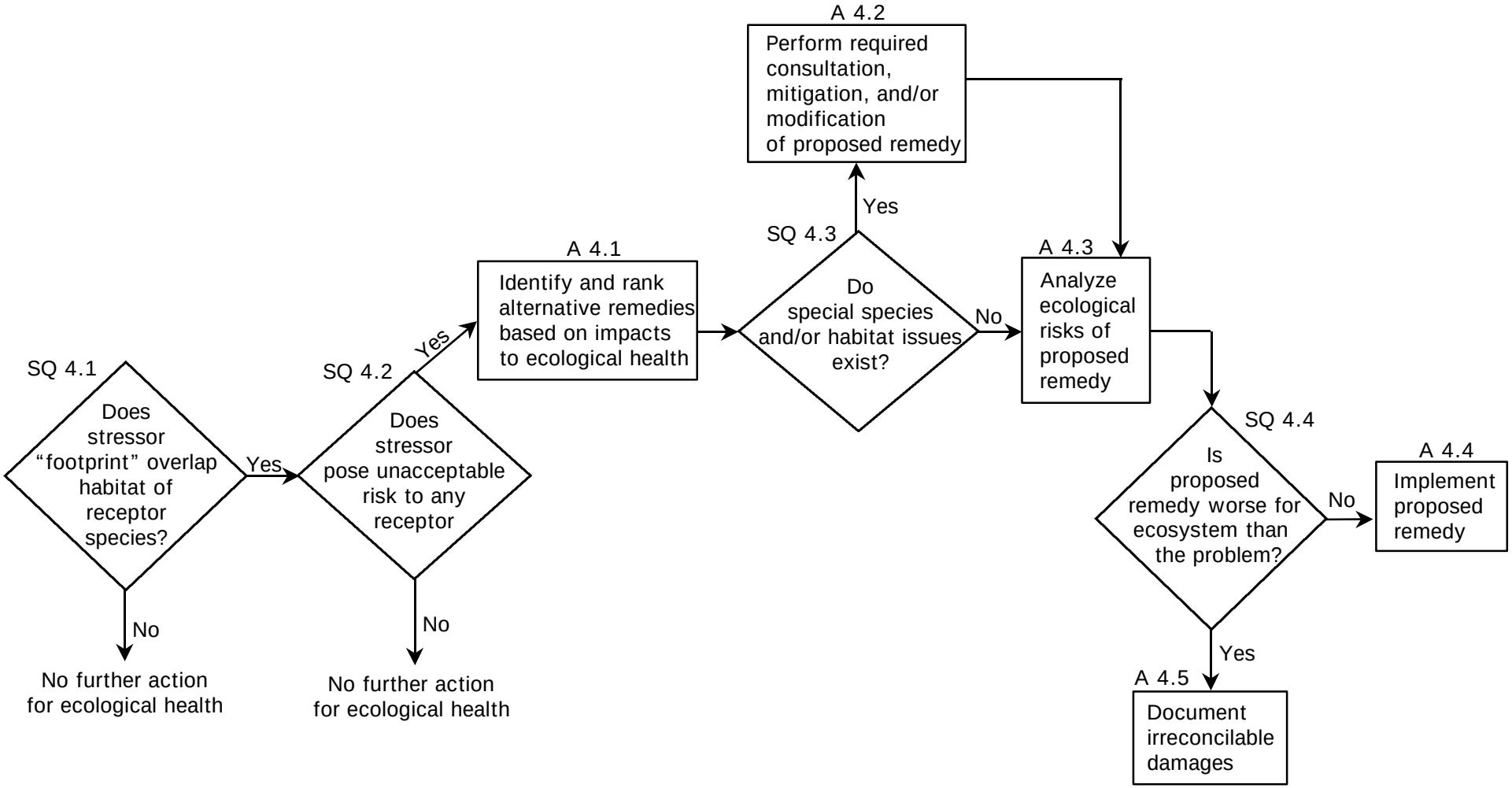

Figure 4 Study Questions (SQ) and Actions (A) for Physical and Biological Stressors

In general, screening-level assessments should be conducted using mean values with conservative confidence limits and realistic action levels. This approach allows different risk estimates to be compared and explained rationally. The typical alternative approach is to use maximum site values and conservative benchmarks, which results in overly conservative, unrealistic estimates of risk that cannot be compared or explained well. Moreover, the unrealistically conservative estimates of risk are often interpreted literally by risk managers and decision makers, resulting in poor decisions.

If the assessment is for a specific activity such as constructing a building, remedies are first identified and ranked (e.g., mitigation, habitat avoidance; A 4.1). All possible combinations of receptors, habitats, and ecosystems with the stressor must be considered. Consideration should then be given to whether special species or habitat issues exist (e.g., the presence of threatened and endangered species at federal or state levels; SQ 4.3). The key activity is A 4.3, in which the problem must be formulated and the risks analyzed in consideration of the management goals (e.g., cleanup goals, site environmental management goals), the general conceptual site model, and the ongoing monitoring programs. Finally, before action is taken, a determination should be made as to whether the proposed remedy is worse than the problem. If it is not, then the proposed remedy can be implemented (A 4.4). But if the remedy is worse, then irreconcilable damages should be documented (A 4.5). When considering the risks associated with different remedial alternatives (i.e., SQ 4.4), the document *Risk Evaluation of Remedial Alternatives for the Hanford Site* (DOE 1995) may be useful.

Programmatic Aids

The most useful programmatic aid for this step would be the existence of a comprehensive environmental and ecological baseline. Having such a baseline would allow ecologists and risk assessors to track the progress and effectiveness of management actions taken in response to the problem being considered. As in Step 1, the codification of the baseline information into a Geographic Information System would be highly desirable.

Programmatic Considerations

A representative list of programmatic considerations for Step 2 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 2 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced to the appropriate number(s) of the step(s).

- How can the multiple objectives of protecting worker health and safety, protecting public health, protecting ecological health, remediating contaminated areas, restoring environmental structure and function, and meeting political goals be accomplished simultaneously?

- Can the DQO process be used in dynamic technical and management environments, where events that cannot be planned for often occur?

- What are the DQOs for on-going monitoring programs? Are the resulting data useable in ecological risk assessments?

- Can the DQO process be applied retrospectively to existing data?

- Should the DQO process be specified when negotiating milestones?

- How can the DQO process be used to help meet existing milestones?

- Can the DQO process help establish a common language with regulators?

- Should the DQO process be used during accelerated actions, and if so, how? [4,7]

- Should separate strategies be developed for using the DQO process during risk assessment and risk management activities?

- How can site-wide guidance and management documents (e.g., remediation work plans, installation work plans) be used as vehicles to conduct integrated ecological risk assessments? [7]

- For the decision being considered, what are the implications of short-term remediation efforts and/or interim remedial actions?

- For the decision being considered, how can conflicts between the budget and schedule mandated by compliance obligations (i.e., remedial investigations, feasibility studies, corrective measures studies) and the need to perform ecological risk at appropriate spatial and temporal scales be resolved?

Step 3: Identify Inputs to the Decision

"The purpose of this step is to identify the informational inputs that will be required to resolve the decision statement and determine which inputs require environmental measurements" (EPA 1994a). Expected outputs identified by EPA include

- "A list of informational inputs needed to resolve the decision statement."
- "A list of environmental variables or characteristics that will be measured."

When planning and conducting an ecological risk assessment, this step is best approached from the perspective of expected outputs. Hence, three substeps are recommended:

- Substep 3.1 - Determine Informational Inputs Needed to Support the Ecological Risk Assessment and Resolve the Decision Statement
- Substep 3.2 - Determine Sources of Information for each Item of Information
- Substep 3.3 - List Environmental Variables or Characteristics to be Measured.

Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 3.

Table 3. Correspondence Between Substeps 3.1 - 3.3 and EPA Activities

Substep	Activity A: Identify the information that will be required to resolve the decision statement.	Activity B: Determine the sources for each item of information identified above.	Activity C: Identify the information that is needed to establish the action level.	Activity D: Confirm that appropriate measurement methods exist to provide the necessary data.
3.1	X			
3.2		X		
3.3			X	X

The information (including data on appropriate variables) needed to support the decision are tentatively identified in Step 3. This information should be refined as necessary in Steps 4 - 7 using the procedures identified in Step 3. During the conduct of Step 3, the planning and decision team must consider whether data for existing variables are adequate, and if not, whether the collection of the data on additional variables is practical. If existing data are inadequate, or the collection of additional data is not practical, or the permissible timeframe for the collection of additional data is inadequate, then alternative approaches providing needed information should be explored.

Substep 3.1 - Determine Informational Inputs Needed to Support the Ecological Risk Assessment and Resolve the Decision Statement

The purposes of this substep are primarily to identify the **kinds** of information that are needed to resolve the decision statement, and secondarily to tentatively identify the specific variables and statistical parameters that will be measured.

In most cases, the kinds of information will fall into five categories:

- background information on the environmental setting and associated processes (e.g., climate, geologic setting, soil type, contaminant types [such as radionuclides, chlorinated hydrocarbons, dense non-aqueous phase liquids], contaminant migration rates, contaminant flux information, seasonal factors, seismic history, depth to groundwater, etc.)

- information on key ecological attributes (e.g., data on terrestrial ecology, aquatic ecology, natural variability of populations, vegetation type and condition, keystone predators, species migration patterns, body burden data), the minimum associated quality of that information, and the ability to reference that information to its source

- models and their inherent assumptions (e.g., hydrologic models, population models)

- attributes of the stressor(s), such as 1) concentrations and activities of chemical and radiological stressors, 2) types and intensities of physical stressors, and 3) types and distributions of biological stressors

- action levels (e.g., standards and criteria as specified under the CWA, CAA, RCRA, CERCLA, etc.; toxicity benchmark information).

The kinds of information identified in this substep must be relevant to the problem stated in Step 1 and the decisions and activities identified in Step 2.

During the conduct of this substep, an opportunity exists to involve the stakeholders in 1) identifying the kinds of information that are relevant to the decision, and 2) allowing them to help provide that information. For example, federal and state agencies often have, or know of, information on large-scale (regional, local) ecological and population trends. They can often provide this

information quickly and inexpensively, allowing risk assessors to compare onsite and offsite conditions.

Substep 3.2 - Determine Sources for Each Item of Information

In this substep, sources of information are identified and evaluated for their ability to support the ecological risk assessment. The identification and evaluation of information sources at this point is an initial step only. As the ecological risk assessment progresses through to Step 7, more refined and focussed evaluations may be conducted as the need becomes apparent. Hence, the information evaluation process must be considered to be iterative, throughout the process of designing and conducting the ecological risk assessment.

Information may be derived from two sources: existing, historical sources and future sampling and analysis programs. Information from monitoring programs may span both dimensions, as it may include historical monitoring data and monitoring data that are yet to be collected. In the latter case, the data collection and analysis specifications may be modified to better meet the needs of the ecological risk assessment.

A framework for the identification and evaluation of potentially relevant data is shown in Figure 5. It should be referred to throughout the process of designing and conducting ecological risk assessment as the need becomes evident. It consists of a flow chart of activities (rectangles A 5.1 to A 5.5) and decisions (diamonds D-1 and D 5.2) that are designed to answer the questions:

- Should existing data be incorporated into the ecological risk assessment?
- If so, how?

The framework in Figure 5 is particularly relevant to Step 3 of the DQO process, wherein the necessary data inputs are identified, and Step 7 of the DQO process, wherein the design of the ecological risk assessment is optimized.

Characterize Data Needs (A 5.1)

The initial activity is to characterize data needs in terms of data types, quantities, and qualities (A-1), so far as they are known at this point. It may be useful to assemble a matrix of the types, quantities, and qualities of needed data, with the desired documentation. This characterization activity is typically conducted during Step 3 of the DQO process, and refined during Step 7 of the DQO process. During Step 3, it is important to consider data needs and eventual uses of those data from an integrated, holistic perspective, as discussed in Steps 1 and 2 above. Part of the holistic approach would be to develop rationales for data aggregation and/or segregation. For example, it might be scientifically expedient to segregate the risk assessment into terrestrial and aquatic components, such that the terrestrial and aquatic data needs are somewhat independent. Alternatively, the regulatory compliance process (e.g., a CERCLA Remedial Investigation and Feasibility Study for multiple

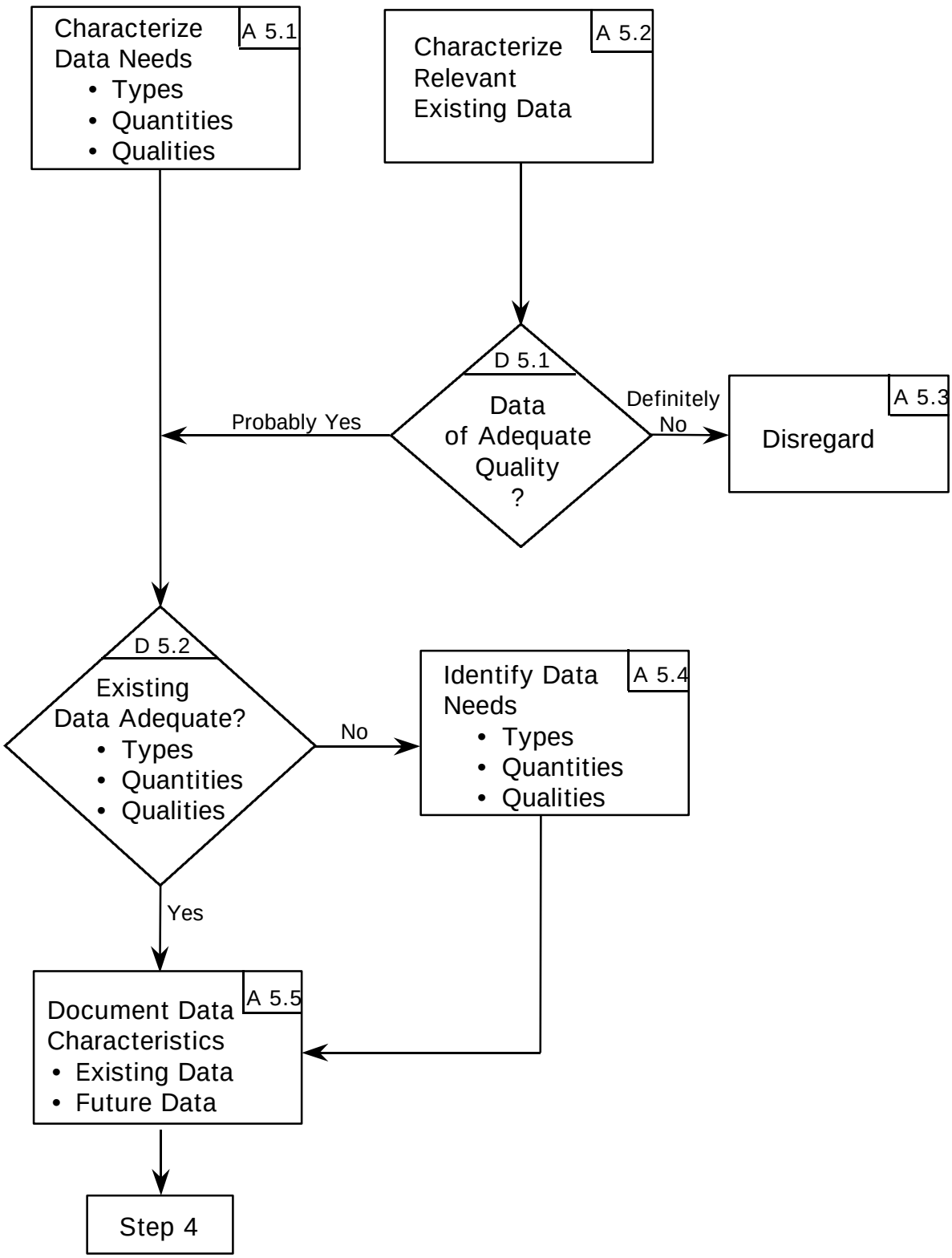

Figure 5. Activities (A x.z) and Decisions (D y.z) Related to Use of Existing Data and Collection of New Data

operable units) may necessitate an aggregated approach to data collection and use because a single decision may be made for all potentially affected media. All data collection and analysis activities would then be coordinated within the Remedial Investigation/Feasibility Study process, and the information needs of all secondary operable units would have to be met using that process.

Characterize Relevant Existing Data (A 5.2)

Existing environmental and ecological data that have the potential to fill data needs are identified in activity A 5.2. It may be useful to cross-match existing data (with accompanying documentation on the sources of those data) against the information needs in the matrix developed in A 5.1. This activity will help identify data gaps and characterize uncertainty associated with the existing data.

Initial Data Screen (D 5.1)

The most important step is to initially screen the existing data for their ability to fulfill data needs (D 5.1). If the data are definitely not of adequate quality, then they should be disregarded when designing the ecological risk assessment (A 5.3). However, if the data are found to be adequate in part or in total, then they may form part or all of the data used in the ecological risk assessment. Existing data typically fall into two major categories: 1) contaminant data (i.e., chemicals and radionuclides in the environment), and 2) effects data (i.e., effects of chemical, radiological, physical, or biological stressors on the biota and ecological processes). Data quality considerations for contaminant and effects data are similar in some respects, but differ in others. Data quality considerations for contaminant data might include

- Can the data collection methods be documented?
- Can the accuracy and precision of the data be documented acceptably? (i.e., Are the data technically defensible? This is a minimum criterion for acceptance).
- What are the assumptions associated with the collection and analysis of the data?
- Are the data pertinent to pathways and receptors?
- Are the data representative of site conditions, exposed organisms, and other variables of interest (as far as can be determined)?
- Are the data of adequate sensitivity to be useful? (e.g., Is the detection limit associated with the analytical method sufficiently low to determine whether the benchmark of interest is, or is not, exceeded?)
- Have data on relevant co-variates been collected, consistent with other data of known quality for the site?

Data quality considerations for effects data might include

- Can the data collection methods be documented?
- Can the accuracy and precision of the data be documented acceptably? (i.e., Are the data technically defensible? This is a minimum criterion for acceptance).
- What are the assumptions associated with the collection and analysis of the data?
- Have data been peer reviewed?
- Is the endpoint receptor or surrogate acceptable, based on relevant experience at this or other similar sites?
- Does the endpoint receptor or surrogate conform to relevant regulatory guidance?
- Do pathways exist for the observed effects? (i.e., Do the observed effects appear to be relevant to known site conditions?)
- Do relevant, associated chemical data exist?
- Can confidence limits be estimated for the observed effects?

Decide on Adequacy of Existing Data (D 5.2)

Having decided that existing data are of adequate quality for use in the ecological risk assessment, it is necessary to compare the existing data (A 5.2) with the data needs (A 5.1) to determine whether the existing data are sufficient by themselves, or must be augmented by the collection of new data. This decision (D 5.1) focuses primarily on the types and quantities of available data. However, secondary issues of data quality may also arise. If the existing data are, by themselves, sufficient to conduct the ecological risk assessment, the assessor may proceed without developing or implementing new data collection efforts.

Identify Data Needs (A 5.4)

If the existing data must be augmented, it will be necessary to identify the types, quantities, and qualities of the needed supplemental data (A 5.4) before proceeding to Step 4. At this point, it is expedient to examine ongoing monitoring programs to determine whether data collection activities can be modified to serve, in part, the needs of the ecological risk assessment.

Substep 3.3 - List Environmental Variables or Characteristics to Be Measured

The characteristics of existing and needed (i.e., future) data should be documented at this point. This documentation corresponds to Activity A 5.5 in Figure 5.

Document Characteristics of Existing Data

When using existing data in an ecological risk assessment, it is strongly advised that appropriate documentation as to the types, quantities, and qualities of those data be provided in an appendix to the risk assessment. That appendix should document

- the types, quantities, and qualities of those data, as defined in A 5.1 and assessed in D 5.1
- all reasonable caveats associated with those data.

Some example caveats for data types, quantities, and qualities might be

- "Data represent mixed samples with differing detection limits and error estimates."
- "Data are from multiple sources. References are noted as appropriate."
- "Marginal data of types x, y, and z are included due to insufficient resources to collect supplemental data of same type and quantities."
- "Data gaps for variable 'x' increase uncertainty by at least an order of magnitude."

Document Characteristics of Future Data

When filling data needs, the first activity is specifying the characteristics of those data and the tools necessary for their analysis and interpretation. Characteristics typically fall into three broad categories: the variables to be measured, the models that are appropriate for analysis and interpretation of data on those variables, and action levels that assist in the interpretation of those data. Examples of each are listed below.

A. Variables to be measured

A.1 Kinds of variables:
bioavailability
body burdens
estimated exposures to radionuclides
distribution of biota
physical parameters

distributions and abundances of threatened and endangered species
climate (e.g., rainfall, mean temperature)
information on effects
chemical speciation with associated abiotic and biotic source information
additional stressor categories
toxicological information

A.2 Sources of data:
sources of existing data
potential sources of future data

A.3 Measurement methods (availability of and references to appropriate methods):
detection limits
benchmarks

B. Models:

B.1 Types:
uptake
transport
site conceptual
dose effects

B.2 Assumptions and constraints
synergism
antagonism
cumulative processes

C. Action levels:
regulatory limits
background levels (including the methodologies used to determine background)
hazard quotients and hazard indices
present and future land use
appropriate default values (e.g,. EPA 1986)

D. Other considerations
NRDA considerations

The second activity is designing the ecological survey. Although the final survey design will be developed in Step 7, it is useful at this point to develop a preliminary survey design with reference to appropriate, practical survey methods. Table 4 lists some useful qualitative and quantitative ecological survey methods. Qualitative and quantitative methodological analogs are listed in the same row, except as indicated.

Table 4. Qualitative and Quantitative Methods for Surveying Ecosystems

Qualitative Methods	Quantitative Methods
Indicator species (e.g., sensitive, pollution tolerant) - presence/absence	Indicator species (e.g., sensitive, pollution tolerant) - abundances
Gradient analysis - presence/absence	Gradient analysis - abundance
Reference vs. impact area analysis - presence/absence	Reference vs. impact area analysis - abundance
Keystone species - presence/absences	Keystone species - abundances
Environmental monitoring data - qualitative	Environmental monitoring data - quantitative
Key ecosystem characteristics (not related to human activities - e.g., other stressors) - qualitative	Key ecosystem characteristics (not related to human activities - e.g., other stressors) - quantitative
(No qualitative analog)	Diversity
Rapid bioassessment protocols (e.g., Index of Biological Integrity)	Rapid bioassessment protocols (e.g., Index of Biological Integrity)
(No qualitative analog)	Hazard quotient
Toxicological screening tests	Laboratory generated toxicological test data
(No qualitative analog)	In situ toxicological test data (stratified sampling, especially for soil and sediment, designed with consideration for patchiness)
Site-specific thresholds of effects	Site-specific thresholds of effects
RELEVE (for plants; see Mueller-Dombois and Ellengerg 1974)	Plot and plotless methods (for plants)
Life history variables (e.g., food preferences, migration patterns, typical body size, life tables, food and water ingestion, population density, home range size)	Life history variables (e.g., food preferences, migration patterns, typical body size, life tables, food and water ingestion, population density, home range size)
Sediment quality (e.g., sediment acid volatile sulfides)	Sediment quality (e.g., acid-volatile sulfides)
Historical research data - qualitative	Historical research data - quantitative
Remote sensing	(No quantitative analog)
Habitat fractionation	(No quantitative analog)
Various biotic indices	(No quantitative analog)

At this point, the preliminary survey design and rationale for that design, proposed data collection methods (with appropriate references), and proposed data analysis and interpretation methods (with appropriate references) should be documented in a draft ecological survey report. The draft report should specify the future land use decisions (as well as is known), assessment and measurement endpoints, the species for which benchmark levels are needed, programmatic considerations (e.g., milestones, budget, schedule), and relevant regulatory considerations [e.g., water quality standards, DOE orders, executive orders, applicable or relevant and appropriate requirements (ARARs) under CERCLA].[(a)]

Before or during the preparation of the preliminary ecological survey report, two data collection issues may arise. First, it may become apparent that site-specific information is needed to establish action levels. In that case, it will be necessary to design and conduct one part of the survey specifically to address that need. Second, it may become evident that methods don't exist to collect needed data at appropriate levels of accuracy and sensitivity to determine whether action levels are being exceeded. In such cases, it may be necessary to re-define the questions being asked so that they can be answered using existing methods (as method development is generally beyond the scope of most ecological risk assessments).

Programmatic Aids

For Step 3, the most useful programmatic aids will be reference materials on designing and conducting ecological risk assessments, including references on survey design, data collection, data analysis, potentially applicable models, and relevant action levels. Materials may be hard copy, electronic copy, or on-line. A list is provided in Appendix F.

Programmatic Considerations

A representative list of programmatic considerations for Step 3 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 3 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced to the appropriate number(s) of the step(s).

- Is a quality assurance program required to implement the DQO process? [7]

- Can natural variability be estimated for variables of interest? If so, can natural variability be accounted for when setting DQOs? [4,6,7]

(a) After Step 7 of the DQO process has been completed and the survey has been conducted, this draft report will be incorporated into the final survey report. Caveats relevant to the collection, analysis, and interpretation of the specified data should be added to that report.

- Should stakeholders and the public be involved in the DQO process? Should they be involved is setting assessment and measurement endpoints? If so, how? [1,4,7]

- Should the DQO process be used to integrate NRDA concerns into the ecological risk assessment process, and if so, how? [4,7]

Step 4: Define the Study Boundaries

"The purpose of this step is to define the spatial and temporal boundaries of the problem" (EPA 1994a). Expected outputs defined by EPA (1994a) include

- "A detailed description of the spatial and temporal boundaries of the problem."
- "Any practical constraints that may interfere with the study."

Within the context of ecological risk assessment, the purposes of this step are to define the spatial and temporal boundaries that are covered by the decision statement, and to determine the geographic area and timeframe over which data must be collected to effectively complete the ecological risk assessment. These boundaries should be ecologically relevant, and should address all on-site and off-site stressors. Fulfilling this purpose requires a preliminary assessment of the scale of the decision based on the decision identified in Step 2, and based on the needed inputs to that decision that are identified in Step 3. For this step, recommended substeps include

- Substep 4.1 - Define the Programmatic Scale of the Decision
- Substep 4.2 - Identify Regulatory and Institutional Considerations
- Substep 4.3 - Define Spatial and Temporal Boundaries
- Substep 4.4 - Determine Areas and Timeframes for Collecting Data.

Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 5.

Table 5. Correspondence Between Substeps 4.1 - 4.4 and EPA Activities

Substep	**Activity A:** Specify the characteristics that define the population of interest.	**Activity B:** Define the spatial boundary of the decision statement. •Define the geographic area to which the decision statement applies. •When appropriate, divide the population into strata that have relatively homogeneous characteristics.	**Activity C:** Define the temporal boundary of the problem. •Determine the timeframe to which the decision applies. •Determine when to collect data.	**Activity D:** Define the scale of decision making.	**Activity E:** Identify any practical constraints on data collection.
4.1	X				
4.2	X			X	X
4.3		X	X		
4.4		X	X		X

Substep 4.1 - Define the Programmatic Scale of the Decision

The programmatic scale of the decision will have considerable influence on the spatial and temporal scales of the supporting ecological risk assessment. A preliminary description of the programmatic scale of the decision is prepared during this activity. The description should clearly state whether the decision pertains to general environmental management activities (e.g., management of a watershed), or to compliance-related activities. It should then describe the relevant scale within the applicable decision category. For example, general environmental management activities may vary in scale from watershed level to remedial activities within one small portion of the watershed. Similarly, compliance-related activities may range from site-wide activities to compliance activities related to a specific facility within an operable unit.

Substep 4.2 - Identify Regulatory and Institutional Concerns

Having defined the programmatic scale of the decision, the regulatory and institutional considerations that must be addressed during the decision-making process should now be described. These considerations usually require informational inputs on the environmental resources (e.g., types of resources, ecologically functional resource units, conditions of resources, potential risks to resources under different management alternatives). Hence, they also help set the spatial and temporal boundaries of the study. Potentially applicable regulatory and institutional considerations include

- provisions of applicable federal environmental statutes and regulations [e.g., CERCLA and the NRDA provisions thereof, Endangered Species Act (ESA), NEPA, CWA]
- provisions of applicable state statutes and regulations
- DOE orders and executive orders
- general natural resource management activities (e.g., forest management plans, watershed management programs)
- stakeholder issues (e.g., fish and wildlife management programs).

As noted in Step 1, the design of the ecological risk assessment including the spatial and temporal boundaries of the study, should be adequate for meeting more than one regulatory need or application. In some cases, it may be necessary to compromise between ecologically relevant boundaries and regulatory boundaries. Such compromises usually occur for programmatic or political reasons, such as resource limitations or stakeholder concerns.

Substep 4.3 - Define Spatial and Temporal Boundaries

General considerations relevant to defining spatial and temporal boundaries of the study area are discussed below, followed by discussions of technical and temporal boundaries.

Spatial - Temporal Boundary Considerations

To effectively define the spatial and temporal boundaries of the study, the risk assessor must have a holistic, conceptual understanding of the natural history of the species present in the environment that could be affected by the decision. This understanding should include information about the habitats, ranges, and life histories of the resident species. In particular, an understanding of plant assemblages (both native and exotic) is critical at this point. This conceptual, holistic understanding must be sufficient to address issues and concerns at the appropriate programmatic scale of the decision (e.g., at the level of the environmental management unit or remediation unit). It must also be sufficient to address major technical issues related to the scale of the decision, such as

- the aggregated scales of the decisions that could be supported by the ecological risk assessment (e.g., facility-specific decisions, operable unit decisions, landscape-level resource management decisions)

- the scale of the stressor, regardless of whether the stressor is chemical, radiological, physical, or biological (e.g., noise, chemical contaminant distribution, area affected by physical disturbance)

- the spatial scale of the resources that potentially could be affected by the decision, regardless of whether or not those resources are within the management jurisdiction (e.g., potential off-site ecological effects that could result from on-site decisions)

- the temporal scale of the resources that potentially could be affected by the decision over time (e.g., the resources that could be affected at a later date because of the movement of contaminated groundwater across the site boundary)

- correspondence between the spatial and temporal boundaries of ongoing monitoring programs and the needs of the ecological risk assessment.

Having the ability to address issues on such large spatial and temporal scales will require the collection and analysis of data on different spatial and temporal scales. While the preliminary spatial and temporal boundaries of the study are determined during this step, further refinement will occur during Step 7 (as discussed below).

As noted in Steps 1 and 2, it will also be necessary in many cases to consider potential future uses of the data and analyses. Hence, at the completion of this Step it may be expedient to revise the logic diagram in Step 2 to reflect more appropriate spatial and temporal scales. A good example might be the realization in this step that a watershed approach to a decision will result in a far better outcome because several large-scale uncertainties exist at the watershed level that cannot be addressed at the operational unit level.

Define Spatial Boundaries

In addition to being programmatically relevant (Substeps 4.1 and 4.2), the spatial scale of the study should also be ecologically relevant. Considerations for choosing an ecologically relevant spatial scale include

- climatic zones
- spatial extents of potentially affected species, habitats, and ecosystems
- surface and subsurface hydrologic patterns, including relevant interactions among media (e.g., groundwater, soil)
- species migration pathways and patterns
- contaminant migration pathways and patterns.

Several options exist for defining appropriate spatial scales, including the use of

- exposure units (see Ferenbaugh et al. 1996)
- watershed boundaries
- species distribution boundaries
- habitat boundaries
- ecosystem boundaries.

Define Temporal Boundaries

In addition to being programmatically relevant (Substeps 4.1 and 4.2), the temporal scale of the study should also be ecologically relevant. Determining the temporal scale of the ecological risk assessment can be difficult because it requires an understanding of the viability of species and habitats over time, and an understanding of how risk may change over time (with or without human intervention). In addition, temporal changes in the risk profile must be considered at multiple levels, from individual species to landscapes and watersheds. Considerations for choosing an ecologically relevant temporal scale include

- life histories of key species
- migration patterns of key species
- seasonal and climatic changes
- successional stages and sequences
- biodegradation over time (for chemical contaminants)

- radioactive decay rates
- bioaccumulation potentials and rates
- contaminant types and migration patterns
- seasonal vulnerability of receptors.

For systems in which a considerable ecological change is expected over time, the challenge for the risk assessor will be twofold: 1) to design the ecological risk assessment to account for this change, and 2) to interpret the results of the risk assessment within present and future ecological scenarios. Representative temporal issues that a risk assessor may need to consider include

- Is the long term viability of species assured?
- What is the role of natural attenuation?
- How will natural species progression over time affect the ecology and the risk profile? (For example, through succession one assemblage of burrowing animals may disappear as the ecosystem progresses from a shrub habitat to a pine forest.)
- Over the course of the natural seasonal cycle for a species, how does a species' changing physiological state alter its susceptibility to contaminants or disturbance?
- How do the life histories of key species relate to temporal changes in the condition of the remediation units?

Substep 4.4 - Determine Areas and Timeframes for Collecting Data

At this point in the DQO process, the risk assessor will have determined what information are available and what timeframe they appear to represent. The types, quantities, and qualities of these data will be understood within the contexts of programmatic and technical information needs, and the study boundaries will have been defined in space and time. In this substep (i.e., 4.4), preliminary determinations are made about specific areas and timeframes within which additional data should be collected.

Data collection efforts will, of course, be highly individualized among different ecological risk assessments. However, several considerations are worth noting, as their consideration can help the risk assessor design a technically effective and cost-effective survey. These include

- when possible, share data collection efforts among related assessments (e.g., among assessments within an ecosystem or habitat) within the geographic area.

- approach data collection logically, tailoring data collection efforts to the perceived levels of risk and concern. For example, be sure to focus sampling efforts on "hot" areas, or on those subpopulations that are expected to be "hotter" than others. Ensure that the levels of sampling in "hot" areas or of potentially susceptible organisms are adequate to characterize the risks, and that those risks can be understood within the larger spatial and temporal risk profile of the region.

- acknowledge and address any practical constraints associated with data collection efforts

- use site-specific knowledge when designing the sampling plan, especially with respect to hot spots, variability, and susceptible organisms. In particular, be sure to account for seasonal variation, life histories, climate, timing of releases, episodic events, seasonal vulnerability of species, and other spatial and temporal characteristics of the local ecology, as noted in Substep 4.3. These issues will help drive design of the biological survey.

Programmatic Aids

Programmatic aids that would help define study boundaries include

- a general conceptual site model (as also noted for Step 2)

- inventories of natural resources (encoded into a geographic information system if possible)

- ground truthing information, such as 1) geographic information system maps (with global positioning system coordinates) that include habitats, areas of contamination, locations of threatened and endangered species, etc.; 2) aerial photographs through time: and 3) remote sensing data

- an approved site land use plan

- results of relevant long-term field studies.

Programmatic Considerations

A representative list of programmatic considerations for Step 4 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 4 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced to the appropriate number(s) of the step(s).

- How can information best be shared among different assessments?
- How can natural resource management be integrated into setting study boundaries? [7]
- Can natural variability be estimated for variables of interest? If so, can natural variability be accounted for when setting DQOs? [3,6,7]
- How can DQO data input needs be coordinated with on-going site monitoring programs? [7]
- Should stakeholders and the public be involved in the DQO process? Should they be involved in setting assessment and measurement endpoints? If so, how? [1,3,7]
- Should the DQO process be used to integrate NRDA concerns into the ecological risk assessment process, and if so, how? [1,3,7]
- How can the DQO process be used to better define spatial and temporal boundaries of the ecological risk assessment (e.g., ecological units versus regulatory units)? [7 with feedback to 4]
- How should spatial and temporal scales be considered when designing and conducting the ecological risk assessment? [7]
- How can the planning and decision team ensure that ecological risk information will be used to support a decision?
- What are the present uses and ecological functions (e.g., habitat for endangered species, wetlands) of existing areas of the site?
- For what areas of the site have future land uses been designated?

Step 5: Develop a Decision Rule

"The purpose of this step is to define the parameter of interest, specify the action level, and integrate previous DQO outputs into a single statement that describes a logical basis for choosing among alternative actions" (EPA 1994a). Expected outputs identified by EPA (1994a) include

- "A statistical parameter (the parameter of interest) that characterizes the population."
- "The action level."[(a)]
- "An 'if…then…' statement that defines the conditions that would cause the decision maker to choose among alternative actions."[(b)]

The recommended substeps for developing a decision rule are

- Substep 5.1 - Identify the Target Species and Variables to be Measured
- Substep 5.2 - Specify the Statistical Parameter that Characterizes the Population
- Substep 5.3 - Specify the Action Level for the Study
- Substep 5.4 - Develop a Decision Rule.

Substep 5.1 is unique to ecological risk assessment. It is needed for most ecological risk assessments because species are usually the primary units for which data are collected and compared with "benchmark" or "reference" conditions for the purpose of assessing risks. Substep 5.1 is a bridge between Step 3, in which the characteristics of existing and future data are determined, and Substep 5.2, in which the statistical parameter that characterizes the population (i.e., usually the species) is specified. Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 6.

(a)The action level is defined as "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 Maximum Contaminant Level for drinking water; a risk-based concentration level; a technological limitation; or a reference-based standard. [Note: the action level is specified during the planning phase of a data collection activity; it is not calculated from sampling data.]" (EPA 1994a)
(b)This "if…then" statement constitutes the decision rule.

Table 6. Correspondence Between Substeps 5.1 - 5.4 and EPA Activities

Substep	**Activity A:** Specify the statistical parameter that characterizes the population (the parameter of interest).	**Activity B:** Specify the action level for the study.	**Activity C:** Develop a decision rule.
5.1			
5.2	X	X	X
5.3	X	X	X
5.4	X	X	X

At the outset of Step 5, the planning and decision team and the project team should have information on the technical dimensions of the risk assessment, including the type(s) of stressor(s) (i.e., chemical, radiological, physical, biological), the potential receptors, the study boundaries, and the key ecological relationships (as characterized by the conceptual site model). Information should also be available concerning the decision aspects of the problem, including the type of decision (e.g., site environmental management, soil and groundwater remediation), the type of risk assessment (e.g., screening assessment, activity-specific assessment), and how the ecological risk information will be used in the decision. The purposes of Step 5 are to specify how the data will be summarized (i.e., a summary statistic) for comparison with action levels for measured variables, and to develop a decision rule that will support the decision. The decision rule is usually expressed in the form of one or more "if … then" statements that support the choice of one or more alternative actions (including no action).

In general, screening-level assessment will have better formulated, more quantitative (and more conservative) decision rules than activity-specific assessments. Screening-level assessments are often based on a single comparison for a key variable (e.g., the concentration of a contaminant relative to a benchmark concentration). The results of the comparison determine whether action is taken. In contrast, activity-specific decision rules often involve multiple variables and depend on weight of evidence and professional judgment for a decision, and hence are less well formulated (and less conservative) than decisions for screening-level assessments. In this latter case, quantitative data with associated estimates of error are frequently used to support a largely qualitative decision-making process.

In addition to supporting the decision, the decision rule must be supportable by relevant technical data that can be collected and interpreted with confidence. Thus, the decisions "drive" the variables to be measured. Because the study must be targeted to the decision at hand, the risk assessor must understand *a priori* how the study variables and resulting ecological risk assessment will be used to support the decision. This is accomplished by assuring that the sampling and analysis design can be related directly to the study questions and actions developed in Step 2 (e.g., Figures 3 and 4).

Another consideration during the conduct of Step 5 is the difference in approach between ecological risk assessment and decision making. While ecological risk assessments are often conducted quantitatively, and qualitative ecological risk assessments are often conducted as quantitatively as possible, environmental management and risk management decisions are often made qualitatively using a weight of evidence approach that is based on professional judgment (see Suter et al. 1995). Thus, while the data supporting the decision may be quantitative, they are interpreted qualitatively by the decision makers based on the probabilities of impact, the severities of impact, and perceptions regarding the relative importance of the impacts (across risk dimensions such as ecological risk, public health risk, and programmatic risk). These considerations of the consequences of the decision and the relative importance of a particular type of impact should be made explicit and compared during the decision process. The comparison process relies heavily on professional judgment and an implicit set of values (e.g., the no action alternative is preferable in Case "X" because the total risk to the biota over time appears to be less than the short-term risk that would occur as a result of habitat disruption during remediation.)

Finally, the risk assessor must approach Step 5 as an iterative process. All four substeps are interdependent, and it may be necessary to cycle through the substeps several times before an appropriate, supportable decision rule is developed.

Substep 5.1 - Identify the Target Species and Variables to Be Measured

The purpose of this step is to identify the target species and focus the variables (identified in Step 3) to be measured. Before target species and variables can be identified, the planning and decision team must have a preliminary risk strategy that includes

- for physical and biological stressors, an understanding of the relationship between the type and intensity of the physical or biological stress, and the spatial extent and magnitude of the resulting impact on affected species and environmental characteristics
- for chemical and radiological stressors, the levels of exposure that are expected to be "triggers" for determining when risks are acceptable and unacceptable
- rationale(s) for the selection of measurement and assessment endpoints
- spatial and temporal dimensions of the risk assessment
- utility of the resulting data in the decision process.

This preliminary risk strategy helps ensure that the existing data and the data to be collected (i.e., the species-specific variables to be measured) either 1) have standards or benchmarks to which they may be compared, embody the potential for the development of site-specific standards or benchmarks. It is only through a comparative process (e.g., comparisons with toxicological benchmarks, gradient analysis, reference area comparisons) that the field data are more easily interpreted, and can be used to support a decision.

Much of the development of the preliminary risk strategy will have been completed in Substep 1.4 (i.e., Develop Detailed Description of the Problem), Substep 1.5 (Define Approach to the Ecological Risk Assessment), and Step 4 (Define the Study Boundaries). In Substep 5.1, the preliminary description of the problem and the preliminary approach should be refined to reflect benchmark and field data that either exist or that can be collected to develop standards or benchmarks, or otherwise support the ecological risk assessment and the overall decision. Critical questions that should be considered include

- For what species and species-specific variables are data available or collectable?
- For what species have benchmarks been determined, and for what variables?
- What relevant regulatory standards exist?
- What species and variables are most critical and informative for the decision?

As noted above, species are typically the primary units for which data are collected and compared with "benchmark" or "reference" conditions for the purpose of assessing risks. Hence, the project team (ideally with the assistance of regulators, native Americans, and other stakeholders) must develop a limited set of species and variables for which data will be collected and evaluated, and upon which decisions will be based.

Having identified the target species and variables to be measured, a preliminary sampling program should be developed in which the quantities of needed data (e.g., numbers of sampling locations, numbers of samples per location, numbers of replicate samples per location) are specified. Several considerations are important to this activity, including the following:

- Sample collection and analysis programs must be designed with the anticipation that the resulting data will be used not only for the ecological risk assessment at hand, but also for a variety of other purposes over time. Because it is easier, less expensive, and more informative (in most cases) to sample once thoroughly than to sample multiple times partially, an effort should be made to anticipate reasonable data needs over time and design sample collection efforts to meet that greater need.

- An integrated approach to data handling is essential. The early phases of an ecological risk are often based on existing data, while the latter phases are often based on the collection of new data. Forethought must be given to how these data will complement each other, and hence, be used to best advantage.

Substep 5.2 - Specify the Statistical Parameter that Characterizes the Population

The purpose of Substep 5.2 is to define the statistical parameter (e.g., areal extent in square meters, total numbers of organisms per unit area, mean concentration) that characterizes the population and best supports the decision. A number of parameters may characterize a given species and variable, but the most appropriate parameter to use in the ecological risk assessment will be the parameter that is most relevant to the decision.

Across the DOE complex, few ecological risk assessments have been performed for physical and biological stressors. Hence, experience specifying statistical parameters for such stressors is minimal, and will require the planning and decision team to exhibit creativity when selecting parameters. Possible examples include

- for physical disturbance, the areal extent of disturbed habitat and the associated mean density of a keystone species after the disturbance has occurred

- for biological disturbance, the rate of invasion of an exotic species and the corresponding mean densities of native and exotic plant species.

Compared with physical and biological stressors, considerably more experience exists specifying statistical parameters for chemical and radiological stressors. The selected statistical parameters for

those stressors are typically an expression of the concentration of the contaminant in the environmental medium (e.g., mg contaminant per kg soil).

Substep 5.3 - Specify the Action Level for the Study

The planning and decision team should now specify an action level, expressed in the units of the statistical parameter of interest. If the value of the statistical parameter measured in the field or laboratory, or derived from modelling efforts exceeds the action level, risk is assumed to be unacceptably high and risk reduction or mitigation activities may be undertaken. For a physical stressor, an example action level might be the minimum density of a keystone species, based on knowledge of the density-dependent reproductive capacity of that species. For a biological stressor, the action level might be a threshold density of exotic plant individuals.

For chemical and radiological stressors, two action levels are often specified. The first is the background concentration of the stressor. If the concentration of the stressor in the environment falls within the range of an "approved" or "agreed upon" background concentration, then risk is assumed to be minimal and no further action is needed (see Box 6).

Box 6. Example Assessment of Contaminant Variable Relative to Background

If: 1) all $[PCOC]_{MI}$ < UTL for approved background data set, *and*
2) distribution of all $PCOC_I$ does not differ significantly from approved background data set, then no further action.

Where: PCOC = Potential Contaminant Of Concern
M = Media
I = area of Interest
UTL = Upper Threshold Limit

If *1) or 2)* are not satisfied, assess variable relative to benchmark.

Necessary supporting activities:
1. Define specific confidence limits for upper threshold limit
2. Define an appropriate, approved set of background data, including biological, geological, pedological, hydrological, and meteorological data.
3. Define an appropriate set of statistical tests (e.g., EPA 1989a, 1989b; Gilbert 1987).

However, if the concentration of the stressor in the environment exceeds an "approved" or "agreed upon" background concentration, then risk is assessed relative to a second action level - a "benchmark" concentration for exposure of the target species to the stressor via the contaminated environmental medium (Box 7). In general, if the concentration of the stressor in the environment does not exceed the benchmark, then no further action is needed. However, if the benchmark is

exceeded, risk may be considered unacceptable, and a decision rule should be developed in preparation for conducting an ecological risk assessment.

Box 7. Example Assessment of Variable Relative to Benchmark

If: Site $data_{MI}$ < benchmark, then no further action.

Where: "Site data" are a conservative estimate (e.g., maximum recorded value, mean upper confidence limit, or other estimate)
M = Media
I = area of Interest
"Site data" exclude background.

If benchmark < site data, then proceed to Substep 5.4 to develop decision rule.

Necessary supporting activities:
1. Select conservative parameters (e.g., maximum recorded value, mean upper confidence limit)
2. Obtain approval of benchmarks from regulators
3. Develop uptake rates from food, water, and soil for birds, mammals, and other relevant biota (e.g., in mg/kg/day). Information on site use factors, food preferences, ingestion rates, and uptake factors will be needed for all three routes of exposure. For food route, bioconcentration factors for separating contributions from food and soil will need to be developed if they do not exist.
4. Develop uptake rates for fish from food and water.

Substep 5.4 - Develop a Decision Rule

Decision rules are drafted during this substep. They are framed as a testable hypothesis, or a string of testable hypotheses, that can be supported by existing ecological data or ecological data that will be collected during the risk assessment. Most frequently, they take the form of "if … then" statements. The hypotheses define the variables for which data are needed, and largely determine the sampling and analytical design for needed studies. When those studies are completed, the resulting data should be sufficient to prove or disprove the hypotheses within acceptable limits of statistical confidence. The results of hypothesis testing across all risk dimensions (e.g., ecological risk, public health risk) are then used by decision makers to support the broader set of management goals. As noted above, the management decision process may be highly qualitative, and may be based on professional judgment and weight of evidence from multiple lines of inquiry.

Decision rules typically have three key attributes

- they define a sequence of risk hypotheses based on the selected endpoints
- they define acceptable levels of impact to endpoints, such as
  - impacts to individual threatened or endangered species

- impacts to populations of other species (e.g., abundance, richness)
- impacts to ecological functions or processes (e.g., primary production)

- they link hypotheses to an "if … then" rule (e.g., if A or B, then C).

In doing so, decision rules should to the greatest degree possible

- account for multiple variables of interest (e.g., contaminant concentrations in different environmental media, uptake factors across species of interest)

- consider all relevant environmental pathways,

- consider the range of possible impacts that could occur as a result of exposure to stressors (e.g., increased mortality, reduced fecundity, changes in the age structure of populations, changes in species abundance and distribution, changes in ecological processes such as soil mineralization and respiration).

When developing the risk hypotheses, it is important that measures of exposure be strongly correlated with measures of effects. Only then will the data be able to support the hypotheses adequately. It is also important that hypotheses not be framed as simply "yes" or "no", but instead as reflections of appropriate thresholds for decisions and actions. Hypotheses concerning existing risks may be supported by existing data and data that will be collected during the risk assessment. Such data may be used without temporal extrapolation. However, when potential future ecological risks are of concern, temporal trends in media quality and exposure scenarios must also be considered.

Example hypotheses are

- for physical disturbance, "If the mean density of keystone species X is less than Y organisms per square meter, then the habitat will not recover"

- for biological disturbance, "If the mean density of exotic plant species X reaches Y per square meter, then the native flora will be completely displaced within 5 years"

- for chemical stressors, "If the concentration of chemical X exceeds Y mg/kg in the soil column, then plants will take up the chemical in sufficient quantities to decrease the reproductive capacity of the pocket mouse".

Programmatic Aids

Four programmatic aids would be useful during the conduct of Step 5

- a general conceptual site model that has been agreed to by all parties. The existence of such a model would greatly facilitate study design. (A general conceptual site model is also noted to be a programmatic aid for Steps 1 and 4.)
- a set of background data for the site
- a set of benchmarks for target species on the site. These benchmarks may be derived from multiple sources (e.g,. regulatory standards, relevant benchmarks found in the scientific literature, benchmarks specifically derived for species and contaminants found on the site of interest)
- a set of uptake rates for contaminants and target species of interest on the site.

Programmatic Considerations

A representative list of programmatic considerations for Step 5 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 5 activities.

- What constitutes adequate risk reduction? (This is a risk management question that is relevant to Step 5. The answer must be based on the endstate resource profile [see Figure 1])
- Is it cheaper to mitigate or remediate without conducting an ecological risk assessment? (i.e., Will the assessment cost more than the action?) Related questions include
  - How much is "perfect"[(a)] information worth?
  - How much uncertainty is acceptable when making the decision?
  - What summary statistics will be used to use to make that decision?
- Is the ecological risk assessment being conducted despite the recognition that ecological risk is not a consideration in the decision? (e.g., Is the assessment being conducted only to fulfill compliance requirements, and not to provide information to support a decision?).

(a)"Perfect" information is information that is always correct.

Step 6: Specify Tolerable Limits on Decision Errors

"The purpose of this step is to specify the decision maker's tolerable limits on decision errors, which are used to establish performance goals for the data collection design" (EPA 1994a). The expected output identified by EPA (1994a) is

- "The decision maker's tolerable decision error rates based on a consideration of the consequences of making an incorrect decision."

As discussed below, recommended substeps for specifying tolerable limits on decision errors are

- Substep 6.1 - Identify the Variables that Affect the Decision
- Substep 6.2 - Choose the Null Hypothesis and Identify the Decision Errors.

Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 7.

Table 7. Correspondence Between Substeps 6.1 - 6.2 and EPA Activities

Substep	**Activity A:** Determine the possible range of the parameter of interest.	**Activity B:** Identify the decision errors and choose the null hypothesis. •Define both types of decision errors and establish the true state of nature for each decision error. •Specify and evaluate the potential consequences of each decision error. •Establish which decision error has more severe consequences near the action level. •Define the null hypothesis (baseline condition) and the alternative hypothesis and assign the terms "false positive" and "false negative" to the appropriate decision error.	**Activity C:** Specify a range of possible parameter values where the consequences of decision errors are relatively minor (gray region).	**Activity D:** Assign probability limits to points above and below the gray region that reflect the tolerable probability for the occurrence of decision errors.
6.1	X			
6.2		X	X	X

The purpose of this step is to identify tolerable limits for the decision error. To do this, the planning and decision team must 1) identify the critical decision(s), 2) determine all possible outcomes of that decision, and 3) evaluate the consequences of each outcome. This step may be very difficult to conduct because baseline information on the variability of the sampling variable of interest (and upon which the evaluation of the consequences of each outcome is dependent) may not be available. Moreover, the resources needed to collect needed baseline data may not be available, forcing the planning and decision team to make decisions based on less than desirable information about decision errors.

For a remediation decision, a matrix of possible outcomes and consequences might look like those in Table 8. In most cases, the least desirable outcome in Table 8 would be not remediating when injury is occurring, followed by remediating when no injury is occurring. Hence, the planning and decision team would least tolerate error associated with a decision not to remediate when injury is occurring. As a result, they would likely spend the greatest proportion of their resources to avoid that outcome. In other words, the more critical the error is to the planning and decision team, the more the responsible party is likely to pay to avoid that error. Hence, the planning and decision team and the risk assessor must reach agreement on the tolerable decision error for that and other outcomes before the risk assessment study is begun.

Table 8. Possible Outcomes of Remediation Decisions

	Injury	**No Injury**
Remediate	OK	Spent money; wasted time; missed opportunities; destroyed habitat
Do not Remediate	Injury occurs; habitat destroyed; possible NRDA liabilities; possible ESA violations	OK

Reaching agreement on tolerable decision error requires free and open dialog between the planning and decision team, the ecological risk assessors (e.g., ecologists), and other stakeholders. The primary goal of that dialog is to identify critical decision point boundaries. Related secondary goals are to identify 1) resource concerns where wide and narrow tolerance exist for decision errors, 2) resource concerns where risks are relevant to stakeholders, and 3) resource concerns where a high degree of uncertainty is acceptable. Consensus need not be reached as an outcome of the dialog. Another acceptable outcome could be a large matrix of resource concerns and their relevant decision errors, with their importance ranked qualitatively. For the remediation example in Table 8, it would be important to determine the boundaries between

- the well-characterized contaminated area within which no further data are needed to make a decision

- the surrounding area within which contamination is present, but existing data are insufficient to adequately characterize the extent and magnitude of impacts, and hence to make a decision.

- the outer surrounding area within which no contamination exists, and no further data are needed to make a decision.

The boundaries for these decision areas may be determined by observed effects, or by the distribution of contaminants plus an understanding of the exposure pathways and the potential effects of the contaminants on resident biota. Among the general analytical approaches that could be taken to determine the boundaries of the decision are

- gradient analysis of contaminants and effects

- comparisons of contaminant concentrations and biotic characteristics between potentially impacted and reference areas

- analyses of toxicological effects of contaminants on biota

- temporal trends in contaminant concentrations and biotic characteristics.

The effectiveness of any of these (or other general analytical approaches) is dependent on the degree of uncertainty (i.e., degree of accuracy and precision) attainable with those samples and sample analyses. An example of a quantitative relationship between the acceptable contaminant concentration in an environmental medium and the probability the contaminant concentration will exceed the threshold concentration in the field (based on sampling information) is shown in Figure 6. In this example, a decision has been made that mean concentrations that correspond to 10^{-4} to 10^{-2} risk from concentrations of the contaminant in the field are within acceptable bounds for achieving a mean threshold concentration of 10^{-3}, based on the knowledge that those concentrations correspond to 40% and 75% probabilities that the actual mean concentration in the environmental medium will exceed the threshold.

All else being equal, the ability to describe limits on decision errors is usually inversely related to the numbers of samples (i.e., greater numbers of samples generally allow the risk assessor to reduce the error associated with a decision). Hence, a tension exists between the numbers of samples collected (and the expense associated with the collection of those samples) and the specification of the tolerable limit on the decision error. At one end of the analytical spectrum, a decision may require only existing qualitative data to ensure that the error associated with that decision is tolerable. In that case, no additional sampling effort may be required to supplement existing data. The challenge in this case is having sufficient qualitative data at the outset to ensure that only existing qualitative data are needed. At the other end of the analytical spectrum, the level of additional sampling required to provide data

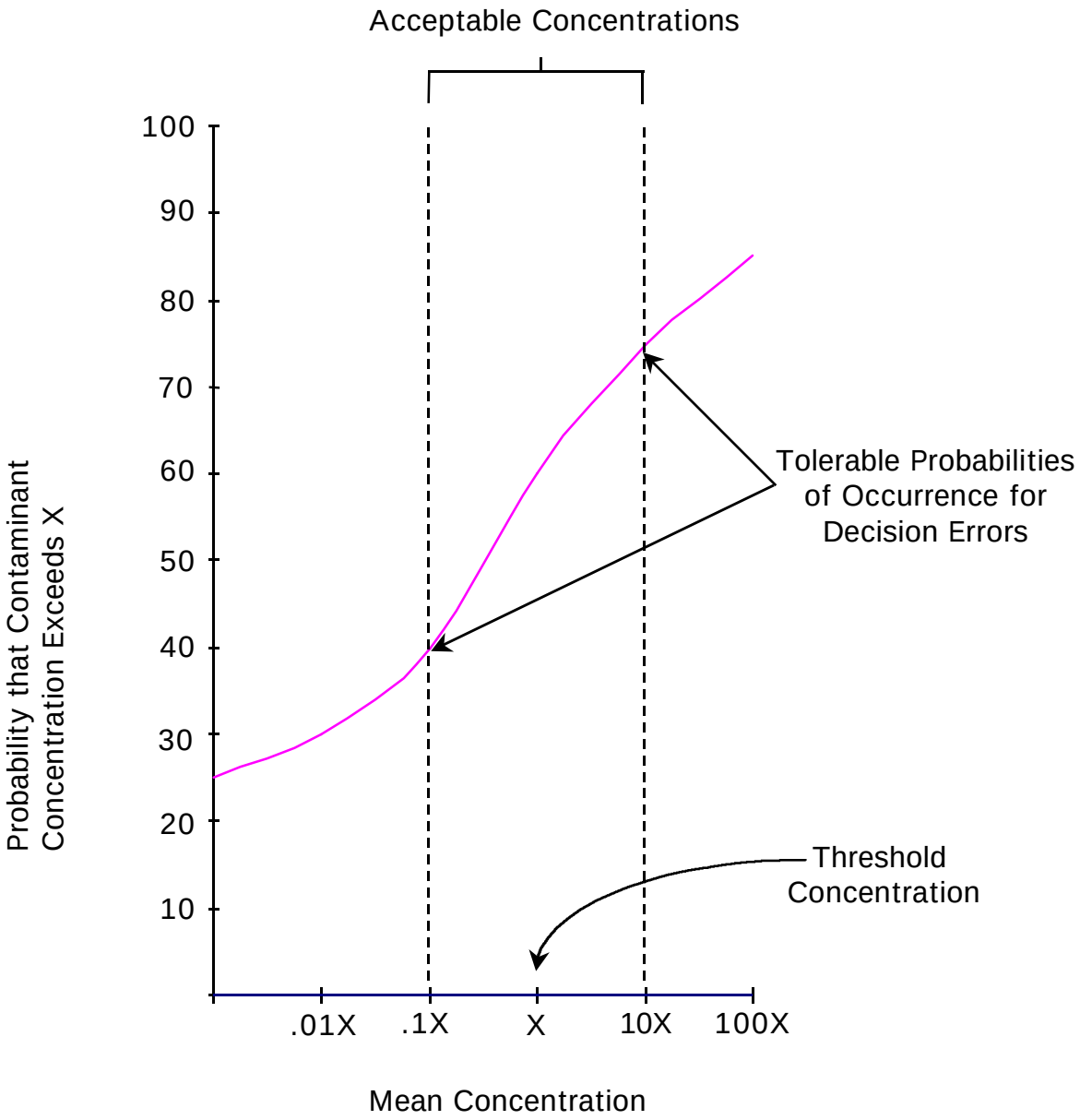

Figure 6. Example of a Quantitative Relationship Between Acceptable Contaminant Concentration and Tolerable Probabilities of Occurrence for Decision Errors

that will reduce the decision error to within tolerable limits may be more than can be collected within the allotted budget. At that point, the risk assessor(s) and the planning and decision team must come to agreement about an acceptable tradeoff between the numbers of samples required and the decision error that can be tolerated. Intermediate points on the analytical spectrum would include decisions for which additional qualitative and/or quantitative data are needed. In general, however, decisions for which the greatest degree of uncertainty exists in the existing data sets will be those for which the decision errors are largest, and around which the most discussion and sampling activity will occur in an attempt to reduce the decision error to tolerable limits.

The approach suggested below in Substeps 6.1 and 6.2 is fairly rigorous. However, such a rigorous analytical effort may not always be justified. The level of analytical rigor that is appropriate will vary with the decision. For example, decisions that could be made with a high degree of confidence using only qualitative information typically would not require a highly rigorous analytical effort.

Substep 6.1: Identify the Variables That Affect the Decision

In this substep, it is recommended that the issues of interest, the variables to be measured, and the endpoints of interest be clearly restated, based on the outputs of Substep 5.2 (i.e., Identify the Target Species and Variables to be Measured). The possible range(s) of the variable(s) of interest (either qualitative or quantitative) should also be described, based on existing information. If warranted, recommendations about the collection of supplemental data should be made at this point.

It is sometimes necessary to make a decision at this point, when only existing information is available. Such a decision is often difficult because the available information does not allow for sufficient reduction in the level of associated uncertainty. When forced to make such a decision, the risk assessor (and/or planning and decision team) must document the fact that the decision is based largely on professional judgment, and must provide caveats to the decision regarding the high level of associated uncertainty. If the high level of associated uncertainty is unacceptable to an interested party, that party will work to secure adequate resources to collect additional information and thereby reduce the associated uncertainty. A related consideration is that the level of uncertainty associated with any part of the decision rule affects the uncertainties associated with both the anterior and posterior parts of that decision rule.

Substep 6.2: Choose the Null Hypothesis and Identify the Decision Errors

In this substep, all of the aforementioned considerations for developing the decision rule (Substep 5.4) and identifying the variables that affect the decision (Substep 6.1) are brought together into formal null hypotheses for testing. The major activities that should be conducted during this substep are to

- define the null hypothesis, identify the inherent decision errors, and describe the potential consequences for each decision error

- assign probability values to points above and below action level that reflect tolerable probabilities for occurrence of decision errors (see the example in Figure 6.).

Supporting activities include

- identifying the variables that affect decision
- determining the important variables, through sensitivity analysis (no sensitivity analyses would have been performed up to this substep)
- specifying the ranges of the important variables
- for each variable, specifying what values within that variable's range indicate that a problem exists
- for each variable, specifying the subrange of values within that variable's range wherein the decision errors are relatively minor (i.e., acceptable)
- assigning a probability level to the subrange of acceptable values (e.g., the "y" axis in Figure 6)
- relating the acceptable range of values directly to the decision at hand.

Programmatic Aids

The most useful programmatic aids for Step 6 would be baseline information on the consequences of decision errors and measurement errors associated with the ecological variables of interest in the risk assessment and decision-making processes. Unfortunately, data on measurement errors tend to be habitat- and species-specific, and are usually not collected because preliminary pilot studies are required.

Programmatic Considerations

A representative list of programmatic considerations for Step 6 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 6 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced to the appropriate number(s) of the step(s).

- Can natural variability be estimated for variables of interest? If so, can natural variability be accounted for when setting DQOs? [3,4,7]
- Can tolerable limits for decision errors be specified when funds are insufficient to collect the necessary baseline information on measurement errors?

Step 7: Optimize the Design

"The purpose of this step is to identify a resource-effective data collection design for generating data that are expected to satisfy the DQOs" (EPA 1994a). The expected output identified by EPA (1994a) is

- "The most resource-effective design for the study that is expected to achieve the DQOs."

As discussed below, recommended substeps for optimizing the design are

- Substep 7.1 - Review DQO Outputs and Existing Environmental Data
- Substep 7.2 - Develop General Data Design Alternatives
- Substep 7.3 - Formulate the Mathematical Expressions Needed to Solve the Design Problem for Each Data Collection and Design Alternative
- Substep 7.4 - Develop and Document the Sampling Strategy.

Correspondence between the above substeps and activities recommended by EPA (1994a) is shown in Table 9.

Table 9. Correspondence Between Substeps 7.1 - 7.4 and EPA Activities

Substep	**Activity A:** Review the DQO outputs and existing environmental data.	**Activity B:** Develop general data collection design alternatives.	**Activity C:** Formulate the mathematical expressions needed to solve the design problem for each data collection design alterative.	**Activity D:** Select the optimal sample size that satisfies the DQOs for each data collection design alternative.	**Activity E:** Select the most resource-effective data collection design that satisfies all of the DQOs.	**Activity F:** Document the operational details and theoretical assumptions of the selected design in the sampling and analysis plan.
7.1	X					
7.2		X				
7.3			X			
7.4				X	X	X

The scope of Step 7 is the collection of new data. In most cases, new data will be collected for the purpose of filling gaps in the existing data set. These new data may consist of

- descriptive information (e.g., anecdotal information, legal precedents, regulatory compliance rulings, newly discovered stressors, pertinent analyses conducted at other sites)

- analytical data (e.g., data on the distribution and/or magnitude of stressors, life history data, does-response data, data on body burdens, data on exotic species, data on the physical environment).

By designing surveys and/or laboratory studies to collect new data, Step 7 wraps up the process of designing the ecological risk assessment to meet management goals and, hence, may have feedback to earlier DQO steps.

Because the needs for new information will vary greatly among individual ecological risk assessments, the discussion provided below is intended to be generic and broadly applicable. It is intended only to be an aid to the planning and decision team and the project team when designing individual, site-specific surveys and/or laboratory studies.

Major factors that should be considered during the conduct of Step 7 include the following:

- Regulatory requirements and/or stakeholder concerns may need to be considered when optimizing the design of the ecological risk assessment.

- Multiple sources and types of stressors may exist, and may or may not be documented in the existing information. For example, concentrations of a chemical stressor may be increasing in an environmental medium from unknown sources, or exotic species may be invading the study area from outside the study area, and from sources beyond the control of those responsible for managing the study area.

- The designs of the surveys and/or laboratory studies must be appropriate for meeting the needs of qualitative or quantitative decisions, as appropriate. (See Table 4 for information on qualitative and quantitative methods for surveying ecosystems)

- The quantity of data to be collected for each species and variable should allow for unexpected events. While it may be attractive from a cost perspective to collect only the minimum numbers of samples and replicates, it is dangerous to do so from a scientific perspective. Samples are often invalidated for various reasons, including equipment failure, errors in sample preparation and analysis, and exceeding sample holding times. Hence, it is advisable to design sample collection and analysis programs for completeness by allowing for what may reasonably go wrong in the process.

Substep 7.1 - Review DQO Outputs and Existing Environmental Data

The first activity in Step 7 is to review the study boundaries (Step 4) and preliminary determinations of data inputs (Step 3) that are required to support the decision (as defined in Steps 2 and 5). All historical data plus data from ongoing programs (e.g., ongoing monitoring and research programs) should be reviewed for the purpose of determining the optimal types, quantities, and qualities of data needed to test the null hypotheses developed in Step 6.

In most studies, a comprehensive review of background data for the study area will also be an important part of Substep 7.1. A preliminary review of background data will have been completed during Step 3 for the purpose of determining whether those data are generally adequate to support the decision at hand. In Substep 7.1, the review should focus on whether those data are adequate to support testing of the null hypotheses generated in Step 6. Relevant questions concerning the background data set might include

- What would constitute a good background data set for testing the null hypotheses?
- Are reference and test sites similar? Do faunal and floral differences result from natural variation or human effects?
- Are stressors that have their origins outside the study area contributing to observed effects within the study area? Can such effects be separated from effects due to stressors within the study area?
- Given resource limitations, can the null hypothesis be tested effectively?

Having completed a review of the existing data, a decision must be made as to whether the existing data are adequate to test the null hypotheses, or whether additional data are needed. When the existing baseline data are sufficiently comprehensive to permit sensitivity testing of the variable(s) of interest, the decision may be based on results of those analyses (see introductory discussion in Step 6). However, in most cases the existing data will not be sufficient to permit sensitivity testing, and the decision will have to be based on best professional judgement. For example, if the risk assessor knows that trichloroethylene is present because it appears in three of twenty samples, that person may decide that additional samples are needed to characterize the spatial distribution and concentrations of trichloroethylene. In most cases, such a decision would be made without benefit of sensitivity testing. When the decision is made that more data are needed, the risk assessor must critically review the study boundaries determined in Step 4, and the tolerance limits specified in Step 6, as the study boundaries and tolerance limits will help define the types, quantities, and qualities of the needed data.

Substep 7.2 - Develop General Data Design Alternatives

Alternative data collection and analysis designs are developed during this substep. "The goal is to find cost-effective alternatives that balance sample size and measurement performance, given the feasible choices for sample collection techniques and analytical methods" (EPA 1994a). Hence, in this substep the risk assessors attempt to find the optimal tradeoff between cost on the one hand, and accuracy and precision of the data on the other. How this is accomplished depends on numerous factors, some of which are the size of the study area, the natural variability of the biotic and abiotic environment, the variability of the stressor(s) that act on that environment, and the appropriate method(s) for surveying the ecosystem at hand. (See Table 4 for a listing of qualitative and quantitative survey methods.) Within those qualitative and quantitative survey methods, data collection design alternatives may include factorial designs, simple random sampling designs, stratified random sampling designs, sequential random sampling designs, systematic sampling designs, and composite sampling designs (EPA 1994a). In cases where information on baseline variability of the system is poor or non-existent, developing data design alternatives that can be implemented with confidence may be a challenge, and best professional judgement may be the primary mechanism by which such decisions are made.

Sampling alternatives should consider the type, quantity, and quality of the data needed to test the null hypotheses. Example dimensions for data type, quantity, and quality are provided below.

Dimensions of the type of data may include

- observational data (e.g., numbers of species, density estimates)
- anecdotal data
- analytical data
- physical measurement data (e.g., of velocity, flow, toxicity).

Dimensions of data quantity may include

- outputs of statistical analyses to determine appropriate numbers of samples and replicates
- outputs of cost benefit analyses
- schedule data
- comprehensive data on spatial and temporal scales of interest.

Dimensions of data quality may include

- data collection specifications
- data analysis methods

- data reporting requirements (especially for field data)
- data storage specifications
- data integrity requirements
- data validation and verification procedures
- required field and laboratory credentials for study personnel (e.g., training)
- specifications for the use of best professional judgement
- field and laboratory quality assurance and quality control procedures
- specifications for levels of analytical rigor.

Substep 7.3 - Formulate the Mathematical Expressions Needed to Solve the Design Problem for Each Data Collection Design Alternative

The purpose of this substep is to formulate the mathematical expressions needed to optimize the data collection design. For qualitative decisions, and to a large extent for quantitative decisions where baseline information on variability of the variables of interest is inadequate to fully support quantitative analyses, best professional judgement is typically used to decide on a preferred data collection design for each variable of interest. This will be the case for most ecological risk assessments, as baseline information on variability is typically not available or, if it is available, is not of sufficient quality or quantity to support rigorous statistical analyses.

When the data must support quantitative decisions, and when baseline information is available on the variables of interest, then it is appropriate to place well-defined limits on the decision errors. In that case, more of a statistical design is needed for data collection efforts. EPA (1994a) outlines the following three steps:

- "Define a suggested method for testing the statistical hypothesis and define a sample size formula that corresponds to the method if one exists (e.g., student's t-test)."
- "Develop a statistical model that describes the relationship of the measured value to the `true' value. Often the model will describe the components of error or bias that are believed to exist in the measured value."
- "Develop a cost function that relates the number of samples to the total cost of sampling and analysis."

Substep 7.4 - Develop and Document the Sampling Strategy

Based on best professional judgement or the mathematical expressions developed in Substep 7.3, the risk assessors must next develop and document the sampling strategy for collecting needed data. The following activities are recommended for ecological surveys, in the order presented:

- Obtain estimates of variability of distributions (e.g., patchiness) for variables of interest, if not already available. (During this activity, it is important to understand that the interaction between natural variability (i.e., the spatial and temporal scales of patchiness) and the sampling strategy (e.g., unit sample size, number of samples per station, number of stations) can influence the estimate of variability.)

- Develop a sampling strategy, to include

  - specified assessment and measurement endpoints, including the rationale for their selection

  - the general strategy (e.g., general strategies as in Table 4)

  - the number of stations

  - station locations

  - the unit sample size

  - the number of replicates per station

  - the temporal distribution of samples

  - co-location of different sample types

  - an archival strategy for secondary sampling.

- Develop a strategy for controlling decision error through the sampling design (e.g., through the number of samples and number of replicates per sample).

- Document all assumptions and operational details.

Constraints that assessors may be required to consider when developing the sampling strategy include

- budget cycle (e.g., if funding is not possible this year, then maybe it will be next year)

- time (e.g., sampling schedule, biological cycles)

- regulatory requirements (e.g., NPDES reports, RCRA corrective measures studies, federal facility agreement time lines, state and federal biological collection permits)
- management requirements (e.g., coordination with related monitoring programs)
- availability of resources (e.g., personnel, equipment, expertise)
- contractual requirements (e.g., performance measures)
- the adequacy of DQO Steps 1-6.

Any of these constraints may force the risk assessors to go back to an earlier step and rework the DQO process.

Programmatic Aids

Two programmatic aids would be helpful during the conduct of this step. The first is a complete reference library of all environmental data and reports pertinent to the study area. The second is a guidance document that can help optimize the design of an ecological risk assessment. It is available at web site **http://etd.pnl.gov:2080/DQO/home.html**.

Programmatic Considerations

A representative list of programmatic considerations for Step 7 is provided below. These and other relevant programmatic considerations that are identified by the planning and decision team and the project team should be considered throughout the conduct of Step 7 activities. Where the programmatic considerations listed below are applicable to other steps in the DQO process, they are cross-referenced to the appropriate number(s) of the step(s).

- Should the DQO process be used to integrate NRDA concerns into the ecological risk assessment process, and if so, how? [1,3,4]
- Should stakeholders and the public be involved in the DQO process? Should they be involved in setting assessment and measurement endpoints? If so, how? [1,3,4]
- How can the DQO process be used to better define spatial and temporal boundaries of the ecological risk assessment (e.g., ecological units versus regulatory units)? [1,4,7 with feedback to 4]
- How should spatial and temporal scales be considered when designing and conducting ecological risk assessments? [1,4]
- Should the DQO process be used during accelerated actions, and if so, how? [2,4]

- How can site-wide guidance and management documents (e.g., remediation work plans, installation work plans) be used as vehicles to conduct integrated ecological risk assessments? [2]
- How should natural variability be accounted for when setting DQOs? [3,4,6]
- How can DQO data input needs be coordinated with ongoing site monitoring programs? [4]
- Is a quality assurance program required to implement the DQO process? [3]
- Does the DQO process have a role in optimizing ecological risk assessments conducted under accelerated actions?
- Will the effectiveness of the remedy or activity be detectable and documentable?
- How can natural resource management be integrated into setting study boundaries?

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Appendix A

Summary Framework for Ecological Risk Assessment

Appendix A

Summary Framework for Ecological Risk Assessment

EPA's *Framework for Ecological Risk Assessment* (EPA 1992) provides a generic framework for conducting ecological risk assessments. The foundation for the EPA framework was the human health risk assessment model developed by the National Academy of Sciences in 1983. That model was augmented to address the more complex system attributes of ecological systems. For example, the human health risk assessment model does not account for a wide number and variety of species, or the dependent relationships among species.

EPA's ecological risk assessment framework is intended to provide general principles, as opposed to detailed, step-by-step instruction. As such, it provides great flexibility and can be tailored to reflect different stressors and adverse effects over differing ecosystems. A more detailed EPA methodology is presently under development. The present ecological risk assessment framework consists of three basic steps: problem formulation, analysis, and risk characterization (Figure A.1). The underlying concepts for each step are described briefly below.

Problem Formulation

The ecological risk assessment process begins with a characterization of the receiving environment and an identification of the stressors and receptors. For situations in which the assessment is performed after the stress has occurred, assessors typically begin by identifying specific stressors and ecological injury (or injuries) that have occurred. Conversely, in predictive situations, it is necessary for assessors to identify potential stressors and potentially sensitive ecological resources that are likely to be exposed to those stressors. In both cases it is necessary to gain a preliminary understanding of the spatial and temporal attributes of both stressors and receptors if viable hypotheses about exposure and risks are to be developed. Policy, regulatory, and institutional considerations, as well as data needs are identified concurrently. This information is then used to define the scope, objectives, and feasibility of the ecological risk assessment, and to identify assessment and measurement endpoints for the pending analyses.

Assessment endpoints are "explicit expressions of the actual environmental value to be protected" (EPA 1992). An example would be the productivity of coastal waters. Measurement endpoints are "measurable responses to a stressor that are related to valued characteristics chosen as assessment endpoints" (EPA 1992, see also Suter 1990). A potential measurement endpoint for the above productivity example would be photosynthetic activity of coastal phytoplankters.

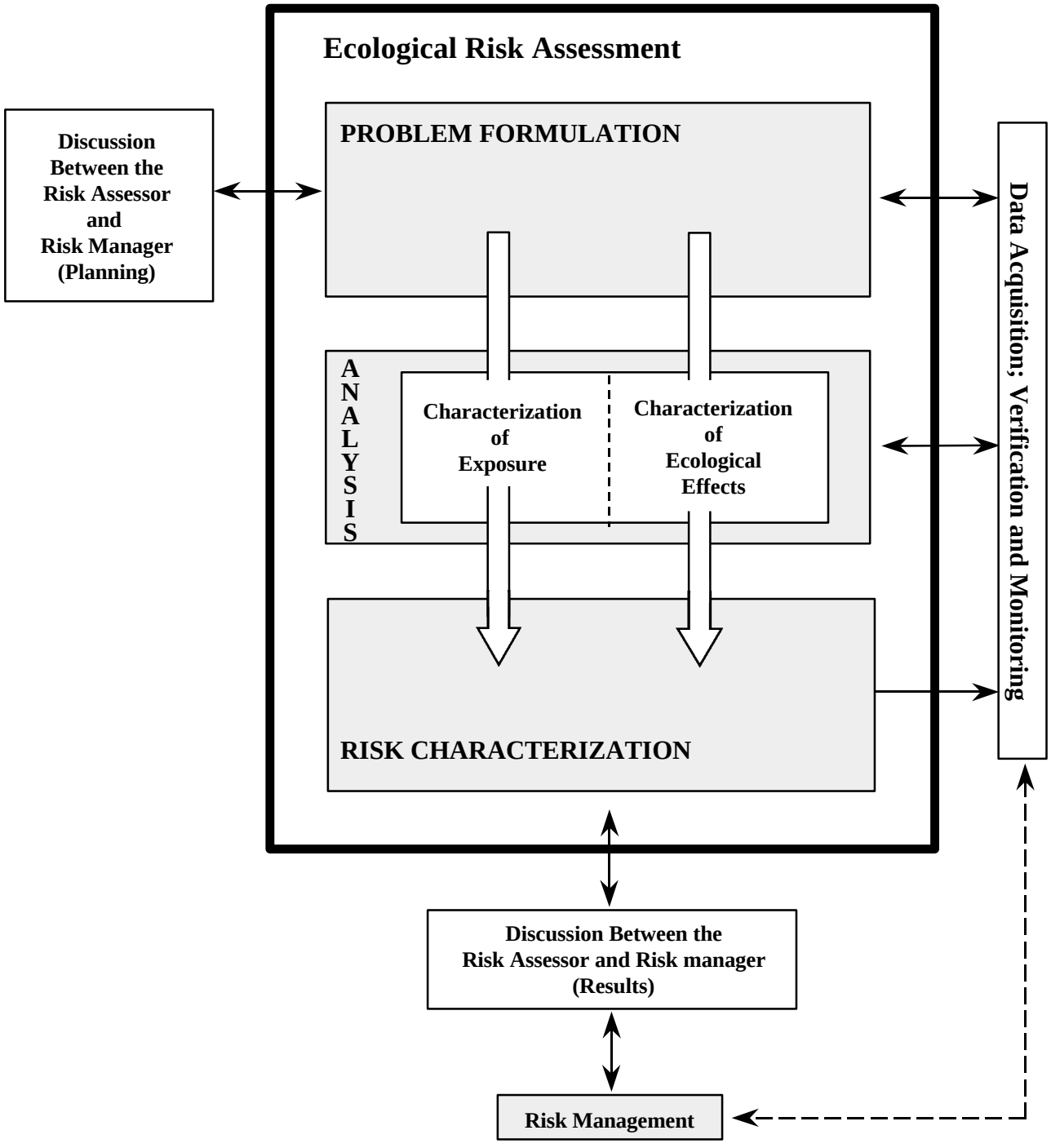

Figure A1. Framework for Ecological Risk Assessment

Endpoints may be chosen based on specific biological concerns, regulatory requirements, or recognized societal values. Endpoints may need to be evaluated at a variety of ecological levels (e.g., individual, population, community, ecosystem). Based on information about stressors and potentially affected resources, various hypotheses are introduced as to how the stressor(s) might affect the natural environment. Many hypotheses may be introduced at this point, but only those "most reasonable and quantifiable" should be selected for further evaluation.

Analysis

In the analysis step of the EPA framework, exposure and ecological effects are characterized. The goal is to determine the intensity, duration, and frequency of the exposure. The exposure analysis requires estimates of environmental concentrations of contaminants (or analogous measures of severity for other stressors, such as physical disturbance), and information about the contact of receptors with those contaminants (or other stressors). In predictive situations, contaminant concentrations are typically obtained through computer-simulated fate and transport modeling. In situations where the stress has already occurred, contaminant concentrations are obtained by direct sampling.

The EPA framework document provides no specific methodology for determining exposure, but overviews basic principles and concepts for its determination. Human exposure assessment techniques encounter difficulty here. For example, the point-to-point contact measurements used in human studies often are not practical because attaching monitors to wild animals and free-ranging organisms is difficult. Boundaries also are not well defined because one habitat or ecosystem often grades into another with few clear boundaries.

Characterizing ecological effects consists of quantitative or qualitative analyses of causal relationships between stressors and their effects on a particular ecological component. Field observations and laboratory analyses are used. The relationship between the degree of stress and the magnitude of the response is determined at this stage. Some concepts applied to understanding causal relationships in human epidemiology (e.g., strength, consistency, temporality) can be useful at this point. Relationships are often derived through the application of statistical procedures. Statistical analysis has been historically demonstrated to be effective at showing these relationships. During the hazard assessment, it is important to remember that statistical figures do not always reflect biological realities. Biological changes can occur that are not detected in the statistical analysis. Conversely, statistically significant relationships among independent variables might not have any ecological relevance. Informed judgment as well as statistical consideration is important during the characterization of ecological effects.

Risk Characterization

The final step in the ecological risk assessment process is characterizing risks. In this step, the likelihood of an adverse reaction from exposure to stressor(s) is evaluated, including the significance or consequences of the adverse effects. The EPA framework report proposes four basic steps:

1. Evaluate the likelihood of adverse effects.

2. Describe the consequence of identified adverse effects.

3. Assess the uncertainty of the risk assessment and the evidence that supports the conclusions.

4. Communicate the results.

Quantitative as well as qualitative information and judgments can be made. In all cases, uncertainties in the results should be assessed and communicated. While no single risk characterization methodology is recommended by EPA, the Quotient Method (Barnthouse et al. 1986) is identified as a "commonly used method of ecological risk characterization." This methodology compares the exposure value to the stressor-response value. "The larger the quotient the larger the risk."

The overall goal of EPA's ecological risk framework is to produce "scientifically acceptable" information that can be used in making risk-management decisions and complying with legal requirements. However, the report warns the reader that incomplete knowledge and large gaps in scientific theory will result in uncertainties that must be clearly communicated.

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Appendix B

Summary Guidance for the Data Quality Objectives Process

Appendix B

Summary Guidance for the Data Quality Objectives Process

The DQO process provides guidance on developing data quality criteria and performance specifications for decision making. Its intent is to help the regulated community collect data of sufficient quality and quantity to support defensible decision making, while eliminating the collection of unnecessary, duplicative, and overly precise data. Seven steps are involved, each of which is identified below with a reiteration of its purpose. For each step, expected outputs and relevant activities are listed, as per EPA (1994).

Step 1. State the Problem

Purpose

To define the problem so that the focus of the study will be unambiguous.

Expected Outputs

- A list of the planning team members and identification of the decision maker.
- A concise description of the problem.
- A summary of available resources and relevant deadlines for the study.

Activities

- Identify members of the planning team.
- Identify the primary decision maker of the planning team and define each member's role and responsibility during the DQO process.
- Develop a concise description of the problem.
- Specify the available resources and relevant deadlines for the study.

Step 2. Identify the Decision

Purpose

To define the decision statement that the study will attempt to resolve.

Expected Outputs

- A decision statement that links the principal study question to possible actions that will solve the problem.

Activities

- Identify the principal study question.
- Define the alternative actions that could result from resolution of the principal study question.
- Combine the principal study question and the alternative actions into a decision statement.
- Organize multiple decisions.

Step 3. Identify the Inputs to the Decision

Purpose

To identify the informational inputs that will be required to resolve the decision statement and determine which inputs require environmental measurements.

Expected Outputs

- A list of informational inputs needed to resolve the decision statement.
- A list of environmental variables or characteristics that will be measured.

Activities

- Identify the information that will be required to resolve the decision statement.
- Determine the sources for each item of information identified above.

- Identify the information that is needed to establish the action level.
- Confirm that appropriate measurement methods exist to provide the necessary data.

Step 4. Define the Boundaries of the Study

Purpose

To define the spatial and temporal boundaries of the problem.

Expected Outputs

- A detailed description of the spatial and temporal boundaries of the problem.
- Any practical constraints that may interfere with the study.

Activities

- Specify the characteristics that define the population of interest.
- Define the spatial boundary of the decision statement.
  - Define the geographic area to which the decision statement applies.
  - When appropriate, divide the population into strata that have relatively homogeneous characteristics.
- Define the temporal boundary of the problem.
  - Determine the timeframe to which the decision applies.
  - Determine when to collect data.
- Define the scale of decision making.
- Identify any practical constraints on data collection.

Step 5. Develop a Decision Rule

Purpose

To define the parameter of interest, specify the action level, and integrate previous DQO outputs into a single statement that describes a logical basis for choosing among alternative actions.

Expected Outputs

- A statistical parameter (the parameter of interest) that characterizes the population.
- The action level.
- An "if…then…" statement that defines the conditions that would cause the decision maker to choose among alternative actions.

Activities

- Specify the statistical parameter that characterizes the population (the parameter of interest).
- Specify the action level for the study.
- Develop a decision rule.

Step 6. Specify the Tolerable Limits on Decision Errors

Purpose

To specify the decision maker's tolerable limits on decision errors, which are used to establish performance goals for the data collection design.

Expected Outputs

- The decision maker's tolerable decision error rates based on a consideration of the consequences of making an incorrect decision.

Activities

- Determine the possible range of the parameter of interest.

- Identify the decision errors and choose the null hypothesis.
  - Define both types of decision errors and establish the true state of nature for each decision error.
  - Specify and evaluate the potential consequences of each decision error.
  - Establish which decision error has more severe consequences near the action level.
  - Define the null hypothesis (baseline condition) and the alternative hypothesis and assign the terms "false positive" and "false negative" to the appropriate decision error.
- Specify a range of possible parameter values where the consequences of decision errors are relatively minor (gray region).
- Assign probability limits to points above and below the gray region that reflect the tolerable probability for the occurrence of decision errors.

Step 7. Optimize the Design for Obtaining Data

Purpose

To identify a resource-effective data collection design for generating data that are expected to satisfy the DQOs.

Expected Outputs

- The most resource-effective design for the study that is expected to achieve the DQOs.

Activities

- Review the DQO outputs and existing environmental data.
- Develop general data collection design alternatives.
- Formulate the mathematical expressions needed to solve the design problem for each data collection design alterative.
- Select the optimal sample size that satisfies the DQOs for each data collection design alternative.
- Select the most resource-effective data collection design that satisfies all of the DQOs.

- Document the operational details and theoretical assumptions of the selected design in the sampling and analysis plan.

Reference

U.S. Environmental Protection Agency (EPA). 1994. *Guidance for the Data Quality Objectives Process*. EPA QA/G-4, Quality Assurance Management Staff, Washington, D.C.

Appendix C

Regulatory Compliance Applications

Appendix C

Regulatory Compliance Applications

Regulations pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (i.e., National Oil and Hazardous Substances Pollution Contingency Plan [NCP]; 40 CFR 300) specifically require an environmental risk assessment. In addition, they encourage the conduct of ecological risk assessments to meet provisions of the Endangered Species Act (ESA). Other than the NCP, no federal laws, regulations, DOE Orders, or Executive Orders specifically require that environmental risk assessments be performed. However, the U.S. EPA is increasingly requiring that ecological risk assessments be conducted to meet regulatory requirements under a variety of environmental statutes. As a result, ecological risk assessment is often the most expedient and effective analytical tool that DOE can use to meet its legal and policy commitments to ecological resource management under a variety of statutes, regulations, DOE Orders, Executive Orders, and binding agreements. Relevant federal statutes, regulations, and orders are listed below.

A listing of potentially relevant state statutes and regulations is beyond the scope of this document. However, the planning and decision team should consult with state (and possibly local) authorities to identify relevant state regulatory compliance applications for ecological risk assessments.

Statutes and Regulations

Atomic Energy Act: 42 USC 2011, Section 161. 10 CFR 830, "Nuclear Safety Management".

Bald and Golden Eagle Protection Act: 16 USC 668 et.seq., 50 CFR Subchapter B--Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants.

Clean Air Act: 42 USC 7401, Sections 103, 108, 109, 111, 112, 118, 162. 40 CFR 50, "National Primary and Secondary Ambient Air Quality Standards"; 40 CFR 52, "Approval and Promulgation of Implementation Plans"; 40 CFR 60, "Standards of Performance for New Stationary Sources"; 40 CFR 81, "Designation of Areas for Air Quality Planning Purposes".

Clean Water Act: 33 USC 1251, Sections 102, 102, 402, 404. 33 CFR 320 - 330, Policies and Programs of the U.S. Corps of Engineers; 40 CFR 122, "EPA Administered Permit Programs: The National Pollutant Discharge Elimination System"; 40 CFR 125, "Criteria and Standards for the National Pollutant Discharge Elimination System"; 40 CFR 230, "Section 404(b)(1) Guidelines for Specification of Disposal Sites for Dredged or Fill Material".

Comprehensive Environmental Response, Compensation, and Liability Act: 42 USC 9601, Sections 105, 107, 120, and 301. 40 CFR 300, "National Oil and Hazardous Substances Pollution Contingency Plan"; 43 CFR 11, "Natural Resources Damage Assessments".

Endangered Species Act: 16 USC 1531, Sections 7, 10. 50 CFR 424, "Listing Endangered and Threatened Species and Designating Critical Habitat"; 50 CFR Subchapter C, "Endangered Species Exemption Process".

Fish and Wildlife Coordination Act: 16 USC 661, et. seq., 50 CFR Subchapter B--Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants.

Migratory Bird Treaty Act: 16 USC 703, et. seq., 50 CFR Subchapter B--Taking, Possession, Transportation, Sale, Purchase, Barter, Exportation, and Importation of Wildlife and Plants.

National Environmental Policy Act: 42 USC 4321, Section 102. 40 CFR 1500-1508, "Regulations of the Council on Environmental Quality (in part)"; 10 CFR 1021, "National Environmental Policy Act Implementing Procedures"; 10 CFR 1022, "Compliance with Floodplain/Wetlands Environmental Review Requirements".

Pollution Prevention Act: 42 USC 133.

Resource Conservation and Recovery Act: 42 USC 6901, Sections 3001, 3002, 3003, 3004, 3005, 3012, 3013, 3019. 40 CFR 261, "Identification and Listing of Hazardous Waste"; 40 CFR 264, "Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities"; 40 CFR 265, "Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities"; 40 CFR 266, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities"; 40 CFR 267, "Interim Standards for Owners and Operators of New Hazardous Waste Land Disposal Facilities"; 40 CFR 268, "Land Disposal Restrictions"; 40 CFR 270, "EPA Administered Permit Programs: The Hazardous Waste Permit Program"; 40 CFR 271, "Requirements for Authorization of State Hazardous Waste Programs"; 40 CFR 272, "Approved State Hazardous Waste Management Programs".

Rivers and Harbors Act: 33 USC 401 et. seq., 33 CFR Parts 320 - 338.

Safe Drinking Water Act: 42 USC 300 et. seq. 40 CFR 141 National Primary Drinking Water Regulations, 40 CFR 143 National Secondary Drinking Water Regulations, 40 CFR 144 Underground Injection Control Program, 40 CFR 145 State UIC Program Requirements, 40 CFR 146 Underground Injection Control Program: Criteria and Standards, 40 CFR 148 Hazardous Waste Injection Restrictions.

Toxic Substances Control Act: 15 USC 2601 et. seq., 40 CFR Part 700 et.seq., Toxic Substance Control Act.

Executive Orders

Order 11514: "Environmental Compliance with Pollution Control Standards".

Order 11644: "Off-Road Vehicles on Public Lands".

Order 11987: "Exotic Organisms".

Order 11988: "Floodplain Management".

Order 11990: "Protection of Wetlands".

Order 12088: "Federal Compliance with Pollution Control Standards".

Order 12580: "Superfund Implementation". (Amends Order 12088.)

DOE Orders

Order 4300.1C: Real Property Management

Order 4320.1B: Site Development Planning

Order 5400.1: "General Environmental Protection Program".

Order 5400.5: "Radiation Protection of the Public and the Environment".

Order 5480.4: Environmental Protection, Safety, and Health Protection Standards

Order 6430.1A: General Design Criteria

Appendix D

Example Memorandum of Decision Responsibility

Appendix D

Example Memorandum of Decision Responsibility

Date:
Subject: Memorandum of Decision Responsibility
To: DOE Site Manager
From: Ecological Risk Assessment Planning and Decision Team for _____ Activity

The purpose of this memorandum is to identify the persons and agencies who have decision responsibility for the _____ activity that will be conducted on the _____ Site. The scope of the activity is to:

- Identify scope element 1
- Identify scope element 2
- Etc.

It is anticipated that this activity will be planned and conducted during the approximate time frame of _____ to _____.

The persons named below are the members of the "Ecological Risk Assessment Planning and Decision Team". They are authorized by their sponsoring agencies to make decisions regarding the _____ activity throughout its design and conduct. By their identification below, it is understood that if any of the below named persons are unable to fulfill their obligations to the "Ecological Risk Assessment Planning and Decision Team" and hence, to participate in decisions regarding the _____ activity or activities of the "Ecological Risk Assessment Planning and Decision Team," their sponsoring agency will identify and empower another representative to fulfill those duties throughout the duration of the _____ activity.

_____	_____	_____	_____
Agency	Name	Signature	Date
_____	_____	_____	_____
Agency	Name	Signature	Date
_____	_____	_____	_____
Agency	Name	Signature	Date

Appendix E

Geopgraphic Information System Applications for Ecological Risk Assessment

Appendix E

Geographic Information System Applications for Ecological Risk Assessment

Introduction

Ecological risk assessment (ERA) is an iterative process, the components of which are not distinct. The process typically involves several areas of expertise, and embodies a need to compile and interpret complex multidisciplinary data and information into a clear and justifiable decision tool. As the discipline of ecological risk assessment has evolved, it has become increasingly apparent that the ability to prioritize threats, integrate efforts, resolve background issues, determine cumulative impacts, and address potential impacts on varying scales requires a level of data management and manipulation that is not readily available.

Geographic Information Systems (GIS) have the potential to provide the comprehensive, integrated data management functions that ecological risk assessments require. Specifically, they can provide data management, manipulation, analysis, and display system functions. However, because the technical analytical aspects of the ecological risk assessment process are not standardized, the process continues to evolve, and therefore presents a challenge for the integration of GIS capabilities to support it. As the ecological risk assessment process evolves, it is expected that this integration process will co-evolve to become more standardized and comprehensive. This appendix discusses some of the important attributes of the integration process.

GIS and ERA Integration

GIS is commonly defined as an organized collection of computer hardware, software, geographic data, and personnel designed to efficiently capture, store, update, manipulate, analyze, and display all forms of geographically referenced information. It can be used to inquire about location, condition, trends, patterns, and modeling aspects of geography by asking such questions as:

- What is at…?
- Where is it?
- What has changed since…?
- What spatial patterns exist?
- What if…?

GIS technology is used extensively in land use planning, natural resource management, environmental assessment, ecological research, demographic research, and many other applications consistent with the ERA process, providing a means of integrating data and information to aid in informative decision-making. Building using a GIS involves several tasks:

- designing a geographic database
- building and managing geographic databases
- performing geographic analysis
- creating maps and reports.

The most beneficial use of a GIS for ERA activities is as a data management and evaluation tool. Site characterization data, including soil, groundwater, surface water, or biotic data can be incorporated into a GIS environment. One of the most time consuming activities is determining what data exist and the applicability of those data to the risk assessment or investigation at hand. With GIS capabilities, one could focus on a study area and determine what data are available, what data are lacking, and what conclusions can be drawn. Field sampling efforts could be geographically referenced, and the collected data could be linked with specific media and ecosystem components. The GIS allows waste unit evaluations to be compiled to address cumulative effects and to support watershed-level or ecosystem-level evaluations. Each entity in an investigation project, from natural resource trustees to the public, may have different interests based on cultural, regulatory, or personal convictions. GIS could enable multiple evaluations to address the concerns of each of those individual entities.

Habitat and Receptor Evaluation

Many examples of GIS applications exist that are appropriate for ERA and GIS integration. Habitat and receptor species evaluations are an obvious example. Aspinall and Veitch (1993) used satellite imagery and wildlife survey data in a Bayesian model to develop a habitat mapping procedure for GIS application. In another application, Palmerimum (1987) used satellite imagery to automate mapping of avian species habitat. GISs have also been used to make population estimates of various wildlife species, including wading birds (Avery and Haines-Young 1990; Herr and Queen 1993) and caribou (Thompson et al. 1980).

Aerial photographic data and other types of remote sensing data continue to be a valuable assessment tool, and continue to become more accessible for browsing and digital manipulation with systems such as the Data Atlas system (Cowen et al. 1995). Much of this information may already be in a digital format ready for GIS use. GIS applications using remotely sensed data have included evaluations of habitats from monitoring wood stork foraging habitat (Hodgon et al. 1988) and crane habitat (Herr and Queen 1993), evaluations of thermal dissipation in stream systems (Jensen et al. 1988), and assessments of the potential impacts of different conservation methods on bobwhite quail habitat (Rosenberry et al. 1994).

Many different approaches to determining potential receptors exist, most of which rely on the type of information that is available and an understanding of the level of detail needed for the evaluation to meet project objectives. Approaches include field-based or table-top methods such as literature searches; personal communications with area experts, regulatory agencies, or natural resource agencies; and field reconnaissance techniques. At the DOE's Savannah River Site, as well as other sites across the DOE complex, existing information can assist in determining the potential receptors for a given area (WSRC 1994). A GIS would be an effective tool for integrating such information. For example, attribute tables could facilitate such evaluations by linking habitat types with species known (or suspected to) reside within or utilize those habitats for breeding or foraging.

Development of Conceptual Site Models

With a GIS, development of conceptual site models could be far more comprehensive than at present, as the model would not be restricted to information that could be represented on a piece of paper. Sampling locations, habitat boundaries, species identifications (including threatened and endangered species), wetland boundaries, and stream system boundaries could be incorporated into a GIS and displayed, thereby aiding the conceptualization process. Attribute data with associated species receptor data (home range, body size, etc.) could be linked with habitat type, and fish assemblage data could be linked with stream corridors. Groundwater plums could be contoured and hydrologic parameters could be modeled to determine the fate and transport of contaminants. Numerous publications exist that discuss contaminant fate and transport modeling, and several are specific to GIS applications. For example, Hepner and Finco (1995) modelled dense gaseous contaminant pathways over complex terrain using a GIS platform, while Bhaskar et al. (1991) used a GIS platform to estimate hydrologic parameters.

The selection process for contaminants of concern could be almost fully automated using statistical software programs embedded within the GIS system. Incorporating this type of data analytical capabilities into a GIS platform would provide considerable structure to the ERA process. The contaminant of concern selection process would be directly accessed through the GIS, thereby standardizing the analytical procedure.

Toxicity and Exposure Assessment

GIS provides a valuable tool for the toxicity and exposure assessment components of the ERA process. Toxicity information is not always readily available to risk assessors. Using a dedicated GIS, such information can be loaded into or accessed within the GIS. GIS database capabilities can be structured to store toxicity data, and can be queried based on receptors and/or specific contaminants of interest. If specific toxicity values are not available, that information could be obtained and incorporated into the system providing a compendium of toxicity data applicable to facility ERAs. While it may not be practical or efficient to reproduce on-line databases such as AQUIRE, such databases can be accessed readily. The best option might be to develop a site-specific toxicity database that is updated as specific project-oriented risk assessments generate toxicity information. The key to conducting an efficient toxicity assessment is having an accessible database from which to obtain the necessary information.

Exposure assessment can also be facilitated with the use of a GIS. Exposure parameters such as age class, ingestion rates, weight, metabolic rates and receptor diet composition information can be linked to species that in turn are linked to habitat types. Exposure models incorporating home ranges and habitat requirements can be developed to produce more realistic risk evaluations. Exposure screening can be conducted using a GIS as discussed in Wartenberg (1992). Wartenberg used a GIS system to screen for lead exposure by mapping cases of exposure, and thereby inferring high-risk areas. The same concept could be adapted to the ERA process using data on contaminant concentrations or observations of adverse effects. In addition, attribute tables containing species-specific parameters could be linked to the model to perform the calculations. The toxicity and exposure information could then be displayed directly from the GIS to facilitate document production.

Summary

From the above discussion it is apparent that components of the ERA process are benefitting or could benefit from GIS integration. Although it is not reasonable to assume that the ERA process can be fully integrated within a GIS environment, the building blocks are beginning to emerge. As regulatory and natural resource trustee agencies continue to focus on larger-scale investigations, the progression to a GIS platform may be realized.

Development and implementation of a GIS for ERA applications will require detailed knowledge of the risk assessment process and GIS capabilities. It is anticipated that most ecological risk assessors and sponsoring organizations will continue to use the tools at hand, and will gradually modify or expand existing GIS functions to address risk assessment needs. Development of an automated GIS should not be considered the goal when integrating the ERA process into the GIS environment, as each step of the integration process will require considerable professional judgment and testing, regardless of the level of GIS integration. Instead, it is expected that using GIS applications in the ERA process will be an evolutionary process. Obtainable intermediate objectives should contribute to the overall goal of producing defensible risk evaluations at various levels of assessment, using GIS platforms as appropriate.

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Appendix F

References for Designing and Conducting Ecological Risk Assessments

Appendix F

References for Designing and Conducting Ecological Risk Assessment

Reference materials for the design and conduct of ecological risk assessments, including the interpretation of the resulting data, are becoming increasingly available. This appendix provides selected references to books, reports, journal articles, and on-line resources that may be useful when designing and conducting ecological risk assessments and interpreting their results. It is not intended to be complete or comprehensive, but rather to reference key materials that could provide a starting point for an ecological risk assessment.

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On-Line Resources

G7 Environment and Natural Resource Management (ENRM) Database:
http://enrm.ceo.org. (A global virtual library of ENRM data and resources).

Oak Ridge National Laboratory ecological risk Web site:
http://www.hsrd.ornl.gov/ecorisk/ecorisk.html

University of Kassel's Register of Ecological Models:
http://dino.wiz.uni-kassel.de/model_db/server.html

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