CCME

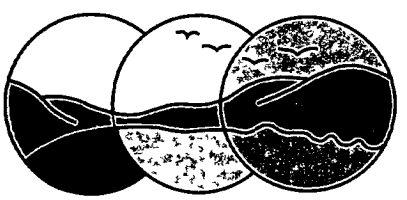
Canadian Council of Ministers of the Environment

Le Conseil canadien des ministres de l'environnement

A Framework for Ecological Risk Assessment: General Guidance

PN 1195

The National Contaminated Sites Remediation Program



A Framework for Ecological Risk Assessment: General Guidance

Oct. 2006
Changes to
this page & the next

9/11/06

The National
Contaminated Sites
Remediation Program

Winnipeg, Manitoba

1996

Notice to Readers

The Canadian Council of Ministers of the Environment (CCME) is the major intergovernmental forum in Canada for discussion and joint action on environmental issues on national, international, and global concern The 14 member governments work as partners in developing nationally consistent environmental standards, practices, and legislation

For additional copies of this report, please contact

CCME Documents
Toll-free (800) 805-3025
www ccme ca

Readers who wish to comment on the contents of this report should address their comments to

Soil and Sediment Section
Guildlines Division
Evaluation and Interpretation Branch
Environmental Conservation Service
Environment Canada
Ottawa, Ontario
K1A 0H3

Ce rapport est aussi disponible en français sous le titre *Cadre pour l'évaluation du risque écotoxicologique Orientation générale*

ISBN 0-662-24246-3

Printed on paper that contains recovered waste

Contents

Tables

Illustrations

Abstract

Ecological risk assessment (ERA) can be used to derive environmental quality criteria or to serve as the basis for making remediation decisions In order to encourage consistency in approaching ERA, a framework has been developed and is recommended The framework consists of three tiers Screening Assessment, Preliminary Quantitative ERA, and Detailed Quantitative ERA Each tier is comprised of the same components receptor characterization, exposure assessment, hazard assessment, and risk characterization Progression through the tiers is motivated by the level of uncertainty associated with the estimate of risk determined at the completion of each tier Extensive planning is required before initiating an ERA, and detailed reporting is essential throughout the ERA process

Résumé

L'évaluation du risque écotoxicologique (ERE) peut être utilisée pour établir des critères de qualité environnementale ou pour servir de cadre de travail à la prise de décisions relatives à l'application de mesures d'assainissement Afin de promouvoir la cohérence dans la tenue de l'ERE, un cadre de travail a été mis au point et est recommandé Ce cadre comprend trois niveaux, soit une évaluation de dépistage, une ERE quantitative préliminaire et une ERE quantitative détaillée Chaque niveau comprend les mêmes étapes caractérisation des récepteurs, évaluation de l'exposition, évaluation du danger et caractérisation des risques Le passage d'un niveau à l'autre est fondé sur le degré d'incertitude associé à l'estimation des risques faite á la dernière étape de chaque niveau Une planification approfondie est requise avant d'entreprendre une ERE et une présentation détaillée de l'information est essential tout au long du processus

Preface

In response to a growing public concern over the potential environmental and human health effects associated with contaminated sites, the Canadian Council of Ministers of the Environment (CCME) initiated, in 1989, the National Contaminated Sites Remediation Program (NCSRP), a five-year program for the assessment and remediation of high-risk contaminated sites in Canada In order to promote consistency in the assessment of sites under this program, a framework for ecological risk assessment for contaminated sites was developed

This document provides general guidance for utilizing the framework It does not establish or affect legal rights or obligations It does not establish a binding norm or prohibit alternatives not included in this document It is not finally determinative of the issues addressed Decisions in any particular case will be made by applying the law and regulations on the basis of specific facts when regulations are promulgated or permits are issued

Acknowledgments

The members of the Canadian Council of Ministers of the Environment (CCME) Subcommittee on Environmental Quality Criteria for Contaminated Sites gratefully acknowledge the work of Deborah Milne (environmental consultant), who prepared the final report, and of EVS Consultants, who prepared the initial drafts

The members of the Subcommittee also gratefully acknowledge the work of the members of the CCME Ecological Risk Assessment Working Group, who provided their expertise and developed this report The Working Group members include Dr Ted Nason (Chair, Alberta Environmental Protection), Gordon Dinwoodie (Alberta Environmental Protection), Mike Macfarlane (British Columbia Ministry of Environment), Marius Marsh (Ontario Ministry of Environment and Energy), and Louis Martel (ministere de l'Environnement du Quebec)

This report is based on discussion, information, and guidance from members of the CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites The members include Dr Connie Gaudet (Environment Canada), Dr Ted Nason (Current Chair, Alberta Environmental Protection), Michel Beaulieu (ministere de l'Environnement du Quebec), Dr Glyn Fox (British Columbia Ministry of the Environment), Renee Gauthier (ministere de l'Environnement du Quebec), Simone Godin (New Brunswick Department of Environment), Lee Hofmann (Previous Chair, Ontario Ministry of Environment and Energy), and Marius Marsh (Ontario Ministry of Environment and Energy)

A Framework for Ecological Risk Assessment: General Guidance

1 0 INTRODUCTION

1.1 Background

The National Contaminated Sites Remediation Program (NCSRP) was established to ensure a coordinated, nationally consistent approach to the identification, assessment, and remediation of the contaminated sites in Canada that impact or have the potential to impact on human health or the environment Under this program, a national set of interim environmental quality criteria for contaminated sites was developed as a basis for the consistent assessment and remediation of contaminated sites (CCME 1992) At a multistakeholder workshop held in November 1990, there was general agreement that the Canadian interim environmental quality criteria met the immediate needs of the NCSRP It was also recognized that in order to fulfil the mandate of the NCSRP to promote consistency in site assessment and remediation in Canada, national guidance was needed in applying these criteria on a site-specific basis Two complementary but distinct approaches were identified as the basis for the establishment of site-specific remediation objectives

- The ***criteria-based approach***, which incorporates such site-specific considerations as background levels of contaminants, technological capabilities, economic limitations, and site/situation-specific negotiations into the development of objectives

- The ***risk-based approach***, which is based on a detailed evaluation of hazard and exposure potential at a particular site Risk assessment is an important tool to use where, for example, national criteria do not exist for a contaminant, where cleanup to criteria-based levels is not feasible for the targeted land use, where criteria-based objectives do not seem appropriate given the site-specific exposure conditions, where significant or sensitive receptors of concern have been identified, or where there is significant public concern, as determined by the lead agency

The NCSRP approach to contaminated sites is described in CCME (1996a), which places ecological risk assessment (ERA) in context with other contaminated site assessment activities The present guidance document is directed toward a risk-based approach and describes a framework for ERA

1 2 Objective

The overall objective of this document is to provide general guidance for ERA This document has the following specific objectives

- to provide a succinct and user-friendly summary of the essential elements of the ERA framework

- to describe the components of the framework, including the criteria needed to select the investigative tools within each component

Additional resources and examples of methods that can be used to carry out an ERA are presented in the technical appendices to this document (CCME 1996b) Demonstrations of the ERA framework and process are presented in CCME (1996c)

1.3 Definition of ERA

Ecological risk assessment has various definitions given by different researchers and jurisdictions A sampling of these definitions is provided in Table 1

Although no consensus definition of ERA exists, Pastorok and Sampson (1990) found that there were common features of all such definitions

- prediction of the probability of adverse effects
- concept of exposure-response relationships

Various terms, as well as definitions, have sprung up for describing ERA and its components In this document, terms will be defined where they are first used, and definitions are generally consistent with those used by

Table 1 Definitions of ERA

Definition	Reference
The process of assigning magnitudes and probabilities to adverse effects of human activities (or natural catastrophes)	Barnthouse and Suter 1986
A formal set of scientific methods for estimating the probabilities and magnitudes of undesired effects on plants, animals, and ecosystems resulting from events in the environment, including the release of pollutants, physical modification of the environment, and natural disasters	Fava et al 1987
A subcategory of ecological impact assessment that • predicts the probability of adverse effects occurring in an ecosystem or any part of an ecosystem as a result of perturbation • relates the magnitude of the impact to the perturbation	Norton et al 1988
The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors This definition recognizes that a risk does not exist unless the stressor • has an inherent ability to cause adverse effects • co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s) ERA may evaluate one or many stressors and ecological components	U S EPA 1992

the U S EPA (Norton et al 1988) A glossary is provided at the end of the document

Historically, potential adverse effects were evaluated by considering impacts only, through hazard assessment (e g , toxicity testing) Acute toxicity tests were generally used, and then safety factors, or application factors, were developed to estimate chronically safe chemical concentrations (Parkhurst et al 1990) The safety factors were assumed to adequately protect ecosystems Environmental evaluation using only toxicity data does not consider probability of exposure

One of the first ERA approaches was developed by Barnthouse and Suter (1986) during the mid-1980s for the Office of Research and Development of the U S EPA According to Parkhurst et al (1990), a need for risk assessment arose with the realization that hazard assessments were generally associated with high degrees of uncertainty concerning the extent, magnitude, and probability of effects Risk, however, is a function of hazard and exposure to receptors

Receptors are components of the environment that can be adversely affected, they can be individuals, populations, communities, or ecosystems

Exposure is the co-occurrence of a stressor with an ecological *receptor* (e g , individual, population, community, or ecosystem) It is usually determined by understanding the fate of the stressor and then measuring or estimating the amount of the stressor in environmental compartments (e g , soil, air, water)

Hazard refers to the type and magnitude of effect caused by a stressor and is usually evaluated by identifying biological effects associated with exposure to different concentrations of the stressor in laboratory or field studies

Risk is the evaluation of whether an adverse effect will occur An adverse effect is likely to occur in the natural environment only if exposure approaches or exceeds the levels associated with the adverse effects identified in the hazard assessment

Early ERAs depended largely on concepts borrowed from the human health sciences and from engineering structure failure assessments A fundamental difference between human health risk assessment and ecological risk assessment is that the former is concerned with estimating effects on individuals (one species, humans), whereas the latter is concerned with estimating effects on populations, communities, and ecosystems (multispecies), and is therefore a much more complex process (Parkhurst et al 1990)

1.4 ERA "Triggers"

To assist decision makers faced with determining whether to select ERA as part of the process of contaminated site assessment, a list of factors that may trigger an ERA is provided in the box below Once into the ERA process, various levels of complexity are possible for conducting it A certain amount of information is assumed to be available for the decision In addition, the protocol for choosing "triggers" may vary with different jurisdictions in Canada, to suit their particular needs

ERA triggers can be grouped into three categories

- factors pertaining to significant ecological concerns
- issues concerning unacceptable data gaps
- points involving special site characteristics

Significant Ecological Concerns

ERA should be seriously considered when a contaminated site includes, or is expected to impact, any of the following

- critical or sensitive habitat for wildlife, migratory waterfowl, or fisheries
- rare, threatened, or endangered species, populations, or ecosystems
- lands designated as a natural area, park, or ecological reserve
- lands that are locally or regionally important for fishing, hunting, or trapping
- organisms that are not representative of the data on which the criteria values are based
- criteria values based on assumptions that do not hold true for the site of concern, for example, most soil criteria assume a minimum clay and organic matter content, which may not be present at all sites
- abiotic and biotic modifying factors (e g , naturally high background levels of heavy metals), providing conditions under which the criteria could not be applied
- a definition of adequate protection that might be changed for a particular contaminated site, requiring site-specific data

Unacceptable Data Gaps

Whenever any of the following conditions are present at a contaminated site, an ERA should be considered

- there are one or more chemicals, about which little is known, present above background concentrations
- exposure conditions are particularly unpredictable or uncertain
- pathways and partitioning of contaminants in ecosystem are not understood
- there is a high degree of uncertainty about hazard levels, and that uncertainty makes the level of risk unacceptable for that site
- there are significant gaps in available information concerning ecological receptors

Special Site Characteristics

An ERA may be a practical selection for sites where

- the costs of remediation to meet existing environmental criteria are extremely high, and priorities must be established to focus remediation efforts and to evaluate potential impacts of remediation
- existing criteria need field-testing or improvement
- no criteria currently exist for chemicals of concern at the site
- the contaminated area is so large that an ERA is needed to provide a framework for site investigation and to set remediation priorities Off-site impacts that are attributable to the site should be examined as well

In addition to the ERA triggers described above, the ERA practitioner is encouraged to consider when an ERA would be inappropriate For example, as understanding of the risk related to some sites improves, the need for ERA may be reduced In addition, the fate and effects of some chemicals may be easily predicted when this information is combined with a well-characterized site, ERA may not be the best option It must be emphasized that ERA is not necessarily superior to other approaches in the development of remediation strategies (for other approaches, see CCME 1996a)

1.5 An Introduction to the Framework

A three-tiered framework composed of sequentially more sophisticated and complex evaluations is recommended and is illustrated in Figures 1 and 2

Figure 1 illustrates the three-tiered organization assessment for a contaminated site

- Screening Assessment
- Preliminary Quantitative ERA
- Detailed Quantitative ERA

Figure 2 shows the components of ERA that are identical for the three tiers

- receptor characterization
- exposure assessment
- hazard assessment
- risk characterization

Each level in this tiered approach to ERA (Fig 1) has the same structure (Fig 2) and builds upon the data, information, knowledge, and decisions from the preceding level Thus, each level is progressively more complex The level of the ERA required to sufficiently demonstrate risk will depend on site-specific factors and will represent a continuum from qualitative to quantitative

If the initial tier cannot adequately characterize the risk with an acceptable degree of uncertainty, the next level of complexity of investigation is necessary If the ERA is adequate for ecologically based decision/risk management purposes, the ERA process stops at that level If the ERA process was triggered due to significant ecological concerns and the results indicate that they are not at risk, the process ends

This iterative aspect of the framework allows for the opportunity to evaluate the progress being made to fulfil the ERA objectives and to realize the assessment endpoints at the end of each tier New information can be added to conceptual models, data gaps can be identified, and/or the level of uncertainty can be evaluated, all of these can aid in planning the tasks required for the next tier if further investigation is deemed necessary or for documenting that the ERA is complete

The impetus for proceeding to the next tier and carrying out another iteration of the process is the level of uncertainty in the estimation of the risk Remedial or risk management decisions must be made with an understanding of the uncertainties associated with the scientific information on which the decision will be based

Sources of uncertainty in risk assessment are

- **stochasticity,** the inherent randomness of the world that can be described and estimated but cannot be reduced because it is characteristic of the system being assessed
- **imperfect or incomplete knowledge** of things that could/should be known
- **human error** in carrying out assessment activities

Uncertainty arising from imperfect or incomplete knowledge is particularly characteristic of ERAs because of the diversity and complexity of ecological systems Models and test methods used to simplify ecosystems in order to make generalizations will be limited in precision Conversely, models and test methods designed for more realism and greater precision will be limited in their possible applications This tradeoff between greater application and realism means that in ERA

- there is no unique "best" model or test system In general, minimizing one source of uncertainty will increase other sources
- in most cases, multiple independent lines of evidence are better than any single approach
- uncertainty increases with the hierarchical level of an assessment endpoint

The level of uncertainty considered acceptable for terminating an ERA must be determined by the professional judgment of the risk assessor Financial and regulatory considerations, as well as public opinion, may also play an important role in determining an acceptable level

1.6 The Tiers of the Framework

This tiered approach is composed of the following levels of ERA complexity, which are also illustrated in Figures 3 and 4

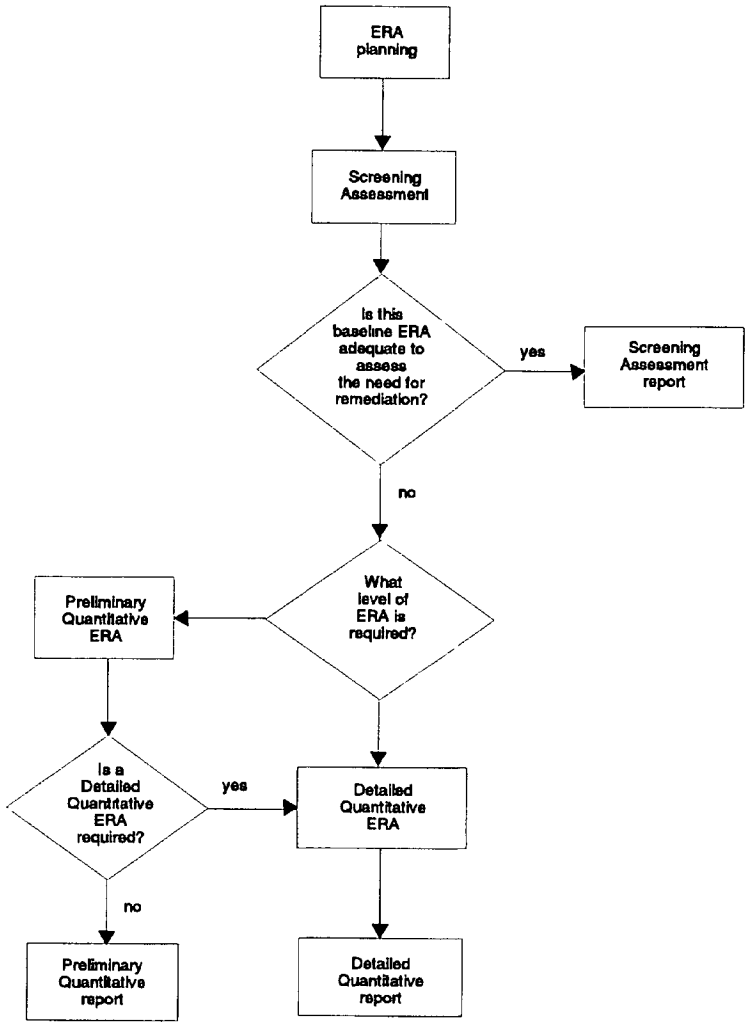


Figure 1 Framework for tiered ERA

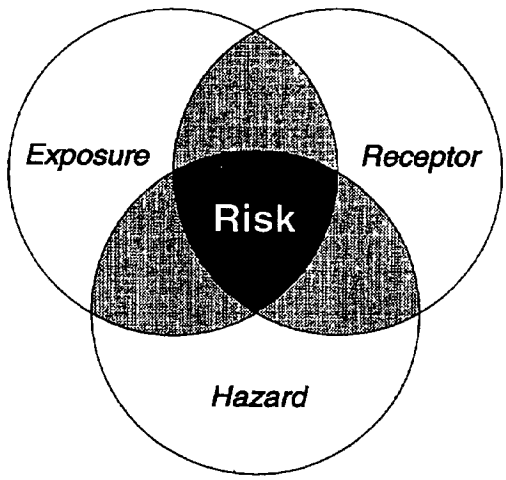


Figure 2. The relationship of the components for ERA. The same relationship exists for each level of ERA

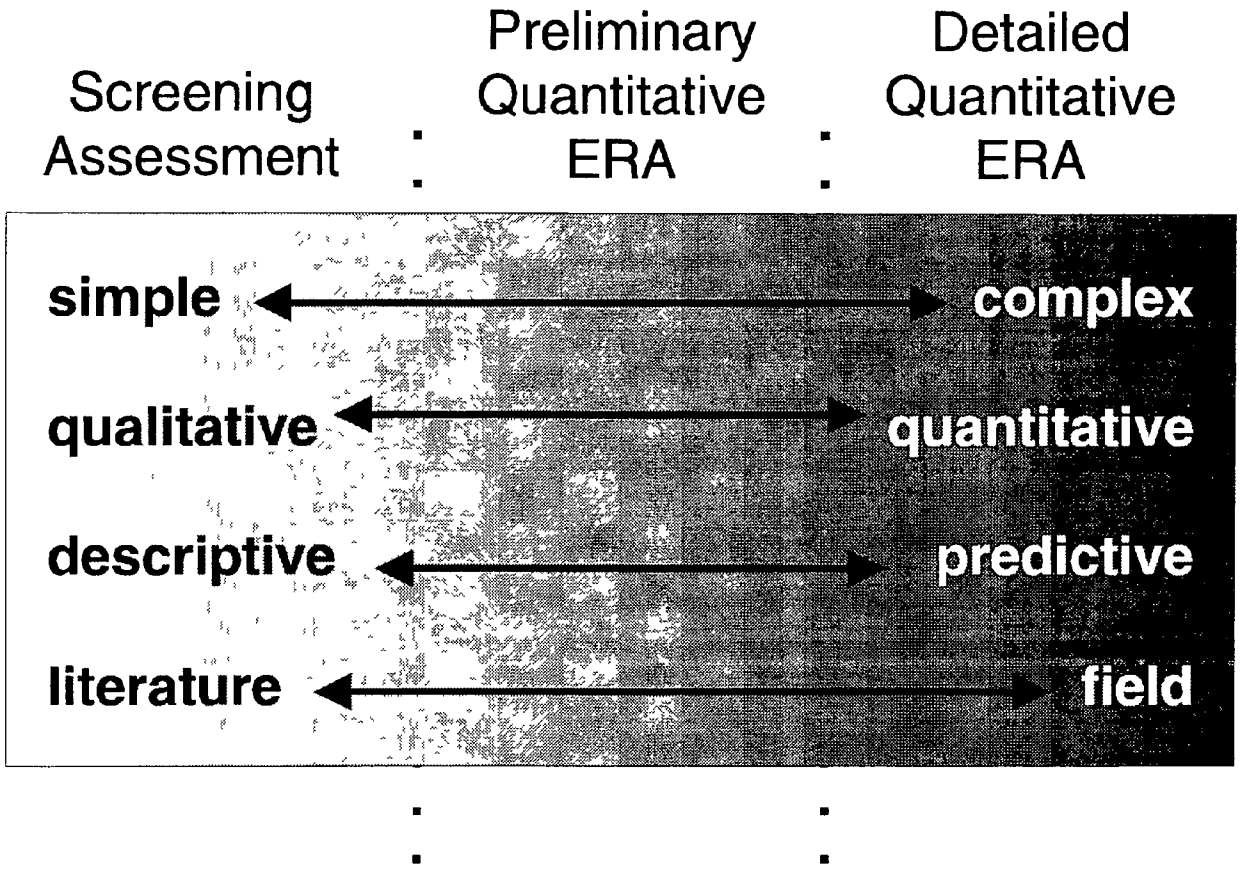


Figure 3 Characteristics of each level of ERA

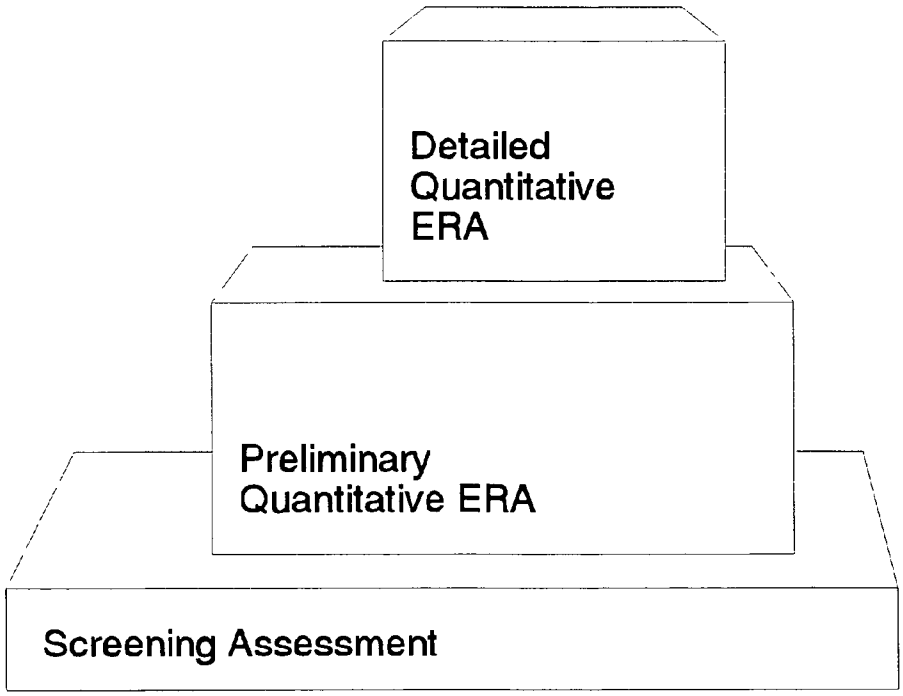


Figure 4 Conceptual structure of tiered approach to ERA

- **Screening Assessment** is characterized by simple, qualitative, and/or comparative methods, and relies heavily on literature information and previously collected data Screening Assessment studies are likely to be focused mainly at the species level and to be descriptive, as opposed to predictive Within the ERA framework, all sites undergo a screening assessment

- **Preliminary Quantitative ERA** is intermediate between Screening Assessment and Detailed Quantitative ERA, and provides quantitative information ERA tools that fit within Preliminary Quantitative ERA include standard environmental methods and models, as well as specialized approaches developed for ERA There is an increased emphasis on data collection with a focus on priority issues, as determined during Screening Assessment investigations

- **Detailed Quantitative ERA** relies on site-specific data and predictive modelling to supply quantitative information, particularly on complex ecosystem responses This is the level at which a number of the more complex U S EPA procedures, methods, and tools operate While the value of this refined and sophisticated approach is recognized, the resources and effort required may not always be warranted

In practical application, the framework contains two additional and equally important elements

- **ERA planning** is a critical step that occurs before conducting an ERA and helps to identify major factors that must be considered in order to produce a technically defensible and efficient ERA

- **ERA reporting** is critical for success and is enhanced by a well-organized summary of findings At each step of the ERA process, findings must be fully documented before proceeding to the next step

2 0 PLANNING AN ERA

The planning stage of an ERA is critical to the overall success of the risk assessment This section addresses some of the steps that need to occur before the ERA is initiated In many cases these steps will already have been conducted as part of initial studies These steps include

- selecting appropriate personnel
- establishing interaction/communication between risk assessor and risk manager
- characterizing the site
- identifying the problem(s)
- identifying valued ecosystem components (VECs)
- establishing the objective(s) of the ERA
- developing a conceptual model of the site
- selecting assessment endpoints
- selecting measurement endpoints
- establishing the level of effort required
- selecting a reference site

Public Participation

The extent of public involvement in the ERA process will vary according to the user and/or jurisdiction If the public is to be involved, the uses and limitations of risk assessment and other evaluation tools should be clearly communicated in the initial stages of the assessment

2 1 Staffing for an ERA

As part of the planning process, individuals with expertise in each of the technical areas required by the risk assessment must be identified and included in the study team The team should be coordinated by a scientist who has good organizational skills and is experienced in the risk assessment process In some cases, someone with good project management experience and a strong science background would be just as effective The risk assessor organizes and analyzes site data, develops exposure and risk calculations, and prepares the risk assessment report The intent is that risk assessments are conducted by technical experts for use as a decision-support tool for risk managers and risk communicators When an ERA is complete, it should be audited by an independent reviewer or regulator, who runs through the entire process in a paper exercise to evaluate the conclusions of the assessment

The risk assessment team includes a multidisciplinary group of professionals with experience in

- toxicology
- ecology (aquatic/terrestrial)
- fisheries/wildlife biology
- botany/forestry
- limnology
- geology/hydrogeology
- chemistry
- environmental engineering/modelling

Professional Judgments in ERA

ERAs are based on scientific data that may be complex, conflicting, and incomplete (U S EPA 1992) The whole ERA process relies on professional judgment based on experience and specialized knowledge in the various aspects required From the regulatory point of view, this presents a problem when it comes to standardization and consistency of the process It is not possible to provide specific guidance on each step of ERA, rather, what is provided herein is guidance on understanding the components and principles of ERA It is up to the reviewers of an ERA workplan to apply professional judgment to evaluate the proposed ERA site specifically

Professional judgment on the part of ERA practitioners is necessary to

- plan the risk assessment
- evaluate and select the tools for each ERA component
- ensure the data are optimal for the objective(s)
- track the uncertainty introduced by each component
- interpret the ecological significance of the data, and relate them to the site

2.2 Interaction Between the Risk Assessor and the Risk Manager

Although risk assessment and risk management are closely related, the tasks should not be confused In the United States, risk assessment and risk management have been kept separate since the National Academy of Sciences released the "Red Book" of 1983 (NAS 1983) to reduce cases where risk management objectives override the risk assessor's impartial evaluation of scientific data (Jasanoff 1993) The role of the risk manager is to serve as the primary decision maker for a site, this person must determine whether remediation is necessary The risk manager uses the results of the risk assessment, along with information on technical feasibility and social, economic, and political concerns to reach a decision

The risk assessor and the risk manager do not need to work closely together, but they should develop a good working relationship by having several meetings during the course of the ERA In addition, written communication through monthly progress reports is a good idea The risk assessor must present the results of the risk assessment in a clear and concise way so that the risk manager can make informed decisions As the ERA process moves through the various stages, the risk assessor and the risk manager should evaluate the progress and determine whether the expectations identified in the planning are being met This maximizes the possibility that the data collected during the ERA will provide relevant information to make decisions for the site of concern

2.3 Site Characterization

Before entering the ERA process, a contaminated site will have been characterized to a certain extent, to obtain at least a preliminary idea about the extent of contamination at the site (CCME 1996a)

Site characterization begins with a compilation of the information available for the site An initial site description should be prepared without conducting additional field studies Based on this information, the risk assessment team can identify issues that should be assessed in the ERA to follow If available, the following information should be provided in the site characterization

- ***site location.*** maps and locations of nearby bodies of water, ecological habitats, soil types, land uses, contaminant sources
- ***site history*** history of site usage, list of potential or measured contaminants and their characteristics
- ***environmental setting*** climate data, ecological background, potential contaminant(s) present, and exposure pathways

Evaluation of the quality of the site characterization data is also important Refer to appendix A in CCME 1996b for further resources regarding sampling principles and methods

2.4 Problem Identification

A clear statement of the problem at the potential contaminated site supports the decision making regarding further action (Fig 1) Problem identification documents the key issues, establishes the breadth and depth of the problem, and initiates the process of prioritization The information collected to date for the site is evaluated for its use in the decision-making process The statement of problem identification should be reported in an ERA This documents the background for the decision to conduct an ERA

2.5 Identification of VECs

In the identification of VECs consideration needs to be given both to use by humans and to resources that have particular value to society The definition of VECs developed by Beanlands and Duinker (1983) has been adopted for this document VECs are resources or environmental features that

- are important to human populations
- have economic and/or social value
- have intrinsic ecological significance
- serve as a baseline from which the impacts of development can be evaluated, including changes in management or regulatory policies

2 6 Establishment of Objective(s) of the ERA

It is critical that the objective(s) be established for every ERA Articulating these in writing will drive the design of the assessment and aid in selecting ecological endpoints of concern, the study methods, and the quality of data required (U S EPA 1989)

Objectives are usually set by those who are responsible to the public and generally set with contributions from the public Technical input may be incorporated but not completely relied upon, as objectives depend on public values For example, a possible objective of an ERA for a contaminated body of water may be maintaining "fishable waters" (Suter 1993)

2.7 Development of a Conceptual Model

Following identification of the site-specific objectives, the risk assessor and the risk manager should develop, as part of the plan, a conceptual model of the site A conceptual model is an abstraction or representation of reality

> The ERA framework presented here is itself a conceptual model of a process It is intended to further our understanding of a complex process by breaking it into manageable and simplified parts in order to organize a problem into a solution or at least a form that can be solved (See Fig 4)

At this point, the conceptual model may be very simple and incomplete, depending on the data that are available However, with each iteration within the ERA framework the conceptual model can be revised and expanded with the addition of new information Conceptual models of other aspects of the ERA can also be formulated and may be particularly important for determining exposure pathways Figure 5 is an example of a conceptual model

> Conceptual models include
>
> - modes of contaminant release
> - receiving environments
> - mechanisms of transport and transformation
> - contaminated media
> - modes of exposure
> - receptors
> - effects of interest
>
> Equally important, conceptual models may exclude some modes of contaminant release, receiving environments, mechanisms of transport, etc , because they are considered unimportant, unlikely, or outside the scope of the assessment (Suter 1993)

2.8 Selection of Assessment Endpoints

The objective of the ERA is usually large in scope and needs to be translated into assessment endpoints that can accomplish the goals, are relevant to the hazard, can be operationally defined, and can be assessed (Suter 1993) These assessment endpoints may be altered over the course of the ERA as new information becomes available

An assessment endpoint that may achieve "fishable waters," as in Suter's (1993) example, might be "no episodic fish kills affecting more than 1% of individuals in any exposed population "

Assessment endpoints are generally at the population level, sometimes at the community level, and rarely at the ecosystem level Responses at lower levels of biological organization are generally considered to have less social or biological significance An important exception is the response of soil communities at the biochemical and cellular level, which can be indicative of community level effects

Local extinction is an example of a population-level assessment endpoint with great significance Suter (1989) recommends using population-level endpoints for contaminated sites when

- individuals of a valued species occur on the site in exposed communities

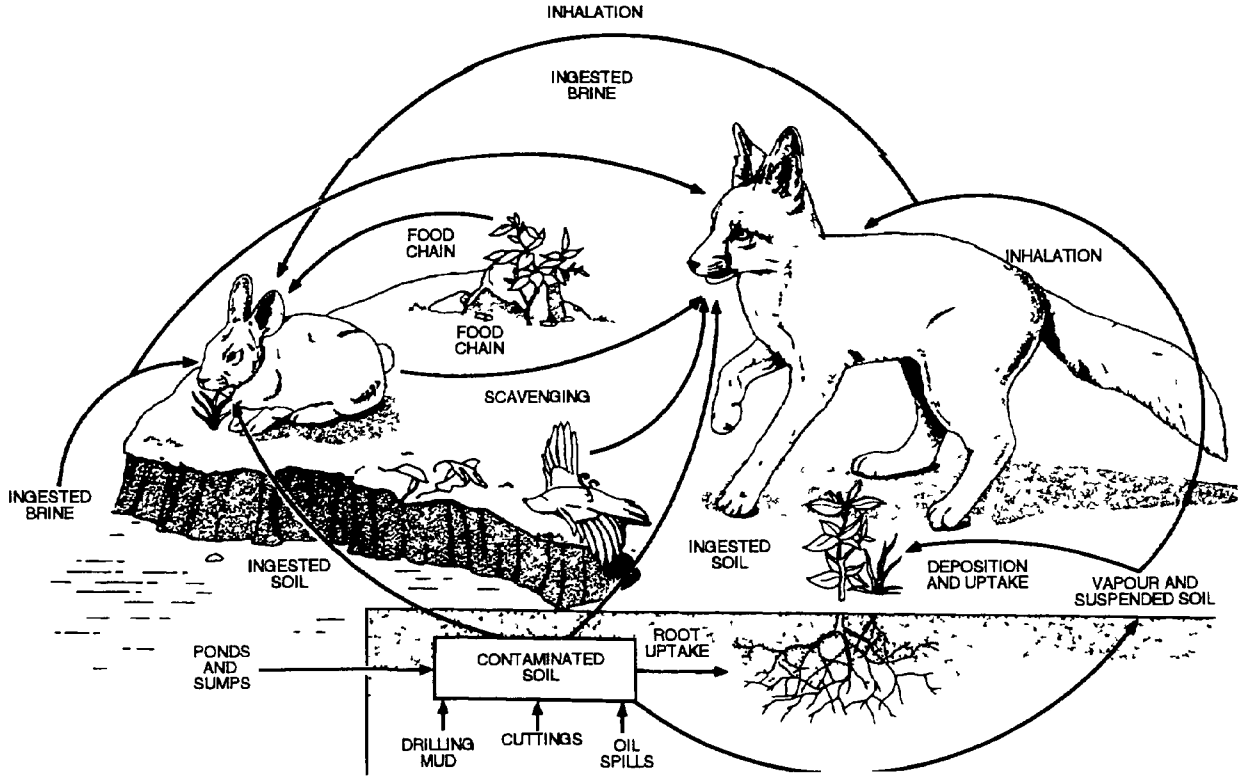


Figure 5. A conceptual model of the various modes of exposure of a fox on an oil field. (from Suter 1993)

- the deaths or injuries of those individuals are believed to cause significant effects on the population as a whole

Changes in the biological community at or near a contaminated site can have major significance and can be used as assessment endpoints For example, changes in community type, such as trophic status of a lake, can be given clear operational definitions (Suter 1989) Community-level assessment endpoints are applicable to ERAs for contaminated sites where a valued community exists on the site or receives site discharges (e g , leachate), particularly when the affected portion of the community represents a significant portion of the entire community

Ecosystem-level endpoints are rarely used in ERAs, primarily because they are challenging to predict or define Both nutrient- and energy-cycling parameters are sensitive to chemical perturbations, but few generalizations can be made in regard to their applications to the detection of stress effects in the field (Sheehan 1987) According to Suter (1989), the only ecosystem property that is generally useful for contaminated site assessment is productive potential However, the Netherlands (Denneman and van Gestel 1990) uses "serious danger for soil ecosystems" as an assessment endpoint, and discusses possible measurement endpoints The particular ecosystem of interest will determine whether practical measurement endpoints exist at the ecosystem level

2.9 Selection of Measurement Endpoints

Although more definitive and assessable than objectives, assessment endpoints are generally not measurable in the practical sense Consequently, assessment endpoints are, in turn, translated into measurement endpoints, which are measurable environmental characteristics that are related to the assessment endpoint Table 2 presents an example of the process of selecting measurement endpoints from a site problem and a defined ERA objective

Measurement endpoints are generally at the individual level or population level and sometimes at the community or ecosystem level Toxicity tests are widely used for hazard assessment, and the measurement endpoints are usually statistical summaries of the responses of test organisms (e g , the lethal concentration affecting 50% of

Table 2 Examples of Translating a Site Problem into Measurement Endpoints

Site Problem	ERA Objective	Assessment Endpoint(s)	Indicators of Effects	Measurement Endpoints
Herbicide used for weed control in lakes	Maintain "fishable waters"	No more than a 10% reduction in game fish population	Laboratory toxicity to fish	Fathead minnow LC_{50}
				Larval bass concentration/ mortality function
			Laboratory toxicity to food-chain organisms	*Daphnia magna* LC_{50}
				Selenastrum capricornutum EC_{10}
			Field toxicity to fish	Percent mortality of caged bass
			Populations in treated lakes	Catch per unit effort Size/age ratios by class

Source Adapted from Suter 1993

the population [LC_{50}], the effective concentration that produces a sub-lethal effect in 50% of the population [EC_{50}], and the no-observable-effect concentration [NOEC]) An approach that uses a battery of two or more toxicity tests is recommended, and tests relevant to the site must be chosen Other individual measures such as behaviour, growth, biomarkers, and fecundity can also be used as measurement endpoints Mortality, reproduction, and growth data can be related to population-level assessment endpoints using population models

The standard population endpoints such as abundance and biomass are widely used for ecological studies According to Suter (1989), the scale of population responses is typically appropriate for very large contaminated sites or for populations with small ranges Effects related to the contaminated site will be obscured by population-level measurements because of movement of individuals within the population

Community measures have been standardized over the years to include endpoints such as species richness, diversity, and evenness/dominance, these measures summarize the data collected in ecological surveys According to Suter (1989), the problem comes in relating these measures to assessment endpoints Usually, the community assessment slips into population-level assessment, because changes in species diversity and community indices are driven by presence/absence of populations However, community-level endpoints are useful at sites where community alterations are striking Indices of community quality can be useful in qualitative assessments, but field investigation through statistical evaluation is best In addition, assessment of microbial communities and populations should not be overlooked Measurement endpoints such as enzyme activity and oxygen consumption/respiration are integrative and therefore provide information at the community, and sometimes population, level These measures can be particularly important as measurement endpoints for soil communities and provide information at the ecosystem and community level

Ecosystem measurement endpoints such as nutrient- and energy-cycling are linked to the ecosystem assessment endpoint of production potential However, the social value placed on community- and population-level endpoints usually gets greater emphasis Also, the scale of ecosystem effects is usually too large for a contaminated site, making measurements difficult to put into context

When the assessment and the measurement endpoints are the same, the analysis of the relationship between the stressor and the response is straightforward Because some potential assessment endpoints are not observable or measurable, and because assessments are often limited to using standard data, measurement endpoints are often surrogates for assessment endpoints In this case, the quantitative relationship between the two needs to be established, and then extrapolations are used to predict changes in the assessment endpoint In some cases, the quantitative relationship between the assessment and the measurement endpoints is not known, and qualitative inferences must be made during risk characterization

According to Suter (1989), in an unfortunately large number of monitoring programs although there are measurement endpoints, the assessment endpoints are not clearly defined, which wastes time and effort This can be alleviated in the planning stages of an ERA Essentially, assessment endpoints describe the effects that drive decision making (e g , reduction in important populations like fish or unacceptable alterations to community structure) The question of why this measurement is being taken needs to be addressed in the planning stage If the hazard assessment is to be a useful part of the risk assessment, assessment and measurement endpoints should be selected so as to be useful for prediction, and relevant to the selection of remedial actions Suter (1989) presents criteria for good assessment and measurement endpoints, as provided in Table 3

2 10 Establishment of Level of Effort

Logistical boundaries

It is useful to establish a level of effort for the ERA process The study team must set the logistical boundaries to establish the constraints of the risk assessment as an iterative process It is widely known that as the ecological relevance of information and the complexity of measurement methods increase, the feasibility of implementation decreases At some point, hard decisions about logistical boundaries need to be made, and these decisions should tie in with the level of the ERA (i e , Screening Assessment, Preliminary Quantitative ERA, or Detailed Quantitative ERA), the objectives of the assessment, the exposure level, and the risk characterization

Within the logistical boundaries set, priority should be placed on direct measurements of risk assessment parameters such as exposure concentrations, bioaccumulation, and receptor responses Estimates of these parameters should be made only if direct measurement is logistically impossible or economically unreasonable

The data available can determine the type of risk assessment procedures that will be implemented, particularly if there are schedule or budget limitations For example, existing data may allow a Screening Assessment If this approach meets the objectives of the assessment, further data collection may not be required However, as is more often the case, the planning phase may determine that the data available for receptor characterization are adequate but that additional studies may be required for the hazard assessment and exposure characterization This will drive the priorities for the time and effort available for further studies within a Preliminary Quantitative ERA and/or a Detailed Quantitative ERA

Spatial boundaries

Besides establishing logistical boundaries for the risk assessment, spatial boundaries such as the size of the contaminated site, its extent of influence (e g , site, watershed, ecosystem) and the size of the exposed habitat will need to be determined

Temporal boundaries

Temporal boundaries also need to be established for all risk assessment components Temporal variation in exposure, and hence effects, can be a critical factor in the estimation of risk and should not be overlooked in ERA

Table 3 Criteria for Selecting Good Assessment and Measurement Endpoints

Criteria for Assessment Endpoints	Criteria for Measurement Endpoints
• social relevance • biological relevance • unambiguous operational definition • measurable or predictable • susceptible to the hazard • logically relevant to the decision	• corresponds to, or is predictive of, an assessment endpoint • readily measured • appropriate to the scale of the site • appropriate to the exposure pathway • appropriate temporal dynamics • low natural variability • diagnostic • broadly applicable • standard • existing data series

Source Suter 1989

During the planning stage, temporal variation in exposure should be considered and if appropriate, incorporated in the study design Temporal variations in exposure can be related to a number of factors, including

- the behaviour of the receptor (e g , changes in feeding behaviour with life stage, seasonal migration)
- changes in the environment (e g , seasonal, weather)
- natural disasters (e g , floods, earthquakes)

In reality, temporal fluctuations in exposure will occur, but assumptions and models can be used to take these into consideration The key is to identify when these fluctuations are extreme enough to impact the result of the risk assessment For example, fluctuations might be of sufficient frequency and low enough amplitude so that organisms effectively average their effects (Suter 1993) However, extreme episodic events such as droughts and floods will need to be recognized in the risk assessment as an exposure condition to plan for

In the exposure assessment, the exposure duration of the organism needs to be defined For example, if the VEC is Barrow's goldeneye, a duck that visits the site for only four months of the year, the exposure evaluation and risk calculation should reflect this temporal boundary As another example, models may need to be modified to incorporate fluctuations in important variables (e g , water flow rate, atmospheric deposition) that are expected to result in fluctuating exposure scenarios Screening level assessments may make a "worst case" assumption of exposure, whereas higher levels of ERA should fine-tune the exposure for realistic scenarios

Ideally, the influence of temporal dynamics of exposure on effects (hazard assessment) would be determined in toxicity tests However, all too often only the endpoint results are available, and extrapolations must be made to the time spans of interest When appropriate, if temporal data are available for biological effects, they can be extrapolated to the time span of concern Pulsed exposures can also be used in toxicity tests Models can be built or modified to reflect temporal variations in exposure

Another aspect of temporal variation is changes in the biological communities exposed at the site Communities that are in a temporary developmental stage such as plant colonization may have different routes of exposure and sensitivity compared to climax communities In the planning stage, the project formulation should take into account the changes in the community that are expected to occur Expected future species/communities can be worked into the risk assessment process

The outcome of this planning phase should be an assessment design that will ensure scientific defensibility of the data and decisions based on those data, while taking into account the schedule and budget constraints faced by decision makers

2 11 Selection of Reference Sites

Reference sites provide a comparison point to sites within the study area and act as a control for field studies The use of a reference site is an important component of sampling design and allows one to test hypotheses such as "there is no difference between contaminant concentrations in reference areas and the contaminated site" and/or "contaminant concentrations have not resulted in biological damage " To test such hypotheses, the reference site(s) should be established within the nearest uncontaminated area of similar habitat type The reference and impact areas should be as similar as possible in all characteristics (e g , soil type, water quality, sediment quality, ecotype similarities), with the exception of the impacted environmental variables being investigated

The choice of appropriate statistical design should flow logically from the purpose, the hypothesis, and the sampling design (Green 1979) This "golden rule" holds true for an ERA during the planning stages, reference sites should be identified in conjunction with the field sampling sites in the contaminated areas The number of reference sites should be sufficient to allow acceptance or rejection of the null hypothesis with a specified likelihood of error (U S EPA 1986)

Reference sites are chosen to address specific questions For example

- Reference sites can provide information about background concentrations of contaminants, to place contaminant concentrations in context with local conditions Background samples should be collected for each medium of interest in areas that could not have received contamination from the site (U S EPA 1989) Reference sites should be as similar to the test sites as possible, with the exception of contamination In addition, reference samples should be collected and

analyzed under the same conditions as the samples of interest

- Reference sites can provide information about expected site receptors and biological communities, from which additions/deletions from the species assemblage can be identified

- Reference sites can provide information about natural variability in systems, to which test-site variability can be compared This can be particularly useful in preliminary surveys, to assist in determining the requisite sample numbers to detect meaningful change Often, rigorous statistical analysis is unnecessary because site and off-site contamination levels clearly differ (U S EPA 1989) For most sites, the issue will not be whether a difference in chemical concentrations can be detected in site and reference areas but whether sampling can define the spatial extent (in three dimensions) of the contaminated site (U S EPA 1989)

The number and location of reference sites should be chosen in conjunction with statistical design and project planning The ERA team should include someone with expertise in statistical design, and consultation regarding reference site selection should begin early in the ERA process

2.12 The Final Product of ERA Planning

The final product of ERA planning should be a series of documents describing the site, the problem, and the priorities For example, a single planning report may be generated that references other reports (e g , site investigation) The documentation should contain a clear statement of the objectives of the ERA, a conceptual model that identifies the environmental values to be protected, and the data required to address the problems identified at the site For each of the three levels of ERA, a work plan should be prepared before initiating any of the studies The work plan should detail the proposed approach to collect information to conduct the ERA The work plan would be submitted for review and approval by the appropriate regulatory agencies These documents should be available to all members of the study team and should form the first step of ERA documentation

3.0 SCREENING ASSESSMENT

3.1 Introduction

Within the ERA framework, all contaminated sites would undergo the first tier of assessment, the Screening Assessment The need for progressing further is based on the degree of uncertainty associated with any estimate of risk and is evaluated upon its completion If necessary, the Screening Assessment will guide and focus the activities associated with quantitative risk assessments the Preliminary Quantitative and Detailed Quantitative ERAs

A Screening Assessment is based primarily on data from the literature, previous or preliminary studies of the contaminated site, monitoring studies, historical data of the site, and a reconnaissance visit to evaluate the receptors, exposure, hazards, and risk at the site In essence, a Screening Assessment is a desktop exercise intended to make full use of existing information to streamline the ERA process

Purposes of a Screening Assessment

- compilation and evaluation of available data and information
- identification of relevant exposure pathways
- identification of chemicals of concern
- identification of critical information gaps
- refinement and update of conceptual models developed in the planning phase
- refinement and update of the assessment and measurement endpoints selected in the planning phase
- determination of whether remedial measures are required
- determination of whether further ERA studies (Preliminary Quantitative ERA or Detailed Quantitative ERA) are needed to design and implement remedial action

3.2 Screening Assessment Components

Table 4 provides a summary of the possible tasks for the components of a Screening Assessment

Table 4 Summary of Tasks Comprising the Components of a Screening Assessment

Sources of Information
• data from the literature • previous or preliminary studies of the site • monitoring studies • historical data • reconnaissance visit
Receptor Characterization **See CCME 1996b, Appendix B**
Identification of receptors • identify potentially exposed habitats, communities, and ecosystems through data review and field reconnaissance • where possible, compile species lists, preferably for the site, but also for the local area • if the site is a natural site, collect qualitative site information • catalogue all potentially significant or sensitive species at or near the contaminated site • identify receptors most likely to be affected by stressors associated with the contaminated site • for the receptors of concern, compile life history and background information • identify missing species using ecosystem classification systems (i e , species that should be there but are absent) • based on any new information, refine and re-evaluate assessment and measurement endpoints and ensure priority receptors are still relevant and emphasized (based on ERA planning)
Relation to exposure assessment • assess possible spatial/temporal overlap of receptors and contaminants of concern, based on the exposure assessment
Exposure Assessment **See CCME 1996b, Appendix C**
Selection of target chemicals • identify chemicals present at the site (utilize source information) • review those chemicals and their concentration with respect to hazard assessment (toxicity, persistence, bioaccumulation) • if toxicity data for the site exist, review and determine where responses indicate exposure • select target chemicals based on review/assessment of their properties • include all chemicals unless there is information that supports exclusion
Contaminant release/transport and fate • identify possible transport pathways • identify data gaps where the flow chart cannot be completed • provide preliminary quantitative estimates, if possible • identify areas to which contaminants have been or may be transported • identify potential reference sites, and obtain information for those sites
Exposure pathway analysis • identify most important exposure pathways • identify where there is not enough information to exclude potential pathways • identify why pathways have been eliminated
Aquatic and/or terrestrial exposure • identify most important exposure pathways and their link to biological components at risk • if possible, provide preliminary estimates of exposure or tissue concentration using bioaccumulation and/or bioconcentration factors, other measurements of exposure should be identified
Uncertainty analysis • identify data gaps • identify key uncertainties, both qualitative and quantitative, and whether they are acceptable or unacceptable • evaluate whether Preliminary Quantitative ERA exposure assessment would reduce uncertainty significantly

Table 4. Continued

Hazard Assessment	See CCME 1996b, Appendix D
• link to exposure assessment to identify contaminants that are at concentrations that can be expected to be toxic/bioaccumulative • consider mixtures of chemicals • utilize toxicity data, if they exist for the site to estimate BCs for selected chemicals and species • choose species for which toxicity data are readily available and extrapolate to VEC • where data are available, examine population/community information • in conjunction with exposure assessment, use toxicological databases such as AQUIRE, IRIS • include an assessment of uncertainty	
Risk Characterization	**See CCME 1996b, Appendix E**
• integrate the other components of the Screening Assessment • identify key uncertainties and data gaps, make recommendations for filling data needs • characterize risk as "high," "intermediate," or "negligible" • make semiquantitative risk estimates using the quotient method, if possible	

3.2.1 Receptor Characterization

The initial receptor characterization should identify the species taxa, communities, habitats, and VECs that are most likely to be affected by the contaminant concentrations believed to be present at the site This will be accomplished through a review of available site information, reconnaissance visits, and expert advice from local universities/colleges, natural history museums, and local/provincial/federal agencies Although various levels of biological organization should be considered, there is usually an emphasis in Screening Assessment on individual species of indigenous populations The list of receptors of concern will be used to establish organisms to focus on in the hazard assessment Life history information should be used to identify sensitive life stages and time periods relative to the contaminated site In addition, missing species that would normally be found at the site should be noted A habitat assessment should be conducted to consider habitat limitations from natural factors such as drought or flood and anthropogenic factors such as the destruction of habitat

3.2.2 Exposure Assessment

The exposure assessment should identify the contaminants, exposure media, and exposure pathways, as well as major uncertainties and data gaps Qualitative methods and simple quantitative methods are appropriate for Screening Assessment Key components of the exposure assessment include an initial screening of potential contaminants of concern and a preliminary selection of target chemicals

Some preliminary quantitative analyses of contaminant release, transport and fate, and demonstration of exposure are necessary to support a preliminary risk characterization using quotient methods, this would help to narrow the range of priority contaminants for either remediation or further risk assessment

The quality and quantity of available monitoring data obviously affect the type of method that can be applied It is usually appropriate to apply simpler methods to all pertinent exposure routes at the start of an exposure assessment as a scoping technique to isolate the pathways requiring the most in-depth analysis

3 2.3 Hazard Assessment

The primary emphasis of the hazard assessment is to obtain toxicity information from the literature for the contaminant(s) of concern Hazard assessment should be related to the endpoints identified during ERA planning The toxicity test species should be related as closely as possible to the VEC, although an exact match is rarely possible In this initial stage of hazard assessment, any toxicity information is useful, particularly if it relates to the contaminated site of interest Mortality data are the most plentiful and provide clear measurement endpoints for use in the risk characterization However, endpoints other than mortality can be very important and should not be neglected

3.2 4 Risk Characterization

The extent and nature of risk and the level of uncertainty associated with the estimate of risk will be derived by weighing all available information to determine whether the project should advance to Preliminary Quantitative ERA This qualitative estimate of risk and uncertainty will be based on the information developed from the exposure assessment, receptor characterization, and hazard assessment components of Screening Assessment

Qualitative and quotient methods are suitable for the risk characterization Professional judgment will be relied upon when using qualitative methods such as ranking systems that determine the level of risk in terms of high, moderate, or low

Quotient methods can be used whenever there is sufficient information to estimate an expected environmental concentration (EEC) in the most important medium or media and where there are adequate studies in the literature to determine a toxicological benchmark concentration (BC) A BC could be used for local species or their close relatives The quotient is calculated by taking the ratio of the EEC and a BC Higher quotients provide greater evidence of a hazard or greater risk (Suter 1993) Quotients <1 imply that risk is slight and little or no action is required (Burns 1991) Quotients near 1 represent uncertainty in the risk estimate and usually require additional data Quotients >1 imply that risk is greater and that regulatory action may be indicated Although this method is widely used, it has several weaknesses, such as the lack of indirect-effect evaluations, the lack of incremental-dose impacts, and the lack of effects at higher levels of organization (Burns 1991)

Safety factors might also be appropriate in Screening Assessment risk characterization, although it is recommended that the uncertainty associated with the use of these factors be applied to the establishment of categories of risk, rather than directly to the quotients (Suter 1986)

Quotient methods are useful for the following specific applications

- determination of priority contaminants when the site is grossly contaminated by many chemicals with many quotients >1
- estimation of relative risk of different exposure pathways or different media

3.2 5 The Outputs

The risk assessor will prepare a Screening Assessment report to provide the risk manager with information on the results of the assessment and to make recommendations for reducing data gaps and conducting further studies/risk assessments The risk manager is responsible for using this information as one component in deciding whether remediation is necessary for the site Additional outputs are listed in the box below

The main outputs of the Screening Assessment include

- a report containing
  - a more detailed site-specific conceptual model of the problem
  - preliminary description of the contaminants of concern
  - description of the receptors of concern
  - preliminary toxicity estimates
  - detailed list of key uncertainties for each ERA component
- qualitative estimates of the potential for ecological effects due to the presence of contaminants at the site and estimates of the degree of uncertainty associated with those estimates
- when necessary, terms of reference for a Preliminary Quantitative ERA or a Detailed Quantitative ERA

3.2 6 The Next Step

Upon completion of a Screening Assessment, the adequacy of that ERA with respect to the site-specific objectives for the contaminated site needs to be evaluated by the risk assessor and the risk manager Whether Screening Assessment serves as a problem definition and planning stage or as a final step, the effort is not lost since the findings are well-documented, and action is taken based on the information assembled

If the perceived risk is low enough to be negligible, the ERA might end at Screening Assessment, and a site-specific report would be prepared The U S EPA (1988) identifies the attributes of sites for which simple qualitative analyses may be adequate These attributes include

- available environmental standards or criteria
- a small number of chemicals
- a small number of exposure pathways
- relatively simple release and transport processes
- a limited need for detail and precision in assessment results

However, if any remedial action is going to take place as a result of the Screening Assessment, a semiquantitative estimate of risk needs to be determined If more than one type of remediation effort is proposed, a more detailed risk assessment should be conducted to compare the estimated risk associated with implementing each remedial measure This is a decision that the risk manager will need to make that will require input from the risk assessor

Sites that are perceived to be at moderate risk would proceed to a Preliminary Quantitative ERA Sites that are perceived to be of high risk could either

- proceed to a Preliminary Quantitative ERA and if necessary, go to a Detailed Quantitative ERA or
- proceed directly to a Detailed Quantitative ERA

Criteria that are used to decide whether or not to conduct a Preliminary Quantitative ERA are provided in Table 5 This list is not exhaustive, since the decision to proceed to higher tiers of ERA is based on site-specific factors

4.0 PRELIMINARY QUANTITATIVE ERA

4.1 Introduction

A Preliminary Quantitative ERA is based on a combination of measured site-specific data and previously compiled information It is a natural progression from a Screening Assessment Preliminary Quantitative ERAs should build on the information compiled for the site, and data should be collected to fill significant data gaps In particular, factors identified as moderate risks in the Screening Assessment will be investigated further in the Preliminary Quantitative ERA

Purposes of a Preliminary Quantitative ERA

- to produce a preliminary quantitative risk estimate for VECs exposed to chemicals at or near the contaminated site
- to refine and re-evaluate the conceptual model(s) developed previously
- to refine and re-evaluate the assessment and measurement endpoints developed previously
- if necessary, to set terms of reference for Detailed Quantitative ERA activities

4.2 Preliminary Quantitative ERA Components

Examples of tasks characteristic of the components of a Preliminary Quantitative ERA are summarized in Table 6

4.2.1 Receptor Characterization
See CCME 1996b, Appendix B

Preliminary Quantitative ERA receptor characterization involves collection of field data on the receptors of concern and therefore requires an appropriate field sampling program (see CCME 1996b, Appendix A) Investigations should focus on species and communities that were identified in the Screening Assessment as VECs and that characterize population life history patterns, habitat requirements, and food web This could include generating preliminary quantitative estimates for overall population density or age-class structure Relevant data required to evaluate health at the population level should be collected relative to the exposure information In addition, the absence of expected species should be noted The information collected in this receptor characterization is used to focus the hazard assessment and may also be used in determining steps in the exposure assessment

4.2.2 Exposure Assessment
See CCME 1996b, Appendix C

Before the effects of a contaminant can be evaluated, the level of contaminant actually or potentially reaching the receptor must be assessed Sources, pathways, and distribution of chemicals around the contaminated site will be determined for all chemicals of concern This will, in most cases, involve field work to obtain site-specific data on the mode, timing, and quantity of contaminant releases, which in turn can be used to estimate the concentration(s) of contaminants and the extent of contamination at the site Assessing the fate and behaviour of the contaminants will provide estimates of exposure (dose or concentration) for receptors via exposure pathways Preliminary exposure assessment should also develop a more detailed understanding of the routes, magnitude, frequency, and duration of exposure to the target chemicals present at or migrating from the site Some estimate of uncertainty should be associated with these estimates of exposure

Table 5. Decision Points for Proceeding to a Preliminary Quantitative ERA

Receptor Characterization	If potential receptors include • rare, threatened, or endangered species • critical or sensitive habitat for wildlife, migratory waterfowl, or fisheries • lands designated as a natural area, park, or ecological reserve
Exposure Assessment	If the target chemicals are numerous and present as mixtures (e g , mix of complex organics and metals) If the information gaps are so large that contaminant release, transport, and fate cannot be qualitatively predicted (particularly if the hazard assessment indicates high toxicity of the target chemicals) If potential pathways cannot be identified, field measurements of chemical concentrations are required, if these data are still not adequate for pathway identification, proceed to a Preliminary Quantitative ERA If the level of uncertainty is unacceptable given the hazard information, and a Preliminary Quantitative ERA would significantly reduce the uncertainty
Hazard Assessment	If there is information to indicate that the mixture of chemicals present will have synergistic toxicity (higher than predicted by consideration of additive toxicity of individual parameters) This kind of information will rarely be available If the potential receptors are exposed to a mixture of chemicals about which nothing is known concerning the toxicity or biological effects, biological testing must occur This can be conducted within a Screening Assessment, but a Preliminary Quantitative ERA will probably need to be conducted, based on criteria for other components If BCs are not available, data from reference areas and the literature can be used as a point of reference, however, if the chemical is an "exotic," a Preliminary Quantitative ERA is likely required to determine site-specific effects levels
Risk Characterization	If BCs are not available and cannot be calculated because there are no toxicity data, a Preliminary Quantitative ERA may need to be conducted, in other words, if there is no information upon which to base even a qualitative risk characterization If the hazard quotient exceeds 1

Methods range from desktop calculations using relatively simple equations to models using direct measurement of environmental media Estimates of uncertainty associated with exposure estimates should be calculated and can be derived from confidence or tolerance limits about actual measured contaminant concentrations in environmental media or from simulations using known or estimated distributions for input parameters

The degree of quantification and complexity should match that for other components, especially hazard assessment and risk characterization, although constraints would also be imposed by cost or logistical limitations on the data that could be collected The exposure assessment should be relatively complete in terms of quantifying exposure for all priority chemicals and pathways

4.2 3 Hazard Assessment
See CCME 1996b, Appendix D

Preliminary Quantitative ERA hazard assessments should provide quantitative estimates of toxicity of field samples from the contaminated site Where possible, toxicity

Table 6 Summary of Tasks Comprising the Components of a Preliminary Quantitative ERA

Sources of Information
• quantitative methods • field and laboratory data collection • direct measurement • local expert knowledge • quotient and continuous exposure-response (individual, population) methods • simple models and calculations with site-specific data
Receptor Characterization **See CCME 1996b, Appendix B**
Data requirements • identify information needed based on Screening Assessment • design a field program that will meet objectives of the ERA • identify the appropriate level of organization to focus on (e g , population, community, ecosystem) • consider the scale of the ERA relative to the scale of the receptor(s) and the scale of the assessment and measurement endpoints (e g , time scale, spatial scale)
Characterization of habitat • consider background data on physical/chemical attributes that could affect receptor responses • consider ecological connections that exist between the contaminated site and adjacent habitats
Characterization of receptors—species and population • consider structural attributes of VECs (population density, biomass, distribution, age-class structure, status [e g , rare, endangered] life history) • evaluate food web interactions • consider functional attributes of VECs (food requirement, ingestion rates, bioaccumulation potential, activity patterns) • consider community and ecosystem level effects
Characterization of receptors—community and ecosystems • consider structural attributes (biodiversity, biomass, guilds successional stage, food web) • evaluate functional attributes (primary production, respiration, decomposition, nutrient cycling, resilience) • consider local/regional significance
Exposure Assessment **See CCME 1996b, Appendix C**
Selection of target chemicals • re-evaluate and revise target chemicals selected previously if necessary
Contaminant release/transport and fate • evaluate the most important release mechanism(s) (e g , dust emissions, volatilization, surface and groundwater contamination, direct uptake by biota) • evaluate the most likely transport routes and resulting contaminant fates • provide quantitative estimates of release, distribution and concentrations of contaminants from direct measurement, desk-top calculations, or simple models
Exposure pathway analysis • identify most important pathways, for each receptor, based on quantitative estimates of exposure • consider exposure pathways from the point of view of the VEC
Aquatic and/or terrestrial exposure • verify exposure identified in Screening Assessment • estimate exposure via most important pathway(s) • in aquatic systems, provide preliminary estimates of exposure or tissue concentration using bioaccumulation factor and/or bioconcentration factor • conduct a literature search/make contacts to obtain data on exposure parameters (e g , ingestion rates, etc) • in terrestrial systems, provide dose information • if appropriate, develop simple food chain models • consider cumulative effects

Table 6 Continued

Uncertainty analysis • categorize and rank sources of uncertainty (e g , data uncertainty, model uncertainty) • provide estimates of uncertainty (confidence or tolerance limits) for exposure concentrations, if possible Typical exposure concentrations are geometric means and reasonable maximum exposure (RME) RME corresponds to the upper 95 percentile confidence interval • verify/calibrate initial estimates using monitoring data
Hazard Assessment **See CCME 1996b, Appendix D**
• confirm or modify list of target chemicals • review toxicity data compiled in Screening Assessment and Preliminary Quantitative ERA • re-evaluate measurement and assessment endpoints • design a sampling and testing plan to assess the effect of site contaminants on the VECs • ensure a link between exposure assessment (i e , contaminant distribution) and sampling for hazard assessment • conduct appropriate toxicity tests, use surrogates as necessary and develop extrapolation procedures These types of tests may need to be specified by the regulator for consistency • use a battery of tests for measurement endpoints • if effects of target chemicals require sublethal or other endpoints, conduct required testing • develop population-level models that can be used to predict effects to contaminant exposure • for field investigations, focus on population and community level effects • estimate uncertainty
Risk Characterization **See CCME 1996b, Appendix E**
• estimate quotient EEC/BC for most sensitive endpoint(s) (use BCs for threshold effect concentration and LOEC if available, otherwise use LC_{50}s and other less sensitive endpoints), with an estimate of uncertainty • individual continuous exposure response estimate probability for several effect magnitudes (e g , 5, 10, 25% reduction in survival, growth, or reproduction) • population models combine estimates of effects on survival, growth, and reproduction to provide average reproductive potential (+/- tolerance limits), probability of extinction, or other appropriate estimate of effects/risks • for all methods, explore effects/risks associated with remediation options • develop terms of reference for Detailed Quantitative ERA, as appropriate

testing should be conducted with the receptors of concern However, toxicity data can be extrapolated to estimate toxicity if necessary The toxicity endpoint is usually mortality, although chronic and sublethal endpoints that relate to the receptors can be very important Where the emphasis is on population or community level assessments, direct measurements are invaluable

The questions of interest in risk assessment can relate to effects on the abundance, production, and persistence of populations and higher levels of organization Despite the fact that population-level endpoints are of great importance, few researchers have developed tools to assess those effects (Suter 1993) Therefore, individual-level toxicity data are integrated with ecological theory to provide useful assessments of population-level effects of contaminants

Population-level studies can include measurement endpoints such as population size, density, class structure, frequency/probability of extinction, and required habitat size

Suter (1993) reviews a variety of approaches to population analysis for ERA and provides case examples He classifies the approaches into reproductive potential, projection matrices, aggregated models, and individual-based models As there has been a lot of recent interest in the latter, further information is provided below

Individual-based models are ones in which population dynamics are represented in terms of the physiological, behavioural, or other properties of the individual organisms According to Suter (1993), there are two broad approaches to developing such models one emphasizes Monte Carlo simulation and the other emphasizes analytical solutions to equations The analytical approach produces results that are general, easy to verify, and easy to understand, however, the level of detail is limited and such models work best for simple organisms The simulation approach can have an unlimited number of variables and parameters Personal computer models can run for hundreds of individuals "living" substantial time periods The limitation of

simulation modelling is that it is data-intensive and complex

In most cases, extrapolation of hazard assessment data from species to species, endpoint to endpoint, or laboratory to field is required and/or population-level models are used These are important components of Preliminary Quantitative ERA hazard assessment, but they are often large contributors of uncertainty

Preliminary quantitative information will be generated concerning bioaccumulation potential Finally, site-specific factors that could be operating to modify predicted effects will be identified

4.2 4 Risk Characterization
See CCME 1996b, Appendix E

Simple quantitative methods will use information generated by the other three components of the Preliminary Quantitative ERA to determine population-level responses by the sensitive species to the priority contaminants Appropriate risk characterization methods for Preliminary Quantitative ERA include quotient methods and continuous exposure-response methods at the individual or population level Estimates of risk provided by quotient methods should be more quantitative than those used in Screening Assessment The use of safety factors should be discouraged unless these factors are empirically supported Confidence or tolerance limits should be provided for the EEC, the BC, or both Comparability of risk characterizations is enhanced if the BC refers to a standard effect level such as LC_{10}, EC_{20}, or some other quantile rather than NOEC, maximum acceptable toxicant concentration (MATC), or lowest-observed-effect concentration (LOEC) Note that if quantile responses are routinely determined, it is relatively simple to proceed to the next level of complexity, continuous exposure-response relationships

Quotient and individual continuous exposure-response methods are most suitable for the following specific applications

- development of remediation criteria
- characterization of risk for small sites or where contamination is limited to a few areas

Most existing Canadian criteria and objectives/guidelines are calculated using a quotient type of approach set at some BC divided by a safety factor This provides a consistent approach to deriving guidelines or criteria, including remediation criteria However, site-specific remediation criteria developed by quotient methods should be evaluated by subsequent monitoring or by comparison with criteria based on other methods such as population models

Estimates of population-level effects or risks may not be necessary in cases where contamination is restricted to small areas However, the risk assessor must consider the type of species being exposed and the influence of temporal variability on this assumption Small contaminated areas may contain only a few individuals, especially of larger species, or the contaminated area may be smaller than the home range of an individual bird or mammal In these small areas, immigration and emigration, rather than survival or reproduction, will control numbers Thus, traditional population models will not apply under these circumstances

Population methods should be used whenever the contaminated site is large enough that numbers of organisms are largely controlled by survival and reproduction within the site, rather than by immigration and emigration Also, at these larger spatial scales, actual field measurements of numbers or reproduction may not be feasible Population models are specifically recommended for

- large sites and regional studies
- sites where field sampling or toxicity testing of endangered, rare, or threatened species is inadvisable
- priority-setting when extensive field monitoring, toxicity testing, and chemical analyses are required
- exploration of alternatives, especially costly remediation alternatives
- verification or evaluation of quotient methods/criteria

The primary limitations on the use of population models will be the availability of exposure-response relationships for survival, growth, and reproduction

The use of population-level models in risk characterization is increasing Monte Carlo simulations are becoming a tool used in ERA The steps involved in a Monte Carlo analysis include (Suter 1993)

1 defining the statistical distributions of the input variables
2 randomly sampling from these distributions of input variables
3 performing repeated model simulations using the randomly selected sets of input variables

4 analyzing the output

The result, after many iterations, is a probability distribution of the risk or exposure with a most likely value, an average value, extreme values, and a shape that describes the variability and uncertainty around the calculated risk or exposure (Gephart et al 1994)

Standardized computer programs that conduct Monte Carlo simulations are now available (e g , @RISK and Crystal Ball) One disadvantage is that users may overlook the implicit assumptions that contribute to the uncertainty of the ERA Also, because Monte Carlo simulations can now be run with ease, they are often used inappropriately Recently Burmaster and Anderson (1994) proposed 14 principles of good practice for the use of Monte Carlo techniques in ERAs to assist people in performing and reviewing probabilistic risk assessments

Suter (1993) points out that it is not always easy to collect data to calibrate a population model Another approach for model validation is to use and compare alternative models to assess the congruency of model predictions

No matter which method of risk characterization is used, the statement of risk should describe the relative risks posed by the chemicals of concern The statement of risk can take several forms, such as the probability that a given contaminant level will be exceeded or the cumulative probability that contaminant concentrations will exceed an effects threshold The assumptions and uncertainties of the model should also be clearly stated so that the statements of risk are put in context

4 2.5 The Outputs

Outputs from a Preliminary Quantitative ERA are summarized in the box below

The main outputs of a Preliminary Quantitative ERA include

- a quantitative estimate of the risk for ecological effects and estimates of the degree of uncertainty associated with that estimate
- a site-specific database pertaining to the priority chemicals, sensitive species, toxicity, and current environmental conditions
- a report specifying project activities, findings, uncertainties, conclusions, and recommendations
- a simple model (ideally calibrated and checked with actual data) predicting future biotic and abiotic conditions with and without mitigation

4.2.6 The Next Step

Upon completion of a Preliminary Quantitative ERA, the adequacy of that ERA with respect to the site-specific objectives for the contaminated site needs to be evaluated by the risk assessor and the risk manager At this point a decision needs to be made between two choices

- action for the site can be taken based on the Preliminary Quantitative ERA or
- some/all of the ERA components need to go to Detailed Quantitative ERA

Examples of criteria that are used to decide about whether to conduct a Detailed Quantitative ERA are provided in Table 7 This list is not exhaustive since the decision is site-specific

It is an option at this level, or at any other, to proceed to the next level of complexity for only one or a few elements in the framework For example, at the end of Preliminary Quantitative ERA, a decision may be made to proceed to a Detailed Quantitative ERA for only exposure and hazard studies if, for example, enough is already known about the sensitive species to warrant no further study on that component

5.0 DETAILED QUANTITATIVE ERA

5.1 Introduction

A Detailed Quantitative ERA is carried out when further data are needed to reduce the uncertainty about the estimate of risk generated in the Preliminary Quantitative ERA This may require more extensive field testing, more complex models, or validation to address issues such as community or ecosystem effects, the effects of chemical mixtures on biota, and/or exposure through multiple pathways Many components require computer models

Purposes of a Detailed Quantitative ERA

- to produce quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to the presence and migration of chemicals at the site and from migration of chemicals off the site
- to develop an adaptive process for selecting unique, site-specific, quantitative remediation objectives, which may be revised through time

Table 7. Decision Points for Proceeding to a Detailed Quantitative ERA

Receptor Characterization	In most cases, adequate receptor characterization can be achieved by a Preliminary Quantitative ERA, if this is not the case, a Detailed Quantitative ERA receptor characterization may be required
	Receptor characterization is more likely to drive an ERA to Detailed Quantitative ERA by way of the receptors that are identified, for sites with receptors of high public and ecological concern, a Detailed Quantitative ERA may be required to reduce the level of uncertainty
Exposure Assessment	More complex quantitative analytical methods are required for sites with a combination of • numerous contaminants • no available environmental standards or criteria • no data with which to calculate benchmarks • multiple exposure pathways • complex contaminant release and transport processes • a requirement for analytical results in great detail and precision
	If the site use is extremely complex, resulting in unpredictable contaminant exposures and pathways, a Detailed Quantitative ERA exposure assessment involving extensive field sampling may be required (particularly if the hazard assessment indicates high toxicity of the target chemical[s])
	If the target chemicals are numerous, present as mixtures
	If the level of uncertainty is unacceptable given the hazard information (i e , extreme hazard) and a Detailed Quantitative ERA may significantly reduce the uncertainty
Hazard Assessment	If the assessment endpoints are at high levels of biological organization (e g , community/ecosystem) and/or the measurement endpoints need to be technically sophisticated (e g , chronic toxicity tests, microcosms, mesocosms)
Risk Characterization	If the assessment endpoint requires a population-level or higher risk assessment for the site (e g , Standard Water Column Model, SWACOM)

5 2 Detailed Quantitative ERA Components

It must be emphasized that a full Detailed Quantitative ERA will be conducted only in specific situations In most cases, only one or two of the components of an ERA (i e , exposure assessment, receptor characterization, hazard assessment, risk characterization) will go to Detailed Quantitative ERA, the others will remain at Preliminary Quantitative ERA The ERA process will be better served by having only component-particular data deficiencies met Table 8 provides a summary of possible tasks characteristic of the components of a Detailed Quantitative ERA

5.2.1 Receptor Characterization
See CCME 1996b, Appendix B

The receptor characterization is expected to be conducted infrequently since Preliminary Quantitative ERA is usually sufficient This most detailed level addresses specific issues with highly valued species or communities Quantitative and data-intensive community and ecosystem studies are more necessary at Detailed Quantitative ERA

5 2.2 Exposure Assessment
See CCME 1996b, Appendix C

Detailed Quantitative ERA exposure assessments are quantitative and generally utilize advanced computer models to describe present and future transport Because the spatial scale of Detailed Quantitative ERA is large, exposure assessments have to consider several different release mechanisms and exposure pathways

Estimation of uncertainty through Monte Carlo simulation, sensitivity analysis, and calibration with monitoring data can be an important part of Detailed

Quantitative ERA exposure assessment, providing adequate parameter distributions are available The major limitations for Detailed Quantitative ERA exposure assessment are likely to be the lack of availability of data for input parameters and suitable models, especially for terrestrial ecosystems

The uncertainty analyses for Detailed Quantitative ERA will often be limited by the lack of availability of exposure data

5.2.3 Hazard Assessment
See CCME 1996b, Appendix D

Chronic and sublethal endpoints will be estimated for the toxicity of chemicals The toxicity of the mixture of chemicals found at the site to sensitive species at the site should be determined using either laboratory or in situ toxicity testing Media from the contaminated site should be the focus of testing

The hazard assessment allows investigators to focus on specific issues related to deleterious biological effects on the contaminated site At this level, the measurement endpoints closely approximate the assessment endpoints Detailed Quantitative ERA requires sophisticated experimental design with clear testable hypotheses Higher levels of biological organization are usually examined to address concerns that laboratory toxicity testing will not cover

There are four types of effects that may occur in ecosystem-level tests and models that do not occur at the organism and population levels (Suter 1993) These include

- effects on a population's ability to interact with populations of other species
- indirect effects on a population due to effects on the populations with which it interacts
- changes in the structure of the ecosystem
- changes in the functional properties of the ecosystem

The first two are, strictly speaking, community-level effects with ecosystem level influence, whereas the last two are observed only in ecosystems Scientists tend to acknowledge the importance of ecosystems, while continuing to use organism-level and population-level biology This is largely due to the lack of tools for ecosystem-level studies Impediments to ecosystem-level assessment are reviewed in Suter (1993)

5.2 4 Risk Characterization
See CCME 1996b, Appendix E

A computer simulation model will likely be required to produce quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to the migration of chemicals from the contaminated site This will form the basis for generating quantitative estimates of ecological risk for scenarios ranging from no mitigation to maximum possible control

The most appropriate risk characterization methods are ecosystem-level models based on continuous exposure-response relationships However, there are two specific instances in which quotient methods might be suitable

- when estimating risk from multiple chemicals by summing quotients
- when estimating risk and developing remediation criteria for aquatic communities

At the present, the summation of quotient values does not include possible synergistic and/or antagonistic toxic effects caused by mixtures of chemicals This is because there is insufficient information to take these effects into account The assumption of additivity is probably most applicable to chemicals that induce the same effect by the same mechanism of action For quotients that are determined using different benchmarks, the types of benchmarks that were used should be noted It would be difficult to separate the quotients by the effect and mechanism of action, and if it were done improperly, it could underestimate the risk In order to be conservative, all effects will be treated equally and summed for each chemical and also across exposure pathways

Development of ecosystem models for cases in which there are multiple contaminants has not been attempted, this may be a difficult task Summing quotients may be adequate for assessing risks to individual species but inadequate for assessing risks at higher levels, unless the quotients are based on effects at the ecosystem level There are higher-level quotient methods available for aquatic communities, such as that used by the Ohio EPA (1987a,b, 1988) More generally, there is a large amount of literature on contaminant impacts on benthic macroinvertebrate communities (Klemm et al 1990) If data are available for reference sites, risks to aquatic communities can be estimated and remediation criteria developed for contaminated sites However, methods such as that used by

the Ohio EPA cannot be used to predict effects associated with remediation alternatives and do not account for the transfer of effects from one level to the next

Detailed Quantitative ERAs and ecosystem models will most commonly be used for highly contaminated sites The models can also be used to guide monitoring efforts and explore remediation alternatives Ecosystem models would be recommended for

- large sites (drainage basins, ecoregions)
- sites containing critical habitats, including unique communities or ecosystems
- verification or evaluation of quotient methods/criteria

5 2 5 The Outputs

The outputs from a Detailed Quantitative ERA are summarized in the box below

The main outputs of a Detailed Quantitative ERA include

- a customized database containing information on target chemicals, receptor biota and communities, toxicity data, and environmental conditions
- calibrated, advanced models (i e , that use field data) that predict future biotic and abiotic conditions with or without various mitigation options
- summary of all of the above in a report providing a synopsis of all phases of the project and covering all activities, findings, conclusions, and final recommendations

5 2.6 Research and Development Needs

Major research and development needs for Detailed Quantitative ERA components include

- development of simple empirical quantitative methods, particularly those based on past retrospective assessments
- assessment of safety factors and extrapolations used in quotient methods and development of alternatives
- development of models for assessing risk from multiple chemicals
- development of models for terrestrial and noncommercial species/ecosystems

Other issues such as density-dependent effects and exposure through multiple pathways are probably less important Density-dependent effects may certainly exist but will usually lower risk estimates if included in risk characterization Regulators may be reluctant to accept these lowered risk estimates unless these effects can be conclusively demonstrated in field studies Multiple exposure pathways are likely to be important for only a limited set of compounds In most cases, one pathway will dominate (LaKind and Rifkin 1990)

Sites at this level of concern are probably severely contaminated and aspects of the remediation program may be experimental in nature An adaptive process in which the success or effectiveness of the mitigation program is verified through an environmental monitoring program is therefore required There is great value in establishing an environmental monitoring program to generate information that, in time, will permit the ERA framework to be refined and the methods tested and improved

6 0 REPORTING AN ERA

The document that results from a risk assessment is the record of how the risk assessment was conducted and what the findings were Standardizing risk assessment documents and ensuring that they are assembled at a central location will ensure a useful library of examples

Although each risk assessment is unique, there are standard features that the documentation should include Obviously, sections such as table of contents, list of figures, list of tables, acknowledgments, references, and appendices need to be included in all reports Other documentation required when reporting an ERA are listed below

The ***executive summary*** summarizes the study, and its findings for nontechnical decision makers should include

- background of the study site
- rationale and objectives for conducting the risk assessment
- description of the level of ERA that was conducted
- description of the risk assessment methods
- description of the key findings of the study

The ***introduction*** to the document should include

- clear statement of the objectives of the investigation
- description of the events leading to the decision to conduct a risk assessment and the level of ERA to that point

Table 8 Summary of Tasks Comprising the Components of a Detailed Quantitative ERA

Sources of Information
• detailed quantitative methods • field investigations, monitoring data, and detailed computer models • models to predict exposure, hazard, and risk for remediation alternatives as well as for existing conditions for multiple exposure pathways/chemicals
Receptor Characterization **See CCME 1996b, Appendix B**
Detailed study • analyze community structure in depth • improve accuracy and precision of quantitative information collected in the Preliminary Quantitative ERA • measure ecosystem functions in the field • assess successional trajectory following remediation
Exposure Assessment **See CCME 1996b, Appendix C**
Selection of target chemicals • revise or confirm from Preliminary Quantitative ERA, if necessary, use advanced quantitative fate models incorporating most important pathways of individual chemicals and mixtures
Contaminant release/transport and fate • combine detailed models with direct measurement (site-specific monitoring data) • apply site-specific complex models (e g , GEMS, EXAMS) • explore long-distance transport and long-term persistence
Exposure pathway analysis • integrate exposure from several pathways • confirm pathways through direct measurement • conduct advanced quantitative fate models incorporating most important pathways of individual chemicals and mixtures
Aquatic and/or terrestrial exposure • integrate detailed exposure models with transport and fate models • make quantitative estimates of exposure from different pathways • evaluate food-web models, if appropriate
Uncertainty analysis • provide estimates of uncertainty for exposure • use Monte Carlo simulations, sensitivity analysis, calibration with monitoring data where adequate data distributions exist
Hazard Assessment **See CCME 1996b, Appendix D**
• re-evaluate measurement and assessment endpoints • use sophisticated hazard assessment methods (e g , mesocosms, microcosms, QSARS, field experiments, growth, reproduction tests with indigenous species, community/ecosystem assessment) • establish extrapolation relationships, if necessary, to reduce uncertainty • assess mixtures and multiple exposure pathways, as applicable • develop well-documented exposure-response relationships for samples collected at the site • evaluate exposure-response relationships for survival, growth, and reproduction of all VECs • evaluate exposure-response relationships for population(s), community and/or ecosystem • estimate uncertainty
Risk Characterization **See CCME 1996b, Appendix E**
• use population, community, and ecosystem models, in rare instances, use quotient methods • provide probability of several effect magnitudes • estimate uncertainty and sensitivity • indicate major sources of uncertainty for any predictions, provide a monitoring program to verify and evaluate these predictions • make quantitative estimates of ecological risk

The ***site description*** should include

- site description and history, including detailed maps and information on adjacent land uses and other potentially impacted media (e g , groundwater flowing to surface water)
- description of the nature and extent of contamination by medium and contaminant type

The section on ***approach*** should follow the level of detail given in this document and should include

- section describing the overall approach used to perform the risk assessment (figures and flowcharts are useful)
- detailed documentation on rationales such as the triggers for ERA
- a section describing the organization of the report

The introduction, site description, and approach sections set the tone for the whole document, and authors are encouraged to prepare these sections before the risk assessment is initiated If the readership is unfamiliar with risk assessment, a short summary of risk assessment theory could be included in the introduction The site description should include reference to pertinent work conducted at the site

The ***body*** of the risk assessment consists of five main sections ERA planning, receptor characterization, exposure assessment, hazard assessment, and risk characterization Within each of these sections, there should be the following elements

- introduction to the particular component of the risk assessment
- specific methods used
- assumptions
- findings, with emphasis on presentation of information in figures and tables
- consideration of uncertainty, including main sources
- conclusions, with particular emphasis on information that will be needed by other components of the risk assessment (e g , the results of a receptor characterization would be needed by the hazard assessment component)

The body of the risk assessment should be detailed enough that a risk assessment practitioner can judge whether the work met its objectives and was conducted properly It is more important to put effort into the actual risk assessment than into producing a detailed report, but the report becomes the only documentation of the completed risk assessment

The ***overall uncertainty*** section of the risk assessment should summarize the uncertainties identified in the body of the report The influence of the uncertainty on the conclusions of the ERA should be discussed

The ***overall conclusion*** of the risk assessment should be brief and use the information provided in the conclusion sections for each of the components of the body of the report Conclusions should be integrative in nature, pulling together all aspects of the assessment The most important thing to keep in mind when preparing the conclusion is to summarize the results within the context of the objectives of the study

A ***glossary*** may be required because risk assessment terminology is not yet in common or consistent usage in many scientific circles

References

Barnthouse, L W , and G W Suter II, eds 1986 User's manual for ecological risk assessment Prepared for U S EPA, Office of Research and Development, Oak Ridge National Laboratory, Oak Ridge, TN

Beanlands, G E , and P N Duinker 1983 An ecological framework for environmental impact assessment in Canada Institute for Resources and Environmental Studies and Federal Environmental Assessment Review Office, Halifax, NS

Burmaster, D E , and P D Anderson 1994 Principles of good practice for the use of Monte Carlo techniques in human health and ecological risk assessments Risk Analysis 14 477–481

Burns, L A 1991 PIRANHA Pesticide and Industrial Chemical Risk ANalysis and Hazard Assessment Version 2 0 U S EPA, Environmental Research Laboratory, Office of Research and Development, Athens, GA

CCME (Canadian Council of Ministers of the Environment) 1991 Interim Canadian environmental quality criteria for contaminated sites Prepared by the CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites Winnipeg, MB CCME EPC-CS34

CCME 1996a Guidance manual for developing site-specific soil quality remediation objectives for contaminated sites in Canada Prepared by the CCME Subcommittee on Environmental Criteria for Contaminated Sites Winnipeg, Manitoba

CCME 1996b A framework for ecological risk assessment technical appendices Final draft

CCME 1996c Illustrations of the ecological risk assessment framework for contaminated sites Final draft

Denneman, C A J , and C A M van Gestel 1990 Soil contamination and soil ecosystems Proposal for c-(test) values based on ecotoxicological risks National Institute of Public Health and Environmental Protection (RIVM) Report No 725201001 Bilthoven, the Netherlands Translated by Environment Canada from Dutch

Fava, J A , W J Adams, R J Larson, G W Dickson, K L Dickson, and W E Bishop 1987 Research priorities in environmental risk assessment Publication of the Society of Environmental Toxicology and Chemistry, Washington, DC

Gephart, L A , J G Tell, and L R Triemer 1994 Exposure factor manual J Soil Contam 3 47–117

Green, R H 1979 Sampling design and statistical methods for environmental biologists Toronto John Wiley and Sons

Jasanoff, S 1993 Relating risk assessment and risk management EPA Journal 19 35–37

Klemm, D J , P A Lewis, F Fulk, and J M Lazorchak 1990 Macroinvertebrate field and laboratory methods for evaluating the biological integrity of surface waters EPA/600-4-90/030 U S EPA, Environmental Monitoring Systems Laboratory, Office of Research and Development, Cincinnati, OH

LaKind, J , and E Rifkin 1990 Current method for setting dioxin limits in water requires reexamination Environ Sci Technol 24 963–965

Norton, S , M McVey, J Colt, J Durda, and R Hegner 1988 Review of ecological risk assessment methods Prepared for U S EPA, Office of Planning and Evaluation, by ICF Inc , Fairfax, VA

National Academy of Sciences 1983 Risk assessment in the federal government managing the process Printing and Publishing Office, National Academy of Sciences, Washington DC

Ohio EPA (Environmental Protection Agency) 1987a Biological criteria for the protection of aquatic life, vol 2 Users manual for biological field assessment of Ohio surface waters Ohio EPA, Division of Water Quality Monitoring and Assessment, Surface Water Section Columbus, OH Doc 0046e/0013e

Ohio EPA 1987b Biological criteria for the protection of aquatic life, vol 3 Standardized biological field sampling and laboratory methods for assessing fish and macroinvertebrate communities Ohio EPA, Division of Water Quality Monitoring and Assessment, Surface Water Section Columbus, OH Doc 0046e/0013e

Ohio EPA 1988 Biological criteria for the protection of aquatic life, vol 1 The role of biological data in water quality assessment Ohio EPA, Division of Water Quality Monitoring and Assessment, Surface Water Section Columbus, OH Doc 0055e/0015e

Parkhurst, B R , H L Bergmann, M D Marcus, C S Creager, W Warren-Hicks, H Olem, A Boelter, and J P Baker 1990 Evaluation of protocols for aquatic ecological risk assessment and risk management Prepared for WPCF Research Foundation, Technology Assessment Department, Alexandria, VA

Pastorok, R J , and J R Sampson 1990 Review of ecological risk assessment methods to develop numerical criteria for cleanup of hazardous waste sites Draft Prepared for Washington Department of Ecology, Olympia, WA

Sheehan, P J 1987 Functional processes of ecosystems their use in assessing the effects of mixtures of chemicals *In* SCOPE 30 Methods for assessing the effects of mixtures of chemicals, ed V B Vouk, G C Butler, and Ph Bourdeau New York John Wiley and Sons Ltd

Suter, G W , II 1986 Toxicity quotients *In* User's manual for ecological risk assessment, ed L W Barnthouse and G W Suter II Prepared for the U S EPA, Office of Research and Development, by the Oak Ridge National Laboratory, Oak Ridge, TN

Suter, G W , II 1989 Ecological endpoints *In* Ecological assessment of hazardous waste sites A field and laboratory reference document, ed W Warren-Hicks, B R Parkhurst, and S S Baker Prepared by Kilkelly Environmental Associates for the U S EPA EPA/600/3-89/013

Suter, G W , II 1993 Ecological risk assessment Ann Arbor, MI Lewis Publishers

U S EPA (Environmental Protection Agency) 1986 Superfund risk assessment information directory U S EPA, Office of Emergency and Remedial Response, Washington, DC EPA/540/1-86/061

U S EPA 1988 Superfund exposure assessment manual U S EPA, Office of Remedial Responses, Washington, DC EPA/540/1-88/001

U S EPA 1989 Risk assessment guidance for Superfund, vol 2 Environmental evaluation manual, interim final U S EPA, Office of Emergency and Remedial Response, Washington, DC EPA/540/1-89/001

U S EPA 1992 Framework for ecological risk assessment Risk Assessment Forum February 1992 Washington, DC EPA/630/R-92/001

Glossary

application factor (AF) – A numerical, unitless value, calculated as the threshold concentration of a chemical for chronic effects divided by its threshold concentration for acute effects An AF is generally calculated by dividing the limits (no-observed-effect concentration [NOEC] and lowest-observed-effect concentration [LOEC]) of the maximum acceptable toxicant concentration (MATC) by the LC_{50} The AF is usually reported as a range and is multiplied by the median lethal concentration of a chemical as determined in a short-term (acute) toxicity test to estimate an expected no-effect concentration for chronic exposure

assessment endpoint – The characteristic of the ecological system that is the focus of the risk assessment

benchmark concentration (BC) – Specific concentrations at which some level of effects is expected (e g , LC_{25}, MATC) These concentrations are derived from hazard assessment

bioaccumulation factor (BAF) – The ratio of the concentration of a compound in the tissues of aquatic organisms relative to the water they live in

biomarkers – Biochemical or cellular indicators of exposure (e g , body burdens, indicators of DNA damage, enzyme activity, and biochemical indicators of reproductive or bioenergetic status)

ecological risk assessment (ERA)

- The process of assigning magnitudes and probabilities to adverse effects of human activities (or natural catastrophes) (Barnthouse and Suter 1986)
- A formal set of scientific methods for estimating the probabilities and magnitudes of undesired effects on plants, animals, and ecosystems resulting from events in the environment, including the release of pollutants, physical modification of the environment, and natural disasters (Fava et al 1987)
- A subcategory of ecological impact assessment that (1) predicts the probability of adverse effects occurring in an ecosystem or any part of an ecosystem as a result of perturbation and (2) relates the magnitude of the impact to the perturbation (Norton et al 1988)
  The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors This definition recognizes that a risk does not exist unless (1) the stressor has an inherent ability to cause adverse effects and (2) it is coincident with or contacts the ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s) (U S EPA 1992a)

expected environmental concentration (EEC) – The calculated concentration of a chemical in a particular medium for a particular site

exposure – The process by which a chemical is delivered to an organism, resulting in a dose (the amount of a chemical either in the organism as a whole or in a target tissue) Exposure is a result of the concentration and form of a chemical in the environment, coupled with the presence of the organism

exposure assessment – The process of estimating the dose received by an organism, population, or ecosystem It may be prospective, in which case estimates of the chemical concentrations and forms in various media or habitats are combined with estimates of the organism's behaviour to predict dose It may also be retrospective, in which case dose is estimated from body burdens of the chemical or changes in the organism caused by the chemical (biomarkers)

hazard assessment – The overall process of evaluating the type and magnitude of adverse effects caused by a stressor

lowest-observed-effect concentration (LOEC) – The lowest amount or concentration of a stressor for which some biological effect is observed

maximum acceptable toxicant concentration (MATC) – The maximum concentration at which a stressor can be present and not be toxic to the test organism The MATC is normally calculated as the geometric mean of

the lowest concentration for which an adverse effect was observed (LOEC) and the highest concentration that did not yield any adverse effects (NOEC)

median effective concentration (EC_{50}) – The concentration of a stressor in water that is estimated to be effective in producing some biological response, other than mortality, in 50 % of the test organisms over a specific time interval (e g , a 48-h daphnid EC_{50})

measurement endpoint – An effect on an ecological component that can be measured and described in some quantitative fashion

median lethal concentration (LC_{50}) – The concentration of a stressor in water that is estimated to be lethal to 50 % of the test organisms over a specific time interval (e g , a 96-h fish LC_{50})

mesocosm – A composite physical and biological model of an ecosystem, intermediate in scale between a microcosm and a macrocosm, with a level of organization as similar as possible to the natural world

microcosm – A laboratory simulation of a portion of an ecosystem (e g , a microbial community in a beaker)

modifying factor – Any characteristic of an organism or the surrounding environment that affects toxicity

Monte Carlo simulation – An iterative process involving the random sampling of stochastic model parameter values from specified frequency distributions, simulation of the system, and output of predicted values The distribution of the output values can be used to determine the probability of occurrence of any particular value (after Suter 1993)

no-observed-effect concentration (NOEC) – The amount or concentration of a stressor that does not result in any adverse effect

QSAR (quantitative structure activity relationship) – A method of estimating unmeasured physical and toxicological properties for a chemical on the basis of chemical structure, functional groups, and similarity to known chemicals

receptor – The entity (e g , organism, population, community, ecosystem) that might be adversely affected by contact with or exposure to a substance of concern

risk – The chance of an undesired effect, such as injury, disease, or death, resulting from human actions or a natural catastrophe

risk assessment – A set of formal scientific methods for estimating the probabilities and magnitudes of undesired effects resulting from the release of chemicals, other human actions, or natural catastrophes

risk characterization – The evaluation of the likelihood that adverse ecological effects may occur as a result of exposure to a stressor, including an evaluation of the consequences of these effects

route of exposure (exposure pathway) –The means by which organisms are exposed to contaminants Routes/pathways would include uptake of contaminants from solution, ingestion of contaminated food/prey, inhalation of contaminated particles, etc More generally, routes of exposure include exposure via water, soil, sediments, food, and other media

site characterization – Evaluation of available data and information concerning the site (e g , site use, geology, hydrology, available chemistry, and toxicity data)

SWACOM – The standard water column model is the best known ecosystem model that considers higher-order processes such as competition, predation, and energy transfer through the food chain

valued ecosystem component (VEC) – Each of the environmental attributes or components identified as a result of societal values and considerations