0232

6/1/1996 Rev

ES/ER/TM-185/R1

Guide for Developing Data Quality Objectives for Ecological Risk Assessment at DOE Oak Ridge Operations Facilities

This document has been approved by the
K-25 Site Technical Information Office
for release to the public. Date: _____

9700

This report has been reproduced directly from the best available copy.

Available to DOE and DOE contractors from the Office of Scientific and Technical Information, P.O. Box 62, Oak Ridge, TN 37831; prices available from 615-576-8401 (fax 615-576-2865).

Available to the public from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

ES/ER/TM-185/R1

Guide for Developing Data Quality Objectives for Ecological Risk Assessment at DOE Oak Ridge Operations Facilities

L. W. Barnthouse
G. W. Suter II

Date Issued—June 1996

Prepared by the
Environmental Restoration Risk Assessment Program
Oak Ridge National Laboratory
Oak Ridge, Tennessee 37831

Prepared for the
U.S. Department of Energy
Office of Environmental Management
under budget and reporting code EW 20

LOCKHEED MARTIN ENERGY SYSTEMS, INC.
managing the
Environmental Restoration Activities at
Oak Ridge K-25 Site Paducah Gaseous Diffusion Plant
Oak Ridge Y-12 Plant Portsmouth Gaseous Diffusion Plant
Oak Ridge National Laboratory
under contract DE-AC05-84OR21400
for the
U.S. DEPARTMENT OF ENERGY

PREFACE

This white paper was prepared to present guidance for developing data quality objectives for ecological risk assessments performed as components of the Remedial Investigation process. This work was performed under Work Breakdown Structure 1.4.12.2.3.04.07.02 (Activity Data Sheet 8304). Publication of this document meets an Environmental Restoration Risk Assessment Program milestone for FY 95. Use of this guidance document will standardize the methodology used in developing data quality objectives for ecological risk assessments and will narrow the scope of subsequent data collection and risk assessment activities by focusing on those aspects of the hazard that are most relevant to decision making.

CONTENTS

PREFACE ii

ACRONYMS iv

EXECUTIVE SUMMARY v

1. INTRODUCTION 1

2. OVERVIEW OF THE DQO PROCESS 1

3. DQO PROCEDURE FOR DOE SITES 4
   3.1 PRELIMINARY PLANNING AND PREPARATION 4
   3.2 PHASES 1 AND 2: STATE THE PROBLEM AND IDENTIFY THE DECISION 5
   3.3 PHASES 3 AND 4: IDENTIFY INPUTS AND DEFINE BOUNDARIES 5
      3.3.1 Conceptual Model Development 8
      3.3.2 Specification of Risk Characterization Approach 10
   3.4 PHASE 5: DEVELOP DECISION RULES 11
   3.5 PHASES 6 AND 7: SPECIFY DECISION ERRORS AND OPTIMIZE THE DESIGN 12
   3.6 INTEGRATION WITH DQOs FOR HUMAN HEALTH RISK ASSESSMENT 12
   3.7 DQO WORKSHOPS 13

4. CONCLUSION 13

5. REFERENCES 14

FIGURES

1. Summary of the U.S. Environmental Protection Agency's DQO process 3
2. Phases 1 and 2 of the U.S. Environmental Protection Agency's DQO process 6
3. Phases 3 and 4 of the DQO process, modified to reflect the central role of the conceptual model 7

ACRONYMS

BMAP	Biological Monitoring and Assessment Program
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPEC	contaminant of potential ecological concern
DQO	data quality objective
DOE	(United States) Department of Energy
EPA	(United States) Environmental Protection Agency
FFA	Federal Facilities Agreement
FS	Feasibility Study
OU	operable unit
RI	Remedial Investigation

EXECUTIVE SUMMARY

For the past several years the United States Environmental Protection Agency (EPA) has been attempting to streamline and increase the efficiency of field data collection programs, especially Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Remedial Investigation (RI) Programs, by encouraging project managers to develop Data Quality Objectives (DQOs) prior to initiation of sampling.

The Agency has been aggressively promoting DQOs as a planning tool for RI/Feasibility Studies (FS) activities at CERCLA sites. The Oak Ridge Reservation Environmental Restoration Program has been actively involved in the DQO process since 1992, when the Clinch River RI Program was chosen as a pilot site for application of EPA's draft DQO guidance. Although DQO experts from EPA conducted the process, difficulties were immediately encountered in applying the guidance to data collection programs intended to support ecological risk assessments.

The DQO process, as defined by EPA, 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 study, and how many samples to collect." It is important to note that DQOs are developed through a *process* that ties data collection to specific problems and decisions. The process involves identification and participation of stakeholders and issues, not simple application of statistical formulas. This technical memorandum provides guidance for the DQO process.

1. INTRODUCTION

For the past several years the United States Environmental Protection Agency (EPA) has been attempting to streamline and increase the efficiency of field data collection programs, especially Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Remedial Investigation (RI) Programs, by encouraging project managers to develop Data Quality Objectives (DQOs) prior to initiation of sampling. The rationale for the DQO process is stated by EPA in its *Guidance for the Data Quality Objectives Process* (EPA QA/G-4):

> "Each year the U.S. Environmental Protection Agency (EPA) and the regulated community spend approximately $4 billion collecting environmental data for scientific research, regulatory decision making, and regulatory compliance. While these activities are necessary for effective environmental protection, it is the goal of EPA and the regulated community to minimize expenditures related to data collection by eliminating unnecessary, duplicative, or overly precise data. At the same time, the data collected should have sufficient quality and quantity to support defensible decision making. The most efficient way to accomplish both of these goals is to establish criteria for defensible decision making before the study begins, and then develop a data collection design based on these criteria."

The Agency has been aggressively promoting DQOs as a planning tool for RI/Feasibility Studies (FS) activities at CERCLA sites. The Oak Ridge Reservation Environmental Restoration Program has been actively involved in the DQO process since 1992, when the Clinch River RI Program was chosen as a pilot site for application of EPA's draft DQO guidance. Although DQO experts from EPA conducted the process, difficulties were immediately encountered in applying the guidance to data collection programs intended to support ecological risk assessments.

The EPA guidance is clearly targeted at assessments in which measured environmental contaminant concentrations are compared to remedial action goals or other regulatory action levels. CERCLA human health risk assessments are based on these kinds of comparisons. Ecological risk assessments, in contrast, are often much more complex, involving field data on population and ecosystem characteristics in addition to media concentrations (Suter 1993, Pascoe et al. 1994). For this reason, a decision was made to limit the pilot study to human health risks. Subsequently, however, the DQO process has been applied in the design of sampling and analysis plans intended to support ecological risk assessments. Ecological DQOs have been developed for the Oak Ridge Reservation-wide Assessment, the Bear Creek Valley Assessment, Waste Area Grouping 2, and Lower Watts Bar Reservoir monitoring. This guidance describes procedures to be used in developing DQOs for DOE sites. It presents an application of EPA's guidance to DOE facilities. As such it emphasizes (1) inherent limitations of EPA's guidance when applied to ecological assessments and (2) the tripartite nature of DOE's Federal Facilities Agreements (FFAs), which require the contents of work plans and other RI documents to be approved by both federal and state regulatory agencies.

2. OVERVIEW OF THE DQO PROCESS

The DQO process, as defined by EPA, 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 study, and how many samples to collect." It

is important to note that DQOs are developed through a *process* that ties data collection to specific problems and decisions. The process involves identification and participation of stakeholders and issues, not just application of statistical formulas.

Figure 1 summarizes the seven-step DQO process recommended by EPA. Step 1 (State the Problem) involves unambiguous specification of the problem for which data collection is required. The process of developing this specification involves (1) assembly of a planning team including representatives of scientific disciplines required for data collection and "stakeholders" (i.e., DOE, the appropriate EPA Region, and the appropriate state agency); (2) identification of the lead member(s) of the planning team (i.e., the decision-makers); (3) development of a concise description of the problem, including history, literature, and regulatory requirements; and (4) specification of available resources and relevant deadlines (e.g., FFA milestones).

Step 2 (Identify the Decision) involves development of a "decision statement" [i.e., a succinct statement that links the "principal study question" (identified from step 1) to possible actions]. The decision may be simple, such as deciding whether contamination levels exceed a regulatory action level that requires a specific remedial action, or complex, such as determining whether a significant risk is imposed, and if it is, then which of a number of alternative remedies would be most cost-effective. Complex decisions can be organized as decision trees.

Step 3 involves specification of the information needed to resolve the decision alternatives (is action x or action y indicated?). This might include specification of measurements and models and identification of sources of the information. It might also include studies intended to demonstrate the validity of proposed measurements.

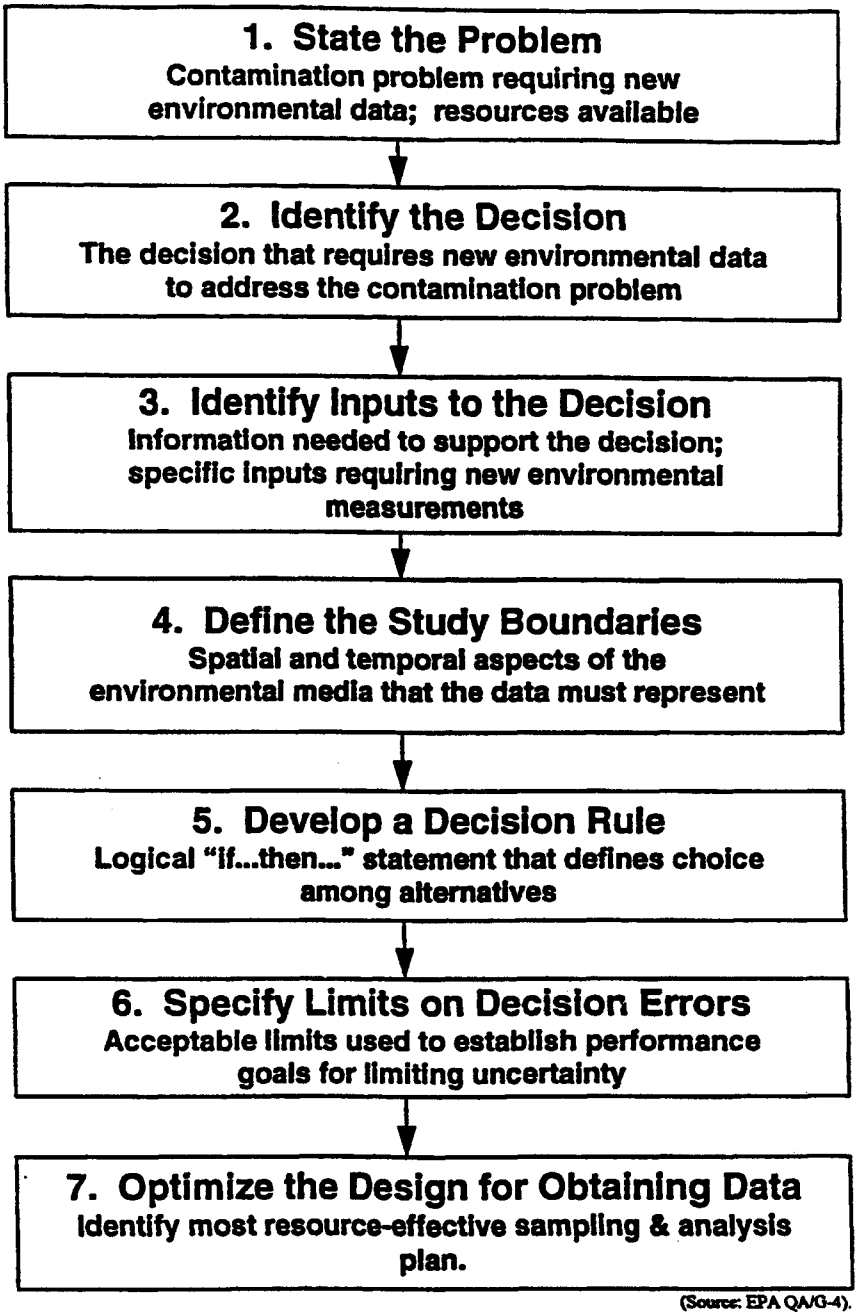
Step 4 involves delimitation of study boundaries: estimation of the size of the area of interest, the required frequency and spatial intensity of sampling, and the period of time over which samples should be collected. This is a classical sampling program design step and may be preceded by a preliminary field investigation.

Step 5 involves specification of an explicit decision rule: what measured values will indicate alternative x vs. alternative y? The objective of this step is to specify statistical confidence limits and action levels for the measured variables. These are expressed in the form of "if..then" statements.

Step 6 requires the decision maker to specify "tolerable limits" on decision errors, based on the consequences of making incorrect decisions. In addition, Step 7 involves optimizing the study design by balancing the precision of the measurements (determined by spatiotemporal sampling intensity, analytical technique, etc.) against the cost of sampling and limits imposed by available time and resources.

The last three steps in the DQO process are difficult to apply to ecological risk assessments because (1) there are no officially approved standards or environmental goals for ecological endpoints, (2) an assessment may have multiple endpoints, and (3) ecological risk assessments often involve weight-of-evidence evaluations of qualitatively different types of measurements (e.g., contaminant concentrations, population or community measurements, biomarkers, toxicity tests). Because of the complexity of the data, the decision alternatives cannot be formulated as probabilistic hypotheses with confidence limits; therefore, simple optimization rules cannot be followed.

Because of the difficulties noted previously, it has been stated that the DQO process is inapplicable to ecological risk assessments. Experience gained in previous DQO exercises performed for the Oak Ridge Reservation show this assertion to be false for two reasons. First, the early steps



(Source: EPA QA/G-4).

Fig. 1. Summary of the U.S. Environmental Protection Agency's DQO process.

in the DQO process closely parallel the "Problem Formulation" phase of the Framework for Ecological Risk Assessment (EPA 1992) and can serve the same function. Second, data collection for both human and ecological risk assessments at CERCLA sites are inextricably linked because they include many common data requirements (e.g., environmental contaminant concentrations and, often, environmental pathways analysis) and are constrained by the same budget and schedule requirements. Therefore, one program planning process needs to serve both types of assessments.

3. DQO PROCEDURE FOR DOE SITES

Ideally, DQOs for both human health and ecological risk assessments should be developed simultaneously using a common process. However, for reasons discussed previously, the procedures described in EPA's guidance are only partially applicable to ecological risk assessments. Experience with the Clinch River DQO pilot study showed that ecological DQOs can be better developed through a separate but parallel process.

DQOs for ecological risk assessment are intended to ensure that field and lab data collected in support of CERCLA actions on the Oak Ridge Reservation will meet the criteria specified in the *Approach and strategy for performing ecological risk assessments for the U.S. Department of Energy's Oak Ridge Reservation* (Suter et al. 1995). This document, referred to throughout this guidance as the *Approach and Strategy*, summarizes the role of ecological risk assessment in the RI/FS process, describes a set of generic conceptual models for use in ecological risk assessment for the Oak Ridge Reservation, defines the criteria to be used to select assessment and measurement endpoints used in ecological risk assessments for the Reservation, defines generic endpoint species and communities, and outlines generic data needs for different types of operable units (OUs). The *Approach and Strategy* is a product of a series of DQO meetings held by the FFA parties for the Oak Ridge Reservation.

The guidance provided in this document describes procedures for using a modified version of EPA's DQO process to develop specific conceptual models, assessment/measurement endpoints, and work plans to support CERCLA ecological risk assessments.

3.1 PRELIMINARY PLANNING AND PREPARATION

DQOs are required to develop the RI work plans described in Subsect. 2.2.3 of the *Approach and Strategy*. Prior to initiation of the work plan development process, a preliminary site characterization and screening assessment should already have been performed, and the FFA parties should have agreed that more extensive data collection may be warranted. The first step in development of DQOs is preparation of a preliminary planning document. This document should (1) summarize potentially significant risks, (2) define preliminary project objectives, (3) summarize existing data concerning the site characteristics, and (4) provide a preliminary work scope and budget. Preliminary project objectives should in most cases be available from existing project planning documents. Information on the site should be available from preliminary surveys and screening assessments. In addition to data on environmental contaminant concentrations on and near the site being investigated, the preliminary planning document should summarize all available ecological information concerning the site. As noted in the *Approach and Strategy*, the Biological Monitoring and Assessment Program (BMAP) routinely collects data on aquatic biota in surface waters throughout the Oak Ridge Reservation. Information on terrestrial ecosystems is available from the Oak Ridge Reservation-wide assessment documents and from the current Oak Ridge Reservation Management Plan. Because assessments performed for individual

source OUs are expected to be integrated into watershed or reservation-level assessments, information on ecosystems adjacent to source OUs should be summarized as well. Because time and available resources may constrain new data collection, the preliminary planning document should identify any RI/FS milestones that have been agreed to by the FFA parties.

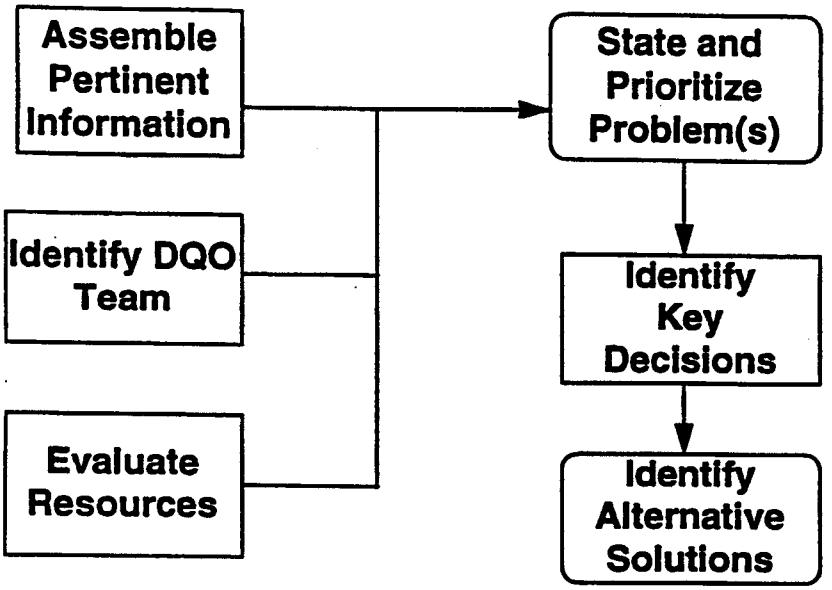
3.2 PHASES 1 AND 2: STATE THE PROBLEM AND IDENTIFY THE DECISION

A DQO team should be established to evaluate the available information and develop problem and decision statements (Fig. 2). This team should include the Risk Assessment Team Leader and the Ecological Risk Assessment Team Leader for the site and technical representatives from (1) the contractor responsible for preparing the RI, (2) DOE, and (3) the appropriate federal and state regulatory agencies. For the Oak Ridge Reservation, these agencies are EPA Region IV and the Tennessee Department of Environment and Conservation. All of the phases of the DQO process should be conducted jointly by the full DQO team, and all products of the process should be consensus products.

The first task of the DQO team is to explicitly state the problem(s) to be addressed that justify the collection of new data (Phase 1). For example, a screening assessment may show that concentrations of five contaminants in soil samples collected at a site exceed screening benchmarks but may be insufficient to establish whether plants or wildlife inhabiting the site are being adversely affected. The problem statement in this case would be that existing data are insufficient to determine the need for remediation to reduce risks to plants and terrestrial herbivorous wildlife. Once the problem has been stated, the DQO team lists the key decisions that will be made based on the outcome of the data collection effort (Phase 2). For the previous example, the key decision could be whether and how ecological remediation goals should be established for soil on the site. The DQO procedure calls for "identification of alternative solutions" as the final stage in these phases (Fig. 2). This step should be conducted only as far as necessary to clarify what results are needed to distinguish among alternatives.

3.3 PHASES 3 AND 4: IDENTIFY INPUTS AND DEFINE BOUNDARIES

Once problem and decision statements have been defined, the DQO team should identify the types of data needed to select among the alternative decisions. As noted in the EPA guidance, this process involves both enumeration of required data types and specification of spatial and temporal boundaries. In ecological risk assessments performed according to the *Approach and Strategy*, the conceptual model satisfies these requirements. As described in an Issue Paper on conceptual models prepared by the EPA Risk Assessment Forum (Barnthouse and Brown 1994), a conceptual model is "... a schematic summary of the planned assessment approach that (1) describes how a given stressor might affect the ecological components in the environment; (2) describes the relationships among the assessment and measurements, the data required, and the methodologies that will be used to analyze the data; and (3) summarizes the steps that will be taken to ensure that laboratory or field data collected for the assessment will be sufficient to achieve the intended objectives." Section 3 of the *Approach and Strategy* describes a set of generic conceptual models for the Oak Ridge Reservation. According to the *Approach and Strategy*, conceptual models for individual sites are to be derived from these templates. Conceptual models defined according to the principles given in the *Approach and Strategy* and in Barnthouse and Brown (1994) provide all the information to satisfy Steps 3 and 4 of the DQO process. A flow chart for Phases 3 and 4 of the DQO process that emphasizes the role of the conceptual model is provided in Fig. 3.



(Source: EPA QA/G-4).

Fig. 2. Phases 1 and 2 of the U.S. Environmental Protection Agency's DQO process.

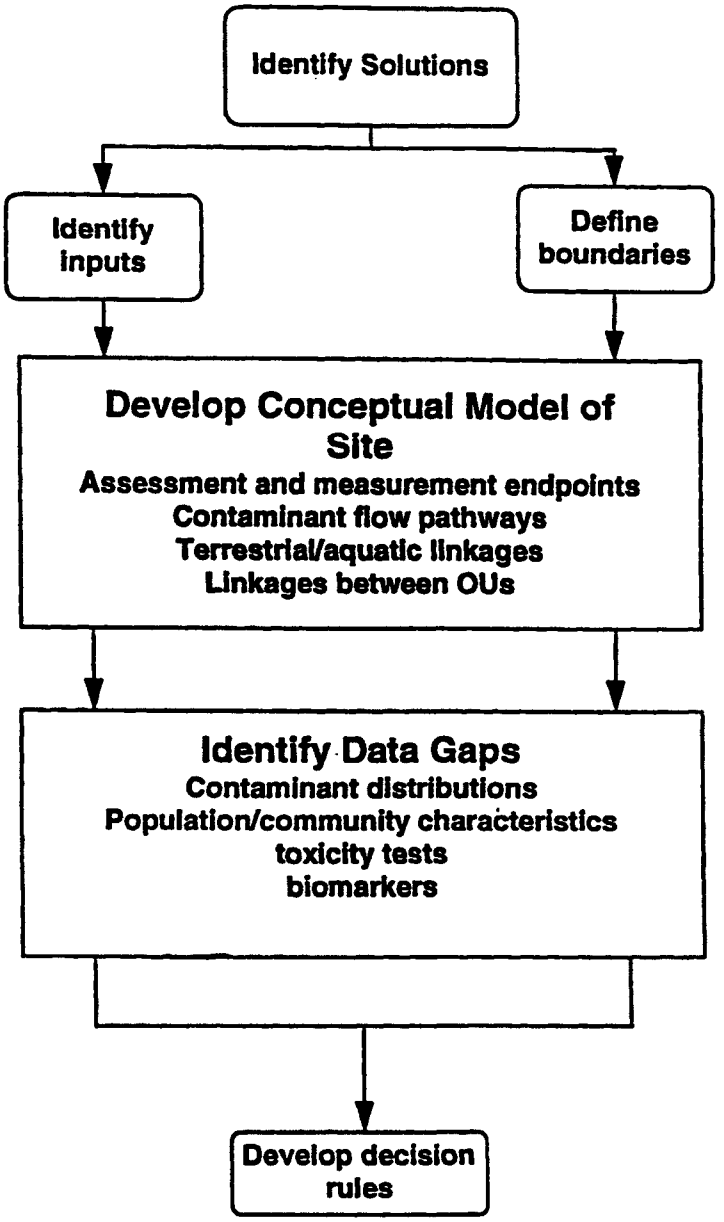


Fig. 3. Phases 3 and 4 of the DQO process, modified to reflect the central role of the conceptual model.

3.3.1 Conceptual Model Development

The generic conceptual models defined in the *Approach and Strategy* depict (1) contaminant transfers between physical compartments (i.e., soil, water, and sediment) within an OU, (2) resulting exposure pathways for organisms residing on or using an OU, and (3) movement of contaminants between OUs. The first step in the process of developing an OU-specific conceptual model involves defining boundaries and specifying assessment and measurement endpoints. Spatial boundaries are defined simply by the boundaries of the OU. Most assessments on the Oak Ridge Reservation are performed for "source OUs," defined in the *Approach and Strategy* as areas containing trenches, pits, tanks, spill sites, or other facilities in which contaminants have been directly deposited. For such sites, the boundary for the assessment should include both the disposal or spill site itself and any adjacent soil, sediment, surface water, or groundwater that may have been affected by migration of contaminants from the site. The Oak Ridge Reservation also contains a number of "aquatic integrator OUs" and a "terrestrial integrator OU" for which separate assessments are being performed.

Aquatic integrator OUs, according to the *Approach and Strategy*, consist of "streams and their associated floodplains." White Oak Creek, Bear Creek, upper and lower East Fork Poplar Creek, Poplar Creek, upper and lower McCoy Branch, the Clinch River, and lower Watts Bar Reservoir have been identified as aquatic integrator OUs on the Oak Ridge Reservation. The *Approach and Strategy* recommends that, for assessment purposes, these OUs be divided into reaches that are "delimited in such a way that they form distinct and reasonably uniform units for assessment and remediation." Five criteria for defining boundaries are provided:

- Sources of contamination should be used as bounds on reaches.
- Tributaries that provide sufficient input to significantly change the hydrology or basic water quality of a stream should serve as bounds of reaches.
- Physical structures that divide a stream, particularly if they limit the movement of animals or trap contaminated sediments, should be used as bounds of reaches.
- Changes in land use should be used to delimit reaches.
- Reaches should not be so finely divided that they are not ecologically distinct.

These criteria are explained in the *Approach and Strategy*.

The terrestrial integrator OU for the Oak Ridge Reservation is currently defined to be the reservation boundary itself. In the future, however, it may be necessary to subdivide the reservation into smaller units. If so, then the following physical features should be used to define subreservation boundaries:

- watershed divides,
- developed plant areas,
- major changes in vegetation type, and
- home range sizes for relevant wildlife endpoint species.

Once boundaries have been specified, assessment and measurement endpoints must be selected. Section 4 of the *Approach and Strategy* provides recommended assessment endpoints for terrestrial and aquatic integrator OUs and source OUs. The principal criterion for endpoint selection is spatial scale. Immobile organisms or those with small ranges are appropriate as endpoints for source OUs and small aquatic integrator OUs; wider-ranging fish and wildlife species and plant communities are appropriate for terrestrial integrator and large aquatic integrator OUs. Specific assessment endpoints for inclusion in the OU-specific conceptual model should be selected based on (1) the recommended endpoint species and communities provided in the *Approach and Strategy* and (2) the confirmed presence on the OU of either those species/communities or of suitable habitat for those species.

Measurement endpoints are the specific field and laboratory measurements used to determine whether species or communities chosen as assessment endpoints have been affected by exposure to contaminants. As noted in the *Approach and Strategy*, multiple measurement endpoints may exist for any particular assessment endpoint. For example, effects of contaminants on fish communities can be assessed using field data on fish population density and community composition, site-specific toxicity test data, and published literature or regulatory standards. Section 7 of the *Approach and Strategy* describes four types of biological data that can be used as measurement endpoints:

- single chemical toxicity,
- ambient media toxicity,
- biological surveys, and
- bioindicators.

The *Approach and Strategy* does not specify which of these types of data should be used for specific assessments. *This selection must be made by the DQO Team*. Single chemical toxicity data are the most readily available type of data. Compilations of data and recommended benchmarks are available for aquatic biota (Suter and Mabrey 1994), sediment-associated biota (Hull and Suter 1994), terrestrial wildlife (Opresko et al. 1995), plants (Will and Suter 1995a), and soil and litter invertebrates and heterotrophic processes (Will and Suter 1995b). These data will be sufficient for many risk assessments. However, if species or communities with special regulatory significance are present or if the remediation decision may be based wholly or in part on risks to biota, site-specific biological data should be collected.

For the purpose of estimating risks to biota, Sect. 6 of the *Approach and Strategy* specifies a minimum data set. For source OUs and for the floodplain component of aquatic integrator OUs, this includes (1) concentrations of contaminants in soil and (2) a plant community survey. The *Approach and Strategy* specifies that contaminant concentrations in plants, invertebrates, and small animals should be measured unless a screening assessment has eliminated the food-chain pathway as a potential hazard to herbivorous and carnivorous animals and birds.

For the surface-water components of source OUs and aquatic integrator OUs (i.e., streams and ponds), the minimum data set includes measurements of contaminant concentrations in surface water and sediment. Decisions regarding other types of data (community surveys, body burden measurements, biomarkers) should be made by the DQO team based on the types of biota and contaminants present.

For all OUs, the DQO team should consider migration of contaminants between OUs. On the Oak Ridge Reservation, the principal routes of migration are surface water flow and shallow subsurface flow.

Information on contaminant fluxes is needed to support risk assessments performed for aquatic and terrestrial integrator OUs. Moreover, potential for reduced contaminant inputs to adjacent ecosystems may be an important decision criterion for some OUs.

In addition, the exposure of endpoint species that are associated with the reservation-wide OU, because they are too wide-ranging for assessment at the scale of a source OU, should be considered. For example, if deer graze on a source OU it would be appropriate to measure contaminant levels in plants so that the contribution of that OU to deer exposures can be considered.

3.3.2 Specification of Risk Characterization Approach

As noted in Subsect. 3.3.1, a variety of field and laboratory measurements are available for use in ecological risk assessments; only a subset of these are needed for any specific assessment. Section 7 of the *Approach and Strategy* provides procedures for using these data to perform weight-of-evidence–based risk assessments. Using this approach, risk assessors must examine all available data from chemical analyses, toxicity tests, biological surveys, and bioindicators to estimate the likelihood that significant effects are occurring or will occur. When an RI is being planned, much of this information is likely to be unavailable. In designing field and laboratory studies to support the RI, the DQO team must first determine which of the lines of evidence described in Sect. 7 of the *Approach and Strategy* are relevant to the decision statement defined in Phase 2 of the DQO process.

The screening assessment included in the Preliminary Planning Document should be evaluated. Media and assessment endpoints for which the screening assessment reveals that no contaminants of potential ecological concern (COPECs) are present can be eliminated from further study, *provided the DQO team concludes that the data set is adequate*. Data adequacy is discussed in the *Guide for Performing Screening Ecological Risk Assessments at DOE Facilities* (Suter 1995). If the DQO team selects an assessment endpoint that was not addressed in the Preliminary Planning Document, than a screening assessment for that endpoint should be performed before any additional data collection is planned. For COPECs, media, and assessment endpoints that are *not* eliminated by the screening assessment, the following criteria should be used in selecting from the potential lines of evidence described in the *Approach and Strategy*:

- Will the data provide information useful for assessing risks to the chosen assessment endpoints?
- What is the likelihood that new information will provide a more accurate or credible risk assessment than the existing information?
- Can the measurements be made at the site being evaluated?
- Can the data be collected within the time allowed in the RI schedule?

These determinations require expert judgment, and no specific rules can be defined in advance. Once the DQO team has selected an assessment approach, the data required to implement the approach can be directly compared to the existing data summarized in the Preliminary Planning Document. The data gaps identified should be included in the RI work plan.

3.4 PHASE 5: DEVELOP DECISION RULES

Phase 5 of the DQO process, as specified by EPA (Fig. 1), calls for the development of decision rules. As described in EPA's guidance, this phase involves (1) determination of measurements of interest, (2) specification of action levels for those measurements, (3) specification of "action statistics," (4) specification of "modes of comparison," and (5) explicit statement of decision rules. In practice, this step has been fully implemented only in model-based assessments that require only environmental contaminant concentrations as inputs.

Because ecological risk assessments are weight-of-evidence–based rather than model-based, it is not possible to state definitively what value of an individual measured parameter would lead to a particular decision. For example, a level of reduction in fish abundance and a frequency of toxicity in tests in ambient water, neither of which would by itself lead to a decision to remediate, could prompt such a decision when they occur together. Therefore, Phase 5 of the EPA guidance cannot be fully implemented for ecological risk assessments. It is possible, however, to define quantitative decision criteria for ecological measurements and to use these as an aid in developing RI work plans.

Subsection 4.2 of the *Approach and Strategy* provides generic decision criteria for ecological measurements based on the DQO process for the Oak Ridge Reservation:

- Organism level— any effect on survivorship, growth, or fecundity in a toxicity test of surrogate species for a threatened or endangered species; any observed death or morbidity of individuals of a threatened or endangered species or any detectable reduction in the abundance or production of an exposed population of a threatened or endangered species relative to reference populations.

- Population level—a 20% effect on survivorship, growth, or fecundity in a toxicity test of surrogate species for an endpoint species or a 20% reduction in the abundance or production of an exposed endpoint population relative to reference populations.

- Community level—a 20% effect on survivorship, growth, or fecundity in a toxicity test of surrogate species for an endpoint community or a 20% reduction in the species richness or abundance of an exposed endpoint community relative to reference communities.

- Ecosystem level—a 20% effect on survivorship, growth, or fecundity in a toxicity test of surrogate species for an endpoint ecosystem, a 20% or greater reduction in functions of a surrogate ecosystem in a microcosm toxicity test, or a 20% reduction in an ecosystem function or a change in 20% of the area of an endpoint ecosystem that is indicative of loss of function or any net loss of wetlands.

Endangered or threatened species and wetlands are protected by statute; therefore, the criteria listed previously should be applied in all cases. For other endpoints (i.e., those for which the "20% rule" applies), the specific value described in the *Approach and Strategy* can be modified at the discretion of the DQO team. However, even a 20% difference between "exposed" and "reference" biota in laboratory toxicity tests and field studies can be difficult to detect. Reliable detection of smaller differences (e.g., 5% or 10%) is not feasible for many kinds of ecological data. The EPA Region IV has emphasized that the 20% level specified in these decision rules are appropriate for the DQO process but that other criteria for the significance of ecological effects may be employed in the process of reaching a decision concerning the need for remediation.

If limited field and laboratory data already exist, they should be used to estimate the expected variability in new laboratory and field data. Given empirically-derived variance estimates, standard

statistical methods can be used to estimate the number of laboratory replicates or field measurements required to detect a 20% difference between "exposed" and "reference" biota.

Specific criteria for the selection of reference sites for biological surveys are beyond the scope of this guidance. However, it must be emphasized that reference sites should be *ecologically similar* to the site being assessed, not simply free from DOE-related contaminants. For aquatic systems, exposed and reference sites must be similar with respect to hydrology, substrate characteristics, and water quality. In addition, terrestrial ecosystems exposed and reference sites must be similar with respect to topography, soil type, and vegetation type. Because no two ecosystems are exactly identical, and virtually all ecosystems in the vicinity of the Oak Ridge Reservation have been at least somewhat modified by human activity, it is recommended that multiple reference sites be used where feasible. This allows the assessors to make inferences about whether the contaminated site falls within the range of uncontaminated reference sites rather than simply inferring the contaminated site is or is not similar to a particular uncontaminated reference site. If no adequate reference sites exist, then biological surveys are unlikely to contribute useful information to the assessment.

3.5 PHASES 6 AND 7: SPECIFY DECISION ERRORS AND OPTIMIZE THE DESIGN

Phases 6 and 7 of EPA's DQO process cannot currently be implemented for ecological risk assessments. These steps require that the risks be based on "bright-line" numeric criteria like the reference doses and 10^{-4} cancer risks used in human health risk assessment. No such criteria exist for ecological risks. Decisions concerning performance goals and optimal resource allocation must be made by the DQO team using best professional judgment.

3.6 INTEGRATION WITH DQOs FOR HUMAN HEALTH RISK ASSESSMENT

Section 8 of the *Approach and Strategy* discusses the relationship of human health risk assessments to ecological risk assessments. Specific types of data that are common to both types of assessments are:

- contaminant concentrations in media,
- chemical inventories,
- operational history and current practices at the site,
- factors affecting the fate and transport of contaminants, and
- background concentrations.

In some cases, measurement methods used for human health risk assessment are inadequate for ecological risk assessments. For example, whole-sediment contaminant concentrations are usually acceptable for health risk assessment purposes, but for ecological risk assessment, pore-water concentrations in sediments and dissolved-phase concentrations of metals in water are often needed. The ecological DQO team should examine the data proposed for collection to support the human health component of the RI. The suitability of these data should be evaluated according to the guidance provided in the *Approach and Strategy*.

3.7 DQO WORKSHOPS

DQOs are critical components of RI work plans and require approval by state and federal regulators. As noted previously, they should always be developed through a joint process involving technical staff from DOE, DOE contractors, and the relevant regulatory agencies. For simple assessments, one or two meetings of the DQO team may be sufficient. However, for large or complex sites in which ecological concerns may have a major influence on the ultimate decision, a facilitated workshop process should be employed.

In a facilitated DQO process, an independent facilitator with experience in developing DQOs is engaged to lead structured workshops and prepare reports documenting decisions reached by the DQO team. The facilitator should meet at least once with the DQO team prior to the first formal workshop to explain the DQO process and ensure that all necessary background information is included in the Preliminary Planning Document.

It is often advantageous to conduct two formal DQO workshops. At the first workshop, the DQO team, assisted by the facilitator, should attempt to complete Phases 1 and 2 of the DQO process. Consensus should be reached on the problem and decision statements. Depending on the content of these statements, the DQO team should determine what (if any) additional information or documentation is needed to complete Steps 3 and 4 of the DQO process. Following the workshop the facilitator should prepare a workshop summary documenting the problem and decision statements; DQO team members should assemble any additional background information required in preparation for the second DQO workshop.

The purpose of the division of the process into two workshops is to allow time for DOE's RI contractor to use the results of the first workshop to prepare material for the completion of the DQO process. The material should include a draft conceptual model, information concerning the practicality of meeting the identified data needs (e.g., availability of appropriate reference sites), and estimates of the level of effort that would be associated with the identified data needs. At the second workshop, the DQO team should attempt to complete Phases 3–5 of the DQO process. At the conclusion of this workshop, the conceptual model, data needs, and decision rules should be documented in the facilitator's report. This report should be used by DOE's RI contractor in developing the RI work plan, which should document all of the DQO elements (e.g., the conceptual model, the data collection tasks, and the decision criteria) that were developed through the DQO process and should include the DQO workshop reports as appendixes.

4. CONCLUSION

The objective of the DQO process is to improve the cost-effectiveness and management relevance of data collected to support CERCLA RIs. The inclusion of regulator technical staff on the DQO team is an especially important aspect of the process because it (1) ensures that the data collected would address the right management concerns and (2) facilitates approval of the ultimate RI work plans by the agencies.

Only the first five steps of EPA guidance on DQOs are currently applicable to ecological risk assessments. However, once specific measurement endpoints and decision criteria have been identified, pilot studies can (where feasible) be performed to aid in optimizing the number and distribution of samples to be collected.

5. REFERENCES

Barnthouse, L. W., and J. Brown. 1994. "Conceptual model development," Ch. 3 in U.S. Ecological Risk Assessment Issue Papers, Risk Assessment Forum, U.S. Environmental Protection Agency, EPA/630/R-94/009.

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

Hull, R. N., and G. W. Suter II. *Toxicological benchmarks for screening contaminants of potential concern for effects on sediment-associated biota: 1994 revision*, ES/ER/TM-95/R1, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.

Opresko, D. M., B. E. Sample, and G. W. Suter II. 1995. *Toxicological benchmarks for wildlife: 1994 revision*, ES/ER/TM-86/R2, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.

Pascoe, G. A., R. J. Blanchet, G. Linder, D. Palawski, W. G. Brumbaugh, T. J. Canfield, N. E. Kemble, C. G. Ingersoll, A. Farag, and J. A. DalSoglio. 1994. Characterization of ecological risks at the Milltown Reservoir-Clark Fork River sediments Superfund site, Montana, *Environmental Toxicology and Chemistry* **13**:2043-2058

Suter, G. W. II. 1993. *Ecological Risk Assessment*, Lewis Publishers, Boca Raton, Florida.

Suter, G. W. II, B. E. Sample, D. S. Jones, and T. L. Ashwood. 1995. *Approach and strategy for performing ecological risk assessments for the Department of Energy's Oak Ridge Reservation: 1995 Revision*, ES/ER/TM-33/R2, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.

Suter, G. W. II, and J. B. Mabrey. 1994. *Toxicological benchmarks for screening potential contaminants of concern for effects on aquatic biota: 1994 revision*, ES/ER/TM-96/R1, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.

Suter, G. W. II. 1995. *Guide for performing screening ecological risk assessments at DOE facilities*, ES/ER/TM-153, Lockheed Martin Energy Systems, Inc., Oak Ridge, Tennessee.

Will, M. E., and G. W. Suter II. 1995a. *Toxicological benchmarks for screening potential contaminants of concern for effects on terrestrial plants: 1994 revision*, ES/ER/TM-85/R2, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.

Will, M. E., and G. W. Suter II. 1995b. *Toxicological benchmarks for screening potential contaminants of concern for effects on soil and litter invertebrates and heterotrophic process*, ES/ER/TM-126R1, Martin Marietta Energy Systems, Inc., Oak Ridge, Tennessee.